2020

Implementation of an Anxiety Screening and Treatment Protocol in Primary Care

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IMPLEMENTATION OF AN ANXIETY SCREENING AND TREATMENT PROTOCOL IN PRIMARY CARE

Presented in Partial Fulfillment of the
Requirements for the Degree of
Doctor of Nursing Practice

Nova Southeastern University
Health Professions Division
Assaf College of Nursing

Danielle E. Garcia
2019

NOVA SOUTHEASTERN UNIVERSITY
HEALTH PROFESSIONS DIVISION
ASSAF COLLEGE OF NURSING

This project, written by Danielle E. Garcia under the direction of Dr. Kelly Henson-Evertz, DNP, RNC-OB, CTTS, NCTTP, Project Chair, and approved by members of the project committee, has been presented and accepted in partial fulfillment of requirements for the degree of

DOCTOR OF NURSING PRACTICE

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Certification

We hereby certify that this DNP Project, submitted by Danielle E. Garcia, conforms to acceptable standards and is fully adequate in scope and quality to fulfill the project requirement for the Doctor of Nursing Practice degree.

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Abstract

Background: Anxiety is a prevalent problem frequently presenting in the primary care setting in the United States. The lack of routine anxiety screening and evidence-based treatment protocols in the adult primary care setting causes physical, social, and economic consequences.

Purpose: The purpose of this Doctor of Nursing Practice (DNP) evidence-based practice (EBP) quality improvement project was to implement an EBP anxiety screening and treatment protocol for adults in a primary care clinic to increase early identification and improve management of generalized anxiety disorder (GAD).

Theoretical Framework: W. Edwards Deming's Plan-Do-Study-Act (PDSA) cycle framework was utilized for this project. The PDSA outlines the necessary cycles of how to effectively identify, develop, implement, analyze, and sustain quality improvement practice changes in an organization.

Methods: Descriptive statistics and Pearson's *r* were used for this retrospective/prospective chart review design.

Results: Findings are clinically significant and demonstrate 69.07% of post-implementation prospective charts utilized the generalized anxiety disorder 7-item (GAD-7) screening tool to screen for GAD, which quantified an anxiety level, and can be utilized to prescribe EBP treatment for adults with GAD in primary care.

Conclusion: Although findings of anxiety score correlating to EBP treatment were statistically insignificant, further studies are necessary to determine if obtaining an anxiety level results in the provider making changes to preexisting treatment plans that align with EBP treatment in adults with GAD.

Acknowledgements

First and foremost, I would like to acknowledge God for guiding my journey. Everything, including our struggles, happen for a reason, even when that reason may not initially be clear. My trust and faith in God have allowed me to confront great challenges and find understanding and appreciation in them and, therefore, in my life.

Additionally, I would like to acknowledge my children Amira, Julian, and Olivia for sacrificing their time with me during this entire journey of my higher educational career. Their sacrifices have allowed me to dedicate my time to the advancement of healthcare and the well-being of others. In particular, Amira and I have been on this journey together from the time that I became a teenage mother to her in high school. She was my sole study partner, my inspiration, my encouragement, my purpose—until Julian and Olivia joined us. My children have spent their entire lives patiently allowing me to continue my education in healthcare to help others. My heart and dreams are fulfilled because of them.

I would like to thank my husband, Mauricio, for never doubting me. And for my mom, Debbie, as a single mother with four children, she instilled in me a great value for education. My mother modeled determination and strength in the face of adversity my entire childhood. She did it alone.

My professors, Dr. Henson-Evertz, Dr. Derby-Davis, and Dr. LaManna, have demonstrated true passion for the advancement of healthcare by being educators. But more so because of their unwavering commitment to advocate for and encourage me in pursuit of realizing my project. Particularly, I want to give a heartfelt appreciation to Dr. Henson-Evertz who has worked tirelessly and selflessly to advocate for this project, myself, and the betterment of our community. She has spent countless hours, on and off the clock, to provide feedback,

support, and clarity to me, which has propelled my education to an exceptionally valuable and meaningful experience.

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Chapter One: Nature of Project and Problem Identification

Evidence-based practice (EBP), which is a synthesis of best practices, clinician expertise, and patient preferences and values, ensures the provision of patient care excellence and improves patient outcomes (Melnyk & Fineout-Overholt, 2015). Best practices recommend screening adults for generalized anxiety disorder (GAD) in primary care, with a screening tool that quantifies anxiety levels and correlating the level to prescribing treatment. Anxiety treatment interventions such as specific selective serotonin re-uptake inhibitors (SSRIs), specific selective norepinephrine re-uptake inhibitors (SNRIs), mental health referrals, and psychotherapy are effective and approved by the United States (U.S.) Federal Drug Administration (FDA) for the treatment of GAD (Abejuela & Osser, 2016; Craske & Bystritsky, 2017; Locke, Kirst, & Shultz, 2015; National Institute for Health and Care Excellence [NICE], 2011; National Institute of Mental Health [NIMH], 2016). A primary care practice lacked consistent, uniform use of a GAD anxiety screening tool and treatment protocol to routinely screen and treat patients with GAD according to best practices. A review of the literature illuminated EBP protocols for screening and treating patients with GAD. Implementation of an EBP GAD screening and treatment protocol in primary care can result in timely and accurate diagnosis and appropriate anxiety treatment, improving the quality of life in adults with GAD (Locke et al., 2015; NICE, 2011; NIMH, 2016; Spitzer, Kroenke, Williams, & Lowe, 2006; Stein & Sareen, 2015).

Background Information

The *Diagnostic and Statistical Manual of Mental Disorders, 5th edition* (DSM-5) informs that anxiety is a term used to describe inappropriate worry or fear that is associated with anticipating an upcoming threat (American Psychiatric Association [APA], 2013). Anxiety induces more than necessary emotions of fear or worry not attributable to an occasional life

experience that is expected to induce anxiety (APA, 2013; NIMH, 2016; Waters et al., 2015). Anxiety can cause a decrease in quality of life related to disruption in sleep quality and patterns, headaches, gastrointestinal problems, muscle tension, restlessness, irritability, chronic fatigue, and the inability to concentrate and control worry or fear (Edmund & Sheppard, 2018; Locke et al., 2015; NIMH, 2018). Mental unease and physical stress related to anxiety also contribute to avoidance behaviors and a decrease in quality of life (Waters et al., 2015). GAD is one subset of anxiety. GAD is distinguished by experiencing more than necessary and difficult to control feelings of anxiety, worry, or fear causing significant impairment and peril occurring more days than not for a minimum of 6 months (Craske & Bystritsky, 2017; Stein & Sareen, 2015).

GAD is considered a chronic condition (Stein & Sareen, 2015). Symptoms of GAD may be experienced intermittently or constantly and last for a short duration or a lifetime (NIMH, 2017a). The symptoms can range from mild to severe (Spitzer et al., 2006). GAD is not a panic attack (APA, 2013; Locke et al., 2015). Symptoms of GAD may, however, induce a panic attack, which is characterized by acute, intense physical symptoms of diaphoresis, chest tightness, tachycardia, and tachypnea that are results of the activation of the autonomic nervous system (APA, 2013).

Research is exploring the pathophysiology of anxiety and affirming various theories of anxiety etiology. Evidence has suggested that anxiety may be attributed to genetics and disturbances of the neural pathways (APA, 2013; NIMH, 2016). Richards (2018) reported that learned processes also change the dynamics of the neural pathways. Learned processes that contributed to the exacerbation of GAD were attentional bias of threat, conditioning, tendencies toward defensive hyperarousal states, and stress (Nikolic, Aktar, Bogels, Colonnesi, & De Vente, 2018; Simpson, 2012). According to Richards (2018), neural pathways utilize the neurochemical

hormones cortisol and adrenaline, which are released during states of anxiety and change the mechanism of action of the nervous system. Neurochemical and learned processes also change the velocity at which sensory information moves through synaptic gaps, leading to the responses experienced in anxiety (Richards, 2018).

Disposition to defensive hyperarousal and perceived stressful situations also contribute to anxiety (Nikolic et al., 2018). An individual with GAD anticipates a perceived threat that leads to aroused awareness, muscular tension, and avoidance behaviors (APA, 2013). Feelings of discontentment, apprehension, worry, and/or fear, associated with anxiety, can affect daily life, resulting in physical, social, and economic consequences (Abejuela & Osser, 2016; Waters et al., 2015).

Significance of Problem

Presently, 615 million individuals worldwide are diagnosed with depression and anxiety disorders (World Health Organization [WHO], 2016). Anxiety is nondiscriminatory, and onset can begin at any age (Essau, Lewinsohn, Lim, Ho, & Rohde, 2018). The NIMH (2017a) reported that the National Comorbidity Study Replication (NCS-R) found 18.1% of adults in the United States have experienced an anxiety disorder within the past year. The study found 2.7% of these anxiety diagnoses are specifically GAD (NIMH, 2017b). Lifetime prevalence of GAD for individuals aged 18-64 years is estimated at 7.7% for women and 4.6% for men (Edmund & Sheppard, 2018).

Accurate and prompt diagnosis of GAD in primary care is suboptimal, even though the Generalized Anxiety Disorder 7-item (GAD-7) screening tool is available for screening and effectively and accurately diagnoses GAD in primary care patients (Jordan, Mora, & Lowe, 2017; Locke et al., 2015; Roberge et al., 2015; Spitzer et al., 2006). Implementation of

appropriate EBP treatment for GAD in primary care is also lacking (Roberge et al., 2015). Benzodiazepines are often used inappropriately for long-term GAD symptom control (Daoud, Hamburg, Sharma, & Blevins, 2018; Furbish et al., 2017; Song et al., 2017). Best practice treatments for GAD that have been proven effective for long-term symptom control include lifestyle modifications, SSRIs, SNRIs, mental health referrals, and psychotherapy (Locke et al., 2015; NICE, 2011). GAD is not without consequences. The physical, social, and economic consequences of GAD are substantial and prevalent.

Physical Consequences of GAD

Physical consequences of GAD include an array of subjective complaints and other mental health ailments. The physical consequences of anxiety include disruption in sleep quality and patterns, headaches, gastrointestinal problems, muscle tension, restlessness, easy irritability, chronic fatigue, and inability to concentrate and control worry or fear (Edmund & Sheppard, 2018; Locke et al., 2015; NIMH, 2018). Gastrointestinal distress and headaches are the most common presenting symptoms of GAD in the primary care setting (Stein et al., 2005). Individuals with GAD are at a greater risk for self-harming behaviors and attempting suicide (Bentley et al., 2016; Stein & Sareen, 2015). Anxiety often precedes the development of co-occurring depression (Adams, Balbuena, Meng, & Asmundson, 2016).

Social Consequences of GAD

GAD can cause debilitating impairments that negatively impact daily functioning, relationships, and job productivity and can lead to substance use. The Sheehan Disability Scale examined the level of impairment in adults with anxiety disorders and found that 22.8% of affected individuals experienced serious impairment, 33.7% moderate impairment, and 43.5% mild impairment, respectively (NIMH, 2017a). A study conducted by Robinson, Sareen, Cox

and Bolton (2011) found roughly 35% of individuals with GAD utilized drugs and alcohol to control their symptoms (as cited in Stein & Sareen, 2015). Individuals with GAD may avoid circumstances or triggers that cause symptoms of physical and mental unease. The symptoms of mental unease and physical stress related to anxiety are contributory to avoidance behaviors and decreases quality of life (Waters et al., 2015). Conditioning to use dysfunctional coping mechanisms like avoidance behaviors can result in dysfunctional personal relationships and job performance issues.

Economic Burden of Anxiety

Anxiety disorders negatively impact finances and increase healthcare costs. In 2013, nearly $49 billion was spent in the United States on anxiety-related healthcare expenses (Shirneshan, 2013). Direct healthcare expenses including pharmacological treatment, inpatient services, and outpatient services accounted for $33.71 billion of the nearly $49 billion, while indirect expenses for morbidity-related expenses cost $12.72 billion, and mortality expenses cost $2.34 billion (Shirneshan, 2013). Mental health issues have a negative financial impact because of loss of job productivity secondary to absenteeism (Madan, Henderson, Hashtroudi, Hope, & Harvey, 2013). Untreated anxiety leads to physical symptoms that result in individuals missing work (Madan, Henderson, Hashtroudi, Hope, & Harvey, 2013). The WHO (2019) estimates that anxiety disorders are responsible for a global $1 trillion loss in productivity.

Misuse of Benzodiazepines

Short-acting rescue medications, such as benzodiazepines, are pharmacologically designed to rapidly reduce severe anxiety symptoms such as those experienced during a panic attack and should only be prescribed for a short-term basis to augment treatment (Locke et al., 2015; NICE, 2011). Commonly, patients and healthcare providers pursue anxiety rescue

medications to manage anxiety symptoms (Furbish et al., 2017; Song et al., 2017). Despite evidence that long-term treatment of GAD typically can be achieved with SSRIs and/or CBT, healthcare providers and patients often default to the misuse of benzodiazepines (Wetherell et al., 2013).

The prescribing and dosages of benzodiazepines have increased over the last 20 years (Lowry, 2016). Oftentimes, GAD is maltreated with untimely, inappropriate, or persistent use of benzodiazepines (Furbish et al., 2017). Benzodiazepines are regularly substituted as long-term anxiety medication therapy, which has proven to be ineffective for this purpose (Song et al., 2017). A study about benzodiazepine use for anxiety by Swift and Charles (2016) revealed 60% of participants had benzodiazepines prescribed for more than 5 years (as cited in Lowry, 2016). Swift and Charles (2016) found individuals who were prescribed benzodiazepines pro re nata (PRN) had an increased risk for misuse of the medication and often took the medication regularly (as cited in Lowry, 2016).

Consistent misuse of benzodiazepines promotes physical dependence and can produce adverse health effects when benzodiazepines are abruptly discontinued (Song et al., 2017). Withdrawal syndrome from benzodiazepines includes symptoms such as confusion, sleep disturbances, irritability, anxiety, psychosis, delirium, seizure activity, and hyperadrenergic conditions (Gresham, 2018). Mortality rates related to benzodiazepine overdose have also increased. Mortality rates related to benzodiazepine misuse for 2016 was reported at 10,684 (National Institute on Drug Abuse, 2018). Long-term GAD symptom control cannot be achieved without alternative and appropriate interventions like antidepressant medications and/or CBT (Locke et al., 2015; Song et al., 2017). Ultimately, the avoidance of the misuse of

benzodiazepines for long-term GAD symptom control is essential for enhancing quality of life in adults with GAD (Furbish et al., 2017; Locke et al., 2015; NICE, 2011; Song et al., 2017).

Lack of Consistent GAD Diagnosis and Appropriate Treatment in Primary Care

Accurate assessment, diagnosis, and appropriate anxiety treatment are essential to ensure appropriate long-term outcomes for individuals with GAD. Oftentimes, individuals experiencing symptoms of GAD seek medical intervention from their primary care provider who may be the sole healthcare team member who manages an individual's feelings of anxiety associated with GAD (Goldberg et al., 2016; Jordan et al., 2017; Weisberg, Beard, Moitra, Dyck, & Keller, 2014; Wiegner, Hange, Bjorkelund, & Ahlborg, 2015). As a result, the initial diagnosis and management of anxiety are often performed by the primary care provider. Accurate and timely recognition of GAD in the primary care setting is lacking (Roberge et al., 2015).

Further, the management of GAD lacks consistent, routine use of an appropriate evidence-based treatment algorithm to assist in long-term anxiety symptom control (Roberge et al., 2015). Currently, only 36.9% of individuals presenting with anxiety are receiving treatment (NIMH, 2017a). Of that treated population, 34.3% of individuals' treatment plans are considered barely adequate (NIMH, 2017a). Pharmacological management of anxiety can be provided by a primary care provider (Locke et al., 2015; NIMH 2018). Primary care providers can diagnose and manage anxiety; however, psychotherapy or individuals who require more complicated pharmacological interventions should be referred to a mental health specialist (Abejuela & Osser, 2016; Locke et al., 2015; NICE, 2011; Stein & Sareen, 2015).

Problem Statement

An adult primary care medical practice lacked consistent, uniform use of a GAD anxiety screening tool and implementation of evidence-based clinical practice guidelines for anxiety treatment.

Purpose Statement

The purpose of this quality improvement project was to implement an EBP anxiety screening and treatment protocol for adults in a primary care clinic to increase early identification and improve management of GAD.

Plan-Do-Study-Act Theoretical Framework

W. Edwards Deming developed the Plan-Do-Study-Act (PDSA) in 1993. The W. Edwards Deming Institute (2019) explains that Deming believes that in organizational change, new knowledge is acquired from learning. Deming developed the PDSA theory for improvement process changes to predict the outcome of an improvement project, analyze the actual outcome of the implemented improvement project, and then study the comparison of the predicted outcome to the actual outcome (The W. Edwards Deming Institute, 2019). Through this process, new knowledge is learned and then, if warranted, adjustments to the improvement project can be made for sustainability (The W. Edwards Deming Institute, 2019). The W. Edwards Deming Institute (2019) explained the PDSA as a systematic process that can be utilized for the acquisition of knowledge needed for sustainable improvement of a service, product, or process.

The PDSA is an effective model for guiding quality improvement changes. The Institute for Healthcare Improvement (IHI) and the U.S. Department of Health and Human Services: Agency for Healthcare Research and Quality (AHRQ, 2015) provide succinct information about

how to utilize the PDSA in practice. The AHRQ (2015) stated that the PDSA is a simplistic method that can assist in the development and evaluation of a process improvement plan in healthcare. According to the IHI (2019), the PDSA has been implemented in hundreds of healthcare institutions. A worksheet was developed by the IHI to help organizations to develop and test a system change using the PDSA. The AHRQ (2015) outlined the necessary phases of how to effectively identify, develop, implement, analyze, and sustain quality improvement practice changes in an organization using the PDSA model. The PDSA model is divided into cycles that guide each aspect of developing, implementing, and analyzing quality improvement changes to achieve sustainability.

Theoretical Framework Concepts and Application to Project

This EBP quality improvement project was developed to implement an EBP anxiety screening and treatment protocol for adults in a primary care clinic to increase early identification and improve management of GAD.

Plan

The *plan* cycle requires the development of a purpose statement for the proposed project, expected outcomes, and steps of execution that include the population and time frame for the project (AHRQ, 2015). This cycle also requires defining details of the change, the prediction, and the data to be collected. The *plan* cycle defines the what, who, when, and where of the change and data and predicts the outcome (IHI, 2019).

Applicable to this EBP project, during the plan cycle, observations for a quality improvement change for GAD screening and treatment in a primary care clinic were made, followed by the development of a purpose statement. The predicted outcome was that

implementation of a quantifiable anxiety screening tool would increase early identification and improve management of adults with GAD was established.

Do

Once all the planning for the project is complete, the *plan* cycle is complete, and the *do* cycle begins. The *do* cycle occurs when the change is implemented and detailed observations about the process are made (AHRQ, 2015). The *do* cycle refers to the implementation phase of a project (IHI, 2019). The *do* describes what was studied, what occurred, observations, and problems noted.

In the context of this EBP project, the *do* cycle was defined as the implementation of a protocol for a quantifiable anxiety screening method and EBP anxiety treatment for GAD in an adult primary care practice followed by a retrospective and prospective review of the electronic health records (EHRs)/charts.

Study

Once the organizational change has been implemented and data has been collected, the *study* cycle begins. The study cycle requires an analysis of the results. The data is analyzed, and then actual outcome(s) are compared to the predicted outcome(s). This is also the time data is analyzed to see if benchmarks that were set have been met. During the *study* cycle, the project team reports the findings to stakeholders, determines the results, and uses the results to identify what, if any, additional changes are necessary (AHRQ, 2015).

In the context of the implementation of an EBP anxiety screening and treatment protocol, the *study* cycle was defined as the period of time for analysis and learning about the processes that occurred during the implementation phase of the EBP anxiety screening and treatment protocol.

Act

After studying the effects of the practice change, warranted changes to be made for a future PDSA cycle are noted, if found (IHI, 2019). During the *act* cycle, changes needed to be made for sustainability are reported (IHI, 2019). In the context of the implementation of an EBP anxiety screening and treatment protocol, the *act* cycle involved reporting the findings to the stakeholders and making necessary recommendations to the protocol process or to existing treatments previously described.

Objectives

The purpose of this quality improvement project was to implement an EBP anxiety screening and treatment protocol for adults in a primary care clinic to increase early identification and improve management of GAD. Therefore, this project had the following objectives:

1. Train five medical assistants on the administration of the GAD-7 assessment tool
2. Implement an EBP Anxiety screening and treatment protocol
3. Conduct retrospective and prospective chart reviews
4. Evaluate the anxiety screening and treatment protocol implementation process and GAD identification and management outcomes

In the context of this EBP project in an adult primary care clinic, implementation meant the practice change occurs by asking every patient, at every health visit, if they had felt anxious, worried or fearful, more times than not, in the last 6 months, as the *Diagnostic and Statistical Manual 5th edition* (DSM-V) diagnostic criteria recommends. Patients who answered "yes" and who agreed were screened with the GAD-7 screening tool; a score is tallied, the primary care provider interprets the score to an anxiety level and then uses the anxiety level to assist in

prescribing EBP treatment, such as lifestyle modifications, SSRIs, SNRIs, mental health referrals, psychotherapy, or combination therapy. In the context of this EBP project, improved management meant the primary care provider prescribed treatment based on the GAD-7 anxiety level according to an EBP protocol.

Significance of Evidence-Based Practice Project

Healthcare Practice

An anxiety assessment tool serves to enhance the provider's assessment, diagnostic, and treatment skills for recognizing GAD, rating its severity, and identifying the need for implementing EBP treatment (Jordan et al., 2017). The routine use of an anxiety screening tool can accurately identify GAD in a timely manner. Implementation of the GAD-7 anxiety screening tool enhances the primary care provider's awareness and understanding of the significance of an anxiety level. A calculated anxiety level can establish a foundation for the provider to implement initial GAD treatment (Abberger et al., 2017). Identifying a patient's anxiety level guides the provider in selecting a corresponding level of appropriate EBP GAD treatment such as education and lifestyle modifications, CBT, SSRI, and/or SNRI therapy, and/or mental health provider referral (Locke et al., 2015; NICE, 2011; Waters et al., 2015).

Healthcare Outcomes

Primary care providers who incorporate routine use of an anxiety screening tool and implement an EBP treatment protocol enhance the quality of life for adults with GAD. An anxiety assessment tool that illuminates anxiety severity assists the provider and the individual with acknowledging the severity of GAD and guiding the selection of appropriate evidence-based treatment. Increasing the quality of life for adults with GAD is achievable by prescribing appropriate EBP treatment that decreases anxiety exacerbations and reduces symptom severity

(Waters et al., 2015). CBT and/or SSRIs or SNRIs, implemented by a primary care provider for GAD treatment, can effectively control GAD symptoms and enhance the lives of individuals with GAD (Locke et al., 2015).

Healthcare Delivery

A study by Jordan et al. (2017) demonstrated that the implementation of an anxiety assessment tool in primary care settings enhances delivery of healthcare, contributes to decreased healthcare costs secondary to accurate and timely diagnosis, and assists clinicians with managing the complexity of GAD symptoms. Timely and appropriate identification and treatment of anxiety in the primary care setting may contribute to collaboration among members of the healthcare team (Jordan et al., 2017). As a result of decreased costs, increased management skills, and collaboration, healthcare delivery for adults with GAD can be more straightforward and effective (Jordan et al., 2017).

The Affordable Care Act (ACA) and the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA) describes value-based purchasing (VBP) as a healthcare delivery reimbursement system that designates pay for services based on the quality and cost-effectiveness of healthcare services rendered (Chee, Ryan, Wasfy, & Borden, 2017). EBP is the standard to which providers should practice healthcare delivery; EBP is examined for safety and effectiveness (Melnyk & Overholt, 2015).

Healthcare Policy

GAD can cause vulnerability for sufferers; therefore, advocating for the well-being of these individuals with a timely diagnosis and appropriate EBP treatment in primary care is pertinent. This EBP quality improvement project advocates for the routine use of an anxiety screening tool in the primary care setting. Additionally, this EBP quality improvement project

advocates for compliance with implementation of appropriate EBP GAD treatments based on the scored anxiety severity.

This EBP project should be adopted as a standard of care. All patients, at every visit, should be asked the basic questions of GAD diagnostic criteria. Every patient who confirms they have experienced GAD symptoms for 6 months, as the DSM-V diagnostic criteria recommends, should be provided the GAD-7 screening tool to quantify an anxiety level (Locke et al., 2015). The primary care provider should interpret the anxiety level and select a corresponding EBP recommendation for treatment.

This EBP project can also provide a standard of care for prescribing benzodiazepines for GAD. Benzodiazepines should only be used short term for severe anxiety, if necessary, to augment treatment. Benzodiazepines should only be used long-term, on a strict as needed basis, if the provider has established that the patient experiences panic attacks (Locke et al., 2015; NICE, 2011). If a patient experiences panic attacks, the provider should consider quantifying the monthly number of panic episodes and only prescribe low-dose benzodiazepines for the exact number of episodes expected monthly, and as-needed follow-up should ensue.

Summary

GAD is a prevalent, chronic condition that disrupts the quality of life in sufferers. Individuals with GAD often present to primary care providers with symptoms of GAD; therefore, a prompt diagnosis and implementation of an EBP treatment plan is necessary. Currently, anxiety screening and evidence-based practice treatment for adults in primary care are suboptimal. Benzodiazepines are often prescribed for GAD and misused, which can lead to increased morbidity and/or mortality rates. Prompt screening for GAD with the GAD-7 screening tool is proven to be accurate and efficient in the primary care setting. Effective EBP

GAD treatment is achievable with lifestyle modifications, relaxation techniques, SSRIs, SNRIs, psychotherapy, and/or mental health referrals. A quality improvement EBP project was developed using the PDSA theory for the implementation of the GAD-7 screening tool and an evidence-based treatment protocol in adults with GAD in the primary care setting.

Chapter Two: Review of the Literature

Performing a systematic review of the literature is an essential component of planning evidence-based practice (EBP) projects. An EBP project is conducted based on existing evidence acquired thorough a review of the literature (Polit & Beck, 2017). This review requires an evaluation and critique of the literature and the dissemination of the literature review's findings into practice for improved patient outcomes (Polit & Beck, 2017). An in-depth literature review was conducted for the purpose of demonstrating the gap in care for individuals with generalized anxiety disorder (GAD) and to find evidence of effective anxiety screening and treatment interventions. This chapter will review the search strategies used for the literature review and discuss the evidence found to support an EBP intervention for screening and treating individuals with GAD in a primary care practice in South Florida.

Search Strategies

A comprehensive review of the literature was conducted using the following search engines: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane, EBSCO Complete, Health and Medical Collection database, Google Scholar, PubMed, PsycINFO, and Up-to-Date. Most of the retrieved articles were published between 2013-2018. Exceptions to the 5-year timeframe were seminal works on the generalized anxiety disorder 7-item (GAD-7) screening tool by Spitzer, Kroenke, Williams, and Lowe (2006) and the GAD clinical practice guidelines by National Institute for Health and Care Excellence [NICE] (2011). The key words used for searching were anxiety, assessment, treatment, management, generalized, and guidelines. The key terms used were: clinical practice guidelines for anxiety screening, clinical practice guidelines for anxiety treatment, evidence-based practice for generalized anxiety disorder screening, evidence-based practice for anxiety treatment,

generalized anxiety disorder, anxiety management in primary care, anxiety screening in primary care, benzodiazepine misuse in primary care, and mental health professionals. The search yielded 57 articles, and of those articles, 17 were included in this literature review. The other 40 articles were excluded because they were older than 5 years, did not examine nonspecific anxiety or GAD, did not include a primary care population or setting, or included children in the studies. The search revealed 17 articles that met the inclusion criteria of within 5 years old, included either nonspecific anxiety or GAD, were pertinent to the primary care setting, researched anxiety prevalence in primary care, and/or inadequate anxiety screening, inadequate EBP anxiety treatment, clinical practice guidelines or recommendations, anxiety screening tools, and/or EBP GAD treatment for adults, and included an adult-only population.

Retrieved information from professional and governmental organizations on the topic of anxiety was also necessary to identify any existing recommendations and/or clinical practice guidelines for anxiety screening and treatment. The websites viewed for professional and governmental organizations were American Academy of Family Physicians (AAFP), American Psychiatric Association (APA), Anxiety and Depression Association of America (ADAA), Community Care of North Carolina, National Institute for Health and Care Excellence (NICE), National Institutes of Health (NIH), National Institute of Mental Health (NIMH), National Alliance on Mental Illness (NAMI), U.S. Department of Veteran's Affairs (VA), and the World Health Organization (WHO) .

Literature Reviewed

A review of the literature elucidated that there is a lack of consistent and uniform use of screening methods to quantify GAD anxiety levels and a lack of EBP treatment being prescribed by primary care providers for adults with GAD (Goldberg et al., 2016; Olarui et al., 2015;

Roberge et al., 2015; Weisberg et al., 2014; Wiegner et al., 2015). The literature also made clear that adults with GAD often presented to their primary care provider with anxiety symptoms, despite the reason for their healthcare appointment (Goldberg et al., 2016; Olarui et al., 2015; Roberge et al., 2015; Weisberg et al., 2014; Wiegner et al., 2015). Despite the lack of uniform, quantifiable screening and best practice treatment being prescribed for GAD, the primary care provider can capture patient diagnosis of GAD and implement appropriate treatment. The literature reveals that screening for GAD with a quantifiable tool, such as the GAD-7 screening tool, and corresponding EBP treatment, such as selective serotonin reuptake inhibitors (SSRIs), selective norepinephrine reuptake inhibitors (SNRIs), mental health referrals, and psychotherapy are best practices for screening and treating adults with GAD in primary care (Jordan et al., 2017; Locke et al., 2015; Spitzer et al., 2006).

The literature review included a large criterion-standard study, which is a study that examines new tests, protocols, and results that examined the reliability of the GAD-7 screening tool (Spitzer et al., 2006). Additionally, two large systematic reviews were included in the literature that examined the efficacy of psychotherapy treatment for GAD (Bandelow et al., 2015; Marin, Campayo, Montoyo, Olmo, & Cuijpers, 2018). Two large meta-analyses were performed to investigate the effectiveness of selective serotonin reuptake inhibitors (SSRIs), SNRIs, and benzodiazepines for GAD treatment (Bandelow et al., 2015; Slee et al., 2019). One randomized controlled trial (RCT) was conducted to compare the efficacy of psychotherapy, SSRIs, SNRIs, and benzodiazepines for GAD treatment (Wetherell et al., 2013). The review of literature revealed clinical practice guidelines that recommended the implementation of a quantifiable anxiety screening tool and using an anxiety level to select EBP treatment for adults with GAD in primary care (ADAA, 2015; Locke et al., 2015; NICE, 2011).

Anxiety Prevalence in the United States

Several professional and governmental organizations have released data disclosing the prevalence of anxiety among adults living in the United States (U.S). Every year, about 40 million adults, ages 18 and older, experience an anxiety disorder (ADAA, n.d.). The ADAA (n.d.), the NAMI (2019), and the NIMH (2017a) present anxiety prevalence statistics from the National Comorbidity Study Replication (NCS-R), which was performed by a telephone survey of adults living in the U.S. who were asked specific questions relating to anxiety diagnostic criteria. The NCS-R found that 18.1% of adults living in the U.S. have an anxiety disorder (ADAA, n.d.; NAMI, 2019; NIMH, 2017a). The NCS-R found that GAD is responsible for 2.7% of all anxiety disorders in adults living in the U.S. (NIMH, 2017b).

Anxiety in Primary Care

A quantitative field study of 587 patients, led by the WHO, was conducted by Goldberg et al. (2016). The aim of the study was to examine the Primary Health Care Version of ICD-11's descriptions for Bodily Stress Syndrome (BSS) and Health Anxiety (HA) to investigate whether those descriptions correlate to primary care provider's observations of BSS and HA and how BSS and HA relate to other depressive and anxiety-related disorders. Participants were given the Clinical Interview Schedule-Revised (CIS-R), which is a diagnostic tool used by trained personnel to detect common mental health disorders, such as anxiety. The study concluded that 78.9% (n = 587) of patients had an associated anxiety or mood disorder when presenting to their primary care provider. This study demonstrated that anxiety disorders are common in the primary care setting and individuals presented to their primary care provider with anxiety, despite the reason for their appointment.

An observational study of 587 primary care patients, among five primary care clinics, was conducted by Wiegner et al. (2015) to investigate prevalence of stress in working adults who were seeking primary care services, despite the reason for the healthcare visit. Participants were provided a questionnaire that quantified stress levels by asking questions about how often the participant experienced stress. For participants with a high stress level, determined by the questionnaire, a separate questionnaire that determined exhaustion/burnout and another questionnaire that determined anxiety and depression were provided to the participants. As a result of a stress level that was higher than a little bit of stress, 59% of the 587 participants had a stress level that qualified them to complete anxiety screening via the self-reporting Hospital Anxiety and Depression Scale (HAD), which quantified an anxiety level. The anxiety screening revealed 64% of the 305 participants presenting to their primary care provider had symptoms of anxiety. This study showed that individuals who go to their primary care provider, despite their primary complaint, may have anxiety that can be detected at that appointment.

A cohort study surveying 373 patients meeting GAD diagnostic criteria was conducted by Roberge et al. (2015). The purpose of the study was to examine the use of mental health services by primary care patients with GAD, determine the detection rate of GAD in primary care, and examine correlates of treatment to clinical practice guidelines. The participants were surveyed in waiting rooms of 67 primary care offices and by telephone and web using a two-part interview. The first part of the study interview included a structured interview, the Composite International Diagnostic Interview-Simplified (CIDIS), to determine if the participant met diagnostic GAD criteria. If so, the second part of the interview included a series of questions regarding the participant's GAD diagnosis including: the type of clinical provider who was sought for consult regarding mental health concerns, the type of provider who diagnosed their GAD, medication

use, and psychotherapy and mental health services. Roberge et al. (2015) discovered that 87.4% of the 373 participants with mental health concerns had consulted a primary care provider in the previous 12 months. Of the 373 participants seeking consultation for mental health concerns, 52.5% had been diagnosed with GAD by a healthcare professional in the previous 12 months. Roberge et al. (2015) concluded that 32.6% of the 373 participants received adequate treatment, such as mental health services and/or medication aligned with clinical practice guidelines. Roberge et al. (2015) provided pertinent data that demonstrated individuals with GAD predominately sought out primary healthcare services for their symptoms; however, GAD was not recognized by primary care providers in nearly half of individuals with GAD, and EBP treatment was inadequate.

Inadequate GAD Screening and Treatment

An Olarui et al. (2015) meta-analysis of 24 studies, with a combined total of 34,902 patients, examined anxiety diagnosis in primary care. The study investigated unassisted (professional diagnostic interviewing with no use of an anxiety screening tool) and assisted (use of any anxiety screening tool that rates anxiety severity) anxiety diagnoses by primary care providers to determine if assistive screening was more valuable for the detection of anxiety than clinical judgment (unassisted screening) by primary care providers. The results of the study showed primary care providers who did not utilize an anxiety screening tool (unassisted) demonstrated a 30.5% sensitivity and 91.2% specificity for classifying anxiety disorders, and primary care providers who used an anxiety screening tool (assisted) were more accurate in identifying anxiety disorders, with a 63.6% sensitivity and 87.9% specificity for diagnosing anxiety. This large sample size study demonstrated there was no uniform and consistent approach to screening for anxiety in primary care because some providers used professional

diagnostic interviewing, and some used an anxiety screening tool. The study revealed utilizing an anxiety screening tool enhanced the accuracy of diagnosing anxiety in primary care.

Weisberg et al. (2014) conducted an observational longitudinal study of 534 adult patients among 15 primary care settings to investigate the adequacy of anxiety treatment in the primary care setting. All participants (n = 534) met anxiety disorder order criteria, which was assessed using a 32-item anxiety self-report survey and a Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV), which was followed by an interview about their anxiety treatment plans at the intake of the study (first appointment) and during follow-up appointments at 6 months, 12 months, and then once a year for a total 5 years. Over a 5-year period, data gathered from the interviews was utilized to examine the adequacy of psychotherapy and/or pharmacological treatment provided by primary care providers for participants with anxiety. At the first appointment of the study, findings showed that 19% of participants were being prescribed adequate pharmacological treatment; 14% were referred for cognitive behavioral therapy (CBT), which is a form of psychotherapy; and 5% of participants received a combination of pharmacological and CBT treatment. Adequate pharmacotherapy was defined as a SSRI, SNRI, or benzodiazepine medication(s) approved for anxiety treatment and given at the recommended dose and timeframe for treating anxiety. Adequate CBT was defined as achieving an adaptive behavior to resolve the anxiety and restructuring thinking during anxiety. At the conclusion of the 5-year study, 60% of participants were being prescribed adequate pharmacological treatment, 36% psychotherapy, and 26% combination therapy.

Bachhuber, Hennessy, Cunningham, and Starrels (2016) conducted a quantitative study to examine benzodiazepine prescribing trends and mortality related to benzodiazepine overdose

in adults living in the U. S. Bachhuber et al. (2016) retrieved data about filled benzodiazepine prescriptions from the Medical Expenditure Panel Survey (MEPS) for the years 1996-2013. The MEPS is conducted by the U.S. Department of Health and Human Services: Agency for Healthcare Research and Quality (AHRQ), which collects and reports data about the use, cost, and health insurance of medical services in the U.S. (AHRQ, 2016). From this data, Bachhuber et al. (2016) analyzed the number of adults who filled prescriptions for benzodiazepines and the quantity of prescription benzodiazepines that were filled each year. Benzodiazepine overdose related mortality, for the years 1999-2013, was also examined by retrieving data from the Centers for Disease Control and Prevention (CDC). The study illuminated that the number of U.S. adults who filled a prescription for benzodiazepines increased 67% between 1996 and 2013, from 8.1 million to 13.5 million prescriptions. The quantity of filled benzodiazepine prescriptions was the equivalent to 1.1 kilograms (kg) in 1996, which tripled to 3.6kg of benzodiazepines per 100,000 adults filled in 2013. Benzodiazepine overdose deaths quadrupled from 0.58 to 3.07 per 100,000 adults over that same period of time. The study revealed 56.1% of benzodiazepines were prescribed for anxiety treatment.

A cross-sectional study of 368,891 veterans was conducted by Carico et al. (2018) to investigate the amount of overlap of benzodiazepine and opioid prescriptions were ordered for U.S. veterans with Medicare Part D and Veterans Affairs (VA) prescription benefits. The study reported 31.4% of veterans (n = 368,891) had overlapping usage of benzodiazepine and opioid medications. Of the veterans taking overlapping benzodiazepines and opioids, 17.3% of those veterans used VA benefits only, 16.5% used Medicare benefits only, and 23.1% used both VA and Medicare benefits. Overlap use of high dose benzodiazepine and opioid medications lasted at least 30 days in 2.3% of VA prescription benefit only users, 2.9% Medicare Part D only users,

and 4.7% of dual users (Medicare Part D and VA prescription benefits). The study concluded by stating that veterans with dual Medicare and VA prescription benefits were at an increased risk of receiving overlapping opioid and benzodiazepine prescriptions, which can be potentially dangerous. This large sample size study illuminated the prevalence of benzodiazepines used in combination with opioids, which places individuals at risk for dangerous complications. This research helps demonstrate that unnecessary, increased prescribing of benzodiazepines can occur concurrently with other dangerous and addictive medications.

Clinical Practice Guidelines for Anxiety Screening and Treatment

The Institute of Medicine (IOM) Roundtable on Evidence-Based Medicine developed a goal to ensure that accurate, timely, and current best evidence is implemented in 90% of clinical decision making by the year 2020 (Olsen, Aisner, & McGinnis, 2007). Clinical practice guidelines and recommendations are based on best evidence that has been examined for effectiveness and optimal patient outcomes (Melnyk & Fineout-Overholt, 2015). The ADAA (2015), Locke et al. (2015), and NICE (2011) have developed and published recommendations for GAD management. The ADAA (2015), Locke et al. (2015), and NICE (2011) all recommend determining an anxiety severity or impairment level that can be utilized to select, in collaboration with the patient, appropriate treatment such as psychotherapy, SSRIs, SNRIs, mental health referral, or combination treatment for adults with GAD in primary care.

The *Generalized Anxiety Disorder in Adults: The NICE Guideline on Management in Primary, Secondary and Community Care, National Clinical Guideline* [CG113] was developed by the National Collaborating Centre for Mental Health and commissioned by NICE. The NICE (2011) clinical practice guidelines provide a stepwise approach that guides the primary care provider through EBP diagnostic and treatment recommendations for adults with GAD. NICE

(2011) recommends prompt diagnosis of anxiety, the establishment of level of anxiety severity and functional impairment, and ruling out any pathological conditions. NICE (2011) presents the GAD management clinical practice guideline's protocol as a series of four steps. According to NICE (2011), selecting treatment for GAD is based on correlate to an anxiety level. Treatment includes lifestyle modifications, specific SSRIs, specific SNRIs, mental health referrals, psychotherapy, or combination treatment. Benzodiazepines may be initiated short term or prescribed for immediate crisis management if an individual is at risk of self-harm. All steps of treatment should be individualized and selected by considering patient history and risks and benefits of treatment.

In *Diagnostics and Management of Generalized Anxiety Disorder and Panic Disorder in Adults,* Locke et al. (2015) defined the clinical recommendations for diagnosing and treating adults with GAD. The recommendations are located on the American Association of Family Physicians' website. The recommendations include diagnosing anxiety with use of a screening tool. Locke et al. (2015) suggested the use of the GAD-7 screening tool because of its validity of sensitivity and specificity. The GAD-7 quantifies an anxiety level. The recommendations inform that a GAD-7 score of 10 or greater requires anxiety intervention. The following recommendations for treating GAD are: (a) to rule out potential pathological medical conditions; (b) provide the individual with education and active listening; (c) implement lifestyle modifications such as cessation/reduction of nicotine, caffeine, and avoidance of triggers; (d) prescribe first-line therapy that includes psychotherapy, such as cognitive behavioral therapy (CBT) alone, or the following SSRIs alone: escitalopram (Lexapro), fluoxetine (Prozac), paroxetine (Prozac), and sertraline (Zoloft), or the following SNRIs alone: venlafaxine extended release (Effexor XR), or duloxetine (Cymbalta); or (e) prescribe pharmacotherapy in

combination with psychotherapy. The benzodiazepines alprazolam (Xanax), clonazepam (Klonipin), diazepam (Valium), and lorazepam (Ativan) should only be used short term for augmentation. A referral to a mental health specialist is warranted for suboptimal/failed treatment response, atypical presentation, or suspected comorbid psychiatric illness.

Locke et al. (2015) recommend using a GAD screening tool for diagnosing anxiety and specifically mention the GAD-7. These recommendations underscore the importance of establishing an anxiety level and correlating the level to EBP treatment selections.

The ADAA published *The Clinical Practice Review for GAD* (2015) that was developed by a clinical taskforce that recommends the following first-line treatments for adults with GAD: psychotherapy, which can consist of cognitive behavioral therapy (CBT), cognitive therapy (CT), or applied relaxation techniques, or pharmacotherapy, which can consist of the SSRIs, escitalopram (Lexapro), fluoxetine (Prozac), paroxetine (Prozac), and sertraline (Zoloft), or SNRIs venlafaxine extended release (Effexor XR), or duloxetine (Cymbalta). These interventions for GAD were developed by the GAD Clinical Practice Review Task Force that included Powers, Becker, Gorman, Kissen, and Smits (2015).

Effectiveness of GAD-7 Screening Tool

Spitzer et al. (2006) developed and tested a short, self-reportable GAD screening tool, the GAD-7 screening tool, designed to assist in diagnosing and quantifying anxiety levels in adults with GAD in primary care. The validity and reliability of the GAD-7 screening tool was tested in a criterion-standard study of 2,740 adults in 15 primary care practices. Analysis of the data revealed the tool was 82% specific and 89% sensitive, with an internal consistency of 0.92 for diagnosing GAD in adults in the primary care setting.

Jordan et al. (2017) conducted a study of 3,404 patients among 33 primary care clinics to examine whether the questions on the GAD-7 screening tool accurately diagnose GAD. Each of the seven items (questions) were individually weighted to determine their grade of reliability to diagnose GAD. Jordan et al. (2017) used psychometric analysis to determine the discriminatory power of each question. The statistical analysis of the seven questions and corresponding scores revealed an overall reliability of 0.91 of the GAD-7 screening tool. The findings illuminate that the GAD-7 is an accurate tool for screening adults for GAD in primary care.

Evidence-Based Treatment for GAD

A meta-analysis of 234 studies, which included 37,333 patients, was performed by Bandelow et al. (2015) to compare psychological, pharmacotherapy, and combined treatment (psychological and pharmacotherapy) for GAD. Randomized controlled trials (RCTs) that investigated GAD, psychological therapies, and pharmacotherapy for GAD treatment were eligible for inclusion in the meta-analysis. An analysis of 234 studies conducted by Bandelow et al. (2015) discovered that treatment for GAD should include psychotherapy, pharmacotherapy, or combination therapy, and selection of treatment should incorporate patient preference, consideration of the side effects of medications, and the cost and/or wait period to start psychotherapy. Further, all GAD treatments were found equally effective at improving the quality of life in adults with GAD. The study, which incorporated a large sample size and a diverse review of studies, enhances confidence that psychotherapy, pharmacotherapy, or combination therapy are effective GAD treatments.

A meta-analysis of 50 studies that included 2,801 patients by Marin, Campayo, Montoyo, Olmo, and Cuijpers (2018) compared CBT to relaxation training for anxiety treatment. A multivariate meta-regression analysis of 50 studies found that relaxation techniques and CBT

provide equivocal results for treating GAD. This meta-analysis also demonstrated psychotherapy is an effective treatment for individuals with GAD.

An RCT of 704 adults among 26 primary care providers conducted by Rollman et al. (2018) examined the outcomes of a collaborative care program that consists of computerized cognitive behavioral therapy (CCBT) and an internet support group (ISG) for anxiety treatment compared to a CCBT-only program in adults with anxiety. The study utilized mental health professionals who telephoned participants to educate them about their randomly assigned therapy: either the CCBT only or ISG/CCBT programs. The mental health professionals acted as care managers who would regularly monitor participation trends throughout the 8-week program and update the primary care providers on the participants' progress. Participants were administered the GAD-7 screening tool before intervention began and after completing their assigned 8-week program. The study concluded that participants assigned to the collaborative ISG and CCBT group did not have added benefits in comparison to the CCBT group that proved more effective in participants with anxiety. This study provided evidence that collaboration between mental health specialists and primary care providers and CBT improve outcomes of individuals with anxiety.

Slee et al. (2019) conducted a systematic review and meta-analysis of 89 RCTs with a total of 25,441 patients to examine the efficacy of medications used to treat GAD. The meta-analysis performed by Slee et al. (2019) found SSRIs (duloxetine, venlafaxine, and escitalopram) effective for treating GAD. The study stated in the implications for practice that duloxetine, venlafaxine, and escitalopram were more efficacious with good acceptability and were effective at controlling/improving GAD symptomology when compared to those who received placebos for GAD treatment.

Wetherell et al. (2013) conducted an RCT of 73 patients to evaluate the long-term GAD symptom management of combined CBT and the SSRI escitalopram therapy. Participants (n = 73) were recruited in three outpatient clinics. Participants completed a Hamilton Anxiety Rating Scale (HAM-A), which measures anxiety and was completed at baseline and every 4 weeks during augmentative therapy and every 2 weeks during maintenance therapy. Participants also completed the Penn State Worry Questionnaire, which measures uncontrollable worry, at baseline and end of the study. The study was divided into three phases: acute, augmentation, and maintenance. Every participant received escitalopram for 12 weeks in the acute phase. At the completion of the acute phase, participants completed the HAM-A. Participants with a 20% improvement in GAD symptoms moved into the augmentation and maintenance phases. The augmentation and maintenance phases included a random assignment to either: 16 weeks of escitalopram and 16 sessions of CBT therapy, with 28 weeks of escitalopram for maintenance therapy; 16 weeks escitalopram only, with 28 weeks of escitalopram for maintenance therapy; 16 weeks of escitalopram and 16 sessions of CBT therapy, with 28 weeks of placebo for maintenance therapy; or 16 weeks escitalopram only, with 28 weeks of placebo for maintenance therapy. The study revealed that there was no significant change between the escitalopram-only group and the escitalopram with combination CBT group for measurements of anxiety when measured with HAM-A. There was, however, a threefold decrease in a state of worry measured by the Penn State Worry Questionnaire for participants who received escitalopram and CBT combined therapy.

Synthesis of Findings

The lack of a consistent and uniform anxiety screening method for GAD in primary care was evident in the literature review. Four studies demonstrated that individuals with anxiety

symptoms commonly present to their primary care provider (Goldberg et al., 2016; Roberge et al., 2015; Weisberg et al., 2014; Wiegner et al., 2015). There was a lack of consistent and uniform use of quantifiable screening methods for GAD by primary care providers (Goldberg et al., 2016; Olarui et al., 2015; Roberge et al., 2015; Weisberg et al., 2014; Wiegner et al., 2015). Further, studies demonstrated primary care providers deliver inadequate EBP treatment for adults with GAD (Furbish et al., 2017; Weisberg et al., 2014). Two large studies illuminated the increasing trend of benzodiazepine prescribing and misuse related to anxiety disorder treatment, which can result in dependency and/or mortality (Bachhuber et al., 2016; Carico et al., 2018).

Despite the inconsistencies of GAD screening methods, the Generalized Anxiety Disorder 7-item (GAD-7) screening tool renders an anxiety level and has been proven effective at accurately diagnosing GAD in primary care (Jordan et al., 2017; Locke et al., 2015; Spitzer et al., 2006). Best practice recommendations for GAD screening and treatment for adults in primary care have been developed and well-studied. Consistent use of an anxiety screening tool, such as the GAD-7, has been carefully examined and recommended for primary care provider use (Jordan et al., 2017; Locke et al., 2015; NICE, 2011; Spitzer et al., 2006). Effective EBP treatment recommendations for GAD state that a provider should collaborate with the patient to select an appropriate treatment that correlates to the patient's anxiety level and preference, such as lifestyle modifications, SSRIs, SNRIs, mental health referrals, psychotherapy, and/or combination treatments (Locke et al., 2015; NICE, 2011).

Advantages and Disadvantages

A review of the literature revealed three disadvantages. The first disadvantage was that not one uniform method for GAD screening in primary care was found in the current literature. Two types of anxiety screening methods are being utilized: interview and anxiety screening

tools. Additionally, various types of interview and anxiety screening tools, including those that are not specific to GAD, are being used in primary care. The second disadvantage was that there is no evidence that GAD treatment is being prescribed in correlation to a measured anxiety level, as recommended by clinical practice guidelines. The third disadvantage was a failure to examine how quantifying a GAD anxiety level can assist primary care providers to prescribe EBP treatment for adults with GAD.

The literature review also revealed advantages. A review of literature illuminated the opportunities that primary care providers had to capture a GAD diagnosis and treat GAD in adult patients seeking primary care services. The literature demonstrated most primary care providers do not implement best practices for GAD screening and treatment (Bachhuber et al., 2016; Carico et al., 2018; Goldberg et al., 2016; Olarui et al., 2017; Roberge et al., 2015; Weisberg et al., 2014; Wiegner et al., 2015). This underscores the need for implementation of a comprehensive EBP GAD screening and treatment change in primary care for adults with GAD.

Gaps in the Literature

There was a lack of precise reproduction of screening methods and treatment for GAD in the studies of the literature review. Studies that examined one uniform GAD screening tool that quantifies an anxiety level to utilize for the implementation of EBP treatment for adults with GAD would enhance the evidence. A total of four studies utilized an anxiety screening method. Three studies utilized three different methods of professional interviewing—the CIS-R, CIDIS, and Structured Clinical Interview for DSM-IV anxiety criteria—and one meta-analysis did not specify the interviewing technique used for anxiety screening (Goldberg et al., 2016; Olarui et al., 2017; Roberge et al., 2015; Weisberg et al., 2014). Two studies utilized an anxiety screening tool, one study implemented HAD, and the other study, a meta-analysis, did not specify the

anxiety screening tool(s) implemented, and none of the studies used a screening tool specific to GAD (Olauri et al., 2015; Wiegner et al., 2015). Further, the review of literature illuminated a lack of EBP treatment prescribed for adults with GAD in primary care. Clinical practice guidelines recommend correlating anxiety level to EBP treatment for adults with GAD in primary care (Locke et al., 2015; NICE, 2011). None of the studies investigated whether an anxiety level was used to assist in prescribing adequate EBP treatment for GAD (Bachhuber et al., 2016; Carico et al., 2018; Roberge et al., 2015; Weisberg et al., 2014). Recommendations for future studies included examining a consistent anxiety screening method, investigating the frequency that primary care providers acquire an anxiety level to use as a foundation for prescribing EBP treatment, and studying how an anxiety level can assist in prescribing GAD treatment.

Utilization of Findings for Intervention

Despite a lack of uniform and consistent screening and treatment for adults with GAD in primary care, several studies demonstrated that anxiety can be promptly diagnosed, and appropriate management with EBP treatment(s) is achievable in the primary care setting. Improving the quality of life in adults with GAD requires prompt and effective treatment. The GAD-7 is a well-studied screening tool with an 82% specificity and 89% sensitivity and is reliable and valid for screening adults in primary care settings for GAD (Jordan et al., 2017; Locke et al., 2015; Spitzer et al., 2006). Clinical recommendations for GAD management were developed by Locke et al. (2015), NICE (2011), and the ADAA (2015), recommending providers quantify levels of anxiety through screening and implement EBP practices that include lifestyle modifications, CBT, SSRIs, SNRIs, mental health referrals and/or combination therapies to ensure optimal patient outcomes and increase quality of life for adults with GAD.

Summary

Commonly, individuals with GAD present to their primary care provider for treatment. GAD screening of adults in primary care is inadequate and does not routinely reveal an anxiety level. There is also an overall lack of routine implementation of EBP treatment for adults with GAD in primary care, and when provided, treatment is often inadequate. The GAD-7 screening tool quantifies an anxiety level and is valid and reliable for use by primary care providers for diagnosing GAD. Clinical recommendations provide algorithms that correspond an anxiety level to EBP treatment for adults with GAD in primary care. Best practice evidence found prompt identification of GAD, followed by the implementation of either CBT, SSRIs, SNRIs, a mental health referral, or combination therapies effectively provide long-term symptom control and enhance the quality of life of adults with GAD.

Chapter Three: Methodology

Symptoms of generalized anxiety disorder (GAD) vary from mild to debilitating and can adversely affect quality of life. Inappropriate treatment of GAD, including the inappropriate prescribing of short-acting benzodiazepines for long-term anxiety treatment, can result in poor symptom control and cause other negative consequences such as medication abuse (Locke, Kirst, & Shultz, 2015). Healthcare providers who are thorough and consistent with implementation of anxiety screening and evidence-based treatment can efficiently and appropriately manage an individual's anxiety symptoms and improve his or her quality of life (Locke et al., 2015; National Institute for Health and Care Excellence [NICE], 2011). This evidence-based practice (EBP) project implemented a systematic change at a primary care clinic in south Florida that included screening patients for anxiety with an evidence-based tool that diagnoses and quantifies a GAD severity level and prescribing GAD treatment according to an EBP protocol. This chapter will discuss the methodologies used for this Doctor of Nursing Practice (DNP) evidence-based practice (EBP) project for implementing a screening and treatment protocol for GAD in an adult primary care practice.

Purpose of the Project

The purpose of this quality improvement project was to implement an EBP anxiety screening and treatment protocol for adults in a primary care clinic to increase early identification and improve management of GAD.

Project Management

Organizational Readiness for Change

The primary care provider, at the project's implementation site, expressed a desire and willingness to change previous practices for anxiety screening and treatment in this primary care

setting. There was a lack of routine anxiety screening performed for individuals who complained of anxiety symptoms and no utilization of an anxiety screening tool at this site. The primary care provider also wanted to reduce the number of benzodiazepines prescribed for individuals with GAD in this practice.

Risk Management Assessment: SWOT Analysis

During a 5-month observational period, the following strengths, weaknesses, opportunities, and threats were observed in this primary care practice. The strengths of this primary care clinical practice included the clinical staff: follows through with tasks, has excellent rapport with patients and with each other, is receptive to change, and has a culture of positive teamwork and genuine commitment to deliver high-quality healthcare. The weaknesses of this practice included: no uniform policy for screening for anxiety existed, a lack of routine screening for anxiety, anxiety severity screening, utilization of evidence-based anxiety screening tools, and providers' inconsistent prescription of EBP treatment(s) that correspond to anxiety severity. The opportunities for this practice included: the primary care provider's genuine sincerity to deliver the best practices available to improve her patients' outcomes, a request for an anxiety screening protocol, and her readiness to implement an EBP anxiety screening tool and EBP treatment by corresponding anxiety treatment to anxiety severity, per a treatment protocol, and the availability of a valid and reliable tool and treatment algorithm. The threats for the practice included a potential for attrition in clinical staff, high daily patient volume, and a busy practice that caused time constraints.

Project Budget

Resources such as people, time, and technology were needed to implement this EBP project. The protocol training session for the four medical assistants (MAs) included a catered

lunch. The catered lunch was provided for all 12 employees at the primary care clinic. A 6-month subscription for IBM SPSS Software was purchased for data analysis. One package of 12 retractable gel pens in black ink was purchased to provide writing utensils for completing the Generalized Anxiety Disorder 7-item (GAD-7) screening tool. One 1000-sheet package of copy paper was purchased for printing the GAD-7 screening tools. One HP Officejet Pro printer ink cartridge was purchased to print the GAD-7 screening tools. Costs for travel to/from the facility to implement the project were also calculated according to the 2018 Internal Revenue Service (IRS) mileage reimbursement rate (See Table 1).

Table 1

Project Budget

Item	Cost
Catered lunches for protocol training ($7.24 x 12 people)	$86.88
IBM SPSS Software (e.g. 6-month subscription x2)	$178.00
Retractable Gel Pens (1 package of 12 pens)	$16.59
Copy Paper (1000 sheets x $0.0339 per sheet)	$33.98
Printer Ink Cartridges (1)	$119.99
Travel to/from facility 92 days (5,016 miles x $0.58 per mile)	$2,909.28
Total Costs	$3,344.72

Design of Intervention

This EBP anxiety screening and treatment protocol, which was a systematic change that included a retrospective/prospective chart review, was approved by Nova Southeastern University's Institutional Review Board (see Appendix A) and the primary care clinical practice site (see Appendix B). The implementation of the EBP project included the following steps:

Phase 1

Provide MA training on anxiety screening protocol: Prior to the training, MAs were explained the purpose of the quality improvement EBP project. Four MAs were trained on the anxiety screening and treatment protocol that was adopted as standard practice in the clinic via an interactive PowerPoint presentation, with opportunities provided for questions and answers. Training included background and significance of anxiety and underscored the importance of screening patients for anxiety. The training also trained the four MAs on their role in the screening and treatment protocol. MAs were provided samples of completed GAD-7 tools and calculated the numerical responses to demonstrate to the project implementer the ability to accurately calculate (not interpret) the GAD-7 score (see Appendix C). The interactive discussion of questions and answers demonstrated the MA's understanding of the training. This 20-minute presentation was provided four times over 1 week to capture and train all four MAs.

Phase 2

Implementation of the EBP anxiety screening and treatment protocol (see Appendix D) included the following steps for the MAs, primary care providers (PCPs), and the adult primary care clinic patients.

Step 1. On intake, in addition to routine intake data collection such as vital signs and changes in medical history, the MA asked all adult patients (at least 18 years of age) the following question: "Have you experienced feelings of worry, fear, or mental unease over the past 6 months?" and then documented the patients' answer of "yes" or "no" in the patients' electronic health records (EHR; approximately 30 seconds). *The Diagnostic and Statistical Manual of Mental Disorders, 5th edition* (DSM-5) informs that anxiety is defined as feelings of inappropriate worry or fear as, more days than not for 6 months (APA, 2013.

Step 2. If the patient answered "yes" to the question "Have you experienced feelings of worry, fear, or mental unease over the past six months?" the MA asked the patient "Are you having thoughts of killing yourself right now?" If the patient responded "yes," which indicates an imminent risk for suicide, the patient was not to be left alone and an immediate mental health evaluation was to be made (NAMI, 2019). If the patient answered "no," the MA asked the patient to complete the self-reportable GAD-7 tool and provided instructions for completing the questionnaire. Per the practice systems change guideline, all patients were informed that they had the right to refuse to complete the questionnaire.

For reference, the following governmental and professional organizations provide open access to the GAD-7: The U.S. Department of Veteran's Affairs, the National Institute for Mental Health (NIMH), Substance Abuse and Mental Health Services Administration (SAMSHA), Patient-Centered Primary Care Collaborative (PCPCC), Community Care of North Carolina, and the Health Information Library.

Step 3. If the patient agreed to and completed the GAD-7, once completed, the MA took the GAD-7 from the patient, tallied the score, recorded the score in the patients' EHR, and placed the GAD-7 on the chart for the primary care provider to review. This step took approximately 3 minutes.

Step 4. Prior to seeing the patient, the PCP reviewed the patients' answers on the GAD-7, validated the MA's scoring of the GAD-7, and reviewed and interpreted/quantified the patients' anxiety level according to the GAD-7 instructions, which includes level of anxiety cutoff points of none to minimal (0-4 points), mild (5-9 points), moderate (10-14 points), and severe (15 or more points) anxiety. This step took approximately 3 minutes.

Step 5. The PCP discussed the GAD-7 anxiety score with all patients who completed a GAD-7 and assessed the patient for any underlying medical conditions that present with the same symptoms of anxiety by performing a full physical assessment and review of systems for any patient who scored greater than four on the GAD-7. This step's time varied between 5 and 15 minutes.

Step 6. The PCP discussed with the patient what his or her anxiety score meant (level = minimal, mild, moderate, or severe) and discussed the following anxiety management based on what the patient scored. This step's time varied between 5 and 15 minutes.

An anxiety level of 0-4 (minimal) required a follow-up at the patient's next regularly scheduled visit. For an anxiety level of 5-9 (mild), the PCP: (a) educated the patient about anxiety, (b) actively listened to the patient's concerns and requests for treatment, (c) considered the patient's request for treatment, (d) recommended lifestyle modifications, and (e) educated patients on what lifestyle modifications should be made to improve symptomology, including different relaxation techniques. For an anxiety level of 10-15 (moderate), the PCP: (a) provided all the recommendations for a mild anxiety level and (b) considered the patient's clinical history, current medications, allergies, and patient preferences before selecting an anxiety treatment that included any of the following EBP treatments (and provided patient education on all options, risks/benefits ratios, and expected outcomes of each option): cognitive behavioral therapy (CBT), a selective serotonin re-uptake inhibitor (SSRI), a selective norepinephrine re-uptake inhibitor (SNRI), or a combination of CBT and either a SSRI or SNRI, and follow-up in 6 weeks. For an anxiety level of 15 or greater (severe), the PCP: (a) provided all the recommendations for a mild anxiety level, (b) provided referral and contact information for a mental health specialist, (c) facilitated scheduling with a mental health provider appointment if possible, (d) followed up

in 6 weeks and PRN, (e) ensured a 6-week follow-up appointment was scheduled, and (f) educated the patient to call the PCP immediately and make an appointment if symptom severity or frequency increased (see Appendix D).

This EBP protocol for anxiety treatment was adapted/modified from Community Care of North Carolina (2018), and anxiety screening and treatment clinical recommendations by Locke et al. (2015), and National Institute for Health and Care Excellence (NICE, 2011; see Appendix E).

Step 7. The PCP documented GAD-7 scores and interpretation and anxiety management plans were collaboratively decided upon with patients.

Phase 3

A retrospective chart review for 2 months of data prior to the implementation of the anxiety screening and treatment protocol implementation was conducted. The retrospective chart review occurred over 4 weeks.

Phase 4

A prospective chart review for 2 months of data after the implementation of the EBP anxiety screening and treatment protocol was conducted. The prospective chart review occurred over 4 weeks.

Setting

The setting for this EBP project was located in an adult primary care practice in Southeastern Florida.

Sample

A combined 673 adult, primary care electronic health records (EHRs)/charts ($N = 673$) were reviewed. The pre-implementation retrospective and post-implementation prospective

chart reviews revealed 178 charts (n = 178) included a documented active diagnosis and treatment for anxiety on the date of service for the time which the chart was reviewed. Of those 178 charts that had an active anxiety diagnosis and treatment plan on the date of service, 81 were retrospective charts and 97 were post-implementation prospective charts.

Inclusion Criteria

Retrospective chart reviews included all primary care patient charts from March 1, 2019-April 30, 2019. The prospective chart review included all primary care patient charts from June 1, 2019-July 31, 2019. Of the 673 charts, 178 were included in the retrospective/prospective chart review for analysis because they included a documented active diagnosis and management for anxiety on the date of service for the time which the chart was reviewed. All primary care patients in this clinic were at least 18 years of age.

Exclusion Criteria

All primary care charts were reviewed; however, charts that did include a documented active diagnosis and management plan for anxiety were excluded from further analysis.

Recruitment Procedure

This EBP quality improvement project involved retrospective and prospective chart reviews where no personal identifiable patient data was collected, so there was no recruitment of participants.

Determination of Sample Size

The implementation phase of this DNP EBP project was 2 months long. Therefore, prospective chart reviews included the 2 months of charts following the implementation of the protocol. To allow for a similar amount of charts to be reviewed in the retrospective chart review, the 2 months prior to the protocol implementation were chosen for chart reviews.

Data Collection Procedures

Instrumentation

The GAD-7 anxiety screening tool consists of seven (4-point Likert scale type) questions and is a free public domain tool that takes approximately 2 to 5 minutes to complete (Jordan et al., 2017; Locke et al., 2015; Spitzer et al., 2006; see Appendix C). Questions consist of asking the patient to self-report on: feeling nervous, anxious, on edge; not being able to stop or control worrying; worrying too much about different things; having trouble relaxing; being so restless that it is hard to sit still; becoming easily annoyed or irritable; and feeling afraid as if something awful might happen, over the past 2 weeks. One additional question asks the patient if they checked off any of the previous seven "problems." If they had, they are asked to answer how difficult these "problems" listed in the seven questions have impacted their work and/or home life by checking one of the following responses: not difficult at all, somewhat difficult, very difficult, or extremely difficult (see Appendix C). Scoring ranges from 0-21, with answer choices of: not at all sure (0 points), several days (1 point), over half of the days (2 points), and nearly every day (3 points). The GAD-7 scoring cutoff point for mild anxiety is set at 5, moderate at 10, and severe anxiety at 15 (Jordan et al., 2017; Locke et al., 2015; Spitzer et al., 2006).

Validity and Reliability

The GAD-7 screening tool was studied over an 8-month period among 15 primary care practices and included 2,740 adult participants. Analysis of the data revealed the tool was 82% specific and 89% sensitive (Spitzer et al., 2006). The GAD-7 is valid and reliable (Cronbach's $\alpha = 0.92$) for diagnosing GAD in primary care, is recommended for anxiety screening, and has

been used extensively in primary care practice (Jordan et al., 2017; Locke et al., 2015; Spitzer et al., 2006).

Data Management and Storage

All confidential paper data was kept secured at the intervention site in a locked file cabinet and only the project implementer has access to the well-hidden key. All data will be kept for 36 months from the end of the project, and then paper data will be shredded by an electronic paper shredder that shreds into fine pieces.

Data Analysis

Descriptive and inferential statistics were conducted. Descriptive statistics describe data and synthesize the findings (Polit & Beck, 2017). The following variables were analyzed: age range and gender; anxiety screening method pre/post-implementation; anxiety score and level; and prescribed anxiety treatment pre/post-implementation, such as the type of anxiety treatment selected, specific lifestyle modifications recommended, relaxation techniques utilized, mental health referrals, CBT referrals, and pharmacological agents ordered (including type and doses of: SSRIs, SNRIs, and benzodiazepines). The descriptive analysis reported percentages, frequency distributions, and means. Descriptive statistics calculated the percentages of the gender and age-range variables of the reviewed charts. Percentages of pre/post-implementation utilization of the two types of anxiety screening methods used (professional interview and GAD-7 screening tool) were calculated to determine if the implementation of a quantifiable anxiety screening method to identify GAD had increased after the training. Anxiety level severity was also calculated and illuminated the mean and percentages of charts with documented minimal, mild, moderate, or severe anxiety level. Frequency distributions and percentages were calculated for the: pre-implementation retrospective chart reviews and the post-implementation prospective chart

reviews to determine if there was a change in anxiety screening method and treatment practices in this primary care practice; post-implementation charts that implemented the GAD-7 screening tool and the percentages of charts that had a correlated anxiety level to prescribing EBP treatment to determine if obtaining an anxiety level assisted the primary care provider in prescribing EBP treatment. Frequency distributions and percentages of post-implementation charts that utilized the GAD-7 screening tool and the percentages of charts that had a correlated anxiety level to prescribed EBP treatment to determine if those charts had received changes to their pre-existing GAD treatment were also calculated.

Inferential statistics conducted included Pearson's Coefficient Correlation (Pearson's *r*). Pearson's *r* is conducted to analyze correlation between variables (Polit & Beck, 2017). Inferential statistics, Pearson's *r,* were utilized to determine whether documented GAD levels correlated to prescribed EBP treatments.

Ethical Considerations

Protection of Confidentiality

No personal identifiers were needed. The information collected from this study did not have any identifiable information associated with electronic health records. The recorded data is a tally of the variables collected, as previously described.

Benefit-to-Risk Ratio

The benefit that is associated with providing anxiety screening resulting in evidence-based treatment is an enhanced quality of life for adults with GAD (Abberger et al., 2017; Locke et al., 2015; NICE, 2011; Waters et al., 2015). Implementation of an anxiety screening tool in the primary care setting contributes to decreased healthcare costs secondary to accurate and timely diagnosis and an increased quality of life (Jordan et al., 2017).

The benefits to the clinical staff were a consistent, thorough, and systematic evidence-based protocol to assist in the screening and treatment of adults with GAD. The clinical staff benefited from maintaining compliance in reducing the misuse of Drug Enforcement Agency (DEA) scheduled medications such as benzodiazepines. In the state of Florida House Bill 21 (HB 21): Controlled Substances now requires that scheduled drugs, including benzodiazepines, are checked and documented in the EFORSCE Florida Prescription and Drug Monitoring Program or risk legal consequence (Scott, 2018). The intent of HB 21 is to monitor the prescribing practices of DEA scheduled medications, such as benzodiazepines (Scott, 2018). This EBP project may protect the provider from potential investigations, liability, or legal consequences induced by improper prescribing of benzodiazepines for GAD.

Further, this EBP project for implementation of an anxiety screening and treatment protocol benefits patients. Best practices recommend screening adults for GAD, in primary care, with a screening tool that quantifies anxiety levels and then correlating the anxiety level to prescribing treatment (Locke et. al., 2015). Implementation of best practices for screening and treating GAD in primary care was proven to accurately identify GAD in adults, decrease symptoms, and enhance the quality of life in adults with GAD (Locke et al., 2015; NICE, 2011). Additionally, patients may benefit from reduced use of or possible dependency of benzodiazepines related to inappropriately prescribing these short-acting medications for long-term treatment and symptomology control.

Summary

An anxiety screening and treatment protocol was implemented in an adult primary care clinic. A retrospective and prospective chart review was performed to obtain the variables: age range, gender, number of screenings for anxiety performed before the training and after the

training, anxiety screening method, level of anxiety, and treatment measures such as lifestyle modifications, relaxation techniques, mental health referral, CBT, SSRIs, SNRIs, and benzodiazepines. Descriptive and inferential statistics with Pearson's *r* analyzed the variables to synthesize the findings.

Chapter Four: Results and Discussion

Generalized anxiety disorder (GAD) can have a substantial impact on the physical and social aspects of an adult's life, causing a decrease in the quality of their life (Bentley et al., 2016; Edmund & Sheppard, 2018; Locke, Kirst, & Shultz, 2015; National Institute of Mental Health [NIMH], 2017a; NIMH, 2018; Stein & Sareen, 2015). Best practices recommend screening adults for GAD, in primary care, with a screening tool that quantifies anxiety levels and then correlating the level to prescribing treatment. A primary care practice did not have a GAD screening tool and treatment protocol to routinely screen and treat patients with GAD according to best practices.

Anxiety treatment interventions such as specific selective serotonin re-uptake inhibitors (SSRIs), specific selective norepinephrine re-uptake inhibitors (SNRIs), mental health referrals, and psychotherapy are effective and approved by the United States (U.S.) Federal Drug Administration (FDA) for the treatment of GAD (Abejuela & Osser, 2016; Craske & Bystritsky, 2017; Locke et al., 2015; National Institute for Health and Care Excellence [NICE], 2011; NIMH, 2016). Healthcare providers who are thorough and consistent with implementation of GAD screening and evidence-based treatment can efficiently and appropriately manage an individual's anxiety symptoms and improve his or her quality of life (Locke et al., 2015; NICE, 2011). The purpose of this quality improvement project was to implement an EBP anxiety screening and treatment protocol for adults in a primary care clinic to increase early identification and improve management of GAD. This chapter describes the outcomes of the EBP quality improvement project and discusses its implications for nursing practice.

Participant Demographics

A combined 673 adult, primary care electronic health records (EHRs)/charts ($N = 673$) were reviewed. Of the 673 charts reviewed, 178 charts were included in the pre-implementation retrospective ($n = 81$) and post-implementation prospective ($n = 97$) chart reviews because they included a documented, active diagnosis and management for anxiety on the date of service for the time which the chart was reviewed.

Expected Outcomes

The expected outcomes of the Doctor of Nursing Practice (DNP) EBP project are outlined in four objectives.

Objectives

The purpose of this quality improvement project was to implement an EBP anxiety screening and treatment protocol for adults in a primary care clinic to increase early identification and improve management of GAD. Therefore, this project had the following objectives:

1. Train five medical assistants on the administration of the GAD-7 assessment tool.
2. Implement an EBP anxiety screening and treatment protocol
3. Conduct retrospective and prospective chart reviews
4. Evaluate the anxiety screening and treatment protocol implementation process and GAD identification and management outcomes.

In the context of this EBP project, implementation meant in an adult primary care clinic, a practice change occurred by asking every patient, at every health visit, if they had felt anxious, worried or fearful, more times than not, in the last 6 months, as the *Diagnostic and Statistical Manual 5th edition* (DSM-V) diagnostic criteria recommends. Patients who answered "yes" and

who agreed were screened with the GAD-7 screening tool; the score was tallied, the primary care provider interpreted the score to an anxiety level and then used the anxiety level to assist in prescribing EBP treatment, such as lifestyle modifications, SSRIs, SNRIs, mental health referrals, psychotherapy, or combination therapy. In the context of this EBP project, improved management meant the primary care provider prescribed treatment based on the GAD-7 anxiety level according to an EBP protocol.

Evaluation of Outcomes

Descriptive statistics and Pearson's *r* were utilized to analyze a total of 673 adult, primary care EHRs/charts that were reviewed. Retrospective charts were reviewed for the entirety of the months of March and April 2019. Retrospective charts were pre-implementation of this EBP quality improvement project. Prospective charts reviewed for the entirety of the months of June and July 2019 were post-implementation of the EBP quality improvement project charts.

An evaluation of each of the project's four objectives is discussed below.

Objective 1

Train five medical assistants on the administration of the GAD-7 screening tool. The objective was not met. All MAs who were actively employed were trained; therefore, four medical assistants were trained. One medical assistant was not trained because they resigned from the position at the clinic.

Objective 2

Implement an EBP anxiety screening and treatment protocol. The objective was met. A post-implementation prospective chart review revealed the EBP anxiety screening and treatment protocol had been implemented, as evidenced by documentation in charts.

Objective 3

Conduct retrospective and prospective chart reviews. The objective was met. A total of 673 charts were reviewed; 49.6% (*n* = 334) were retrospective charts and 50.4% (*n* = 339) were prospective charts. Of the 673 charts, 178 charts were included in the retrospective and prospective chart review data analysis because those charts had an active assessment and treatment plan for GAD. Of the 178 charts that were included, 45.5% (*n* = 81) were retrospective charts and 54.5% (*n* = 97) were prospective charts.

Gender of patient charts was not equally distributed and included 82.6% (*n* = 147) female patients and 17.4% (*n* = 31) male patients (see Table 2).

Table 2

Gender and Age Distributions of Patient Charts with an Anxiety Diagnosis (n = 178)

Gender	***n***	**%**
Male	31	18
Female	147	82

The patient age ranges of charts reviewed was varied and as follows: 5.6% were 18-30 years old (*n* = 10), 22.5% were 31-45 years old (*n* = 40), 36.5% were 46-65 years old (*n* = 65), 29.2% were 66-79 years old (*n* = 52), and 6.2% were 80 years old or older (*n* = 11) (see Figure 1).

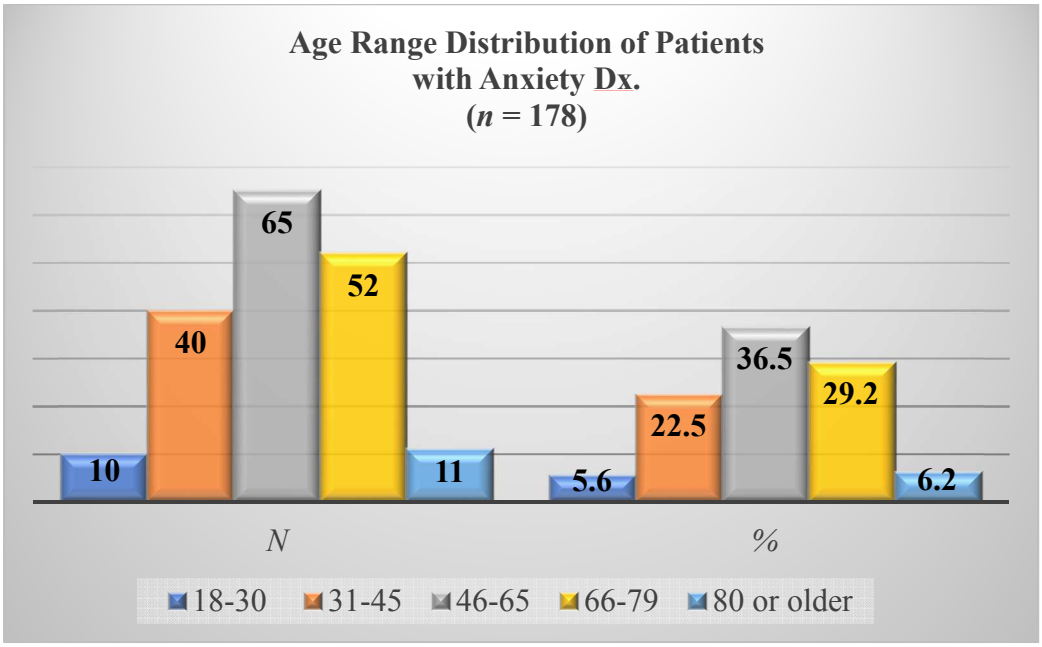

Figure 1. Age range distribution of patients with anxiety diagnosis (*n* = 178).

Objective 4

Evaluate the anxiety screening and treatment protocol implementation process and GAD identification and management outcomes. The objective was met. Post-implementation prospective chart reviews revealed the process of the anxiety screening and treatment protocol was implemented and GAD identification and management outcomes were measurable.

Two anxiety screening methods were identified in the chart reviews, an interview method that consisted of a verbal assessment of symptoms based on the DSM-V diagnostic criteria and the GAD-7 screening tool method, which quantified an anxiety score. The GAD-7 anxiety score was interpreted to an anxiety level by the provider (Spitzer, Kroenke, Williams, & Lowe, 2006). Regarding the anxiety score and level, a frequency distribution illuminated that pre-implementation of the anxiety screening and treatment protocol, 0% of retrospective charts (*n* = 81) utilized a quantifiable anxiety screening tool (see Figure 2)' therefore, 0% of retrospective charts (*n* = 81) obtained an anxiety score/level. Analysis of the frequency of post-

implementation utilization of the GAD-7 screening tool illuminated that 69.1% of prospective charts (n = 67) utilized the GAD-7 screening tool to screen for GAD, which quantified an anxiety level, whereas, 30.9% of prospective charts (n = 31) did not utilize the GAD-7 screening tool to screen for GAD and did not quantify an anxiety level (see Figure 2).

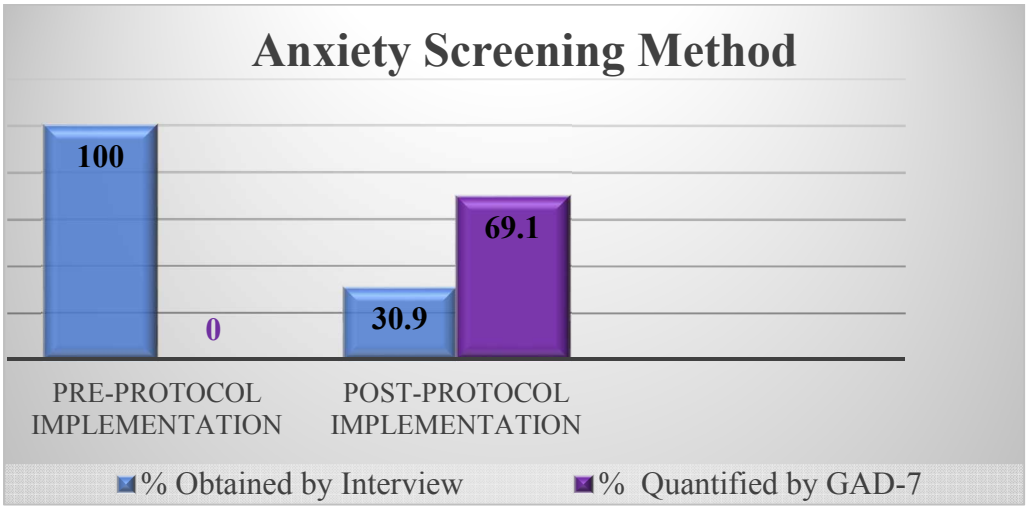

Figure 2. Frequency of anxiety screening methods utilized pre-implementation and post-implementation.

An anxiety level should be obtained and utilized to select and monitor treatment for GAD (Locke et al., 2015). Each chart's treatment plan was manually reviewed by the project implementer for correlation to anxiety level and EBP recommendations. Every chart was assigned "yes" if the treatment had correlated an anxiety level to EBP treatment recommendations and "no" if the treatment did not correlate an anxiety level to EBP treatment recommendations. The anxiety level distribution of patients screened with the GAD-7 screening tool was varied and as follows: 17.90% had a minimal anxiety level (n = 12), 22.40% had a mild anxiety level (n = 15), 22.40% had a moderate anxiety level (n = 15), and 37.30% had a severe anxiety level (n = 25) (see Figure 3).

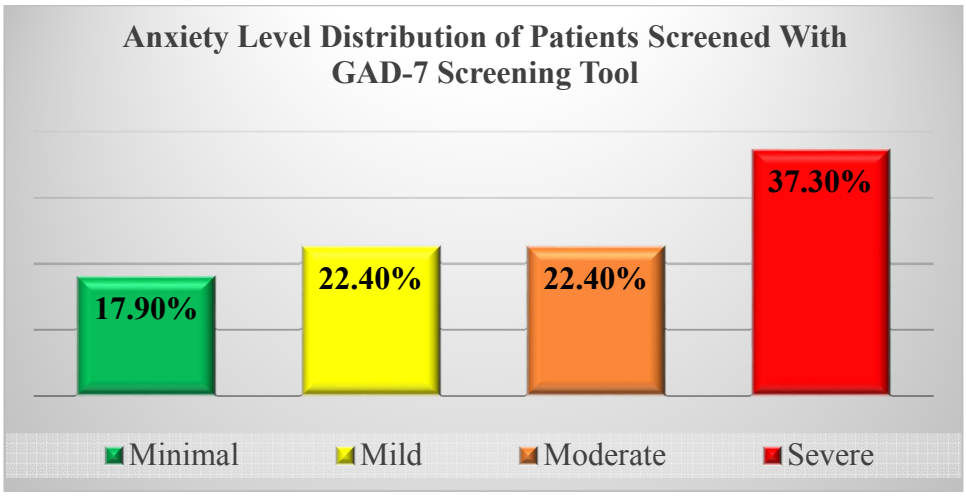

Figure 3. Anxiety level distribution of patients screened with GAD-7 screening tool (n = 67).

During the beginning of the implementation phase, occasional utilization of the pre-implementation professional interview method for GAD screening was noted. A frequency distribution was calculated and converted to percentages of post-implementation prospective charts that documented a prescribed EBP treatment based on a GAD-7 anxiety screening tool level. Analysis illuminated 31.30% (*n* = 21) of post-implementation charts had a GAD-7 quantified anxiety level documented that correlated to EBP treatment and 68.70% (*n* = 46) of post-implementation charts had a GAD-7 level that did not correlate to EBP treatment (see Figure 4).

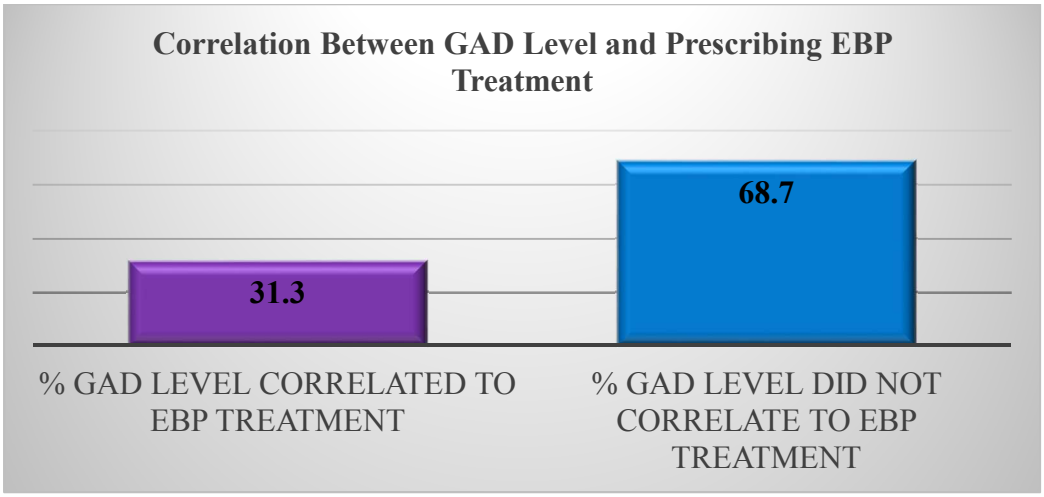

Figure 4. Correlation between GAD level and prescribing EBP treatment (n = 67).

The chart reviews revealed pre-existing treatment plans for GAD that were not based on a GAD-7 quantified anxiety severity level. These pre-existing treatment plans included benzodiazepines, SSRIs, SNRIs, or combination treatments. To maintain patient safety, these types of medications must be titrated to discontinuation or effect (Furbish et al., 2017; Locke et al., 2015). Therefore, the "change made to pre-existing treatment plan" variable was created to identify and document any change that occurred to the treatment plan of a chart with a pre-existing GAD treatment, yet this variable is not an indication that change was made in a positive or negative direction to achieve EBP treatment based on anxiety level.

Of the post-implementation charts that documented use of the GAD-7 anxiety screening tool (n = 67), 99% of those charts had a pre-existing GAD treatment plan. A frequency distribution was calculated and converted to percentages for post-implementation charts that utilized the GAD-7 screening tool and had a positive correlation between GAD level and prescribing EBP treatment (n = 21), analysis revealed 90.5% (n = 19) had a change to the pre-existing treatment plan and 9.5% (n = 2) did not have a change to the pre-existing treatment plan (see Figure 5). This demonstrated that post-implementation prospective charts showed an

increase in new EBP treatment plans added, or pre-existing treatment plans changed, based on GAD-7 scores obtained.

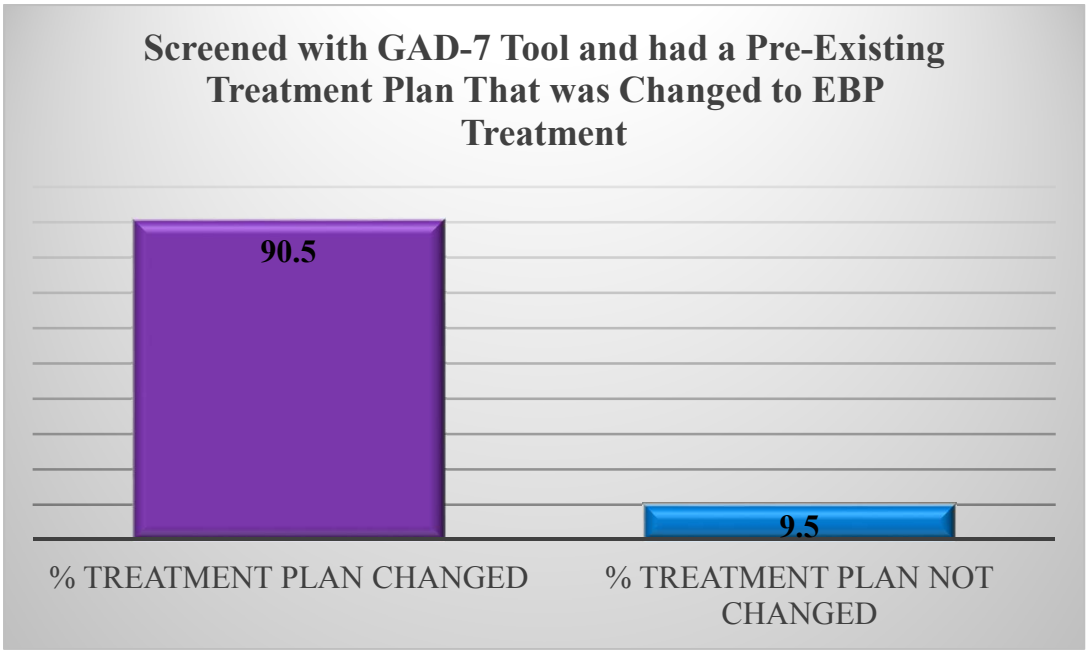

Figure 5. Change made to pre-existing treatment plan (n = 21).

Pearson's r was utilized to assess for statistical significance of post-implementation charts utilizing the GAD-7 screening tool and whether GAD level correlated to prescribed EBP treatment (n = 67) and found that correlation between GAD level and prescribing EBP treatment was not statistically significant (see Table 3).

Table 3

Pearson Correlation-GAD Level Correlated to Prescribed EBP Treatment (n = 67)

		Score	Correlated Treatment
Score	Pearson Correlation	1	-.122
	Sig. (2-tailed)		.325
	N	67	67
Correlated Treatment	Pearson Correlation	-.122	1
	Sig. (2-tailed)	.325	
	N	67	67

**Correlation is significant at the 0.01 level (2-tailed)

Discussion

Strengths

This DNP EBP project showed a quantifiable anxiety screening tool for GAD was not used in the primary care clinic before implementation of the EBP anxiety screening and treatment protocol project. Best practices recommend correlating anxiety level to EBP treatment (Locke et al., 2015; NICE, 2011). This project implemented a protocol that facilitated best practices by screening and treating adults with GAD with a quantifiable screening tool (GAD-7) to assist in prescribing treatment for GAD. Every patient who confirmed they had experienced GAD symptoms over the past 6 months, as the DSM-V diagnostic criteria recommends, and denied suicidal ideation, was provided the GAD-7 screening tool to quantify an anxiety level. The primary care provider interpreted the anxiety severity level and selected an EBP treatment that corresponded to the patient's anxiety level. No patient answered "yes" to this question during implementation.

The findings of this EBP project illuminated that post-implementation, this primary care practice had a 69% increase of utilizing a quantifiable anxiety screening tool (GAD-7). Of those

charts, 99% (n = 66) had a pre-existing GAD treatment plan. Additionally, the findings demonstrated that 31.3% (n = 21) of post-implementation charts documented utilization of the GAD-7 screening tool and an anxiety level that correlated to prescribed EBP treatment. Analysis further revealed that 90.5% of those charts with a preexisting anxiety treatment plan also documented that an algorithm-based change had been made to the preexisting treatment plan.

Implementing EBP ensures the provision of patient care excellence and improves patient outcomes (Melnyk & Fineout-Overholt, 2015). There was a 69% increase in the utilization of a quantifiable anxiety screening tool for adults in this primary care practice. A quantified anxiety severity score should be utilized to prescribe EBP treatment for adults with GAD (Locke et al., 2015). Additionally, the anxiety severity level can be utilized to track future patient progress and be utilized for prescribing additional EBP treatment. Implementation of best practices for GAD screening and treatment in primary care improves the quality of life in adults with GAD (Locke et al., 2015). This EBP project was clinically significant because it screened primary care patients for anxiety, identified patients who were suffering with anxiety and quantified their severity level, and provided the primary care provider with a best practices algorithm to prescribe anxiety treatment plans based on patients' anxiety severity level.

On the premise that EBP improves patient outcomes, future analysis of the clinical findings that analyze the correlation of anxiety level to EBP treatment, at this primary care site, may determine that patients are receiving EBP treatment that is appropriate for their anxiety level and are experiencing improved outcomes. The primary care provider and medical assistants were enthusiastic and supportive and implemented the systems change for EBP screening and treatment for adults with GAD at the clinical practice site.

Limitations

This project had several limitations. The anxiety screening and treatment protocol was not consistently implemented at the beginning of the implementation phase because one MA did not consistently provide patients with the GAD-7 screening tool when indicated. Consequently, full implementation of screening for GAD with a quantifiable screening tool was not achieved. Therefore, only 69% (n = 67) of prospective charts documented that the patient was screened with the GAD-7 screening tool to quantify an anxiety level. However, once recognized that the MA was not screening all patients according to the anxiety screening and treatment protocol, the primary care provider intervened and informed the MA to follow the anxiety screening protocol and provide the GAD-7 screening tool to patients when indicated.

As a result of the slow adoption of the tool at the beginning of the project, only 67 of the 97 post-implementation phase charts that contained a treatment plan for GAD could be analyzed for correlation to EBP treatment prescribed based on a quantified level of anxiety level. Another significant limitation noted related to preexisting treatment plans for GAD, such as benzodiazepines, SSRIs, SNRIs or combination treatments. To maintain patient safety, these types of medications could not be immediately changed to align with EBP protocol guidelines, as they must be titrated to discontinuation or effect (Furbish et al., 2017; Locke et al., 2015). To account for this, a "new intervention" variable was created to document any change that occurred to the treatment plan of a chart with pre-existing GAD treatment. However, the new intervention variable is not an indication that change was made in a positive or negative direction to achieve EBP treatment based on anxiety level. Hence, it was unclear whether a gap still exists for correlating anxiety severity level to EBP treatment. In addition, the primary care provider found that providing timely and accessible mental health services was difficult for a majority of

patients with non-private health insurance; nonetheless, patients were provided with the contact information for mental health resources, such as the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Helpline that provides free, 24/7 access to mental health referrals and information.

Implications for Nursing Practice

An EBP project implemented a systematic change at a primary care clinic in south Florida that included screening patients for anxiety with a valid and reliable evidence-based tool that identifies and quantifies GAD severity level and prescribing GAD treatment according to an EBP protocol.

The EBP quality improvement project can be used to advocate for the routine use of an anxiety screening tool in all primary care settings in order to align with best practices. Additionally, the EBP quality improvement project can be used to advocate for compliance with implementation of appropriate EBP GAD treatments based on GAD-7 quantified anxiety level severity. The EBP project should be adopted as a standard of care. All patients, at every visit, should be asked the basic questions of GAD diagnostic criteria. Every patient who confirms they have experienced GAD symptoms for 6 months, as the DSM-V diagnostic criteria recommends, should be provided the GAD-7 screening tool to quantify an anxiety level (Locke et al., 2015). Primary care providers should interpret patients' GAD-7 quantified anxiety level and select corresponding EBP recommendations for treatment.

The EBP project illuminated an EBP standard of care for prescribing benzodiazepines for GAD. Benzodiazepines should only be used short term for severe anxiety, if necessary, to augment treatment. Benzodiazepines should only be used long-term, on a strict as needed basis, if the provider has established that the patient experiences panic attacks (Locke et al., 2015;

NICE, 2011). If a patient experiences panic attacks, the provider should consider quantifying the monthly number of panic episodes and only prescribe low-dose benzodiazepines for the exact number of episodes expected monthly, and as needed follow-up should ensue.

The American Association of Colleges of Nursing's (AACN; 2006) *Essentials of Doctoral Education for Advanced Nursing Practice*, commonly known as the *DNP Essentials,* describes eight pertinent components of DNP education. According to the AACN, the curricula of DNP programs must prompt the DNP candidate to acquire knowledge and demonstrate competence in the following eight *DNP Essentials*: Scientific Underpinnings for Practice, Organizational and Systems Leadership for Quality Improvement, Clinical Scholarship and Analytical Methods for Evidence-Based Practice, Information Systems Technology and Patient Care Technology for the Improvement and Transformation of Health Care, Health Care Policy for Advocacy in Health Care, Inter-professional Collaboration for Improving Patient and Population Health Outcomes, Clinical Prevention and Population Health for Improving the Nation's Health, and Advanced Nursing Practice. The project implementer demonstrated competency in the AACN's eight *DNP Essentials* by implementing the EBP project *Implementation of an EBP Anxiety and Treatment Protocol in Primary Care*.

Scientific Underpinnings for Practice

The AACN (2006) described scientific underpinnings for practice as utilizing theory and evidence-based practice as a foundation to guide practice. The Institute for Healthcare Improvement (2019) suggested the use of a systems model, such as the Plan-Do-Study-Act (PDSA), for developing and testing processes, with a goal of sustainability. An extensive literature review and a clinical practice assessment of GAD screening and treatment practices in a primary care practice was conducted. Lack of use of a uniform, quantifiable screening method

for GAD was noted (Olarui et al., 2015; Weisberg et al., 2014). EBP recommends utilizing an anxiety level to prescribe treatment for GAD in adults (Locke et al., 2015; NICE, 2011). Best practices for prescribing GAD treatment were also lacking (Bachhuber et al., 2016; Carico et al., 2018; Weisberg et al., 2014). Utilizing the PDSA model, a DNP EBP quality improvement protocol was developed that implemented current and tested best practices for screening and treating adults with GAD in primary care.

The GAD-7 (see Appendix C) is a well-tested and reliable tool, specific to screening for GAD in primary care (Jordan et al., 2017; Spitzer et al., 2006). Current clinical practice guidelines suggest screening adults for GAD by utilizing a quantifiable anxiety screening tool, such as the GAD-7 (Locke et al., 2015). Further, the evidence has demonstrated that implementation of EBP treatment such as lifestyle modifications, SSRIs, SNRIs, mental health referrals, and psychotherapy, correlated to the individual's anxiety level, decreases GAD symptoms, and can increase the quality of life in sufferers (Locke et al., 2015; NICE, 2011).

Organizational and Systems Leadership

The AACN (2006) described organizational and systems leadership as sensitivity to delivery of leadership to diverse organizational cultures and patient populations. A leadership style that is welcoming and adaptable to healthcare changes is a pertinent factor of success, because healthcare is evolutionary, and adaptions and modification are a necessity for success (Hargett et al., 2017).

This EBP project met the needs of the diverse organizational culture of this project's setting. During the developmental phase of this EBP, close observations of organizational practices and workflow were made. Observations noted were: individual tasks of the clinical employees, a general timeline of completing the tasks, and the ability of clinic personnel to adapt

and participate in a team player approach. Acknowledging employees' strengths and weaknesses and how to best assist each employee to successful implementation of this project required leadership. To maintain employee tactfulness and cooperation, concise communication and easy access to the GAD-7 screening tool was delivered to each employee. The GAD-7 screening tool is available in multiple languages and easily accessible (Mills et al., 2014). This EBP quality improvement project was developed to safely and successfully implement change in the way that patients were screened and treated for GAD, with a goal of ensuring EBPs and optimal outcomes for a better quality of life.

Sensitivity to patient populations was also met during this EBP project. This EBP project was a quality improvement system change comprised of inter-professional collaboration, individualized care, and educating clinical employees about best GAD screening practices. From the GAD-7 screening tool to the selection of an evidence-based treatment, this project educated patients about their anxiety disorder and how to improve their quality of life through individualized treatment. Upon interview, numerous patients misunderstood GAD and, in fact, described it as a panic attack. Individuals with GAD can suffer panic attacks, but they are not the same disorder (Locke et al., 2015). It appeared these patients who misinterpreted their GAD for a panic disorder tended to be the same patients who used benzodiazepines daily. Educating patients about GAD, their GAD-7 score, and appropriate EBP treatment helps them understand their disease process and the most appropriate treatment for symptom management.

The findings of the DNP EBP project can help shape leadership in healthcare because it contributes to evidence that the process of implementing a quantifiable GAD screening method can assist in prescribing EBP treatment and achieving the outcome of early identification and improved management of GAD in adults.

Clinical Scholarship and Analytic Methods

The AACN (2006) defines clinical scholarship and analytic methods as an initiative to pursue discovery and problem solve complex situations through knowledge and disseminating research; therefore, adopting and adding EBP among disciplines to improve healthcare outcomes is essential. The EBP project demonstrated clinical scholarship by discovering that screening and treatment practices for adults with GAD in primary care were lacking, not uniform, and/or inconsistent. Through analytic methods, the EBP project reviewed current literature and research to discover current, best practices for screening and treating adults with GAD. A quality improvement process was then designed and implemented utilizing a well-tested, valid, and reliable GAD screening tool and EBP treatment with the intent to increase early identification and improve management of adults with GAD in a primary care clinic.

Information Systems/Patient Care Technology

According to the AACN (2006), information systems and patient care technology requires the DNP to access and utilize technology. Healthcare technology is classified as soft, hard, or soft-hard. Soft technology consists of triage, professional-patient encounters, and rapport. Hard technology consists of exams, treatments, organizing information, and instruments. Lastly, soft-hard technology refers to the knowledge acquired from the healthcare team (Feitosa et al., 2015). This EBP project utilized soft, hard, and soft-hard information technologies and technological databases. The GAD-7 is a measurable tool that allowed the clinical staff, patients, and inter-professional collaborators to measure, communicate, and implement individualized treatment plans based on severity of anxiety. Further, this EBP project required documentation of the GAD-7 score/level and treatment plan to be recorded in the EHR as a baseline to be easily accessed for reassessment purposes in the future treatment of the

patient. This process contributed knowledge about the individual's GAD baseline level that can be referred to for future assessment and treatment. The development of this EBP project required utilization of information databases to search, find, and disseminate evidence and to compose an EBP protocol for screening and treating anxiety. The DNP EBP project also utilized technology for analysis of data. The data analysis software used were Microsoft Excel and International Business Machines Statistical Package for the Social Sciences (IBM SPSS). Microsoft PowerPoint was utilized to train the medical assistants.

Healthcare Policy for Advocacy in Healthcare

According to the AACN (2006), the DNP should be engaged in the undertaking of policy development, political activism, and advocacy for an array of healthcare issues with emphasis on cultural sensitivity, healthcare access, healthcare disparities, affordable care, social justice, and quality care. The DNP student advocated for timely diagnosis and quality GAD treatment for adults. Anxiety often precedes depression, and the physical and social consequences of GAD are cumbersome and threaten the quality of life in sufferers (Galyamina, Kovalenko, Smagin, & Kudryavtseva, 2017; Locke et al., 2015). In response to the quality of life consequences of uncontrolled depression, the United States (U.S.) Preventive Services Task Force [USPSTF] (2016) issued a final recommendation of screening all adults for depression, with a uniform screening tool, to ensure early identification and prompt treatment to increase the quality of life in adults with depression. The DNP student advocated for adoption of a national recommendation to routinely screen all adults for GAD with a uniform and anxiety level quantifiable screening tool, at least annually, to increase early identification and prompt EBP treatment for adults with GAD.

Interprofessional and Intraprofessional Collaboration

Collaborative efforts are needed to provide comprehensive healthcare (AACN, 2006). Interprofessional and intraprofessional are two forms of collaboration. Interprofessional collaboration occurs when members of at least two different healthcare professions agree to work closely to goal set, share responsibility and accountability, and seek successful results (Green & Johnson, 2015). Interprofessional collaboration also occurs when different types of healthcare members provide delivery of healthcare services across the healthcare spectrum. This type of collaboration is a crucial component to ensuring the most optimal healthcare outcomes for patients (Green & Johnson, 2015). Intraprofessional collaboration functions similarly; however, it occurs among members of the same professional discipline (Meijer, Groot, Westerlaken, & Damoiseaux, 2016).

Interprofessional and intraprofessional collaboration was a vital component of the successful implementation of this EBP project. For this EBP project, the primary care provider implemented clinical recommendations for screening and treating GAD to select an individualized plan for each patient. In part, best practices for treating GAD include mental health referrals and psychotherapy (Locke et al., 2015; NICE, 2011). The EBP anxiety screening and treatment protocol included the utilization of mental health services for GAD treatment. Intraprofessional collaboration was supported during this project, which incorporated collaborative efforts among the medical assistants to consistently deliver the GAD-7 screening tool to patients.

Clinical Prevention and Population Health

According to the AACN (2006), clinical prevention and population health is intended to improve the nation's health outcomes. This EBP project was designed to increase the early

identification of GAD and to enhance compliance with EBP treatment recommendations for GAD in primary care. Often, individuals with GAD present to their primary care providers, despite the reason for their health visit (Goldberg et al., 2016; Roberge et al., 2015; Weisberg et al., 2014; Wiegner et al., 2015). This provides an opportunity for a diagnosis of GAD to be captured promptly. Prompt GAD screening can lead to timely treatment and improve patient outcomes (Locke et al., 2015). Utilization of an anxiety screening tool that quantifies level of severity helps the provider to prescribe appropriate, best practice treatments based on anxiety severity for adults with GAD. Implementation of an anxiety screening and treatment protocol in primary care for adults with GAD can decrease its consequences and improve quality of life in sufferers (Locke et al., 2015; Roberge et al., 2015).

Advanced Nursing Practice

The AACN (2006) defines advanced nursing practices as using advanced clinical judgment, accountability, and systems thinking to comprehensively conduct an assessment of wellness and illness parameters in complex situations; design, implement and evaluate practice changes; and provide guidance and education during complex and/or situational changes. Advanced nursing practice was demonstrated by developing, implementing, and evaluating an EBP quality improvement anxiety screening and treatment protocol project for primary care adults with GAD.

Final Conclusions

The purpose of this quality improvement project was to implement an EBP anxiety screening and treatment protocol for adult patients in a primary care clinic to increase early identification and improve management of GAD. Findings were clinically significant and demonstrated 69.07% of post-implementation prospective charts utilized the GAD-7 screening

tool to screen for, and quantify severity level of, GAD that could be utilized to prescribe EBP, which is best care recommendations for treatment for adults with GAD in primary care. Further, the findings demonstrated that post-implementation EHR's that documented utilization of the GAD-7 screening tool were able to be analyzed for correlation to EBP treatment. As a result, these charts can also be analyzed and utilized to justify that the primary care provider is practicing according to clinical guideline recommendations. On the premise that EBP improves patient outcomes, future analysis of the clinical findings that analyze the correlation of anxiety level to EBP treatment, at this primary care site, may determine that patients are receiving EBP treatment that is appropriate to their anxiety level and are experiencing improved outcomes. There was an increase of new or changed anxiety treatment to preexisting GAD treatment plans noted during the implementation of this project, in comparison to retrospective charts reviewed. Further studies are necessary to determine if the changes made to the preexisting treatment plans will eventually result in a treatment plan that aligns with EBP treatment in adults with GAD.

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Appendix A

IRB Approval Letter

MEMORANDUM

To: **Danielle Garcia**

From: **Vanessa A Johnson, Ph.D.,**
Center Representative, Institutional Review Board

Date: **May 14, 2019**

Re: **IRB #: 2019-285; Title, "Implementation of an EBP Anxiety Screening and Treatment Protocol in Primary Care Practice"**

I have reviewed the above-referenced research protocol at the center level. Based on the information provided, I have determined that this study is exempt from further IRB review under **45 CFR 46.101(b) (Exempt 2: Interviews, surveys, focus groups, observations of public behavior, and other similar methodologies)**. You may proceed with your study as described to the IRB. As principal investigator, you must adhere to the following requirements:

1) CONSENT: If recruitment procedures include consent forms, they must be obtained in such a manner that they are clearly understood by the subjects and the process affords subjects the opportunity to ask questions, obtain detailed answers from those directly involved in the research, and have sufficient time to consider their participation after they have been provided this information. The subjects must be given a copy of the signed consent document, and a copy must be placed in a secure file separate from de-identified participant information. Record of informed consent must be retained for a minimum of three years from the conclusion of the study.

2) ADVERSE EVENTS/UNANTICIPATED PROBLEMS: The principal investigator is required to notify the IRB chair and me (954-262-5369 and Vanessa A Johnson, Ph.D., respectively) of any adverse reactions or unanticipated events that may develop as a result of this study. Reactions or events may include, but are not limited to, injury, depression as a result of participation in the study, life-threatening situation, death, or loss of confidentiality/anonymity of subject. Approval may be withdrawn if the problem is serious.

3) AMENDMENTS: Any changes in the study (e.g., procedures, number or types of subjects, consent forms, investigators, etc.) must be approved by the IRB prior to implementation. Please be advised that changes in a study may require further review depending on the nature of the change. Please contact me with any questions regarding amendments or changes to your study.

The NSU IRB is in compliance with the requirements for the protection of human subjects prescribed in Part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46) revised June 18, 1991.

Cc: Kelly Henson-Evertz
Vanessa A Johnson, Ph.D.

Appendix B

Clinical Site Approval Letter

SITE APPROVAL LETTER

Nova Southeastern University 3301 College Avenue
Fort Lauderdale, FL 33314-7796
Subject: Site Approval Letter

To whom it may concern:

This letter acknowledges that I have received and reviewed a request by Danielle E. Garcia, MSN, APRN, FNP-C to conduct a research project entitled "Implementation of an EBP Anxiety Screening and Treatment Protocol in Primary Care Practice" at [redacted] and I approve of this research to be conducted at our facility.
When the researcher receives approval for his/her research project from the Nova Southeastern University's Institutional Review Board/NSU IRB, I agree to provide access for the approved research project. If we have any concerns or need additional information, we will contact the Nova Southeastern University's IRB at (954) 262-5369 orirb@nova.edu.

Sincerely,

[redacted]
Medical Director/ Medical Doctor

5-13-19

Appendix C

Generalized Anxiety Disorder 7-item (GAD-7)

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

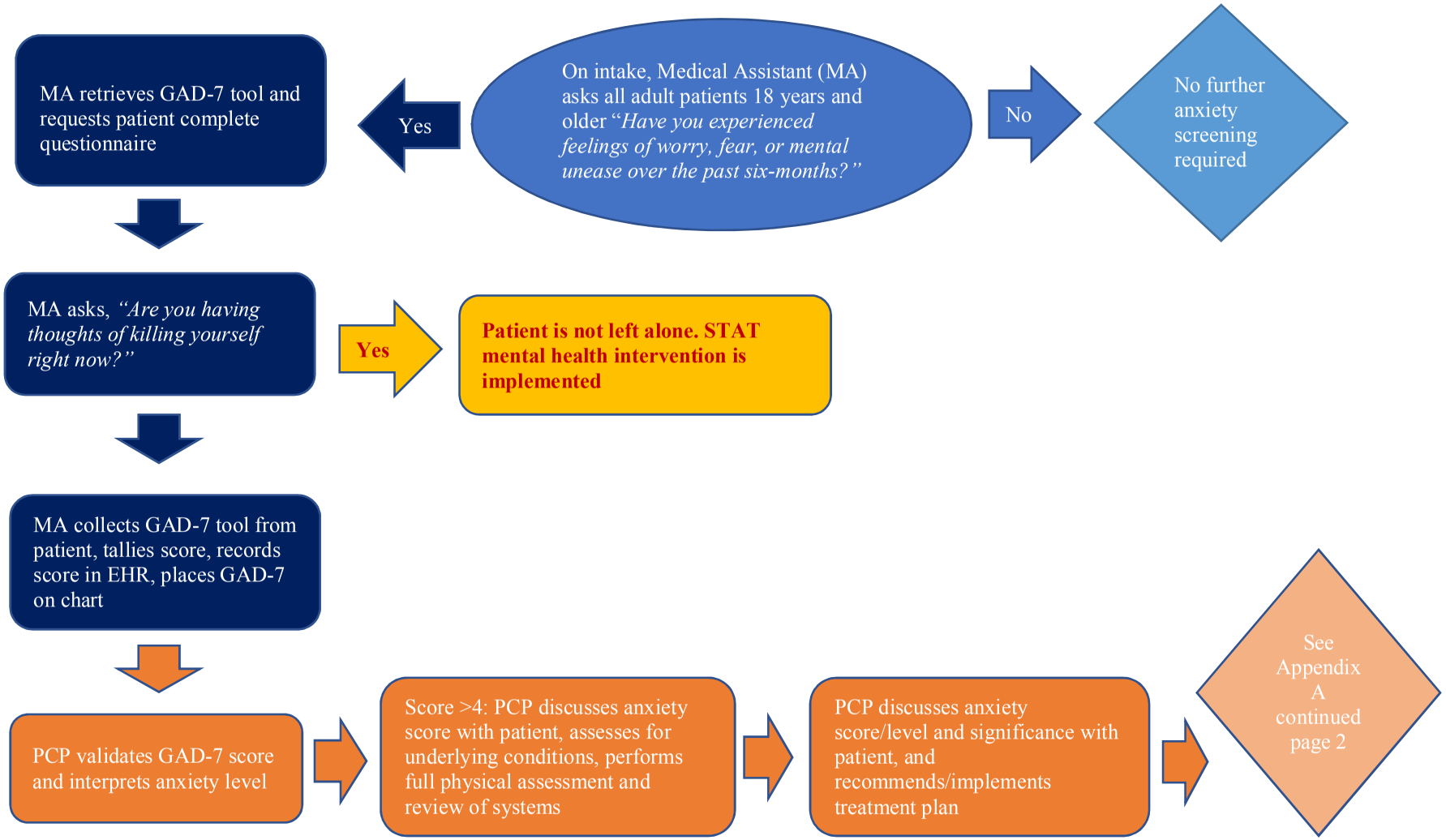
Total Score ___ = Add Columns ___ + ___ + ___

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

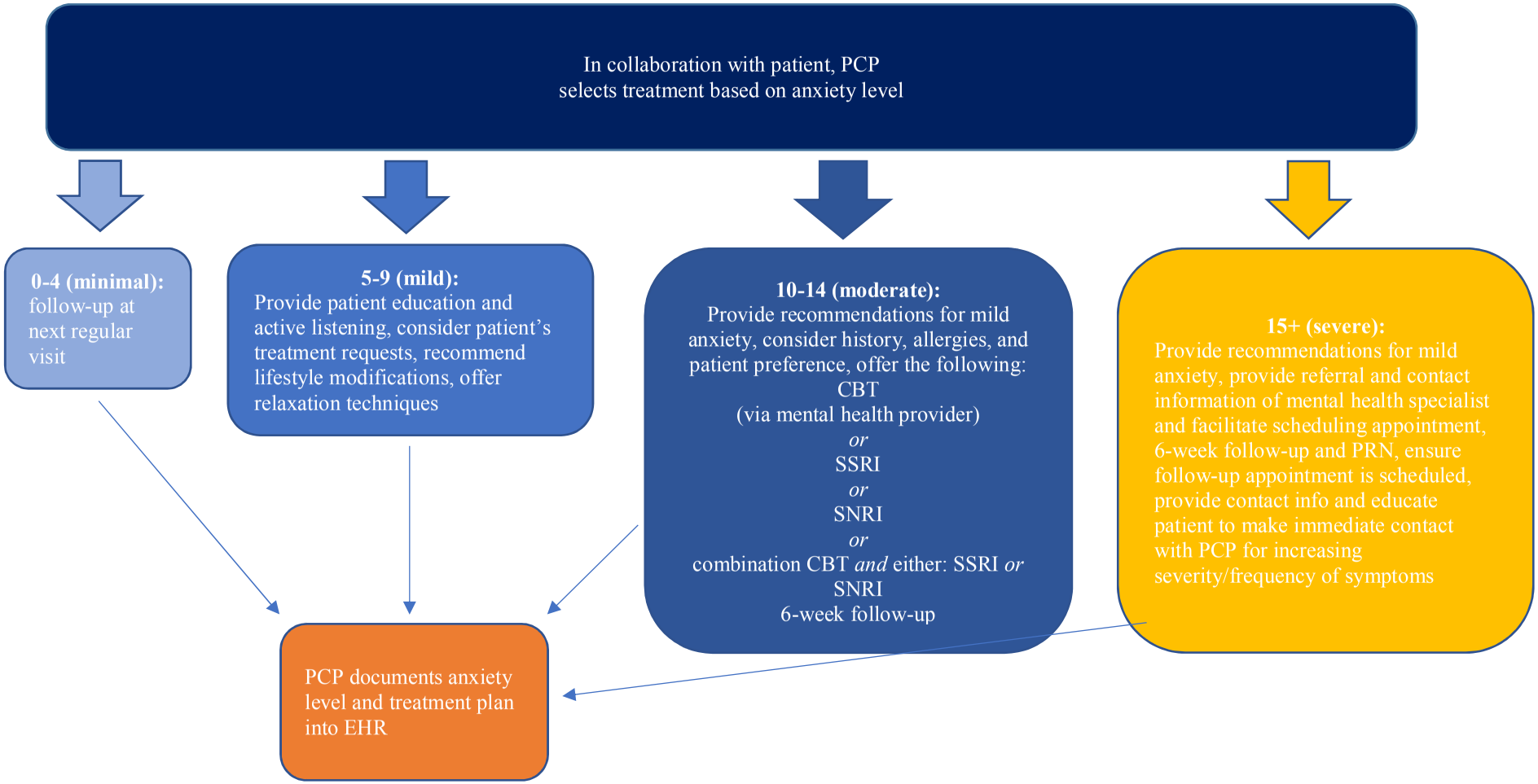
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐	☐	☐	☐

Appendix D

Anxiety Screening and Treatment Protocol



*Medical Assistant (MA)
*Primary Care Provider (PCP)



*This EBP protocol for anxiety treatment was adapted/modified from Community Care of North Carolina anxiety treatment recommendations.

Appendix E

Statement of Use

Introduction

In the Fall of 2017, in response to requests from our CCNC Primary Care Providers, a Community Care of North Carolina (CCNC) workgroup formed to create a resource guide designed to assist primary care practitioners in screening and treating adult anxiety in the primary care setting. This workgroup was comprised of Network Psychiatrists, Network Pharmacists, Network Behavioral Health Coordinators, the CCNC Central Office Behavioral Health Team, and physician representatives from area medical practices.

This resource guide is designed to assist busy primary care practitioners in accessing practical, evidence-based tools to help them successfully treat anxiety in adults. It includes algorithms to aid in the initial assessment and corresponding treatment approach of adult generalized anxiety disorder (GAD) and panic disorder, screening tools, a medication guide, and billing and coding guidance. In addition, the resource guide highlights anxiety-depression comorbidity prevalence, and gives suggestions for anxiety-driven referral language and grounding (breathing) techniques that can be performed by both the patient or the practitioner.

Our hope is that this resource guide proves useful, and we greatly look forward to continuing to work together on achieving the highest attainable levels of patient care across our wonderful state of North Carolina.

If you have any questions, or would like assistance in connecting with your local CCNC Network and its resources, please contact a member of the Central Office Behavioral Health Team: (Current as of Summer 2018)

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