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Thomas Fisher

Lori Barkley

Tawanda Johnson

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SUICIDE SCREENING IN PRIMARY CARE WITH PATIENTS DIAGNOSED WITH  
DEPRESSION

by

Thomas Fisher

Lori Barkley

Tawanda Johnson

Research Project

Submitted in Partial Fulfillment of the Requirements for the  
Degree of Master of Science in Nursing, College of Nursing  
and Speech Language Pathology

Mississippi University for Women

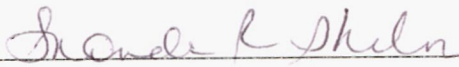
Columbus, Mississippi


July 2013

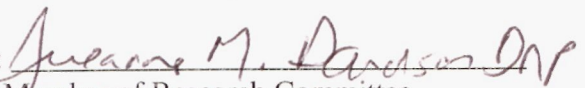
Graduate Committee Approval


The Graduate Committee of Thomas Fisher, Lori Barkley, and Tawanda Johnson hereby approve their research project as meeting the partial fulfillment of the requirements for the Degree of Master of Science in Nursing.

Date: July 29, 2013

Approved:   
Chair of Research Committee

Approved:   
Member of Research Committee

Approved:   
Member of Research Committee

  
Director of Graduate Studies

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## DEDICATION

I would like to dedicate this research to friends and family members who have personally experienced some of the issues in this project. I would like to thank my wife for being the provider and supporter while I embarked on this endeavor. Without her constant support, this year would have been an extremely difficult and seemingly impossible to accomplish. I would like to thank my 88 year old father for being there emotionally, financially, and spiritually while offering any support that he could. I am so thankful that he is able to see his son obtain a master's degree.

Thomas Fisher

## DEDICATION

I would like to dedicate this research to my family and friends who have experienced the effects of suicide personally by a loved one or the feeling of hopelessness resulting in the act of harm to themselves. I would also like to dedicate the project in memory of my mother and father whose love and support aided me in obtaining my goal of first becoming an RN 27 years ago. They are greatly missed. Additionally, I would especially like to thank my husband Glen for 30 years of support, encouragement and love. Without his support the goal of a master's degree would not been attainable.

Lori Barkley

## DEDICATION

First and foremost, I would like to thank God from whom all blessings flow. I am humbled at this experience as I have learned an abundance of information over the course of this year. I wish to dedicate this research to my daughter, Jordyn Cristina, who has given me unimaginable strength and a reason to push forward and strive to be my very best. To my husband, parents (Roy and Shirley Price), and also my sister (Crystal), “I made it”, but it would not have been possible if it wasn’t for your prayers, support, love and unwavering faith. For that, I can’t say thank you enough.

Tawanda Johnson

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We would like to thank our research advisor, Shonda Phelon, for her advice and support with this project. She was always available regardless of how busy her day was. She allowed us freedom to guide the project but would gently nudge us in the right direction when needed. We would also like to thank our committee members, Dr. Patricia Smyth and Dr. Sueanne Davidson for their gentle, yet affirmative advice. Each of them was very encouraging toward our project which bolstered our effort to continue the push to see it come to fruition. We would like to thank the rest of the staff at the Mississippi University for Women for sharing their combined vast knowledge of body, mind, spirit, and politics!



## Abstract

Suicide is a delicate health care issue affecting many Americans. Focused and efficient suicide screenings are greatly needed in primary care practices. Early recognition and diagnosis of suicide in primary care leads to appropriate referral and management. Thus, prompt referral and treatment can prevent undue tragedy and loss of life. Many myths surrounding depression and suicide may prevent primary care providers from addressing the subject. Such myths suggest that bringing up the topic of suicide may further increase thoughts of suicide. Many providers may possibly lack necessary skills in recognizing signs and symptoms of suicide, especially in the elderly population. A large proportion of those that commit suicide see their primary care providers only weeks to months before (Feldman et al., 2007). Roy's Adaptation Model was the theoretical framework for this study. This model was designed to describe how people respond and adapt to a constantly changing environment through coping mechanisms and control processes. A retrospective chart review was performed on a convenience sample (n=300) of clients, age 21 and older with a diagnosis of depression. A data collection worksheet created by the researchers was used along with multivariate descriptive statistical analysis. The study found that, of the charts reviewed, 91 were men while 209 were women. Also, 49.7% of patients with a diagnosis of depression were not screened and 50.3% were screened. Of those that were screened, 15.9% were referred to another facility which would include mental health facilities, counselors, psychologists, psychiatrists, group therapy, and emergency rooms.

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## Chapter I

### Dimensions of the Problem

#### Introduction

Suicide is one of the 10th leading preventable causes of death in America. In 2009, almost 37,000 deaths resulted from suicide in the United States. (Centers for Disease Control and Prevention [CDC], 2012). Between 2005 and 2009, the highest rates of suicide occurred among American Indian/Alaskan Native at 27.61 per 100,000, followed by Non-Hispanic White at 25.96 per 100,000 (CDC, 2012). It is estimated that up to 7% of all patients seen in primary care clinics may have suicide ideation and that greater than 50% of patients with major depression experience suicidal ideations. The suicide rate in Mississippi in 2007 was 13.4 per 100,000; thereby, being 21.7% higher than the national average (Mississippi Injury Report, 2008). Also, Mississippi ranks 30 in the nation for suicides (American Foundations for Suicide Prevention, 2010). Many people in Mississippi utilize their primary care provider for various aspects of their care including mental health. Researchers submit that primary care providers must recognize when to effectively screen all ages of depressed patients for suicide risks and how to differentiate symptoms presented by patients across the life span. For example, younger patients may be more likely to verbalize behavior pattern changes whereas older adults may not.

#### Problem Statement

Almeida et al. (2012) concluded that providers educated in depression and suicide screenings were more likely to manage early warning signs of the condition. However, a

significant number of health care providers lack adequate knowledge in recognizing early warning signs and symptoms of suicide; or they may feel uncomfortable broaching the topic with the patient or caregiver (Parker et al., 2008). Despite readily accessible screening tools, many healthcare providers omit screening adults diagnosed with depression, for risk of suicide. Two thirds to three fourths of patients who commit suicide are seen by their primary care provider just weeks before (Lawrence et al., 2010). In Mississippi, depressed individuals may not have adequate access to mental health care due to lack of providers resulting in primary providers managing their care and prescribing the majority of psychotropic medications. Despite some providers beliefs, screening for suicide or broaching the subject has not been shown to increase the likelihood of suicide in depressed patients. On the contrary, research indicates that when providers are educated about suicide, screenings, and referral options, significant increases in appropriate measures are taken to assure safety in depressed patients (Parker et al., 2008).

### **Statement of Purpose**

The purpose of this study is to identify how many patients in the primary care setting diagnosed with depression were appropriately screened for suicide and, if screened, were referred to another facility. The study will be conducted through systematic chart reviews with no patient contact. The goal of the research is to determine the number of patients seen in primary care clinics diagnosed with depression that are appropriately screened and referred to another facility.

### **Significance of Study**

In 2009, Mississippi's suicide rates were 13.2 per 100,000 and the national rate

was 11.8 (State Health Facts, 2008). Suicide affects all ages, gender, and socioeconomic class. There are several factors that may make this health issue so important: (1) Patients and caregivers may be reluctant to talk about depression and suicide secondary to its stigma, (2) Many general health practitioners may not have adequate knowledge of referral options or feel comfortable about addressing suicide in patients (Parker et al., 2008), (3) It could be that primary care providers' schedules are not conducive for the additional time required to assess for suicide risks, (4) Patients in Mississippi do not have adequate access to mental health facilities and rely on primary care providers to manage their mental health needs (DMH, 2011), and (5) an ever increasing elder population may require specific techniques in recognizing signs and symptoms of depression because chronic disease may mask or exacerbate symptoms. Furthermore, older adults may express depression differently than younger adults (Almedia, et. al 2012).

Bajaj et al. (2008) noted that approximately 25% of patients who are depressed get alarmed at questions relating to thoughts of suicide. However, 80% felt that a general practitioner should routinely screen an individual who is depressed. Almost 40% of depressed patients welcomed these types of questions while 26% were a little surprised. Feldman et al. (2007) noted that physicians only explored suicide in 36% of patients (portrayed by actors) with depression and adjustment disorders. Interestingly, it was demonstrated that physician's personal experience with suicide along with those that worked in an academic setting increased the chances of suicide exploration.

Parker et al. (2008) noted that 77% of the providers did not feel comfortable either recognizing or addressing the signs and symptoms of suicide in the 10 to 24 age group, and that greater than 87% were unaware of referral facilities. There are many

myths about suicide that healthcare providers may believe such as: (1) If someone wants to commit suicide, no one can stop them; (2) Asking about suicide may increase the risk; (3) Suicides happen without warning; and (4) Only experts can prevent suicide. Also, having updated referral options significantly reduces frustrations in the clinics. After suicide education was completed at the clinics participating in the study, appropriate referrals nearly doubled in three years.

Mental health assessments often require a significant amount of time due to the in-depth evaluation needed. In a busy primary care environment, this type of assessment may become very brief or not performed at all. Bajaj et al. (2008) and Parker et al. (2008) both note insufficient time as being a significant factor in absent suicide screenings. Because access to mental health care in Mississippi is often not ideal or readily accessible, primary care providers are often the front line for suicide screening.

Almeida et al. (2012) noted that health care providers that were specifically educated in assessing older adults with depression were more likely to manage the early warning signs. The need for trained providers in managing depression in elders may be further supported by Balsis and Cully's (2008) study which concluded that the elderly population was less likely to express depression and behavioral changes than younger adults. While older adults express certain behavioral changes such as sleep disturbances, they were less likely to express suicidal ideations. Compounding the problem is an exploding population of older adults that have other vulnerable health conditions such as multiple chronic diseases which, in turn, has the potential to exacerbate depression (Dozeman et al., 2010).



## Theoretical Framework

Roy's Adaptation Model was used in this study to describe how providers or groups of providers (termed systems) respond and adapt to a constantly changing health care environment through coping mechanisms and control processes. Roy based the conceptual model on observations of children's resilience to adverse effects. The theory infers that in order for enhancement and adaptation to occur, the system must respond positively to the constant internal and external stimuli. If true adaptation occurs, then survival, growth, reproduction, mastery, and transformation will follow suit. Health care providers must adapt to constant changes in their environment, such as ever increasing pharmacological discoveries, rapidly evolving technological advances, complex regulations, changes in reimbursement, patient perceptions, and many other factors. As these providers as individuals or groups adapt positively, then enhancement occurs in the quality of care, accuracy of diagnoses, patient satisfaction, and compliance with regulations.

Environmental stimuli are defined as focal, contextual, and residual. Focal stimuli are those that most intimately surround and confront the provider, requiring awareness. Some examples include interactions with patients and caregivers, technological benefits and challenges (such as computer charting), relationships with co-workers, and others. Contextual stimuli are all of the other stimuli that can have a positive or negative effect. The residual stimuli are internal, external, contributing, and noncontributing factors, the effects of which remain unknown. Some examples of contextual and residual stimuli in caregivers may include support and socialization.

Two types of control mechanisms in the theory include regulator and cognator. Regulator mechanisms are automatic responses such as neural, endocrine, or chemical. In dealing with the stressors of the busy practice of the clinic, ER, or hospital, these regulator controls play a vital role in the provider's response to stress. Cognator control mechanisms are those that involve perception, information processing, emotion, learning, and judgment. These controls are constantly used by the providers, both new and seasoned, as they experience the varieties of challenges presented to them daily. Cognator controls are demonstrated when, for example, a seasoned provider has a "gut" feeling about a patient's complaint or becomes emotionally attached.

There are four adaptive modes in the model: (1) physiological-physical, such as elimination, oxygenation, nutrition, and others; (2) self-concept-group identity, including the need for spiritual and psychic integrity, among others; (3) role function, which describes how people in different positions (such as boss and employee) should react to one another (can apply to groups); and (4) interdependence, involving security in relationships, giving and receiving love, and others.

In this study, the Model relates to patients because of their ability or inability to adapt with a changing environment. The coping mechanisms may be inadequate or simply non-existent, therefore leaving the patient no choice but to end his or her life. Various stimuli in the patients' environment such as job, family, and financial stressors all play in role in the patients' response via control mechanisms.

### **Research Questions**

The research questions for this study were as follows:

1. What percentage of adult patients over the age of 21 with depression, have a recorded screen for suicide risk?
2. What percentage of adult patients that received a suicide screening was referred to another facility?

### **Definition of Terms**

#### **Adult patient.**

**Theoretical definition.** An adult is a fully developed mature grown person 21 years of age or older who is waiting, or is under medical care and treatment (Webster, 2012).

**Operational definition.** Persons over the age of 21 who were seen in primary care clinics with a diagnosis of depression and whose charts were reviewed.

#### **Depression.**

**Theoretical definition.** Depression is a medical illness that causes a constant feeling of sadness. It may be demonstrated by physical symptoms such as loss of interest, trouble doing normal day-to-day activities. Patients with depression may feel that life is not worth living (Mayo Clinic Staff, 2012).

**Operational definition.** ICD-9 codes for depression include the following:

Atypical Depressive Disorder (296.82); Manic Depressive Disorder (296.89); Depressive Type Psychosis (298.0); Depressive Disorder not otherwise classified (311.0); Major Depressive Disorder (296.29); Mood Disorder (296.90); Bipolar Disorder (296.6); and Major Depressive Disorder (296.3).

#### **Suicide screening.**

**Theoretical definition.** A suicide screening is an instrument that is sensitive at identifying the potential for suicide and specific at ruling out patients who are not at risk for suicide (Horowitz, Ballard, & Pao, 2009).

**Operational definition.** A suicide screening is documentation used in a primary clinic by the primary care provider to determine the degree to which, or if the patient is considering ending his or her own life. An example would be “in the past two weeks have you thought about harming yourself or ending your own life?”

#### **Other facility.**

**Theoretical definition.** Another facility is something that facilitates a process or action or something that is created to serve a particular function. (The Free Dictionary By Farlex, 2012).

**Operational definition.** Another facility is an appropriate location to refer a patient that has been screened for risk for suicide. This would include: mental health facilities, counselors, psychologists, psychiatrists, group therapy, and emergency room.

#### **Assumptions**

1. The providers in the clinics are adequately and accurately documenting patients with diagnoses of depression.
2. The information on the charts will be accessible to the researchers.
3. The clinics will grant permission to access the information.
4. The information can be accessed by the researchers in a timely, accurate, and secure manner.

#### **Limitations**

Data were collected through quantitative, retrospective chart reviews on patients

ages 21 and older with a diagnosis of depression. Accuracy was assumed by the researchers on each chart reviewed. One limitation was the sample size which included only 300 chart reviews from a total of three clinics. A second limitation was that all three clinics were located in north central Mississippi. A larger sample size along with inclusion of additional clinics from a larger geographical area would likely have given the researchers a more representative patient pool. Another limitation was the possibility of inadequate charting by the health care providers in the clinics.

### **Summary of Dimensions of the Problem**

Suicide affects a significant portion of the population in the United States with Mississippi ranking at number thirty. Many depressed patients in Mississippi use their primary care provider for management of depression. A significant number of patients who commit suicide visit their primary care provider weeks to months before committing suicide. Many primary health care providers may not feel comfortable broaching the subject of suicide in depressed patients or may not be trained to recognize specific signs and symptoms of those at risk such as in the elderly population. Therefore, primary care must be adequately prepared to utilize screening and heighten surveillance of depressed patients who are at risk for suicide.

## Chapter II

### Literature Review

Suicide is a major concern for community health care providers. The risk of suicide or attempted suicide has affected many families in our communities. Suicide was the eleventh leading cause of death in 1999 as well as 2007 (United States Office of Statistics and Programming, 2009; United States Preventive Services Task Force 2004). The risk of suicide is highest among elderly white men. Risk factors are the strongest among adults who have mood disorders and substance abuse disorders (United States Preventive Services Task Force, 2004). Suicide screenings are not routinely performed on patients diagnosed with depression because of several factors including: inadequate provider knowledge about suicide risk, time constraints in busy primary care clinics, stigmas associated with depression, and others.

### Conceptual Framework

The Roy Adaptation Model was the conceptual framework for the study. The Roy Adaptation Model relates to the potential lack of adaptive capabilities of suicidal patients and their families, and the potential causative environmental influences. The Roy Adaptation Model was used in this study to examine how patients respond to stimuli from the external and internal environment through coping mechanisms and control processes. The Roy Adaptation Model's environmental, focal, contextual and residual stimuli were utilized. The focal stimulus was the relationship between the provider and the patient. The contextual stimulus was the stimulus which contributes to the focal stimuli indirectly. In this study the contextual stimuli was the screen for suicide.

According to Roy adaptation is the process in which persons use conscious awareness and choice to create human and environmental integration (Roy, 2011). In order for enhancement to occur, the system must respond positively to these stimuli. True adaptation to these environmental stimuli promotes survival, growth, reproduction, mastery, and transformation.

The model defines environmental stimuli as focal, contextual, or residual. Focal stimuli are those stimuli that most intimately surround and confront the patient and require the highest awareness. The contextual and residual stimuli are the education and experience one receives (Roy, 2011). The focal stimulus was the relationship between the provider and the patient. The two types of control mechanisms for individuals are regulator and cognator. Regulator control mechanisms are those that respond automatically, and include neural, endocrine, or chemical responses, such as an increased respiration related to increased blood carbon dioxide. Cognator control mechanisms are those that involve perception, information processing, emotion, learning, and judgment.

The Roy Adaptation Model has provided the theoretical basis for research projects as well as the development of research instruments. Roy herself recalls the first research to utilize her model when a group of five researchers presented a synthesis and critique of studies based on the model about 20 years ago (Roy, 2011). Roy's middle-range theory of cognitive process begins with the person as the core of the theory. The person's cognitive process includes arousal versus attention, sensation versus perception, coding versus concept, formation, memory, language planning, and motor response. The second level of the theory is consciousness of the person. The third and fourth levels in the theory are the focal stimuli and contextual-residual stimuli (Roy, 2011). Roy's

adaptive modes of cognator help to explain coping from both a cognitive and emotional standpoint. The cognator is a major coping process which involves four channels. The channels are information processing, learning, judgment, and emotion (Roy & Andrews, 1999). The concepts of coping, theory development, and empirical strategies were the basis for the development of the middle-range theory (Roy, 2011). Coping must be understood in both physical and mental stress because the nurse's purpose (according to Roy) is to promote coping for patients and families (Roy, 2011).

Serçeku and Mete (2010) used the Roy Adaptation Model to guide their study of the effects of antenatal education on maternal prenatal and postpartum adaptation. The study utilized the stimuli model, including the focal, contextual, and residual stimuli from Roy's Adaptation Model. The study defined the child bearing woman as the adaptive system. In this study, focal stimulus was the antenatal education. Maternal demographic information was the contextual component (Serçeku & Mate, 2010). Results of the study showed positive improvement for prenatal adaptation, but showed no effects on postpartum adaptation. The study showed that the Roy Adaptation Model is a good tool to use in the development of antenatal education programs (Serçeku & Mete, 2010).

Serckeu & Mete (2010) guided the researcher's application of Roy's Adaptation model to the current project. The contextual stimuli in the study by Serckeu & Mete was the maternal demographic. The contextual stimuli in the researcher's study referred to the practitioner completing and documenting the suicide screen. The focal stimuli in the study of Serekeu & Mete was education. The focal stimuli in current study was the practitioner's knowledge of patient criteria for suicide screen. The adaptation model is



realized when the practitioner successfully identifies the risk of suicide and completes a documented suicide screen.

Buckner et al. (2006) also used the Roy Adaptation Model for a study which was completed on adolescents at an asthma camp. The researchers used the relationship of the conscious awareness and choice of humans to integrate with their environment. The basis for the study was the cognator model which uses cognitive channels of perception, information process, learning, judgment and emotion. The theory was that adolescents adapt through physiologic response to the outdoors as well as to asthma education. The focal stimulus was the environment asthma triggers of the camp experience. Existing degrees of asthma was the contextual stimulus while the residual stimulus was the developmental age of the child. The results of the study showed a clear transfer of the asthma care from parent to adolescent with participation in an asthma camp. Transfer of responsibility, partnered with the enhanced relationship with healthcare providers, supports a positive outcome (Bucker et al., 2006).

The study by Bucker et al. (2006) was applicable to the current as it related to Roy's cognator. The cognator for the study of Bucker et al. was defined as the ability of the adolescent to physiologically adapt to the external stimuli. The cognator for this study was the ability of the practitioner to recognize the patient as demonstrating suicidal ideations and follow up with suicidal screen. The Roy's adaptation interdependence mode is defined as closed relationship with people in an effort to satisfy needs. The interdependence mode includes relationship with parents, close relatives, as well as health care providers. The Interdependence mode we defined for this study was the relationship of the healthcare provider and the patient. In this study the provider would

meet the goal of satisfying the needs of the patient with the identification of the risk of suicide and providing a documented suicide screen.

### **Related Research**

The research study concentrated on literature reviews from three major focus areas which were: Depression and suicide, suicide screenings in primary care and primary care provider's perception of screening for suicide in the depressed patient. The review of the literature gave the researchers a better understanding of the relationship between depression and suicide. The screening tools available to primary care providers and the process for selecting patients which would benefit from a suicide screen were most helpful to the researchers. The literature reviewed gave the researchers a better understanding of the barriers providers' face that prevent suicide screenings from being consistently conducted.

### **Depression and Suicide**

Approximately 38.9 million Americans, age 65 and older, live in the USA (United States Census Bureau, 2011). As the number of baby boomers continues to increase, medical providers are challenged with assessing and evaluating the physiological and psychosocial clinical presentations in the elderly population. In particular, an area that goes sorely missed is the absence of prompt identification and intervention of suicide in depressed individuals.

A quantitative study by Suokas et al. (2011) explored the relationship between suicide attempts and mental disorders in young adults, ages 20 through 34. Soukas et al. (2011) sought to determine if there was a link between history of mental health illness and suicide attempts later in life. The study was conducted in Finland and a random

sample of 1,894 young adults were offered the chance to participate in the study.

Candidates were selected for inclusion in the study based upon responses to mental health screening questionnaires.

### **Statistical Significance and Study Findings**

Suokas et al.'s (2011) study design was based on the Mental Health in Early Adulthood in Finland (MEAF) study. MEAF questionnaires were sent to 1,863 individuals, ages 20 through 34. One thousand three hundred and sixteen young adults responded to the survey invitation. Of the 546 participants chosen to participate in the MEAF interview, 316 women and 230 men participated in the study. Participants were then provided questionnaires to complete at two and four year intervals which assessed if factors such as childhood, health, demographical, socioeconomic, or education contributed to the occurrence of suicide attempts. MEAF questions focused on an individual's attempts and/or reattempts to suicide. Next, participants participated in a mental health interview addressing the Structured Clinical Interview for DSM-IV-TR (SCID-I). SCID-I items captured history, life history, or past one-year history of suicide attempts. SCID-I also provided insight into previous history of suicidal behavior and ideation. Additionally, medical records from inpatient and outpatient facilities were obtained to validate suicide attempts and mental health history.

As a result of the study, 58 young adults were identified who had a history of suicide attempts. Of the 58 young adults identified, 34 were found to have a single attempt at suicide while 24 had multiple attempts at suicide. Suokas et al. (2011) revealed that suicide attempts were more prominent in young adults with personality, psychotic, substance abuse, and bipolar disorders (p. 969). The authors stressed the

apparent link between comorbid mental health disorders and suicide attempts in this young population. Interestingly, the authors identified that women in the young adult population were more likely to attempt suicide than their male counterparts. Low socioeconomic status and underprivileged individuals in regards to education and financial status were more likely to portray repetitive suicide attempts throughout life.

### **Strength and Weakness of Study**

Suokas et al. (2011) lists several strengths of the study. First, the meticulous detail to the study design was composed of a nationwide representation of the population. Suokas et al. (2011) iterate that their study is the first study to precisely identify the occurrence of attempted suicide in young adults. However, the authors acknowledge that few suicide attempts reported in the study could contribute to an inaccurate account of suicide attempts, therefore, weakening the study's statistical power. Also, the small sample size may give a misrepresentation of the young adult population. Additionally, the reliance on patient memory to recall past events from two and four year intervals may lead to inaccurate recall of events. Suokas et al. (2011) emphasize the need for future research examining the risk suicidal behavior plays in psychiatric disorders.

### **Significance of the Study**

This study is pertinent to our research because it stresses the need for educational and outreach opportunities to young adults suffering from mental illness. Effective coping strategies, counseling, and screening is needed to assess those young adults with mental disorders. It is highly important that these individuals are not made to feel secluded from care. With appropriate screening and treatment, young adults suffering from mental illness can become functional and productive members of society.

The next review was a quantitative study by Almeida et al. (2012). Almeida et al. explored the relationship between suicide and depression rates among patients under the care of medical providers specifically trained to assess for depression. These providers used indicators to aid in prompt diagnosing of depression and suicide. Almeida et al. randomly sent invitations to 19,046 medical providers who were registered with the Australian Medical company and practiced in Western Australian states. Out of the 772 medical providers that responded to the invitation to be included in the study, 373 providers agreed to participate in the study and recruit patients from their respective practice. Over twenty thousand adults, age 60 and above, were recruited by their primary care physicians and included in the study. One hundred and eighty six providers along with their patients participated in the intervention group and the remaining 187 providers and their patients made up the control group. All participants in the study were provided informed consent and inclusion was strictly on a voluntary basis. Almeida et al.'s main purpose in conducting this research was to examine if medical providers with additional resources and tools to aid in detecting depression and suicide risk, increased their ability to identify patients at an increased risk.

Almeida et al. based their research on interventional concepts aimed at prompt identification and treatment of depression in the elderly population. These interventions focused on "(1) Printed educational material about practical aspects of the assessment and management of depression and self-harm later in life, (2) practice audit of 20 active patients with detailed personalized audit feedback that took place within the first six months of the study and (3) newsletters outlining progress of the study" (Almeida et al., 2012, p. 348). The project, entitled DEPS –GP (Depression and Early Prevention of

Suicide in General Practice) was a randomized cluster trial that followed patients at 12 and 24 months to determine effectiveness of interventions aimed at recognizing early onset of depression and suicide. Throughout the course of this two year study, patients were assessed for signs and symptoms of depression using the Patient Health Questionnaire (PHQ-9) and the Depressive Symptom Index Suicidality Subscale (DSI-SS) (p. 349). PHQ-9 scores of 10 or greater prompted providers to assess for depression, while DSI-SS scores of three or greater identified the potential risk of suicidal tendencies. Significantly, Almeida et al. used patient reported questionnaires as guidelines for providers in the intervention based group to detect and identify suicidal tendencies in depressed elderly patients. In addition, these providers received education focusing on “assessment and diagnosis of depression, identifying and managing suicidal risk in older adults, using antidepressant medication with this age group, and crisis support contact information” (Almeida et al., 2012. p.p. 349). However, providers in the control group were not given this information or the results of participant questionnaires. Control group providers received no knowledge of participants’ PHQ-9 and DSI-SS scores (Almeida et al., 2012).

### **Statistical Significance and Study Findings**

Once patient questionnaires were received, data were evaluated with statistical methods such as Stata 11.1 and cross tabulations. A comparison of results between patients participating in the intervention group and those of the control group at 12 and 24 months were evaluated in relation to depressive symptoms and threat of self-harming behavior. Logistic regression was used to examine the relationship between study outcomes and provider driven interventions. The researchers were able to avoid bias in

the sample by allowing participating providers to choose their own patient population. Another way in which bias was reduced was through the use of sound, statistical tools in data collection and analysis. Almeida et al. (2012) concluded that providers who were educated on the management of depression and suicide in elders were more likely to identify and manage the early warning signs of these conditions.

### **Strength and Weakness of Study**

The strength of this study was the consistent use of validated tools to collect data and preservation of an acceptable normal limit of loss of few participants during the 12 and 24 month study. The authors inform of certain weakness to their study. First, the author's perception of depression was exclusive of a clinical view of depression. They believe that this view of depression frees bias (Almeida et al., 2012). Although, control providers were not given interventional tools as providers in the interventional group, it is unknown if they provided education "off the record" to assist depressed patients. Additionally, providers voluntarily agreed to participate in this study and were not part of a random sample of providers. Also, the shortened duration of the study did not allow sufficient time to evaluate long term effectiveness of similar intervention led programs. Information obtained from patient questionnaires were taken at "face value" and not verified for accuracy (Almeida et al., 2012).

This screening tool quickly identified those having depression at baseline and allowed their immediate exclusion from the targeted sample. The Center for Epidemiologic Studies Depression Scale (CES-D) was another screening tool used to measure depression at baseline, six months, and 18 months. Statistical correlations such as odds ratio (OR) and the 95% confidence interval (CI) were calculated at 6 and 18

months using univariate logistic regression. Also, a p value of 0.2 was used to evaluate and assign variable inclusion for the study.

### **Significance of the Study**

The study of Almeida et al. concluded that providers who were educated on the management of depression and suicide in elders were more likely to identify and manage the early warning signs of these conditions. The study was significant to this study by helping identify the importance of knowledge of the practitioner in the management of depression and conducting suicide screenings. A beneficial goal of this study was the increased awareness to the need for suicide screening documentation by the healthcare provider.

The study of Balsis and Cully (2008) applied to our research because it demonstrated why it is so important for health care providers to effectively evaluate the geriatric population for signs and symptoms of depression. Often, symptoms of depression in the geriatric population may be masked by symptoms of other chronic disease. The approach that health care providers employ in the assessment and screening of depression in the elderly population must lead to early diagnosis and treatment of depression. As a result, this leads to better health outcomes and increases the longevity of the elderly patient.

Interestingly, the absence of common signs and symptoms of depression in elders has baffled many geriatric providers compared to their younger counterparts. Balsis and Cully (2008) conducted a quantitative cross sectional study comparing screening methods and expression of depression in the younger and older adult population. The researchers



hypothesized that DSM screening criteria detected depression differently in these two populations.

### **Statistical Significance and Findings of the Study**

Data for the study was composed of a 2000-2001 NEARC study lead by The National Institute of Alcohol Abuse and Alcoholism. Eighteen hundred skilled interviewers collected data on 43,093 participants. Telephone interviews and questionnaires served as sources of data collection. Study inclusion was contingent upon a positive response to at least one of the two main questions on the DSM IV screening tool. DSM IV question one focused on elements of low mood while question two focused on symptoms of anhedonia (inability to feel pleasure). The remaining DSM IV screening questions consisted of changes in appetite, sleep, behavior, and concentration. In addition, suicidal behavior was screened using the DSM IV screening tool. Participants who responded “no” to one of the top two DSM screening questions related to mood and anhedonia were excluded from the study. Also, participants with mental and physical disabilities were omitted from the study. In addition, participants who were eligible for the study but failed to complete all items of the questionnaire were excluded. Balsis and Cully (2008) chose subsamples for their study consisting of 3,734 young adults (18-34 years of age) and 1,808 older adults (65-98 years of age) living in the United States. The DSM screening tools were measured based on existing signs and symptoms of depression or the most recent depression exacerbation (Balsis and Cully, 2008).

The researchers used an IRT framework to analyze their data. Bias was measured between the two subsets using logistic models and characteristic curves to examine results from DSM IV surveys. If an item was found to have a high finding in a subset,

that group was more likely to endorse or express those signs and symptoms. The researchers found a significant statistical finding in anhedonia which was expressed more in younger adults. Young adults were more likely to express behavioral changes and sleep pattern disturbances than their older counterparts. In addition, older adults were less likely to express suicide behavior (Balsis & Cully, 2008).

### **Strength and Weakness of Study**

Statistical findings in this study identified a relationship between age and prevalence of signs and symptoms of depression. Statistical analysis in the study confirms the relationship exists, therefore giving credibility to the need for future studies. Additionally, the study by Balsis and Cully (2008) included both strengths and weaknesses. One strength of the study is the understanding that depression and suicide is underreported in the elderly population. The authors recognized this may be attributed to older people's fear of loss of independence and autonomy if signs and symptoms of depression were reported. Also, measurement interferences such as artifacts did not pose a threat to the validity of results, suggesting that DSM screening items are compatible with both age groups. Limitations of the study include the design. Researchers were unable to distinguish if the results were influenced by group placement, illness, or mental disorder alone. Also, the use of only DSM IV screening for depression may limit the study. The exclusion of data from those who responded negatively to one of the two initial screening questions and those who did not successfully complete all items of the questionnaire further limited the study. The authors recommend further research to include more depression screening tools and a more generalized population to limit bias and increase effectiveness for future studies (Balsis & Cully, 2008).

## **Study's Usefulness in the Research Project**

The study by Balsis and Cully (2008) was useful to our research endeavor because it evaluates the different ways in which depression is expressed in the younger, versus older adults. The differences include physiological and psychological changes which may conceal symptoms of depression in elderly patients. Elderly patients are often unaware that the symptoms they are experiencing are related to depression and attribute them to other disease processes or the normal aging process. Thus, untreated depression complicates underlying medical conditions and retards management of these conditions. It is up to medical providers to recognize these signs and symptoms by appropriately screening the elderly population for depression.

## **Suicide Screenings in Primary Care**

The risk of suicide remains a public health concern especially among primary care providers. Studies were reviewed with identified patients who were presenting to primary care clinics. The patients were screened for depression and those which were identified as having depression were screened for risk of suicide. The Agency of Healthcare Research and Quality (AHRQ) prepared a systematic evidence based practice review which recommended suicidal screenings for patients with depression (United States Preventive Services Task Force, 2004). Three literature reviews were conducted which evaluated the available data related to suicide screenings in primary care.

## **Statistical Significance and Findings**

Lawrence et al. (2010) researched suicidal screening among patients with human deficiency virus (HIV) and AIDS. The research was a published journal article by the Infectious Disease Society of America. The study was quantitative and assessed patients

with HIV and AIDS who had thoughts of suicide. Suicidal ideations as well as suicides are a continued risk among HIV and AIDS patients despite the treatment advances in the disease. The study indicated that up to “two-thirds of patients who committed suicide were seen by a health care provider the month before their death” (Lawrence et al., 2010) p. 1166. The study involved 1216 patients in two primary academic care clinics. One clinic was at the University of Alabama at Birmingham in which 740 patients participated in the study. The second clinic was at the University of Washington where 476 patients were involved in the study. The study used a computer based, self-report computerized questionnaire screen for the study. The patients were predominately white men with the mean age of 44 and a standard deviation of 10 years. Of the patients surveyed, 170 had suicidal ideations. Thirty three patients admitted having suicidal ideations daily. The statistical significance concluded that suicidal ideation risk became lower with advancing age 0.74 per 10 years at a 95% confidence interval (CI 0.58-0.96) and became higher with current substance abuse with a 95% confidence interval (CI 1.03-3.44). Depression also influenced the degree of suicidal ideations with moderate depression 95% (CI 2.12-7.22) and severe depression 95% confidence interval (CI 12.73-51.30) ( Lawrence et al., 2010).

The goals of the study were to implement routine, self-administered, computerized screening for suicidal ideation. The test had an automated activation of a psychiatric qualified response team. An additional goal was to identify factors associated with suicidal ideations within the homogenous sample of HIV infected patients. The study was a 100% quality controlled observation cohort study which was recognized for excellence in information integrity. The clinics involved were members of the Center for

AIDS Research Network of Integrated Clinical Systems which is funded by National Institutes of Health. The Institutional Review Board at each site reviewed and approved the study. Psychosocial instruments were used to validate the tool used to assess the patients. The tool was termed Patient Reported Outcome (PRO). The PRO assessments were conducted by using touch screen desktop computers at University of Alabama in Birmingham and tablet computers at University of Washington. The use of computers over face to face interviews decreased the bias related to social desirability or respondents attempting to answer questions in order to satisfy the reviewer. Questions were also carefully worded in an effort to decrease perception of judgment of the patient. The patients were provided written informed consent as well as instructions on completing the computerized assessment. The study did not include those patients that were cognitively impaired, unstable in their medical condition, or could not speak English. Patients were also excluded if they did not answer the 9-item Patient Health Questionnaire which was the depression instrument (Lawrence et al., 2010).

As an added safe guard a response team was available to respond to patients which were identified as high risk for immediate suicidal tendencies. The patient was assessed for high risk plans of lethality as a result of current thoughts. The patient was provided additional follow up care such as contracts for safety, follow up appointments, new appointments, or immediate emergency room referral for a psychiatric evaluation (Lawrence et al. 2010).

The study was statistically significant with an overall CI of 95%. The 2-sample t test was used. The Wilcoxon rank-sum test and  $X^2$  as well as the logistic regression analysis which helped to determine which factors were associated with the presence of

suicidal ideations. A self-reported depression screen was conducted on all patients who experienced suicidal ideations. The independent variable of mild depression was used as the referent group. Anxiety was excluded from the regression modeling because of the collinear relationship of anxiety and depression. The statistical analysis of the study identified that 97% of the patients with reported suicidal ideations had concurrent depression. Those patients with suicidal ideations which had concurrent substance abuse were at even higher risk of developing suicidal ideations (Lawrence et al. 2010).

### **Study's usefulness to the research project**

The conclusions of the study were that patients would disclose recent suicidal ideations during a computer screening tool. The risk of suicidal ideations increases with patients who are more at risk for depression and or are current substance abusers. The older the patient the less suicidal ideations were present. The findings may not be generalizable to other national or international settings because it was a homogenous sample within two distinct geographical areas. The study did, however, advance the importance of suicidal screenings among patients in HIV primary care clinics (Lawrence et al., 2010). The study was validated the need to research suicide screening in primary care clinics.

### **Strengths and Weakness of the Study**

One strength of the study included the fact that it was conducted under the supervision of the National Institute of Health. An additional strength in the study was a self-reporting document which eliminated observer biases. The study also had limited situational contaminants and administration variations since it was conducted in two controlled environments. The study had a high sensitivity because of the ability to

identify “caseness” related to the fact that all participants were HIV/AIDS patients. The weakness of the study was the generalization which may be limited to other populations. The study was among a very limited homogenous population of patients within two clinics that all had the chronic illness of AIDS/HIV. Additional variables which were weaknesses of the study include possible transitory personal factors which may have influenced answering the self-study questionnaire. There is no way to qualify the data regarding the understanding of the participants to the item sampling with a computerized self-reporting questionnaire (Lawrence et al. 2010).

Crawford et al. (2011) researched suicide screening by randomized controlled trial in primary care in *The British Journal of Psychiatry*. The study focused on the impact of screening for suicide in patients with mental health issues. The data source was a self-report from the patient regarding feelings of suicide or self-harm. Participants were recruited from four primary care practices in the inner city areas of London.

The type of study the researchers conducted was both quantitative and qualitative. The patients who were 18 years or older, registered with the clinics and were asked to answer a two question questionnaire. The first question was “During the past month, have you often been bothered by feeling down, depressed or hopeless?” (Crawford et al, 2010, p. 379). The second question was “During the first month have you been bothered by little interest or pleasure in doing things?” (Crawford et al, 2010, p.379). The patients who answered yes to at least one question were given written and verbal informed consent on the study. The patients who agreed to participate signed written consents. Study participants were interviewed again by telephone on two additional occasions. During these phone conversations, participants were asked the original questions again as

well as additional questions. One set of questions consisted of a 12 item General Health Questionnaire. The General Health Questionnaire focused on the patient's mental health. Those patients with suicidal ideations were asked an additional six questions. Demographic data were also collected; such as family history of suicide and other basic data (Crawford et al., 2010).

Additional interviews were conducted by a different set of researchers. During the additional interviews researchers were unaware of previous data collected on the patients. During the follow up interviews the patients were screened with a 6 question suicide questionnaire. The patients who voiced suicidal thoughts or ideations were encouraged to follow up with the resources they had available to them. The patients who voiced suicidal plans were referred to clinical staff by the interviewers themselves (Crawford et al., 2010).

### **Statistical Significance and Study Findings**

The study had a total of 443 patients. The mean age was 48.5 years and 137 were men. Forty-three percent of the patients had long term relationships including marriage. Forty-seven percent of the patients were working or in school, 134 were unemployed and 86 were retired. All of the patients scored at least one out of two on the initial screening questionnaire with a total of 255 scoring two out of two questions. Two hundred and seventy eight patients met the threshold for mental "caseness". On the initial set of phone interviews, 46 were identified as positive for suicidal ideations with 46 identified as hopelessness or life not worth living. Thirty eight reported wishing they were dead. Twenty four patients voiced that they had thoughts of taking their life. One patient had



attempted to take his life. No one was identified as actually taking their life (Crawford et al., 2010).

### **Strengths and Weaknesses of the Study**

The study had its limitations or weaknesses which included a limited homogeneous sample. The sample of participants came from only four inner city clinics in London. The study also had many different researchers which lent itself to influences on measurement error such as situational contaminants, transitory personal factors, and administration variations. The reliability of the study was increased by the use of the test-retest method used in conducting the questionnaire. The study appeared well prepared at face value and the confidence interval was 95% (Crawford et al., 2010). The statistical significance of the study was based on an odds ratio for suicidal ideation of (OR = 1.2 with CI of 0.72-2.00). The odds ratio was broad but the authors concluded that "screening did not increase the likelihood of such thoughts" (Crawford et al., 2010, p. 382). The strength of the study is the fact that it was conducted by different interviewers on different occasions therefore a comprehensive assessment of the patients with the suicidal ideations was obtained. Another strength of the study is the number of participants who completed the study. The study begins with n-443 and was completed with n-351. The overall percentage of participants who completed the study was 79% (Crawford et al., 2010).

### **Study's Usefulness in the Research Project**

The study revealed that many people who seek care in a primary care clinic that have signs of depression, have suicidal ideations or tendencies. The study concluded that screening does not lead to an increase in suicidal thoughts. The data also revealed that

often times the patients are not seeking care for their suicidal ideations or thoughts, and unless asked or prompted, they may not come forth with the information. The study supported our research by validating that patients seek care in primary care clinic often have suicidal ideations which can be identified by screening by the provider.

The next literature review also focused on suicidal screenings by the provider. Heisel, Duberstein, Lyness, and Feldman (2010) researched suicidal screening among older adults by primary care providers. The objective of the study was to research the identification of suicidal ideations by conducting simple screenings in primary care. The study focused on low complex screening tools which were able to be administered with little time. Suicide is one of the top ten leading causes of death among all adult age groups (CDC, 2009). The primary care clinics were the target site for the research project because older adults seek the majority of their medical care at primary care sites (Heisel et al., 2010).

The researchers conducted a qualitative study in private or university clinics using patients age 65 and older and were published in the Journal of American Board of Family Medicine. The patients were selected from those who presented for care on selected days from the waiting room. The study received appropriate approval from the ethics review board of the University of Rochester. The clinics provided general internal medicine, family medicine, and or geriatric care and were located in the Northeast United States. Verbal and written consent was received by each patient who participated in the study. As a safety initiative of the study, any patient who was recognized as having suicidal ideations was immediately referred to a supervising psychiatrist. The patients who were identified as having serious suicidal risks were brought to the emergency psychiatric

intake for appropriate evaluation. Even though the safety procedures were in place, no patient required implementation of the procedure during the study (Heisel et al., 2010).

The measure and procedures which were used to complete the study begin with an assessment of the severity of the patients' depressive symptoms. The symptoms were assessed by a 15 question self-reporting Geriatric Depression Screen. Without knowing the results of the Geriatric Depression Screen, interviews used questions from the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (SCID) and the Hamilton Rating Scale for Depression (Ham-D) (Heisel et al., 2010; First, Spitzer, Gibbon, & Williams, 1997). The patients also completed demographic measures and the trained interviewers conducted brief assessments of cognitive functioning, physical functioning, and medical burden. The physician used both the physical findings and reviewed the medical records to make the determination. The study then examined the patient's suicidal ideations by using the Geriatric Depression Scale-Suicide Ideation Screening Items (Heisel et al., 2010; Sheikh & Yesavage 1986). The suicidal ideations were assessed for both the desire for death and/or for suicide. The study used both the defined questionnaire and the GDS score to identify those patients who were at risk for suicidal ideations. The rationale for this was to lower the level of severity of suicide ideation and to enhance the detection of those patients. Both the interview and written questionnaires were used because of the reluctance of many adults who would not verbalize their thoughts of suicide but would be willing to document on a form. The sample of patients who did not identify on either test as having suicidal ideations was classified as nonideators. The study used both the patients with a diagnosis of depression as well as those without (Heisel et al., 2010).

## Statistical Significance and Findings of the Study

Data were analyzed by using counts, means, standard deviations, and percentages. “All AUC scoring exceeded 80%, the AUCs were compared against a null hypothesis of 50% coverage using a Wisconsin rank sum test.” (Heisel et al., 2010, p. 263). The sample consisted of 1412 patients who were approached to participate in the study. Those that actually completed the intake study were 704, while those that actually completed the final portion of the study were 626. This final sample was n-626 with 235 men and 391 women. The sample had 221 patients who scored as active mood disorder including, 109 for major depression and 108 for minor depression. Overall, 69 patients scored positive for suicide ideation with 557 which did not. The Ham-D test identified 42 positive and 62 were identified positive on the SCID test. Women n-49 scored a higher prevalence of the suicidal ideations than men n-20. Findings from the study identified that patients who scored higher on the GDS and the Ham-D test were more likely to have suicide ideations than those who scored lower. The data would suggest that a correlation exist between depression later in life and suicide (Heisel et al., 2010, pp. 263-264).

The study revealed that older adults both men and women with suicide ideations are routinely receiving care at primary care clinics. The data reveals that the patients are not always seeking care for the suicidal ideations but the ideations may be underlying. The findings suggest that screenings during the routine appointment may prove valuable in identifying depressive tendencies and suicidal ideations. The scales are easily performed and are able to be completed using a limited amount of the provider’s time. The study identified that suicidal tendencies are identified in both sexes and are more likely present in those patients who present with depression. The study revealed that the

GDS along with the GDS-SI was able to identify those patients who express suicide ideations from those which do not have the ideations (Heisel et al., 2010, pp.265-267).

### **Strengths and Weaknesses of the Study**

One limitation of the study was that it only screened older primary patients who were willing to participate in the study. The study is also limited to the specific tools and measurements which were used. Scores could have been significantly different in different environments. The test also used low level suicidal risk as the determinant identifying factor as a risk for suicide. The low level risk may not be an actual determinant for those patients who follow through with committing suicide. The study group consisted of predominantly white individuals who had an above average education level, therefore the study was not a cross section of the general older adult population. Another limitation of the study was that the patients' history was not available for evaluation. The findings were only able to be analyzed for a specific day in time and not a quantitative analysis. The sample was from who presented to the clinic on a given day and the findings could be different given a different sample of patients with history of depression (Heisel et al., 2010).

### **Study's Usefulness in the Research Project**

It is important to continue to study the use of suicidal screening tools which practitioners use to identify an evidenced based tool that can help identify those at risk for depression and/or suicidal risk (Heisel et al., 2010). The study was useful as we researched the prevalence of suicidal screenings in the primary care setting especially the tool used for administering the screenings. The study identified some of the barriers which may prevent primary care clinics from conducting screenings. The study identified

gender as a datum point; this study identified this as well. The study did not address any correlation to whether a suicidal screening in the primary care clinics is even beneficial to preventing suicide. Longitudinal data would be needed to compare the success rates of screenings.

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### **Patient and provider perceptions of suicide screenings**

Primary care providers need to know the signs and symptoms of patients at risk for suicide and should be able to address the subject with the patient in a manner that promotes maximum efficacy. This screening is very important in areas of Mississippi, where patients typically have limited transportation or support mechanisms, and mental health issues are likely to be managed, if at all, in the primary care setting.

The article by Bajaj et al. (2008) is a qualitative study that assesses how providers and patients feel about screening and being screened for suicide. The location of the study was in North West London and took place in three different general practice areas. In this study, the authors were seeking to discover the general attitudes of patients and general practitioners toward screening of suicide. There were a total of 27 articles reviewed. The average year of publication was slightly more current than 2002. The oldest article was from 1987 and the newest was 2005.

The methods of the study involved the researchers obtaining permission from the staff of three general practice clinics in North West London to recruit study participants. The recruiting phase searched for patients in these clinics with non-urgent issues. The researchers explained to the potential participants that they were interested in questions that general practitioners may ask about emotional issues. Those who agreed to participate were screened for depression using a two part questionnaire developed by Arroll and colleagues. If a participant answered yes to either question, they were then asked to take part in a telephone survey containing five questions directly related to suicidal ideation. The article states that the five questions used are widely accepted in other studies and settings involving depression and suicide risk. In addition to the five questions, the participants were also asked if someone close to them has attempted or committed suicide. Next, the participants were asked four questions regarding how they felt about being screened for suicide by their general practitioner. The second methodological aspect of the study involved a survey asking the general practitioners similar questions to those asked of the participants. The questions included whether they screened for suicide, which patients they screened and why, and personal training. To

assure confidentiality, the participant's demographic and other information used to identify the respondents was not included in the questions to the general practitioners.

### **Statistical Significance and Findings of the Study**

A total of 101 of 132 patients agreed to take the phone survey, while 103 out of 300 general practitioners returned a copy of the survey. The responses were described via simple descriptive statistics using SPSS (Version 16.0) and analyzed using a thematic framework. When asked, 38.6% of the participants did not mind the screening questions, 26.7% were surprised at the questions, and 25.7% were alarmed at the questions. Also, 80.2% felt that a general practitioner should routinely screen an individual who is depressed, while only 4% felt that routine screening was unnecessary and 15.8% were unsure. On the final question, half of the participants favored a direct approach toward suicide and half favored a more careful approach. Several quotes of participants regarding their feelings were stated in the article (Bajaj et al., 2008).

Of the general practitioners who participated, 93.2% stated that they performed suicide screens on patients with suicidal ideation, 86.4% did so with patients having signs or symptoms of depression, and 21.4% screened those with both psychosis and chronic physical conditions. Interestingly, few general practitioners screened those with substance abuse or history of self-harm. The most common reason general practitioners identified for screening patients with suicidal ideation was to manage risk, which was 86.4%. Twenty-nine percent said that screening was part of their contribution toward preventing suicide, while 20.4% stated that screening opened up a sensitive subject that they wanted patients to be able to discuss. Only 6.8% stated they screened for legal reasons. About 60% of the general practitioners had not received formal training on



suicide screening, whereas a little over 38% said they had received formal training during psychiatric rotations. Two common barriers to screening cited by the general practitioners were (1) time issues, and (2) ethnic issues related to interpretation of sensitive questions along with uncertainty of cultural attitudes. Only a small percentage of general practitioners stated they were embarrassed to ask these types of sensitive questions. Almost 36% of the general practitioners felt that exposure to questions about suicide could have an inductive effect; although 60% said that it would not. Finally, 68% of the general practitioners stated the suicide screenings would not trigger suicidal behavior in vulnerable groups (those with personality disorders and substance abuse problems) and 25% thought it would (Bajaj et al., 2008).

### **Strengths and Weaknesses of the Study**

One of the strengths of the study was that all the participants demonstrated evidence of depression and were asked about their personal reaction to the screening questions. A second strength in the study is the fact that the sample group of general practitioners and patients were equal in number. One of the weaknesses of the study was that all patient interviews were conducted over the phone, which may have had a different effect than a face-to-face encounter (Bajaj et al., 2008).

A second limitation was the poor general practitioner response. Only a third of the general practitioners responded, which may dilute authenticity of generalizability in the general practitioner sample. Patients with depression appear to be screened much more often than those with substance abuse problems or with a history of self-harm. Fortunately, a relatively small percentage of general practitioners and patients (one quarter) were uncomfortable with screening for suicidal ideation. It is interesting;

however, that one fourth of general practitioners and one fifth of patients thought that approaching the subject would actually increase the likelihood of someone harming themselves. This study highlights some of the issues that may affect whether screenings are performed, such as time pressure, cultural, or language barriers (Bajaj et al., 2008).

### **Study's Usefulness in the Research Project**

This research study was useful to our project by demonstrating how, why, and when general practitioners in primary care settings screen potential high risk patients for suicide. In light of the large numbers of patients in underserved areas, combined with the lack of transportation and lack of local mental care services, these questions need to be addressed. The study supported our project by demonstrating evidence of barriers to suicide screenings. The study supported the need to collect data on the percentages of patients who have documented screenings.

Feldman et al. (2007) conducted a mixed study demonstrating that, without active inquiry by the primary provider, patients with suicidal thoughts may be reluctant to discuss their intentions. In this study, the authors were seeking physician characteristics that relate to the inquiry of suicide in patients with symptoms of depression, as well as the influence patients had on physicians when requesting particular antidepressants. The authors also suggested that information is limited regarding the factors that induce primary care providers to approach the subject of suicide with patients. Although much work has been done on detecting depression in primary care, little has been done to ascertain suicide risks (Feldman et al., 2007).

This article explored several factors related to the analysis of suicide risk in patients. These include the patient's behavior and symptoms, as well as characteristics of

the provider. The question in the study asks what factors influence the caregiver's likelihood of raising the subject. Specific questions asked in the study were: (1) what clinical and demographic factors influence the caregiver? (2) Does severity of symptoms make a difference? (3) Does a patient's request for antidepressants influence the provider to investigate thoughts of suicide?

After approval by the IRB, the study's design utilized 18 individuals who were trained to portray a total of 6 roles lasting from May 2003 to May 2004. Since only actors were used in the study, there were no patient rights issues to address. The roles involved actors (termed "standardized patients") with two clinical conditions of adjustment disorder and major depression during new patient visits lasting 15 to 20 minutes. The types of medication requests used were a brand specific medication request, a general medication request, and a request for no particular medicine. The first role was a divorced 48 year old white woman with moderate severity major depression, along with wrist pain. The second role consisted of a divorced 45 year old white woman with depressed mood, adjustment disorder, and back pain. The actresses were required to play the roles with 95% accuracy. In following the design of the study, three medication requests were made: (1) Paxil, (2) one that may help, and (3) no particular medication request. The first two were labeled "prompt", whereas the third was "no prompt". The providers gave consent to see the patients with the session being covertly recorded. The 152 physicians who participated in the study were similar in age and sex to physicians who did not participate (Feldman et al., 2007).

After signing the consent, at least two months passed before the physicians actually saw one of the standardized patients. After the visit, the standardized patients

listened to the audio recording of the encounter; an independent judge also listened to the recordings randomly. Both groups filled out a reporting form demonstrating an overall 92% agreement. In a two week follow-up, 12.8% of the physicians demonstrated some suspicion that one of their patients was, in fact, one of the standardized patients involved in the study. The reporting form filled out by the standardized patients focused on history taking for the depression symptoms. Questions included whether the physician asked the patient if she wanted to commit suicide, be dead, or harm themselves. The authors of the study obtained the questions from the advisory panel, as well as published suggestions (Feldman et al., 2007).

At least 4 weeks after the last standardized patient was seen, the physicians filled out a questionnaire. The questionnaire contained questions regarding age, sex, specialty and setting as well as treatment of depressed patient. The physicians were also asked eight questions relating to their confidence level, nine questions about their perceived barriers, and finally, whether they have had personal experiences with depression themselves (Feldman et al., 2007).

The audio recordings were analyzed using the Measure of Patient-Centered Communications (MPCC) score which was thought to represent the physician's way of communicating and would show their likelihood of suicide exploration with patients. (Feldman et al., 2007). The reporting form filled out by the standardized patients focused on history taking for the depression symptoms. Questions included whether the physician asked the patient if she wanted to commit suicide, be dead, or to self-harm. These questions were based on Albert Bandura's Social Cognitive Theory and rated on a four-point Likert scale.

## **Statistical Significance and Findings of the Study**

Analysis of the reporting form focused on whether the physicians examined suicide with the standardized patients in the study. The MPCC score was also analyzed with logistic mixed models, to see the relationship between exploration of suicide by the physician and characteristics of the patients (major depression verses mood disorder). Each patient-physician encounter was analyzed as an observation by random intercept and mixed effects regression analyses. A random effect, also called a variance component, allowed “calculation of the consistency with which physicians explored suicide in the encounters” (Feldman et al., 2007, p.414). A physician variance component P value of less than 0.05 was considered statistically significant. Encounters where the physician suspected a standardized patient were not presented. The results showed that, of the 29% encounters, suicide was addressed in 36% of the cases. Exploration of suicide was more common when the patient demonstrated major depression verses adjustment disorder, and was also higher when the patient had a general request for medications. Two other factors that increased exploration of suicide were academic settings and physicians who either had a personal experience or had a family member or close friend who had experienced depression (Feldman et al., 2007).

## **Strengths and Weakness of the Study**

There were several potential weaknesses in the study. First, there were differences among physicians in their likelihood of approaching the subject of suicide. Second, methodological advantages of standardized patients were not necessarily entirely representative of an actual patient encounter. Third, the sample of standardized patients were single women in their 40's, which may not represent physicians overall exploration

in all populations. Fourth, the quality of discussions between the physician and patient about suicide could not be demonstrated using the current methods of measurement. Fifth, the study was unable to identify specific physician factors that determine whether or not they explore suicide. Finally, all data came from the reports filled out by the actors that portrayed the standardized patients, which raises questions about its validity. It was not stated if the patients playing these roles were trained actors; however, it did mention that they were required to act with 95% accuracy. Strengths in favor of the actor's ability were partially demonstrated when only 12.8% of the physicians reported suspicion of an actor. Another indicator of strength is the 92% agreement between the independent judge (who listened to 36 random recordings) and the standardized patients (Feldman et al., 2007).

### **Study's Usefulness in the Research Project**

Feldman's study is significant in this study because it demonstrates that implementation of routine screening for suicide may be lacking in primary care environments, indicating the need for more studies and education. The authors recommend that various social marketing avenues or public service messages be used in prompting patients on how to address these issues with their primary care provider. Earlier studies demonstrate that changes in behavior of primary care providers in administering care to depressed patients may improve outcomes more than simple monitoring depression. More studies need to be done to determine the extent of suicide exploration in depressed patients in primary care settings. Increased and improved surveillance and exploration of this delicate subject may help lower the frightening statistics of this very preventable health care challenge.

Parker et al. (2008) conducted a qualitative study which suggested a significant number of care providers lack adequate knowledge to recognize early warning signs of suicide or may feel uncomfortable approaching the topic of suicide. The study took place in Oklahoma where suicide is the third leading cause of death in the 10 to 24 age group, and the second leading cause in the 25 to 34 age group. Findings of the study concluded that many teens saw a primary health care provider within six weeks prior to attempting or completing suicide. They were seeking to discover current provider awareness and how improved provider awareness in the Oklahoma area would be beneficial to early detection, resulting in appropriate actions such as referrals. The study was conducted in the heartland of America and was likely a well generalized representation of many communities in this country (Parker et al., 2008).

After IRB approval, the study was conducted by distributing a questionnaire to a sample of 52 physicians, nurses, physician assistants, and nurse practitioners which focused on providers' knowledge of suicidal signs and symptoms of patients at risk as well as knowledge of mental health referral locations. Educational material on recognition of signs and symptoms, as well as providing information on current referral options or facilities for depressed patients at risk was distributed to the clinics. The education material consisted of a pamphlet sidebar regarding rates of adolescent suicide, myths, triggers, and overall clinical signs and symptoms of suicide. The education material outlined warning signs such as talking about suicide or death, severe mood swings, gender identify issues, alcohol or drug use, and isolation. It emphasized warning signs that indicate a need for immediate attention, such as announcing a plan, expressing feelings of meaninglessness, giving away possessions, and obtaining a weapon, among

many others. The sidebar was concise, and easy to read and pass around. A referral list which was updated every six months was given to the clinics after the researchers contacted directors of local mental health services within each of the local counties (Parker et al., 2008).

### **Statistical Significance and Findings of the Study**

The results demonstrated that 77% of the providers did not feel comfortable recognizing or addressing the signs and symptoms of suicide in the 10 to 24 age group and that greater than 87% were unaware of referral facilities. Significantly, none of the clinics kept suicide prevention handouts or other materials to give to patients or caregivers. The fact the handouts and other materials were not kept clearly demonstrated to the research group that the need existed on educating community primary care providers on the need for suicide screenings. The study participants were allowed to voice their concerns about patients needing assistance, parent's lack of awareness, and the fact that referral opportunities remain scarce (Parker et al., 2008).

The significance of the study was demonstrated after implementation of suicide education when physician referrals went from a total of 59 in 2005 to 96 in 2006, and 102 by 2008. By the year 2008, the program had been presented to over 4000 health care providers and educators in clinics, hospitals, public schools, and universities, and had become part of many orientation programs and curriculums.

### **Study's Usefulness in the Research Project**

Specific strengths and weaknesses were not mentioned in the study, some factors that may demonstrate limitations would include, size of the sample, type questions asked in the questionnaire, and what were the percentages of each type of provider. Failure to



identify time factors or constraints within the clinic setting was also an identified weakness. Strengths of the study included a well-constructed pamphlet sidebar which proved that effective awareness of suicide, communication and referral knowledge among providers influences rates of appropriate intervention (Parker et al., 2008).

Parker's study applied to this study because it demonstrated that similar research is needed in Mississippi to understand and address many key issues and treatment modalities for those with depression and suicide ideation. The alarming statistics in Oklahoma along with other national statistics on depression top of the list for needed research. In Mississippi, the proposed study sought to discover provider screening depression and suicide ideation seen in primary care.

### **Summary of Literature Review**

Suicide is a preventable leading cause of death. These studies demonstrate the important role primary care providers play in detecting early warning signs and preventing unnecessary tragedies. The studies suggest healthcare providers have a significant role in identifying patients at risk for suicide. For the purpose of this study, the researchers focused on whether or not providers screened for suicide in adult patients with the diagnosis of depression. The evidence of the literature reviews suggested that suicidal ideations and the risk of suicide are common in patients with a diagnosis of depression. Additionally, the evidence suggests that suicide screening tools, when utilized can identify at risk patients.

## **Chapter III**

### **Methodology**

#### **Introduction**

Rural health facilities across Mississippi provide the basis of primary care to many residents. These clinics are easily accessible to patients who routinely would have to travel long distances to seek care. Providers at rural health clinics are often the sole providers for managing patient's physiological and psychological states. This study aimed at evaluating the effectiveness of rural health providers' screening for suicide in patients with a diagnosis of depression. Since rural health providers are likely the only available source for treatment of mental disorders, it is paramount that they screen patients with depression for suicide risk so that early identification, prompt intervention, prevention of injury and loss of life may take place. This section provides a step by step approach to data collection, analysis, and interpretation for the study. The study's goal is to examine the prevalence of suicide screening and referral practices of providers in patients with depression.

#### **Design and Setting**

The research study was a quantitative retrospective chart review that took place at three rural health community based clinics across central and northern Mississippi. Each participating clinic was staffed by family nurse practitioners and/or medical doctors serving as primary health care providers managing mental, physical, acute, and chronic illness. The chosen research design provided a convenient method of data collection for

the time allotted. In addition, the design was chosen to provide further insight to previous research aimed at evaluating the prevalence of suicide screening in depressed patients.

### **Population and Sample**

The target population for the study consisted of adults, age 21 and older, with a diagnosis of depression being seen in rural health clinics across central and northern Mississippi. The accessible population for the study consisted of men and women, age 21 and older, with depression that were seen at three rural health clinics located in central and northern Mississippi. A convenience sample of the records of 100 adults, age 21 and above with a diagnosis of depression, at each of the three rural health clinics were accessed for the study using retrospective chart review audits. A convenience sample (N=300) was selected because of ease of accessibility and time factors and was agreed on by the researchers.

### **Implementation of the Project**

The researchers selected 100 office visits of patients' within the last five years with depression from each of the three participating clinics that were representative of the patient selection criteria. Temporary passcodes were given to the researchers to allow access to the Electronic Health Record database. The researchers tracked their data using a password protected worksheet available only by flash drive that was used solely for storing data for the study.

### **Protection of Human Rights**

Prior to the start of the study, written approval was obtained from Mississippi University for Women's Internal Review Board. Next, written consent was obtained from each of the participating clinics in the study (see Appendix A: Letter of Consent). The

data collection tool used lacked identifying patient information such as date of birth, name, medical records identifiers, or social security information. Patient records which were reviewed on the Electronic medical records were done in a secure area of the clinic, away from patient areas, and did not draw attention to the researcher or impede patient care or normal operation of the clinic. Patient confidentiality, with the highest regards to HIPAA was strictly enforced. Only the records of patients diagnosed with depression were accessed. Under no circumstances were any records removed from the clinic at any time. All information obtained from the data collection tool was entered into a Microsoft Excel spreadsheet within one business day of data collection and saved to a password protected flash drive only accessible to the researchers. Worksheets used for data collection were shredded following transfer to the password secured flash drive. At the conclusion of data analysis, the password encrypted flash drive was destroyed.

### **Data Collection and Analysis**

Data for the study was collected over a 30 day time frame and charted using a data collection tool (see Appendix B: Data Collection tool) that was developed by the researchers. This tool consisted of measurements which assigned parameters such as: age, sex, provider title, suicide screening, and referral evaluation (see Appendix C: Data Collection Tool Legend). Electronic health records of 100 patients at each of the three participating facilities with recent office visits using ICD 9 codes of atypical depressive disorder (296.82), manic depressive disorder (296.89), depressive type psychosis (298.0), depressive disorder not elsewhere classified (311), major depressive disorder single episode (296.29), mood disorder (296.90), bipolar disorder (296.6), and major depressive disorder (296.3) were included. Data were analyzed using descriptive statistics that

expressed comparisons and differences in the data collected. Percentages noting the prevalence of provider screenings for suicide in patients diagnosed with depression were examined to reveal differences between providers who screened these individuals for suicide and providers who failed to do so. The researchers were able to calculate their findings using visual illustrations of data interpretation with the use of histograms and pie charts which provided insight into frequency distribution, standard deviation, mean, median, and mode.

### **Summary of Methodology**

The research study consisted of a quantitative retrospective chart review to determine if patients, age 21 and above, diagnosed with depression were screened for suicide. Patient data were collected from three participating rural health clinics across central and North Mississippi using a worksheet created by the researchers. Patient confidentiality was maintained to the highest standard throughout the study. Data were collected and analyzed using descriptive statistics.

## Chapter IV

### Presentation of Findings

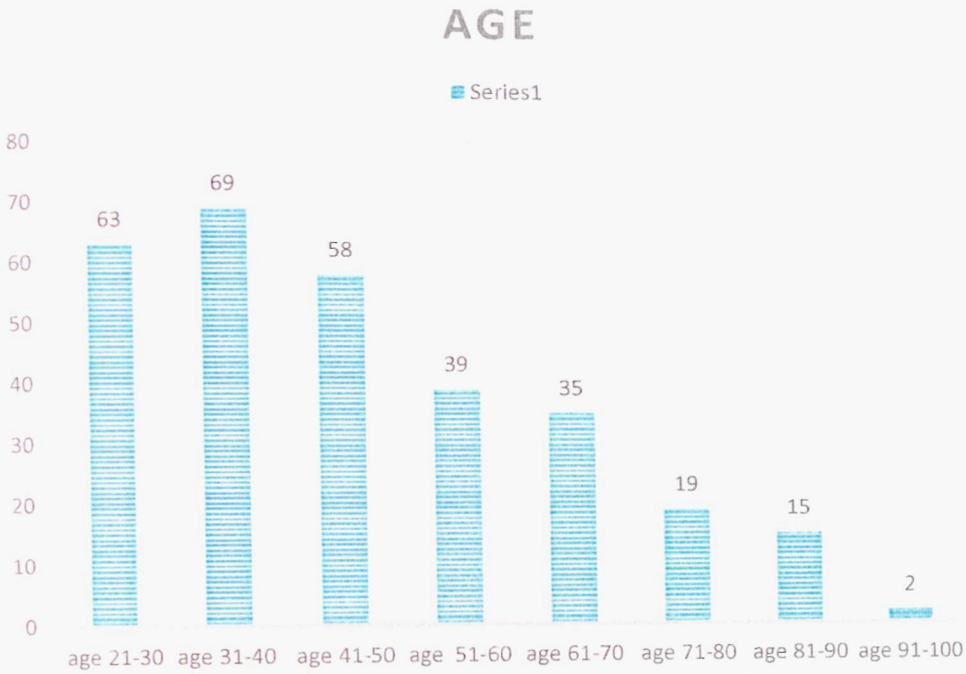
The purpose of this research project was to identify if patients diagnosed with depression are appropriately screened for suicide in the primary care setting. Data were obtained from patients 21 years and older in three clinics in central and northern Mississippi. A presentation of the sample characteristics, research questions, and data analysis will be presented in this chapter.

#### **Description of the Sample**

The study was conducted by three different researchers with one hundred charts reviewed from each clinic for a total of 300 charts. A data collection tool was created and adapted to collect data. Charts reviewed were male and females 21 years of age and older. The charts reviewed had the following ICD codes: atypical depressive disorder (296.82), manic depressive disorder (296.89), depressive disorder not elsewhere classified (311), major depressive disorder single episode (296.29), mood disorder (296.90), bipolar disorder (296.6), and major depressive disorder (296.29). Data collected included age, gender, provider title, and whether individuals with the diagnosis of depression were screened for suicide. The researchers also sought whether the patients screened were referred to another facility. The data were collected from the documentation which was made by the provider either electronic or manual in the SOAP notes.

Data were collected by the researchers from a sample (N=300) of patients age 21 years and older. The age ranges of the sample were as follows: 21-30 (n=63), 31-40

(n=69), 41-50 (n=58), 51-60 (n=39), 61-70 (n=35), 71-80 (n=19), 81-90 (n=15), and 91-100(n= 2).



*Figure 1.* Age distribution of sample.

Data were collected by researchers from a sample (n=300) of males and females from the three selected clinics. Male gender accounted for 30.3% (n= 91) of the sample. Female gender accounted for 69.7% (n=209) of the sample.

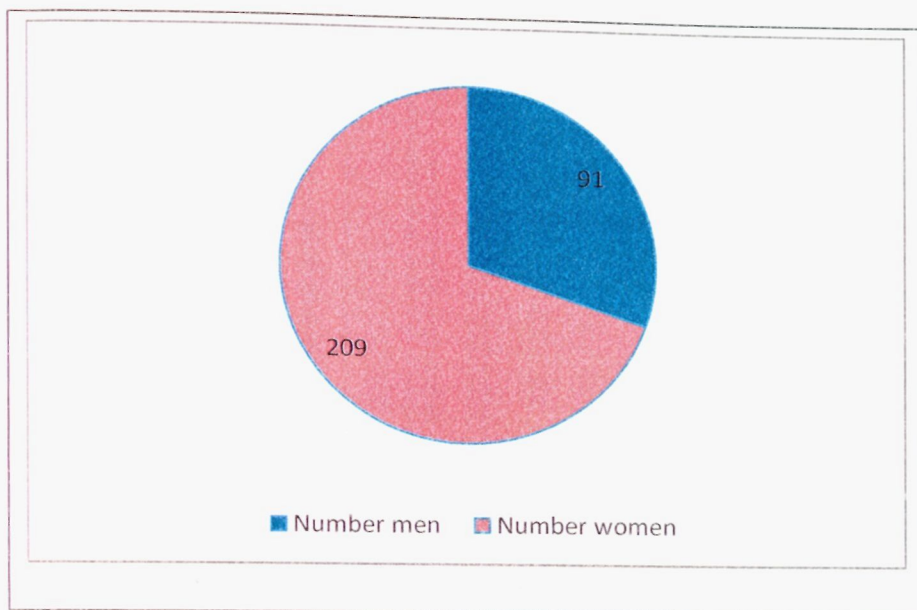


Figure 2. Sex distribution of the sample

### Research Questions

The researchers evaluated the following questions:

1. What percentage of adult patients over the age of 21 with depression, have a recorded screen for suicide risk?
2. What percentage of adult patients that received a suicide screening was referred to another facility?

Each research question was evaluated through chart reviews. Statistical analysis of the data was used to determine percentages for the individual research questions using frequency distribution tables.

*Research question 1.* What percentage of adult patients over the age of 21 with depression, have a recorded screen for suicide risk? 50.3% (n=151) of the 300 individuals



were screened for suicide risk. 49.7% (n=149) of the patients with depression did not have a recorded screen for suicide risk.

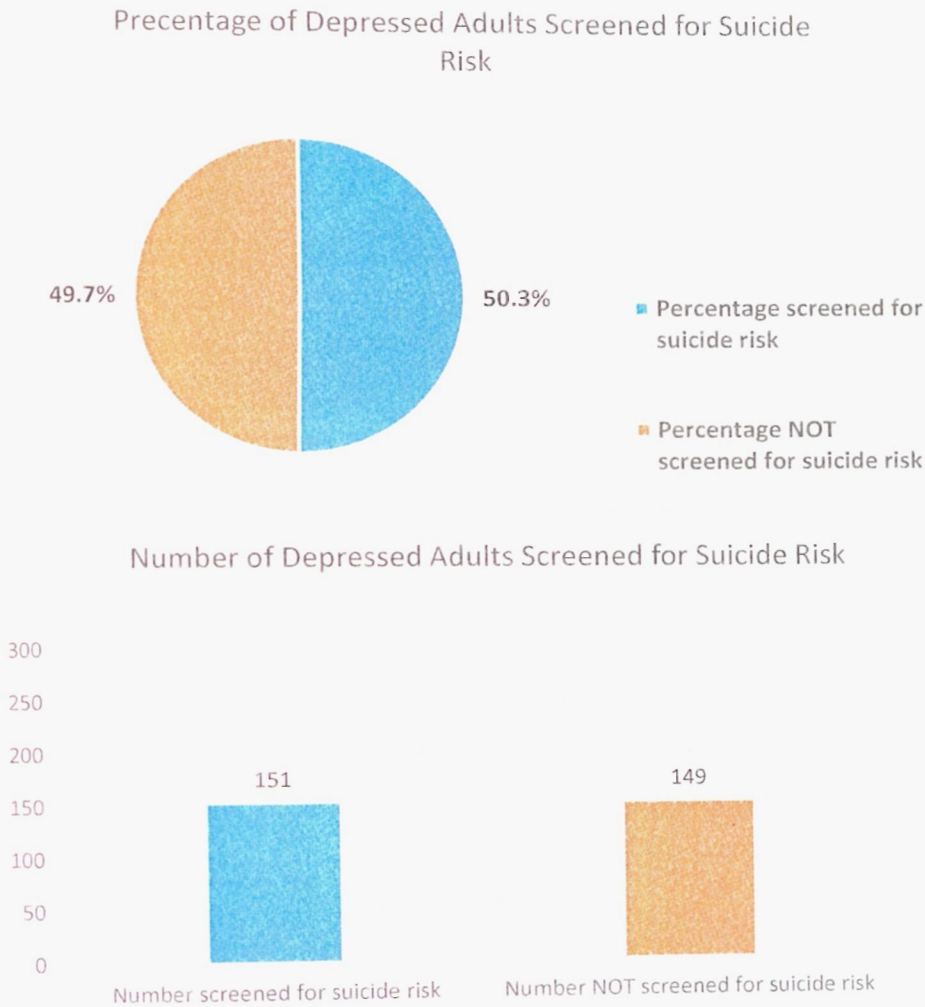


Figure 3. Percentage and number of depressed adults screened for suicide risk.

*Research question 2.* What percentage of adult patients that received a suicide screening was referred to another facility? 15.9% (n=24) of the patients screened were referred to another facility. 84.1% (n=127) were screened and not referred to another facility.

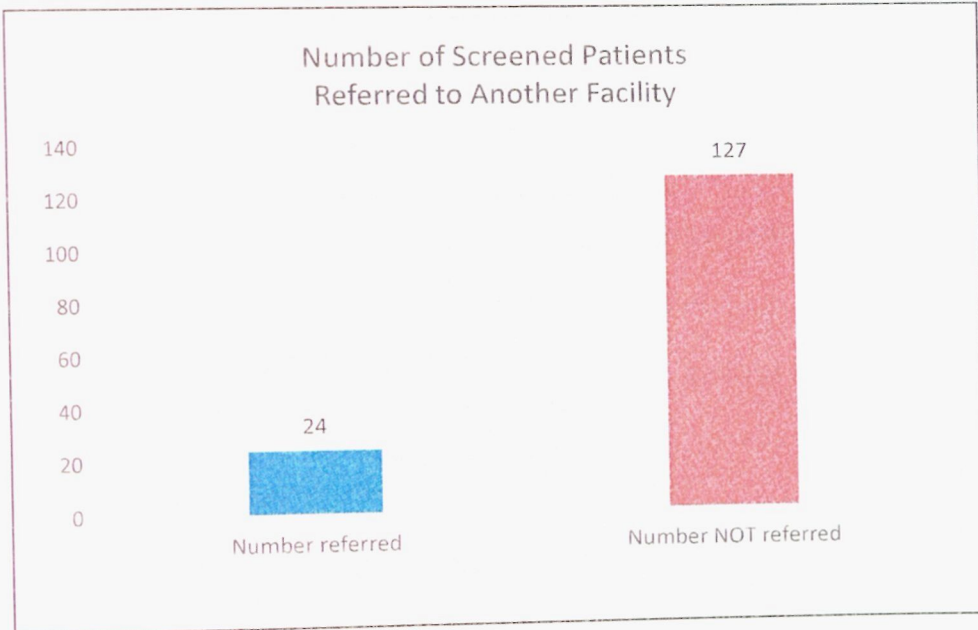
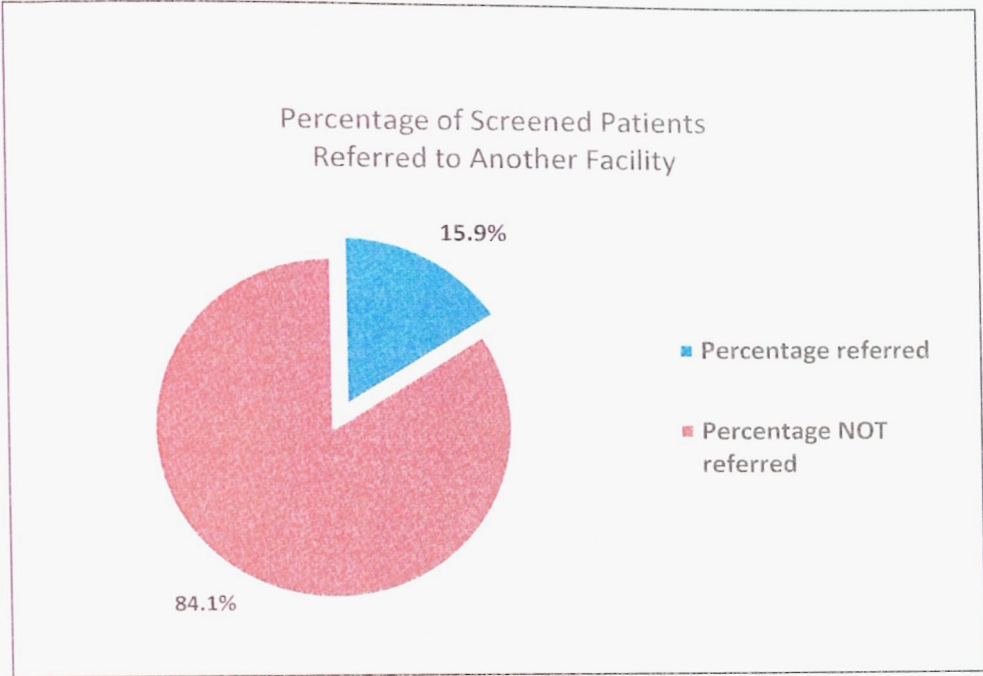


Figure 4. Percentage and Number of patients who were screened and referred

### Data Analysis

A data collection tool was created to collect data from the selected clinics. Three hundred charts were reviewed from patients with the diagnosis of depression and age

over 21 years old and up. Data collected included age, gender, provider, if the patients with a diagnosis of depression had a documented suicide screen and if referral was made to another facility. The patient records were reviewed for diagnosis of depression and the soap notes were reviewed for documentation of a suicide screen and whether a referral was made to another facility. The data were entered into Excel system by researchers for analysis. Using descriptive statistics percentages were obtained regarding the research questions and were put into table format.

### **Summary**

The chapter presented by the researchers' findings was derived from chart reviews of adult patients 21 years of age and older, and have a diagnosis of depression. The researchers determined if screening for suicide risk was being performed by primary care providers in the three selected clinics. The findings from the chart reviews were recorded on a data collection worksheet developed by the researchers, and results were analyzed using quantitative and statistical methods. The results were explained throughout the chapter in narrative form and were illustrated using a chart format. In this project, the primary care providers consisted of both medical doctors and nurse practitioners practicing in three primary clinics.

The researchers determined that primary care providers are not effectively screening for suicide risk in patients with a diagnosis of depression. The researchers determined that a very small percentage of patient with depression are being referred to outside facilities. Furthermore, the findings support that a large percentage of patients with the diagnosis of depression are seen in primary care and are not being referred to an outside facility. Only 3.5% of nurse practitioners referred patients that were screened to

another facility while 21.7% of medical doctors referred. Although it was not addressed in the initial research questions, interestingly enough, a total of 10 patients with a diagnosis of depression were referred to another facility and were not screened for suicide. This practice raises questions about the use of and the variation of suicide screens used in the clinics.

## Chapter V

### Summary and Conclusions

#### Summary of the Investigation

The purpose of this study was two-fold. First, the research would determine what percentage of patients at three clinics in north central Mississippi, ages 21 and over with a diagnosis of depression had recorded suicide risk assessments. Second, to determine what percentage of patients screened was referred to another facility for further evaluation, treatment, and management. To accomplish that goal, study prerequisites were established. It was necessary to make a distinction in terminology between the theoretical and operational components of the study specifically, the definition of adult patient, depression, suicide screening, and other facility. Additionally, it was necessary to determine specific depressive diagnoses by ICD-9 codes. Further, it was necessary to identify the target population within several clinical settings in central and northern Mississippi to obtain an adequate randomized sample of charts for review within a given timeframe. Once these fundamental steps were initiated, we were able to advance with our research. This chapter documents the research findings, conclusions, and recommendations for future study.

#### Summary of Statistical Results

One key intention of this research was to determine if general health practitioners' level of comfort in screening adult patients diagnosed with depression for suicide during primary care visits; and if they had adequate knowledge of referral options for patients identified to be "at risk" for suicide for further evaluation, treatment, and management.

Three clinics in central and northern Mississippi participated in this research. Three researchers were committed to reviewing 100 charts from their respective clinical sites for a period of 30 days to determine if practitioners conducted and recorded suicide risk assessments; and the percentage of those referred to outside facilities for further evaluation, treatment, and management.

### **Outcomes Related to Research**

#### **Research Question 1: What percentage of adult patients over the age of 21 with depression, have a recorded screen for suicide risk?**

The Roy Adaptation Model and its appropriateness for this research is critical in assisting practitioners in primary care settings in determining the need for developing strategies that will effectively identify adult patients with a diagnosis of depression who are at risk for suicide. The ultimate goal is to make timely referrals to mental health professionals so that interventions are employed, thus reducing the potential for undue tragedy and loss of life.

As discussed in Chapter 2, the focal stimulus for this study is the relationship between provider and patient. The researchers hypothesized that there is a direct correlation between provider's level of comfort in conducting a suicide screen and timely referral to an outside entity for appropriate evaluation, treatment, and management. In her 20 years of research, Roy (2011) concluded coping must be understood in both physical and mental stress. The practitioner's role in the process is to promote coping for patients and families. This is best accomplished when practitioners are knowledgeable in patient criteria for suicide screening; and successful identification, documentation, and referral of

patients at risk to outside agencies for timely and appropriate evaluation, treatment, and management.

To assist researchers in data collection, a collection tool was designed to abstract relevant information including patient's age and gender, the existence or non-existence of suicide screen, practitioner type (medical doctor or nurse practitioner), and whether a referral occurred in the instance of suicidal ideations warranting outside intervention. Male patients 21 years and above represented 91 or 30.3% of the charts reviewed, and women represented 209 or 69.7% of the charts reviewed. Average and median age for men was 47 and 43 years respectively. Average and median age for women was 46.5 and 42 years respectively. The total average and median age for men and women combined was 46.7 and 43 years respectively.

Researchers found of the combined 300 charts reviewed (manual and electronic) a total of 151 or 50.3% of the patients had a documented suicide screen. Researchers were unable to find documentation that a suicide screen was conducted on the remaining 149 or 49.7%. Nurse Practitioners (NPs) who conducted suicide screenings totaled 57%. No Physician Assistants (PAs) participated in this study.

### **Research Question 2: What percentage of adult patients that received a suicide screening was referred to another facility?**

Based on the criteria, research findings indicated 54 or 41.9% of the Medical Doctors (MDs) who conducted suicide screenings only 18 or 33.3% made referrals whereas of the 97 that NPs screened only 6 got referred. Most alarming, is the awareness that of the number of MDs who conducted suicide screens, 36 or 66.7% did not refer their screened patients to other facilities for evaluation, treatment, and management. Likewise,

only 6 or 6.2% of the NPs that screened for suicide referred their patients to other facilities; and 91 or 93.8% did not refer the screened patients for further evaluation, treatment and management.

### **Literature Application to the Outcomes**

This research study represented a similar design to provide a broad representation of the general population in consideration of strengths and weakness. The study conducted by Suokas et. al (2011) provided data that precisely identified the occurrence of attempted suicide in young adults and the need for further examination of the association between the role of suicidal behavior in psychiatric disorders and treatment to reduce the risk of suicide. Additionally, research conducted by Almeida et. al. (2012) is relevant to this research in understanding the provider-patient relationship and level of comfort, timeliness in assessing suicide risks, and providers' knowledge of outside referral source trained in the proper evaluation, treatment, and management of adult, depressed patients with other chronic illnesses in an effort to minimize the risk of suicide. In essence, interventional concepts aimed at prompt identification and treatment would provide evidenced-based signs and symptoms, rather than reliance on clinicians' perception of depression.

Further, the literature reviewed was critical to research outcomes in demonstrating that primary care providers need education and training in suicide screening; and in incidences where suicide screenings were conducted, patients were not referred to outside facilities to further evaluate, treat, and manage to reduce the number of incidences of suicide in clinically depressed patients with or without a previous history of attempted suicide.



## **Limitations**

Data were collected from 300 charts (100 from each of the three participating clinics) in north central Mississippi. This small sample and geographic area was inadequate in providing a true representation of the target population, particularly the elderly. This is especially true since a large percentage of this small population, 49.7% were not screened. An even larger percent of depressed patients age 21 and older that were screened, 84.1%, were not referred. Another limitation was the possibility of inadequate charting by the health care providers in the clinics. Furthermore, collecting data in a period of 30 days may have limited researchers' ability to investigate the existence of documented screens in charts.

## **Implications**

The outcomes of this research have serious implications for nursing practice, theory development, and nursing education. Nurse practitioners represented a larger number of providers (57% versus 43% MDs) that performed suicide screens on patients and even larger percent of providers (93.8% NPs versus 66.7% of MDs) who failed to refer patients who were screened for suicide to outside facilities for further evaluation, treatment, and management. This finding is significant. The legal implications and emotional consequences could prove costly to health professionals on all levels. For example, professional liability insurance premiums may potentially increase in the event of costly litigation. The reputation of providers and clinics involved, including patient trust in the health care system will be seriously impaired.

## **Recommendations for Nursing Theory**

Nursing theory in suicide prevention should explore the application of grounded theory in developing protocols and processes for suicide screening in depressed patients in primary care settings to ensure appropriate and timely access to referral to mental health resources. Grounded theory includes an array of research methods designed to provide the research with inductive type research based in the observation of data collected. In essence, grounded theory research should include self-administered risk assessments during patient triage or wait-time, not limited to those diagnosed with depression. This practice will significantly reduce the incidence of suicide attempt and loss of life. An additional tool the practitioner can use to identify those who may be at risk for suicide includes the Healthcare Effectiveness Data Information Set (HEDIS) and Performance Measures.

## **Recommendations for Nursing Research**

The outcomes of this research clearly demonstrate the need for extensive research in suicide screening in primary settings for physicians and nurse practitioners. Specific focus for research should seek to identify gaps in services including continuity of care, collaboration with outside facilities, and barriers to accessing mental health services. Additionally, implications for future research should include human subjects on a more personal level conducting surveys or patient interviews, and on a larger geographic scale. This will provide future research with more accurate data for analysis.

## **Recommendations for Nursing Practice**

The results of this research increases awareness of the need for training and

education in mental health screening, especially relating to assessing those at risk for suicide. The advanced practitioner must constantly explore opportunities to enhance skills and promote best practices. Time constraints in per patient visits in many primary care settings often force the practitioner to focus on illness and disease management rather than on preventive measures to alleviate crisis. Emergency psychiatric admissions, outpatient mental health services and other community counseling and mental health services can be minimized when preventive mental health information and education is accessible and available.

The goal of suicide prevention is to identify depressed patients who may be at risk for crisis and to access mental health services in a timely manner to diminish the need for the suicide to occur. As part of nurse practitioner education, core components should include extensive education and training in all levels of suicide education namely: primary, secondary, and tertiary. Primary prevention provides alternatives to suicide. Proper and timely evaluation, treatment, and management are critical to incidence. Secondary prevention is effectively dealing with current crisis. Education in risk assessment and suicide screening will assist nurse practitioners' level of comfort and timely referral to outside agencies.

### **Summary**

Suicide is a delicate health care issue affecting many Americans. Focused and efficient suicide screenings are greatly needed in primary care practices. Early recognition and diagnosis of suicide in primary care leads to appropriate referral and management. Thus, prompt referral and treatment can prevent undue tragedy and loss of life. The legal implications and emotional consequences could prove costly to health

professionals on all levels in the event of irreversible patient outcomes or loss of life. The key to minimize the risk for suicide events involves development, implementation and incorporation of screening tools in the primary care setting on all patients as part of their health facilities' standard of care and best practices.

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## Appendix A

### Application for Approval of Mississippi University for Women's Committee on Use of Human Subjects in Experimentation



Mississippi University  
for Women

1000 University Blvd., Columbus, MS 39701

Provost and Vice President for Academic Affairs  
1000 College St., MUW 1003  
Columbus, MS 39701-5800  
(662) 329-7042  
(662) 329-7141 fax

[www.muw.edu](http://www.muw.edu)

December 12, 2012

Mrs. Shonda Phelon  
Mississippi University for Women  
College of Nursing and Speech-Language Pathology  
MUW - 910  
Columbus, Mississippi 39701-5800

Dear Mrs. Phelon:

I am pleased to inform you that the members of the Institutional Review Board (IRB) have reviewed the following proposed research and have approved it as submitted:

<b>Name of Study:</b>	Suicide Screenings in Primary Care with Patients Diagnosed with Depression
<b>Investigator(s):</b>	Thomas Fisher, Lori Barkley and Tawanda Johnson
<b>Research Faculty/Advisor:</b>	Shonda Phelon

I wish you much success in your research.

Sincerely,

Dan Heimmermann, Ph.D.  
Provost and Vice President for Academic Affairs

DH/jh

pc: Tammie McCoy, Institutional Review Board Chairman

## Appendix B

Letter of Consent

March 5, 2013

Allcare of Mississippi  
301 West Jackson Avenue  
Oxford, MS 38655

Subject: Permission to participate in a research project

As graduate students in the family nurse practitioner program at the Mississippi University for Women in Columbus, MS we are required to conduct a research project which includes a retrospective record review. The project which we will be conducting includes a review of patient records with a diagnosis of Depression. We will be reviewing records for suicide screen as well as for any intervention and/or treatment as a result of a positive screen. We will be reviewing the records of patients age 21 or older. The students which are participating in this project are Lori Barkley, Thomas Fisher and Tawanda Johnson.

Your participation in the project would be granting us the privilege of reviewing medical records of your clients. We understand as researchers, we must maintain the confidentiality of all the information we collect from the records. This information includes any identifying subjective or objective data we review in the record as well as any HIPPA information contained within the record. We will refrain from disclosing any information orally or written we receive about the client. The information will be redacted in a manner not to disclose any identifiable information regarding the client. The following areas will be reviewed and collected on a Data Collection Worksheet: age, gender, provider title (MD, NP, or PA), suicide screening, and referral assessment.

The data will be collected on a worksheet and entered into a computer. The data will only be accessible to the above mentioned researchers. Once the project is completed, the worksheets and data entered into the computer will be appropriately destroyed. The project may be published with no identifiable demographic information except for the "State of Mississippi" and no clinic or client name will be identified. The project data collection time will be approximately one month and once the research project is complete, we will provide you with the findings from the study.

Your participation in this study is strictly voluntary. You may withdraw from the consent or the study at any time by contacting one of us or the chair of our research committee. The possible benefit of your participation is that the research project will serve to enhance the care we provide. If you have any questions concerning the research project, please call Lori Barkley, RN BSN at (662) 419-1906, Thomas Fisher, RN BSN (601) 906-0373, Tawanda Johnson, RN BSN (662) 719-9912 or contact the chair of our research project, Shonda Phelon, MSN, FNP-BC (662) 226-7151.

Sincerely,



Lori Barkley, Thomas Fisher, and Tawanda Johnson  
MUW Nurse Practitioner Students Class of 2013

I have read this letter and have been given the opportunity to ask questions. I give my consent to participate in the above study.

3-20-2013

Date

Kymerly Van Every

Print-Office Manager

Signature-Office Manager

OLNEP

Letter of Consent

Date 3/27/13

Yazoo City Medical Clinic  
805 Fifteenth St  
Yazoo City, MS 39194

Subject: Permission to participate in a research project

As graduate students in the family nurse practitioner program at the Mississippi University for Women in Columbus, MS we are required to conduct a research project which includes a retrospective record review. The project which we will be conducting includes a review of patient records with a diagnosis of Depression. We will be reviewing records for suicide screen as well as for any intervention and/or treatment as a result of a positive screen. We will be reviewing the records of patients age 21 or older. The students which are participating in this project are Lori Barkley, Thomas Fisher and Tawanda Johnson.

Your participation in the project would be granting us the privilege of reviewing medical records of your clients. We understand as researchers, we must maintain the confidentiality of all the information we collect from the records. This information includes any identifying subjective or objective data we review in the record as well as any HIPPA information contained within the record. We will refrain from disclosing any information orally or written we receive about the client. The information will be redacted in a manner not to disclose any identifiable information regarding the client. The following areas will be reviewed and collected on a Data Collection Worksheet: age, gender, provider title (MD, NP, or PA), suicide screening, and referral assessment.

The data will be collected on a worksheet and entered into a computer. The data will only be accessible to the above mentioned researchers. Once the project is completed, the worksheets and data entered into the computer will be appropriately destroyed. The project may be published with no identifiable demographic information except for the "State of Mississippi" and no clinic or client name will be identified. The project data collection time will be approximately one month and once the research project is complete, we will provide you with the findings from the study.

Your participation in this study is strictly voluntary. You may withdraw from the consent or the study at any time by contacting one of us or the chair of our research committee. The possible benefit of your participation is that the research project will serve to enhance the care we provide. If you have any questions concerning the research project, please call Lori Barkley, RN BSN at (662) 419-1906, Thomas Fisher, RN BSN (601) 906-0373, Tawanda Johnson, RN BSN (662) 719-9912 or contact the chair of our research project, Shonda Phelon, MSN, FNP-BC (662) 226-7151.

Sincerely,



Lori Barkley, Thomas Fisher, and Tawanda Johnson  
MUW Nurse Practitioner Students Class of 2013

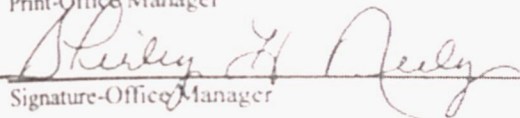
I have read this letter and have been given the opportunity to ask questions. I give my consent to participate in the above study.

3/27/13

Date

Shirley Neely

Print-Office Manager



Signature-Office Manager

## Letter of Consent

03/05/2013

Delta Health Center  
702 MLK Road  
Mound Bayou, MS 38762

Subject: Permission to participate in a research project

As graduate students in the family nurse practitioner program at the Mississippi University for Women in Columbus, MS we are required to conduct a research project which includes a retrospective record review. The project which we will be conducting includes a review of patient records with a diagnosis of Depression. We will be reviewing records for suicide screen as well as for any intervention and/or treatment as a result of a positive screen. We will be reviewing the records of patients age 21 or older. The students which are participating in this project are Lori Barkley, Thomas Fisher and Tawanda Johnson.

Your participation in the project would be granting us the privilege of reviewing medical records of your clients. We understand as researchers, we must maintain the confidentiality of all the information we collect from the records. This information includes any identifying subjective or objective data we review in the record as well as any HIPPA information contained within the record. We will refrain from disclosing any information orally or written we receive about the client. The information will be redacted in a manner not to disclose any identifiable information regarding the client. The following areas will be reviewed and collected on a Data Collection Worksheet: age, gender, provider title (MD, NP, or PA), suicide screening, and referral assessment.

The data will be collected on a worksheet and entered into a computer. The data will only be accessible to the above mentioned researchers. Once the project is completed, the worksheets and data entered into the computer will be appropriately destroyed. The project may be published with no identifiable demographic information except for the "State of Mississippi" and no clinic or client name will be identified. The project data collection time will be approximately one month and once the research project is complete, we will provide you with the findings from the study.

Your participation in this study is strictly voluntary. You may withdraw from the consent or the study at any time by contacting one of us or the chair of our research committee. The possible benefit of your participation is that the research project will serve to enhance the care we provide. If you have any questions concerning the research project, please call Lori Barkley, RN BSN at (662) 419-1906, Thomas Fisher, RN BSN (601) 906-0373, Tawanda Johnson, RN BSN (662) 719-9912 or contact the chair of our research project, Shonda Phelon, MSN, FNP-BC (662) 226-7151.

Sincerely,  
Lori Barkley, Thomas Fisher, and Tawanda Johnson  
MUW Nurse Practitioner Students Class of 2013

*Lori Barkley, Thomas Fisher, and Tawanda Johnson*

I have read this letter and have been given the opportunity to ask questions. I give my consent to participate in the above study.

3/18/2013

Date

Neeravika D. Siddhant coolers

Print-Office Manager

Neeravika D. Siddhant, coolers

Signature-Office Manager



**Appendix C**  
**DATA COLLECTION TOOL**  
**2012-2013**

Number	AGE	SEX Men (1) Women (2)	Provider MD (1) NP (2)	Suicide Screen Done Yes (1) No (2)	Referral Yes (1) No (2) NA (3)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

**Appendix D****LEGEND for Data Collection Tool****Number:**

Each sample will be assigned a number

**Age:**

The numeric age of each sample

**Sex:**

Record M for male and F for female

**Provider:**

1. Medical Doctor
2. Nurse Practitioner

**Screen:**

1. Yes, suicide screen is present
2. No, suicide screen is not present

**Referral:**

1. Yes, referred to mental/behavioral health for treatment
2. No, no referral to mental/behavioral health
3. N/A, referral not applicable for visit

# Mississippi University for Women Institutional Review Board

Identification of Investigators, Brief Description of Investigators and  
Brief Description of Proposed Research Review

## Form A

Instructions: Complete this form for all research proposals. If a question is not applicable, please write or mark "not applicable." Do not delete or add any text to the spaces on this form. If you wish to use a multi-page form, please submit all supporting documents, supporting documents, copies of all supporting documents.

Send the forms to Dr. Tammy Murray at [TMurray@umw.edu](mailto:TMurray@umw.edu).

### 1. About the Researchers:

February 4, 2013

Thomas Fisher, John Barkley, and Tawana Thomas are conducting a study to fulfill the requirements for the Master of Science in Nursing at the University of Mississippi.

Principal Investigator: Thomas Fisher

Email Address: [tfisher@umw.edu](mailto:tfisher@umw.edu)

Department: Department of Graduate Nursing

Telephone: 662-906-0374

- If student, list their Research Advisor: [tfisher@umw.edu](mailto:tfisher@umw.edu)  
 Research Advisor's email: [tfisher@umw.edu](mailto:tfisher@umw.edu)

### 2. Purpose of the Research:

- Undergraduate Research  
 Master's Thesis  
 Doctor of Nursing Practice  
 Coursework  
 Faculty Research  
 Assisting Faculty Research  
 Other

### 3. Title of the Research:

Suicide Screenings in Primary Care with Patients Diagnosed with Depression

### 4. External Funding:

Has this project been submitted for external funding?  Yes  No

If yes, list all agencies (Agency, Agency, list the status (Approved, Pending, Denied) and date.

### 5. Location of the Study:

The study will be conducted at 11 community-based primary care clinics in Mississippi.

### 6. Projected Duration of the Study:

Up to 12 months (to December 31, 2014)

**7. Project Summary:** (2-3 sentences)

The study will look at a form of folk medicine that is used by young, middle age and older from three rural hospitals in Mississippi. The research will look at the prevalence of the disease to have a diagnosis of depression. Once a diagnosis is made, identified with a diagnosis of major depression. The research will determine if a suicide screening was done and if a referral was made.

**8. Number of Participants Expected:**

One hundred thirty two will be recruited from the following source:

**9. Human Participants\*:** (check all that apply)

- Adults (18 years and older)
- Minors (with the signature of the parent/guardian and on the consent form for the parent/guardian signature)
- Pregnant Women
- Fetus
- Economically disadvantaged (e.g., low income)
- Elderly
- Patients
- Non-English Speaking
- Mentally Disabled
- Prisoners, inmates, or detainees
- Elected or Appointed Members of the Executive, Legislative, or Judiciary
- Students from a school with a program of research

\*Human participants include individuals who are being used to generate research data through intervention or interaction with the individual or environment (e.g., research on the effects of a new drug, or research on the effects of a third party, etc.).

**10. Type of Data:** (check all that apply)

- Interviews
- Questionnaires/Surveys
- Medical Records/Charts
- Existing Data/Records/Archives/Repositories
- Physiological Measurements (e.g., EEG, MRI)
- Observational Recordings (e.g., video)
- Educational Tests (e.g., written, aptitude, etc.)

**11. Nature of Information to Be Obtained:** (check all that apply)

- Participant and/or data are being collected for research
- Filming, video, or other audiovisual
- Involving the use of force, coercion, or other means of persuasion
- Collected with permission from a third party (e.g., employer, agency/institution)

**12. Other:** (check all that apply)

- Participant or group is vulnerable (e.g., extremely young, elderly, etc.)

Revised October 2002

- Research conducted in a department setting
- Project involves temporary faculty or research assistant
- Project is similar to other projects that have been funded. (See research opportunity)

Principal Investigator Signature

Date: 2/1/11

Faculty Advisor Signature

Date: 2/4/11

Please note if you are a faculty advisor on this project, you must be approved by your faculty advisor. To indicate that a project has received the IRB approval, the principal investigator must check this box.

## Form B

Check one of the following

- This is a new research project
- This is an on-going investigation. (For on-going investigations complete all items included those in the shaded areas)

### I. Research Summary

Briefly describe the purpose and rationale of the proposed research proposal. State what, if any, benefits to be gained by the subjects and what contribution will be made to the general body of knowledge as a result of this research. The purpose of this study is to determine if providers working in community-based clinics with a diagnosis of depression were screened for suicide risk. We will screen 100 patients 21 years and older with a diagnosis of depression. No patient data will be collected from either of the 2 groups. The providers will be physicians, nurse practitioners or physician assistants. The study will add to the general body of knowledge by demonstrating the need for suicide screenings in patients with a diagnosis of depression. Identification of suicide risk is vital in decreasing suicide. The study's findings will be used with the participating providers. The providers can utilize the results of the study as a quality improvement project to assist in making the quality of care they provide.

### II. Participants and Recruitment

- How many subjects will be recruited? (The number of subjects or estimates or ranges are acceptable. Please be aware that if you recruit over 250 subjects, you will need to submit a request to modify your recruitment numbers.)  
A total of 100 patients will be screened in the participating community-based clinics in Mississippi.
- Describe how subjects will be recruited. Describe any compensation or incentives that will be offered. Please provide the IRB with a copy of any materials that will be used (*flyers, letters of invitation, email messages, recruiting scripts*, etc.).  
Since the study will only consist of the screening of a chart reviewed there will be no patient recruitment.
- Describe inclusion and exclusion criteria and eligibility requirements for subjects (describe screening procedures, including the term for inclusion and exclusion of otherwise acceptable subjects).  
The only exclusion of the study will be patients younger than 21.

Revised Edition 2010

4. Explain any sampling strategy used to select the subjects in the populations. The charts reviewed for this study were selected from a population of more than 21 years of age.
5. Disclosure of information about the study to the subjects, such as, teacher/student, employer/employee. There will be no disclosure of the study to the subjects since the study will conduct research on record review only.
6. Check any vulnerable populations that may be included in the study.
- Minor children (If checked, please provide the signature of the parent/guardian on the consent form for the parent/guardian signature)
  - Pregnant women
  - Refuses
  - Economically disadvantaged
  - Elderly
  - Patients
  - Non-English speaking
  - Mentally disabled
  - Prisoners, Excluded or Inmate
  - Excluded or Appointed Health Care Proxy
  - Students (If checked, please provide the name of the student)
7. If you have the authority of the population, please indicate the necessity for doing so. Please indicate the approximate age range of the subjects in the study.

## Form C

### I. Research Procedures and Methods

1. Describe the informed consent process. Provide a brief description of what you will
- a. From whom will you obtain consent? (Check all that apply) (To obtain consent from a parent/guardian)
  - b. State exactly what you will be asking the parent/guardian
  - c. If assent is required, describe the assent process
  - d. Alternatives to the assent process if assent or informed consent will not be obtained
- Informed consent will be obtained from the research subjects and their providers in the clinics to review the medical records. There will be no disclosure of the study to the subjects since there will be no participants in the study.
2. In lay language, describe completely all procedures that will be used during the course of the experimentation. Provide sufficient detail to allow the IRB to evaluate the potential risks to human subjects. An abstract for the IRB to review is provided at the end of the study. In your project, please provide a detailed outline of everything that will be done with the records of all participating in your project. Since the study is a retrospective study, there will be no direct contact will be made. The charts / medical records will be reviewed to identify the patients who were identified as a case screening or referral was done. There will be no patient data that will be used in the study, only the age, sex, diagnosis, screening, and referral will be used. All patient data will be stored by using password protected computers and a jump drive and will not be made available to anyone outside of the study.
3. Describe how you intend to disseminate the results of the project.

N/A There will be no data collection or storage with these procedures.

4. Describe the data collection procedures and materials. To the extent possible, provide actual or sample materials used in the study. Describe the data collection procedure. The participants will have at the top "Number 56" (for men) and "Number 57" (for women) and will be asked to click on the "Done" button. The data will be Screen Done (Yes 1, No 2), and Refused (No 3, No 2, and N/A) will be the data collected.
5. How will data be stored and protected?  
The data will be stored on a secure server on the computer and not on jump drive. The data will only exist on any one of these devices. The data will be stored on the server and will be embedded as soon as it is entered into the computer.

## I. Potential Risks

1. State the potential risks (physical, psychological, financial, or other) connected with the proposed procedures and risks to the subjects of the proposed study.  
Since the study will be conducted in a secure environment, there is no potential psychological, social, physical, financial, or other risk will be to the subjects.
2. Will there be any potential for harm to the subjects (consider to be personal or sensitive (e.g., private behavior, ethnicity, race, sexual orientation, or other matters that if made public might impair the subject's employment, education, or financial status) or the subjects at risk of criminal or civil liability)?  
 Yes  No  
If yes, describe the nature of the risk and the steps that will be taken to minimize these risks.
3. Could any of the data collected be considered offensive, threatening, or degrading to the subjects?  
 Yes  No  
If yes, please describe the nature of the risk and the steps that have been made for handling an emotional reaction to the data.
4. Describe the necessary safeguards to be taken to protect the subject. In this section make sure to include provisions for (a) the confidentiality of the data, (b) the destruction of personal information. Since the study will be conducted in a secure environment, no contact will be made. All data will be stored on a password protected server and will be destroyed at the end of the study.
5. Is there any reason to think that the data collected in this study? If yes, please describe why it is necessary and describe the steps that will be taken to minimize these risks.  
No
6. Is this study going to be made public or disseminated to the participants in the study? If yes, potential or existing risks to the subjects of the study will be provided in investigation are.  
No

Revised 07/2014 2/04

### 7. On-Going Investigations Only

- Number of subjects studied
- Documented adverse events (i.e., behavioral, physiological and pharmacological effects of study)
- Precautions used to detect, prevent, identify and reverse adverse side effects.
- Change in methods or procedures, when applicable.
- Change in intent, if not possible, of subjects, when applicable.

## II. Potential Benefits

This does not include a description of the study's purpose.

What, if any, direct benefits are expected to result from the study? If benefit is expected, but indirect benefits may be expected, how will the participant benefit from the study? Please provide explanation.

Since the study will not be for the benefit of the individual subjects, how will benefit be made with the participants, therefore they will receive no direct benefit from participating in the study.

## IV. Compensation

Please keep in mind that the University of North Carolina at Charlotte is not a for-profit organization. If your business office requires payment of subjects who are not employees of the University, you must provide appropriate confidentiality protections. If, when applying for subject compensation, you are not an employee of the University, you must provide confidentiality provisions for your research. You must contact the IRB if you require subject compensation.

- Describe the amount of compensation to be provided to the subjects.
  - Since this is a research project, no compensation will be made with the participants themselves, as they are not employees.
- Describe the period of time that compensation will be made with the subject to completion of the study.
  - Since this is a research project, no compensation will be made with the participants.
- Indicate how the compensation will be provided to the subjects.
  - This will be to learn the same amount of credit. N/A.

## V. Additional Information

- If a question arises, please contact the IRB chair by e-mailing, attaching a copy to this proposal.
- Attach a copy of the IRB form to your application.
- Please provide a contact person for the IRB chair in making its decision.

## VI. Additional Resources for IRB Federal & University Guidelines

- Mississippi University for Women, 45 CFR 46.101-114 (1980)
  - United States Department of Health, Education and Welfare, 45 CFR 46.101-114, Policy on Protection of Human Subjects, 1979
  - Human Subjects Research, 45 CFR 46.101-114, Policy on Human Subjects, Effective July 14, 2009
- <http://www.fda.gov/oc/ohrt/45cfr46.htm>
- <http://www.fda.gov/oc/ohrt/45cfr46.htm>

REVISED 03/2012



