IMPROVING CARE FOR DEPRESSION AS PROVIDED IN THE FAMILY PRACTICE SETTING

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ABSTRACT

This Dissertation is a synthesis of current literature and guidelines to develop the Simplified Prescribing Tool. The Simplified Prescribing Tool provides a guide to treating depression within the Family Practice discipline. The tool contains information that focuses on correctly diagnosing depression and the severity of the depression. The tool provides general guidelines for pharmacological treatment and an algorithm created by the author. The algorithm guides the provider through the process of prescribing. Finally, the tool also includes information on the management of depression throughout treatment until remission of the depression or referral onto a psychiatric care specialist. The main focus was pharmacological treatment; however, the tool also included non-pharmacological consideration for treatment of depression.

Data on the applicability of the synthesized tool were gathered by first surveying a group of psychiatric professionals for accuracy of the content contained in the tool. The second step in evaluation of the tool was to survey a group of practicing providers; the group included nurse practitioners, physicians, and physician assistants. This final step was carried out to fulfill the main goal of the paper, namely to see if the tool's content was accurate and if the layout of the tool would lead to use in practice.

After surveying the opinions of primary care practitioners, the data were grouped based on flow of the tool, the accuracy of the content, and applicability to practice. The general consensus was that primary care practitioners could readily use the Simplified Prescribing Tool in practice. This was seen as both a successful development of Simplified Prescribing Tool and as an indication for further research into this type of treatment modality.

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CHAPTER ONE. INTRODUCTION

Treatment of mental illness can be a challenging endeavor. Persons diagnosed with mental illness generally face a plethora of issues, which are often presented to the practitioner. psychologists and psychiatrists, who are educated in the various treatment modalities for mental illness, are in most cases the best option for patients with mental illnesses. However, the option to visit one of the two previously mentioned mental health practitioners is not always feasible for many reasons. Because of the deficit in availability of psychiatric providers and because of a host of other factors, general healthcare practitioners (i.e. family practice physicians, family nurse practitioners, and other primary care providers) are more frequently treating persons with mental illness in the role of the primary care provider, or in many cases, as the only care provider for many mentally ill persons (Fleury, Imboua, Aubé, Farand, & Lambert, 2012). The shift from primary care for persons with mental illnesses being provided by trained psychiatric practitioners to care being provided by primary care providers presents challenges for both health care policy and patient care practice.

The first challenge lies in the preparation of the Primary Care Provider (PCP) to handle the care of persons with mental illnesses. Fleury et al. (2012) and Burman, McCabe, and Pepper (2005) suggested that in many cases PCPs are willing to treat mentally ill persons, but that often PCPs felt unprepared to provide quality care for the mentally ill. The second challenge faced by PCPs is the diverse nature of the treatment of psychiatric diagnoses. Treating psychiatric diagnoses is rarely the only concern when treating persons with mental illness, as mentally ill patients are also known to be more at risk for certain medical comorbidities, such as hypertension, cardiovascular disease, and diabetes (Chafetz, White, Collins-Bride, & Nickens, 2005). Mentally ill persons are also known to be at higher risk for use of tobacco products,

alcohol and illicit drug abuse (Piatt, Munetz, & Ritter, 2010; Brown, Birtwistle, Roe & Thompson, 1999). PCPs are generally well trained to both treat common comorbid conditions and to know when to refer persons to specialists. Knowledge pertaining to treatment makes the PCP center of reference for other disciplines and increases the PCP's need to be well versed in all of the treatments and interactions of the various treatments. The combination of treatments needed to handle both the psychiatric condition and medical conditions or comorbidities quickly becomes a confusing web, which the PCP is expected to navigate, even if he/she is not fully able to do so.

Depression as the Focus

Because of the broad nature of mental illness and the complexity of the various mental health diagnoses, this practice improvement project's focus was the diagnosis and treatment of depression. The choice of depression as the project's focus was made for two reasons. The first is because of the prevalence of depression in society. The second reason is that of all mental health diagnoses, depression is one of the most commonly treated by PCPs.

Prevalence of Depression

Depression was the logical diagnosis of choice as this project's focus. Depression is highly prevalent within the United States and in the region of North Dakota and Minnesota. A high prevalence means that the disorder impacts a significant number of people within the aforementioned populations. The Center for Disease Control and Prevention (2010) released data from a survey (n=235,067) that indicated depression rates in adults in the United States were as high as 9.1%. Although the rates varied greatly from state to state, of the 45 states that participated in the survey all showed significant rates of depression. Regional data for adults 18 years and older suggested the depression rate is 4.8% for North Dakota and 5.9% for Minnesota

(CDC, 2010). Depression is also a recurrent and often a chronic disease. Research by Katon, Unützer, and Russo (2009) indicated that 70% of patients diagnosed with depression had recurrent episodes. The data suggests that depression is impactful in terms of both total numbers of persons and in duration of the disease. The data presented thus far is, however, descriptive and does not fully address the social, economic, personal and physical impacts of depression (Donohue & Pincus, 2007; Fostick, Silberman, Beckman, Spivak, & Amital; 2010; Louch, 2009, Russell, 2010; Simon, 2003). More detailed descriptions of the social, economic, and health impacts of depression will be provided in the literature review.

Depression Treatment by the PCP

The second reason for depression as the project's focus is that depression appeared to be the mental health diagnosis most often treated in Primary Care (PC) (Whitebird, Solberg, Margolis, Asche, Trangle, & Wineman, 2013). Rates of treatment of depression in the PC setting have been shown to be as high as 5-10% of the total number of patients seen (Louch, 2009). Data presented by the American Center for Progress indicated that nationally PCPs wrote approximately 41% of antidepressant medication prescriptions (Russell, 2010). Russell (2010) also indicated that one-third to half of all persons with a mental health diagnosis are being treated by PCPs, and in many cases, the PCP is the sole provider of care. More detailed information about the relationship between PCPs and patients with depression will be provided in the literature review.

Statement of the Problem

Persons with depression are a diverse and challenging population to treat. The issue addressed in this paper is how PCPs can become better prepared to handle the diverse and often challenging nature of treating depressed persons. The primary objective is to find a means that

can help prepare PCPs to treat depression effectively. The effort of choosing a treatment option for implementation in this project is complicated by the variety of different approaches possible for treating patients diagnosed with depression. There is evidence that treatment of depression through medication, multidisciplinary approaches, alternative therapies, exercise, counseling, and various combinations of treatment all positively impact the quality of life for persons with depression (Hagen, Wong-Wylie & Pijl-Zieber, 2010; Cleary, Hunt, Matheson & Walter, 2008; de Oliveira, 1998; Antonuccio, 1995). A major modality used by PCPs in the treatment of middle level or major depression is medication. In addition to prescribing medication, which is the focus of the SPT algorithm, it is important for PCPs to simultaneous encourage patients to comply with supplemental interventions such as exercise, proper diet and emotional support.

Purpose of the Project

As identified in the previous section, pharmacological treatment is an option appropriate for use by the PCP when treating persons with depression. Research has shown that adherence to appropriate medication regimens increases the quality of life for persons with mental illness (Miller, et al. 2004). The purpose of this project was to use evidence-based guidelines and treatment strategies to create a tool for the treatment of depression in the primary care setting. The tool development included verification of content validity by experts in the field of mental health. PCPs evaluated the tool's applicability for use in practice. The process by which this will be accomplished will be further detailed in the following two sections.

Objective One

Objective one for this Process Improvement Project was to find evidence-based research that provided tools and/or guidelines to simplify the medication prescribing process. The evidence-based research used in the first phase needed to be of a quality standard that could

easily be used by PCPs when treating persons with depression. To accomplish this objective, the research and tools found in the literature search were: 1) synthesized into a tool, 2) evaluated for content validity by psychiatric specialists, and 3) distributed to a PCP review group. The researcher's assumption is that, in a general sense, better-educated providers, who have effective tools, would be more readily able to treat persons with depression. Preparation on the part of PCPs could lead to improved confidence in their ability to treat and manage depression. This could then lead persons with depression to be more trusting of their PCP and more willing to adhere to medication regimens. As a result patients may be better able to cope with mental health issues. In no way did the practice improvement project assume that one intervention would overcome all of the challenges faced by persons with depression; however, the project's purpose was to better prepare PCPs to help persons with depression.

As previously mentioned, there are many ways PCPs could increase knowledge related to treatment of depression. The current project focused on the prescribing of medication since prescribing is within the scope of the PCP. Interventions, such as psychotherapy, may be appropriate for treating persons with depression, but not as appropriate for the PCP as is the intervention of prescribing medications. As PCPs become better equipped to handle psychotropic medication prescription, they will also be more prepared to facilitate discussions of other treatment options. This may lead to depressed persons becoming more connected to resources that can improve their quality of life. Hopefully, the final outcome will be that depressed persons are more connected to coping methods that can help them overcome the challenges they face.

Objective Two

The goal related to objective two was dissemination of the tool for treatment of depression through medication prescription. This happened in two phases. First, the tool was introduced to a group of psychiatrists for review. This allowed the tool to be evaluated for content, accuracy, and acceptability. The input provided by the psychiatrists was taken into account and changes were made to the tool. Next, a review group of PCPs evaluated the tool's applicability for use in the primary care setting and completed a survey indicating the likelihood of using the SPT in practice.

Significance to Nursing

The project's significance to advanced practice nursing rests on the assumption that improvements made in the ability of PCPs to treat depression will result in improved quality of life for depressed persons. Although the project focused on providing education to PCPs via access to tools, the intended result is an increase in both the quality and quantity of life for those persons facing depression. By simplifying the treatment process, PCPs may feel more adequately prepared to further treat depressed persons. Research has shown that when medication interventions are combined with other evidence-based treatments, improved outcomes for depressed patients occurred (Trivedi, et al., 2004). This added weight to the idea that by bolstering the ability of PCPs to provide quality care to the mentally ill population, including depressed persons, the quality of life for mentally ill individuals can improve significantly.

As will be shown in the literature review section, persons with mental illness, many of whom are depressed, face a plethora of problems, which include social, psychiatric, and physical issues. The project's final intended outcome is to improve the quality of life through medication

prescription for patients with depression who are then able to better cope with issues caused by debilitating signs and symptoms of depression. Stabilization can lead to depressed persons being able to more fully function in other roles, for example, within the family and in society in general.

The primary purpose of this project and significance to nursing is in the benefit which stabilization can have on depressed persons. Secondary to benefits experienced by depressed persons is the idea that the knowledge provided to PCPs can help other patients as well. As PCPs feel more prepared to treat mentally ill persons, the trend of underservice to this population could decrease. Also, success in treatment of depressed patients can elevate the confidence of PCPs in a more general sense, which could assumedly improve their ability to provide quality care to all patients within their practice (Duffy, 2013).

Finally, the project specifically focused on PCPs and the treatment of persons known to have depression. PCPs that are more adept in diagnosing will most likely be able to see and recognize the signs and symptoms of depression in patients who are not currently diagnosed with depression. The improved ability of PCPs to diagnose depression early is important as early diagnosis and treatment of illnesses has been shown to improve outcomes. (Penn, Waldheter, Perkins, Mueser, & Lieberman, 2005)

CHAPTER TWO. LITERATURE REVIEW AND THEORETICAL FRAMEWORK

Literature Review

Statistical data about the prevalence of depression were presented in the Introduction section of this paper. Understanding that depression affects a significant population and that changes need to occur to improve treatment of depression leads to the questions that will be addressed in review of the literature. The questions are as follows: What are the impacts of depression on the person, the person's surroundings, i.e. family, friends, and on society? Does sufficient data exist to indicate that depressed persons are being treated in PC settings? Finally, how effective is treatment of depression by PCPs? The literature review will also seek to show evidence-based data on the diagnosis, management, and treatment of depression that can be synthesized into a tool to be used by PCPs as they interact with depressed persons.

Impacts of Depression

Simon (2003) described the negative effects that depression has on a person by delineating the impacts into three categories. The first is decreased quality of life. Persons suffering from depression reported being less functional both physically and mentally than those not suffering from depression. The second category was lost productivity. Persons with depression were 2.5 times more likely to miss work and were seen to have a 50% increase in actual time lost compared to "non-depressed" persons. Finally, persons suffering from depression had higher rates of the use of general medical services with rate increases of 50-75% (Simon. 2003). Fostick, et al. (2010) concurred with Simon (2003) and showed that as the severity and length of time of the disease increased, so did social and economic impacts. The combination of these three factors led depressed persons to be less able to function in familial and social roles, decreased their ability to earn an income, and increased health care costs to the

depressed persons, all of which have negative personal, social, and economic impacts. Louch (2009) reported that depressed persons had higher rates of suicide and accidental deaths and were more prone to participate in hazardous health behaviors. Louch (2009) also showed that depressed persons were more likely to have endocrine, neurological, and immune related issues. Depressed persons were noted to have less motivation toward recovery and lower rates of compliance as compared to persons without depression (Louch, 2009). Smith and Smith (2010) reported the results of a 40 year study, performed by the U.S. Panel Study of Income Dynamics (PSID), which studied the impacts of mental illness, especially depression, on economic earnings. The study showed that educational accomplishments were decreased and adult family incomes were reduced by as much as 20%. Smith and Smith (2010) found that the lifetime cost to family income was approximately 300,000 U.S. dollars (USD), with the total lifetime economic loss for the surveyed group estimated at 2.1 trillion USD. All of the data presented illustrated that depression does have significant and often negative personal, social, and economic impacts.

Depression can lead to suicide, one very final and irreversible event. If suicide occurs, all outcomes are changed for both the depressed person and others involved with the person. Ceccherini-Nelli and Priebe (2011) indicated that suicide in the U.S. accounted for more than 30,000 deaths per year and was the eleventh leading cause of death. Although the authors did not report whether the presented statistics correlated to depressed persons who are receiving treatment, the article described multiple factors leading to suicide. Many factors, including low-income, unemployment, and poor health of persons prior to their suicide were reported, factors also commonly seen in depressed persons. Ceccherini-Nelli and Priebe (2011) presented data describing factors that led to suicide and in doing so described diagnostic criteria commonly used

to determine depression. Pfeiffer, Kim, Ganoczy, Zivin, and Valenstein (2013) related that persons with depression have a twofold to a fourfold increased risk for suicide. Beyond just an increased risk for suicide, Pfeiffer, et al. (2013) reported that as treatment options failed and depression persisted, the risk for suicide increased. Early detection and treatment of depression should be addressed to help decrease the suicide rate in persons with depression.

Treatment of Depression by PCPs

Timonen and Liukkonen (2008) found that PCPs could expect 5-10% of their patients to struggle with depression. Russell (2010) reported the number for treatment of mental illness in the primary care setting at a much higher rate. When considering a broader group of patients with mental illness, Russell (2010) cited that 50% of mentally ill patients received some form of care from a PCP and that two-thirds of mentally ill persons were receiving care only in the PC setting. Bland (2007) and Whitebird, Solberg, Margolis, Asche, Trangle, and Wineman (2013) indicated that treatment of depressed persons in PC could be as high as 90%. Louch (2009), Bland (2007) and Whitebird, et al. (2013) all introduced the idea that treatment of depression in the PC setting is increasing, but the rates presented do not address the amount of patients that are seen in PC where depression was not identified. The numbers for treatment of depression in PC vary, but the trend that was identified in the literature review was that PCPs would be one of the providers of treatment or the sole provider of treatment for depressed persons at some point in their practice.

Effectiveness of Depression Treatment by the PCP

A review of literature showed that even with existing guidelines, treatment in the PC setting did not always meet established standards. Craven and Bland (2013) agreed with the research that showed there is a large population of depressed persons who receive treatment for

their illness from PCPs, but that only approximately 50% were receiving adequate care. Adequacy was based on guidelines of care for Major Depressive Disorder (MDD) as defined by multiple professional and quality assurance organizations (Craven & Bland, 2013). Whitebird, et al. (2013) also showed that PCPs fall short of optimally treating depressed patients in the PC setting. The authors progressed beyond simply identifying a lack of quality care by detailing reasons why care fell short of nationally recognized standards. The gaps articulated were that PCPs were unfamiliar with treatment guidelines or lacked access to guidelines (Whitebird, et al.,2013). Louch (2009) detailed how treatment for depression can fail in that of the total number of depressed patients only 50% actually seek treatment. Of the 50% who seek treatment, depression was diagnosed correctly in only half of the patients. Of the half that are diagnosed correctly, only 50% actually receive treatment, and of this final group only 50% finish the treatment prescribed. The tallied results indicate that less than 10% of persons with depression receive treatment in a manner that can aid them in overcoming the disorder (Louch, 2009).

Introduction of the Texas Medication Algorithm Project

During the project's library research phase, a search was conducted of the current literature on medication prescribing strategies for treating persons with mental illness. One particular set of tools that appeared in the results of multiple different searches was the Texas Medication Algorithm Project (TMAP). TMAP provides medication-oriented algorithms for the treatment of mental illnesses. The project originated in 1995 with cooperation between the Texas Department of Mental Health and Mental Retardation (TDMHMR) and several Texas universities. TMAP grew to also garner support from the National Institute of Health (Crismon, Argo, Bendele, & Suppes, 2007). After reviewing the information presented in the varying algorithms, the format used in TMAP was found to be the most user-friendly. Thus, the tool

designed by the author entitled the Simplified Prescription Tool (SPT) used the same format as TMAP. The SPT evolved from the synthesis of various resources geared to the treatment of mentally ill persons. TMAP was used as a template in the design of the SPT because the procedural manual for TMAP included:

a. algorithms for the treatment of multiple mental health disorders (Schizophrenia, Major Depressive Disorder, and Bipolar Disorder)

b. criteria for evaluating both the severity of the disorder being treated and for evaluating success of the medication regimen being used for treatment

c. evidence-based research and the input of professionals within the field of psychiatry

d. support from the National Institute of Health

e. independent, peer-reviewed studies that exhibited the validity of treatment per TMAP algorithms. (Miller, et al., 2004, Madhukar, et al., 2004; Sutherland, Sutherland & Hoelns, 2003)

Literature Review Associated with Creating the SPT

Guidelines for treating depression in primary care were sought through a literature review. The review used the following library indexes Academic Search Premier (EBSCO), JSTOR, and ProQuest. The main terms used to find data were depression, and major depressive disorder. These terms were combined with primary care and primary care providers. To further delineate the articles the preceding terms were combined with diagnosing depression, initiating treatment, managing patients, and the referral process for treatment of depression. The data from the various sources reviewed in the literature search phase were then synthesized, resulting in the creation of the Simplified Prescription Tool (SPT). The SPT met the objectives established in the Purpose of the Project section of the paper and includes references that can be guides for

PCPs as they seek other methods for treatment. Information about each section of the SPT, as described in the first sentence of this paragraph, will be addressed in detail in the subsequent paragraphs.

Diagnosing Depression

The literature reviewed supported that depression was likely to be seen in PC. However, even when depression was present a large number of depressed persons were likely to be misdiagnosed or not diagnosed at all (Bland, 2007; Timonen & Liukkenon, 2008). Understanding that adequate diagnosis of depression is lacking in PC led to the idea that for PCPs to be effective in treating depression they would need to be more effective in identifying the disorder. The SPT presented in this research project includes strategies for diagnosing depression. To better understand how depression is diagnosed, accepted evidence-based guidelines were sought. As the American Psychiatric Association (APA) is the accepted governing body for the treatment of mental illness the works of this organization were reviewed. The Diagnostic and Statistical Manual of Mental Disorders 4th ed. Text Revision (DSM-IV-TR, 2000) indicated that within a two-week period of time functioning deficits had to be present in the patient with depression. DSM-IV-TR (2000) detailed that when five or more of these functioning deficits were met the diagnosis of depression, also known as Major Depressive Episode, could be made. Table 1 presents an adapted version of DSM-IV-TR criteria for diagnosing depression.

Table 1. DSM-VI-TR Criteria for Diagnosis of Major Depressive Episode

DSM-IV-TR Criteria for the Diagnosis of a Major Depressive Episode
A. At least 5 of the following, during the same 2-week period, representing a change from previous functioning; must include (a) or (b) a. Depressed mood. b. Diminished mood. c. Significant weight loss or gain. d. Insomnia or hypersomnia. e. Psychomotor agitation or retardation f. Fatigue or loss of energy. g. Feeling of worthlessness. h. Diminished ability to think or concentrate: indecisiveness. i. Recurrent thoughts of death, suicidal ideations, suicide attempt, or specific plan for suicide.
B. Symptoms do meet criteria for a mixed episode (i.e. meet criteria for both manic and depressive episodes).
C. Symptoms cause clinically significant distress or impairment of functioning.
D. Symptoms are not due to the direct physiologic effects of a substance or a general medical condition.
E. Symptoms are not better accounted for by bereavement (i.e. the symptoms persist for longer than 2 months or are characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideations, psychotic symptoms, or psychomotor retardation.

Permission to reproduce the contents of Table 1 obtained from the American Psychiatric Association, see *Appendix G*

Of note to the reader is the use of the DSM-IV-TR (2000) within the body of the paper and in the SPT. As is known, the APA has now issued the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (2013) (DSM-5). The choice to continue to use the DSM-IV-TR (2000) was based on the fact that the majority of the work for this paper and the majority of the literature reviewed for this paper preceded the publication of the DSM-5 (2013). A review of the DSM-5 criteria for diagnosing depression was performed. The results were that the majority of the criteria matched the DSM-IV-TR. The DSM-5 added criteria to rule out the possibility that the depression was caused by another mental health disorder; other than this only a few wording changes separated the criteria from that found in the DSM-IV-TR (2000) (APA, 2013).

Table 1. is helpful to PCPs as it describes screening questions that can aid in identifying depression in patients. The DSM-IV-TR (2000) criteria is also the basis for other screening tools that have been developed and can help guide the PCP when depression might be a differential diagnosis. Wu (2011) looked at multiple tools, such as the Center for Epidemiologic Studies Depression Inventory, the Beck Depression Inventory, the Symptom-Driven Diagnostic System for Primary Care, the Medical Outcomes Study Depression Measure, and the Quick Diagnostic Interview Schedule. Wu, (2011) indicated that these tools had sensitivities of 89% to 96%, with specificities of 51% to 72% for diagnosing Major Depressive episodes. The tools were reviewed by searching for them via literature and general Internet query. After reviewing a variety of screening tools for depression the decision was made to use one particular grading scale, the Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PHQ-9), in the SPT. Rationale for the choice is found in the next paragraph.

The Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PHQ-9) was one tool identified by multiple authors. As the PHQ-9 is widely used, it was adopted as the diagnostic tool that is included with the SPT. Of note is the fact that the PHQ-9 is a guide to help establish the diagnosis. The literature review established the importance of PCPs using their clinical judgment aided by evidence-based research to form a diagnosis of depression (Trangle, et al., 2011; Anderson, et al., 2008). The PHQ-9 tool was chosen because the questions closely follow the diagnostic criteria found in the DSM-TR-IV. For disclosure purposes the PHQ-9 was also chosen because, per Pfizer Inc. (11.22.2013), the tool is available for public use without copyright infringement. The PHQ-9 used in the SPT was taken from the form found at http://www.phqscreeners.com on 11.22.2013. This site can be helpful to PCPs as it contains multiple screening tools. For a full copy of the PHQ-9 see *Appendix B*.

Multiple articles found during the literature review for the creation of the SPT agreed with the use of the DSM-TR-IV criteria and/or the PHQ-9 as guides to aid the PCP in establishing the diagnosis of depression (Counts, et al., 2008; Timonen & Liukkenon, 2008; Trangle, et al., 2011; Trivedi, et al., 2004; Wu, 2011). Of final note is the National Institute of Health and Clinical Excellence's (NICE) charge to assure that diagnosis and treatment of depression be patient-centered and be made only after a thorough and comprehensive examination avoiding diagnostics that revolve around symptom counts (NICE, 2009). The authors referenced earlier in this paragraph concur with NICE (2009).

Initiating Treatment

The SPT's main focus is guiding the PCP through the process of pharmaceutically treating depression. As identified in other sections of this paper and in the SPT, itself there are other options for the treatment of depression. The PCP should be aware of these alternate treatments, as combination therapy strategies have been shown to be effective in the treatment of depression (Spijker, van Straten, Bockting, Meeuwissen, & van Balkom, 2013). The alternative treatment options are not the focus because they are not always available to the PCP who is treating persons identified as being depressed, whereas medication is usually available. As other forms of treatment are also successful, in certain situations, these alternate treatment modalities could be introduced by the PCP, through the process of referral to providers who specialize in these alternate treatment options.

Pharmacological Treatment

The majority of resources reviewed for the creation of the SPT showed that treatment of depression with antidepressants (AD) was effective in decreasing the symptoms of depression. A number of articles also agreed that although there are different classes of AD medications, the

Selective Serotonin Reuptake Inhibitors (SSRI) were the first line of choice for treating depression (Anderson, et al., 2008; Hollen & Sexton, 2012; Suehs, Argo, Bendele, Crismon, Trivedi, & Kurian, 2008; Thompson, Whittingham, & Walsh; 2012, Timonen & Liukkonen, 2008). Many of the works reviewed also introduced other medication classes; however, this project and the SPT focused on the use of SSRIs. SSRIs were chosen as the focus for this project because other medication classifications were better used for depression that was treatment resistant. What was found in the literature review was that treatment resistant depression is best cared for by a mental health professional, and if possible, the patient exhibiting treatment resistant depression should be referred for treatment and management by a psychiatric specialist (Anderson, et al., 2008; Hollen & Sexton, 2012; Suehs, et al., 2008; Thompson, Whittingham, & Walsh, 2012). Specifics for treatment and the course of treatment can be seen in more detail in the SPT's algorithm found in *Appendix C.* Other considerations for medication choice included patient preference, cost of the prescription, and side effects. (Sutherland, Sutherland, & Hoehns, 2003; Anderson, et al., 2008).

Managing and the Referral Process

Depression Management

The management phase of treating depression happens directly subsequent to initiating the diagnosis. As this project primarily addresses medication prescription, the focus for management of depression is on describing the monitoring process used to ascertain the effectiveness of the medication used. If other treatments were used instead of medication or used along with medication, the outcomes sought would be the same, namely a decrease in the severity or remission of the depression. The literature reviewed discussed two goals that a PCP should strive for when monitoring a pharmaceutical regimen for the treatment of depression.

The first goal is to assure that the depressed person has an adequate trial time on the medication. The reviewed literature offered varying lengths for the duration of an adequate trial time for a medication, but all generally stated a trial time of no less than six to twelve weeks. The literature reviewed stated the trial time could last up to six months, as the longer timeframe was needed in many patients to achieve optimal symptom remission (Gaynes, Rush, Trivedi, Wisniewski, Spencer, and Maurizio, 2008; Timonen & Liukkonen, 2008; Trangle, et al., 2011). Symptom relief with depression remission is the primary goal of the treatment time. The literature was also searched for the preferred length of treatment. Again the articles gave varying lengths of overall treatment time but generally all agreed that treatment should last until symptoms subside and then continue for approximately six months past that time to reduce the risk of relapse (NICE, 2009; Trangle, et al., 2011; Gaynes, et al., 2008).

The second goal of treatment is to assure that the medication is titrated to the indicated maximum dose required to reduce symptoms (Gaynes, et al., 2008;Timonen & Liukkonen, 2008; Trangle, et al., 2011). Maximum dosage varied significantly among the differing AD medications and included factors for consideration such as weight, gender and age. The primary concern of the PCP during the titration phase was to achieve the best symptom relief while keeping the possible side effects to a minimum (Anderson, et al., 2008). Therapeutic dosages for the various AD medications, especially SSRIs, will not be given in this paper as each medication has a differing maximum dose, but recommendations are included in the SPT. The PCP should familiarize himself/herself with medications of choice before prescribing. During this timeframe the PCP should have regular visits with the depressed person. The visits should include monitoring the effectiveness of the drug through assessment of symptom relief and assessment of the person for any side effects. The first visit should occur one to two weeks after initiation of

treatment (Gaynes, et al., 2008; Timonen and Liukkonen, 2008; Trangle, et al., 2011). Also, during the initial one to two week timeframe titration of the drug to the maximum therapeutic dosage to obtain the maximum symptom relief should begin (NICE, 2009; Trangle, et al., 2011; Gaynes, et al., 2008).

Referral

As the literature was reviewed the referral process, namely when to refer the depressed person to a psychiatric professional when treatment in the primary care setting is unsuccessful, showed the greatest variance. This variance can possibly be explained by the fact that each article addressed different populations and different demographics and the recommendations for when and why to refer a patient were given to fit the specific situation. A general consensus was drawn from the varying articles that referral should happen when the patient is at a high risk for self-harm or harm to others, the patient is non-compliant, and/or the patient has failed to achieve remission of symptoms after multiple trials on AD medications (NICE, 2009; Trangle, et al., 2011; Gaynes, et al., 2008; Anderson, et al., 2008; Trivedi, et al., 2004; Wu, 2011).

Theoretical Framework

Provision of evidence-based research to help patients overcome illness, regardless of the presenting conditions, should be the focus of treatment by the health care professional. Many experts argue that treatment-centered care focuses too much on the process and not enough on the patient. On the other hand, arguments are made that solely focusing on the caring aspect of health care causes practitioners to turn away from evidence-based research, which has been shown to have positive outcomes and is the standard for treatment (Duffy, 2013). The project's theoretical framework, Joanne Duffy's Quality-Caring Model (QCM), was chosen because the model establishes appropriate equilibrium between these concerns and helps establish that when

practitioners implement evidence-based interventions the result is that patients feel "cared for" (Duffy and Hoskins, 2003). The QCM allows the provider to use evidence-based research and still fulfill the caring role that is a hallmark of the health care field.

The QCM is based on a structure-process-outcomes model of care delivery that is a linear model and then is blended with major constructs from Watson's Human Caring Model (Duffy, 2013; Duffy & Hoskins, 2003,). The blending of the two models satisfies both society's need for measurable outcomes and the patient-centered processes that are the hallmark of nursing practice (Duffy & Hoskins, 2003). The result is a "postmodern approach that may benefit patients/families, members of the health care team, and nurses themselves" (Duffy & Hoskins, 2003, p. 80).

The first aspect of the model is structure. Structure as it pertains to the QCM is centered on the participants. The project identified three participant groups: the provider, the patient, and, the system. Within the system subcategory of the QCM the main topic addressed is resources. The QCM suggests that providers and patients are both vital contributors in achieving the end goal of quality health care delivery (Duffy, 2013). The patient, provider and system all bring important insights and characteristics to the treatment process which the Quality-Caring Model describes using the terms phenomenal field, descriptors, unique life experiences, attitudes and behaviors, severity of illness, comorbidities, staff mix, organizational culture, and resources. Phenomenal Field relates to unique frames of reference or context known only to the participants (Duffy & Hoskins, 2003). Descriptors relate to specific demographics, various physiological, psycho-sociocultural, and spiritual factors that both the provider and the patient bring to the treatment relationship. The needs, knowledge and various factors of the patient are combined with skills and knowledge of the providers as the treatment process begins (Duffy & Hoskins,

2003). Resources then augment both the provider and the patient. In the context of this project the resource used is the SPT that will be provided to PCPs. Hopefully, by providing the SPT to providers the process, which leads to improved outcomes for the patient, can be bettered.

The next aspect of the QCM is process (Duffy & Hoskins, 2003). Process focuses on the relationship that is developed between the provider and the patient. The patient-provider relationship is based primarily on achieving healthy outcomes for the patient. The QCM describes the process with the term Independent Relationship (Duffy & Hoskins, 2003). The Independent Relationship is one that is discipline-specific and exists while the process of obtaining improved health is underway. The introduction of a quality evidence-based tool will hopefully bolster the confidence of the provider, which in turn will allow the Independent Relationship to be stronger. The Independent Relationship definition sets the relationship apart from Collaborative Relationships, which is another type of relationship included in the QCM and not a major focus of this paper (Duffy & Hoskins, 2003). The Collaborative Relationship focuses on relationships that are formed on a larger scale when the Independent Relationship extends into a multidisciplinary sphere (Duffy & Hoskins, 2003). Collaborative Relationship, which could include associations with counselors, psychiatrists, and state and federal mental health authorities, would be the result of the improved ability of PCPs as they become more knowledgeable in treating depression and therefore assume broader roles in the overall care of depressed patients.

As with most models the QCM is geared to lead to the outcomes of improved health states. In the QCM there are two goals. The first goal is described as an intermediate outcome and is measured in the patient feeling cared for by the healthcare professional (Duffy & Hoskins, 2003). The final or terminal outcome looks at the effect that the process had on the participants

in the structure aspect of the model. For the provider the primary terminal outcome is satisfaction in the personal progress of the patient, but can also include personal growth as a provider. The main focus of the entire model is the patient, and the list of terminal outcomes for the patient can be numerous. The summarization of the terminal outcomes for depressed persons would be remission of the depression and a return to functioning.

The project's end goal is an improvement in quality of life in the persons suffering from depression. Improvement should follow patient satisfaction resulting from quality care provided by the practitioner. The terminal outcome for the resource is based on the usability of the resource. As it is the most easily changeable variable in the model, multiple resources should be sought until one is found that strengthens the Independent Relationship and provides the best terminal outcomes (Duffy & Hoskins, 2003). Duffy (2013) indicated that for the Independent Relationship to be most effective there must be accountability from the provider, engagement in high-level decision making on the part of the provider, and use of evidence-based practice in everyday practice by the provider. Duffy (2013) also indicated that for the practitioner to maintain professionalism, which allows for the best interactions with patients, certain characteristics were needed. Characteristics include adherence to ethical practice principles, commitment to autonomous maintenance and continuous improvement of competence (Duffy, 2013).

The project's focus is to improve the ability of the provider to give quality care through the SPT, which will help the provider attain the qualities that Duffy (2013) described. This, in turn, should increase the likelihood that the intermediate and terminal goals within QCM are met. Duffy (2013) asserted that for the optimal Interpersonal Relationship to exist practitioners must first be adequately prepared to identify patient needs and intervene appropriately. The

application of appropriate interventions that results in the patient, "feeling cared for" will then lead to patients being more apt to disclose important information, engage in health improvement and follow recommended treatment guidelines (Duffy, 2013). For a visual depiction of the QCM see Figure 1 on the following page. Within the figure is the patient who is the focus of the QCM, the provider, and resources. The combination of the patient with the provider and a resource, i.e. the SPT, should lead to the formation of an Independent Relationship. If the provider exhibits a level of professionalism the formed Independent Relationship should be optimal and lead to both intermediate and terminal outcomes, primarily for the patient, but also for the provider.

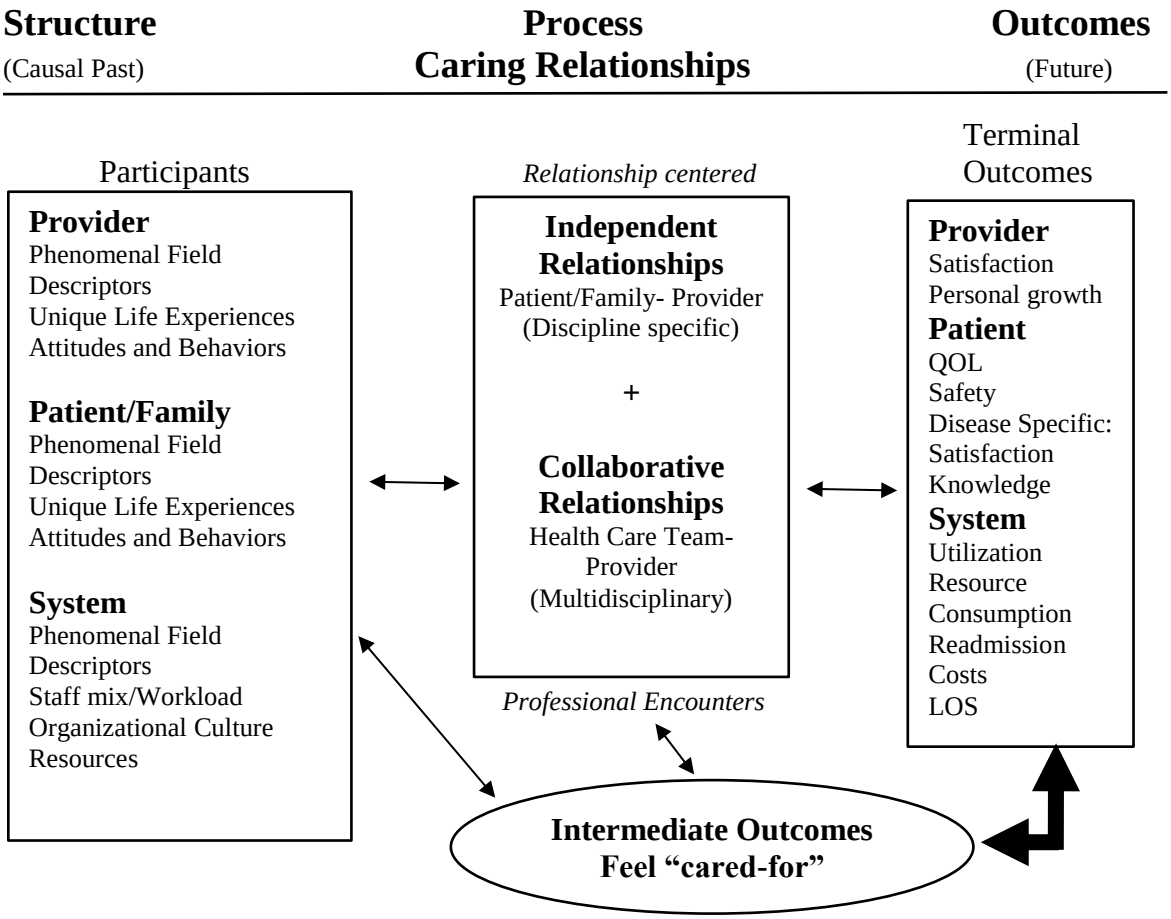

Figure 1. Joanne Duffy's Quality Caring Model Adapted from: Duffy and Hoskins, 2003, permission to reproduce obtained 02/11/2014 see *Appendix H*

CHAPTER THREE. PROJECT QUESTIONS, OBJECTIVES, AND DESIGN

Project Questions

The literature review identified a series of common issues faced by persons suffering from depression. Among these issues, depressed persons appeared to have difficulty maintaining healthy lifestyles, and at times suffered from problems with addiction (Fabricius, Langa, & Wilson, 2008). The deficits in health caused by depression and other mental illnesses and issues resulting from mental illness led to the project's first question: What can be done to help overcome issues faced by the mentally ill, especially those with depression? The first thing that can be done is to increase the knowledge base of PCPs, as the literature indicated that PCPs will continue to play an important role in treating depressed persons. The assumption that PCPs could benefit from tools for prescribing medication leads to the project's second question: Can a tool be useful to the PCP in treating mentally ill persons? To answer the second question, tools that already exist were sought. Finding already created and evaluated tools helped show that tools can be effective aids for depression treatment. A synthesis of the information was performed using the existing tools and knowledge from other treatment modalities resulting in the creation of the SPT.

The SPT was then presented to a group of PCP reviewers. Specific details of the PCP reviewer group and the selection process will be detailed later in the paper. Input as to the practicality of the presented tool was requested and ideas for improvement of the SPT were sought. Information about the effectiveness of the provided tool (SPT) was obtained by a survey presented to the participating PCPs. The survey included the following questions about:

1. Flow of the tool
2. Accuracy of the content contained in the tool

3. Applicability of the tool in the primary care setting

4. What was liked about the Simplified Prescribing Tool

5. What could be done to improve the provided Simplified Prescribing Tool

The questions contained in the survey were designed to discover if the Simplified Prescribing Tool was easily understood and could be readily applied to use by PCPs in the primary care setting. The project's primary objective was to see if the designed tool met the needs of PCPs but, secondary to this, the project attempted to see if there was a desire to have available different tools for use when treating mentally ill persons. Knowledge about an existing desire through introduction of the SPT could lead to further research and development of other tools in the future. The survey as provided to the participation group can be found in *Appendix B*.

Project Objectives

The project's main objective was to provide a concise practical tool, the Simplified Prescribing Tool, for use by PCPs in the treatment of persons with depression. Creation of the tool was developed through a review and synthesis of:

1. Existing knowledge of available diagnostic methods, treatment options and management strategies.

2. Existing tools/algorithms for the treatment of depression.

As described, the SPT covers treatment of depression and can be found at the end of this text in *Appendices A-E*.

Project Design

The design of the process improvement project was the development of the SPT, which can be used to guide the prescribing practices of PCPs who are treating persons with depression. The developed tool includes the following diagnostic criteria; an evidence-based validated

diagnostic tool; an algorithm for pharmacological treatment of depression; and a section providing information about management of depression and referral references. The SPT and survey tools were designed by the author and were created after review and synthesis of existing evidence-based research. The author then presented the SPT and survey tools to PCP reviewers for appraisal. Presenting the handouts involved providing each PCP within the survey review group with the following:

1. A copy of the SPT. *See Appendices A-E*
2. A survey, which included the questions posed in the Project Questions section of the paper. *See Appendix F*
3. Means of returning the survey to the researcher at no cost to the PCP.

More detailed information about PCP reviewer group and the survey process can be found in the next chapter of the project.

CHAPTER 4. PROJECT EVALUATION

Project Evaluation Overview

The evaluation of the project was carried out in two phases. The first phase was accomplished by sending the SPT to an expert group of psychiatric professionals for review. This first phase was done to assure the content was accurate and followed evidence-based practice guidelines. The second phase consisted of sending the SPT and a survey to PCP reviewers for further evaluation and was the primary means of evaluating the project's success. The results of both of these phases will be detailed in the following sections of the paper.

Phase 1: Evaluation by Psychiatric Professionals

This phase was included in the project for the purpose of validating the content of the SPT by experts in the field of psychiatric medicine prior to sending the SPT to the PCP reviewers. A group of practicing psychiatric professionals was chosen. The group was a convenience sample as the practitioners were chosen because they were locally available and the author had a professional association with them. The group included five psychiatrists and a psychologist. The group was asked to review the content of the SPT for accuracy in treating depression and to give any input on the general set-up and usability of the tool. As this group consisted of trained certified psychiatric specialists, their insight was seen as helpful in identifying any deficits that might be contained in the SPT and for assuring content validity. A survey was sent along with the tool as a means to guide the group (*See appendix I*). For disclosure, the survey group consisted of specialists employed at a local health care facility and working primarily in treatment of mentally ill patients in an inpatient hospital setting in the upper Midwest. After receiving the SPT and survey on an individual basis, the group met together and combined their suggestions for changes in the SPT in a single response. The author reviewed the

suggestions offered by the group and those suggestions that were backed by evidence-based research were added to the SPT. Examples of modifications made to the SPT after review by the psychiatric specialists included:

1. Adding more focus to identifying depression severity and treatment needs based on factors presented by the patient.
2. Changes to medication indications, dosage, and warnings. Many of these changes resulted from new guidelines that were published after the creation of the SPT.
3. Changes in appointment scheduling for follow-up and insight about when to refer the patient to psychiatry.

All of the suggestions that were supported by evidence in the literature were incorporated into the SPT resulting in the refinement of the SPT into a more readily usable, patient focused, and evidence-based tool.

Phase 2: Evaluation by PCPs

After the SPT had been modified to reflect the insight provided by the psychiatric professionals, the tool was then sent to a PCP review group. Since this project reflects requirements for graduation from North Dakota State University's Doctor of Nursing program the survey group consisted of Nurse Practitioners. As is evident, nurse practitioners are not the only PCPs that treat depression; therefore, the SPT was also sent to primary care physicians and physician assistants. Responses from all three of the reviewer groups of professionals are included together. A breakdown of the reviewers includes: seven nurse practitioners, three physicians, and one physician assistant. The reviewers included four males and seven females. Nine of the reviewers practice in the upper Midwestern States. The other two reviewers practice

in Southwestern States. The reviewers were chosen by both a convenience method as six of the eleven were already known to the author. The remaining reviewers were chosen at random by selecting the reviewers based on the fact that they were PCPs. A general internet search was done for nurse practitioners and other PCPs. The clinics where these PCPs practiced were then contacted and asked if the PCP would be interested in participating in the review. If the provider was willing the SPT and review form was sent to the reviewer.

For guidance in the review process a survey form was sent along with SPT. The form included questions to help evaluate specific aspects of the SPT and included room for comments and suggestions for improvement to the SPT. The three aspects the PCP reviewers were asked to evaluate were: 1) flow of the tool; 2) accuracy of the tool; and 3) applicability of the tool (*See Appendix F*).

CHAPTER 5. RESULTS AND DISSEMINATION

Presentation of Findings

There were eleven responses returned to the author. As stated earlier in the paper a survey was sent to the PCPs as a means of evaluation. In addition to the designed questions on the survey, the PCP review group was also given the option to evaluate the SPT in any manner that seemed helpful. The information that is reported below will follow the format of the survey as all of the participants chose to use the provided survey as their primary means of evaluation. Of the eleven participants one chose to also include suggestions directly on the SPT itself. Those suggestions were reflected in the participant's survey and will be stated later in the chapter. The three sections of the survey were: 1) flow of the tool; 2) accuracy of the tool; and 3) applicability of the tool. At the end of the survey a space was allotted for additional comments (*See appendix F*).

Responses to Flow of the SPT

The first question in this section of the survey was: "Were the steps in the tool easy to follow?" The question was designed to be answered via a three point Likert scale (1. not easy to follow; 2. somewhat easy to follow; 3. easy to follow). Of the eleven participants seven answered that the steps were easy to follow. Four of the eleven reported that the steps were somewhat easy to follow. None of the survey group reported that the tool was not easy to follow.

The second question in Section 1, designed to be open ended asked, "What did you like best about the tool?" This question prompted the participant to evaluate in more depth the overall flow of the tool. The participants' comments varied from short and precise to a more detailed breakdown of specific areas of approval. Some of the participant's comments were:

"Easy to follow," "Straight forward," "The design gives a guide and outline in determining treatment options," and "I like that all of your links to the tools are evidence-based and cited." Other responses mirrored the proceeding quotes. Two terms used by more than one participant to describe what was best liked about the SPT were "logical flow" and "comprehensive." Two participants mentioned the use of the PHQ-9 scale as an item they liked. Other positive comments given included mention of the thorough medication classifications and dosages. Overall the comments on the flow of the SPT were positive. One participant stated a dislike for algorithms in treatment, but also clarified the opinion by stating, "for those who like algorithms it's ideal."

The third question, also open ended, asked, "What improvements do you recommend?" This question allowed the participants to offer suggestions on improving the tool. Among the responses was the suggestion to include changes to the follow-up schedule for longer times between appointments if the patient is seeing a counselor or therapist and to include follow-up that is provided by health coaches and/or telephone contact. The length of the tool was also mentioned as a possible suggestion for change as some participants felt the SPT was too long. One participant suggested a more distinct separation between the SPT and the algorithm for treatment and would retitle the algorithm as The Algorithm for Treatment of Depression, which would then be helpful distinguishing the diagnosis and management steps from the pharmacological treatment steps. Multiple participants suggested including more information about medication side effects and rationales for use with specific medications in relation to patient characteristics. Also mentioned were two newer medications to incorporate into the tool, i.e. Desvenlafaxine (brand name: Pristiq) and Vilazodone (brand name: Viibryd).

Responses to Accuracy of the SPT

This section contained two questions. The first question was, "Did the content provide accurate diagnostic/treatment options for depression?" This question was also designed to be answered via a three point Likert scale (1. the tool was not accurate; 2. one area of the tool was not accurate; 3. Yes, the tool was accurate.) All of the participants reported that to the best of their knowledge the tool was accurate. The second question was, "If you found the tool to be inaccurate, what is/are the area(s) and what would you recommend for correction?" This question helped to guide the researcher to improvements to ascertain that the tool followed evidence-based guidelines. Of the eleven participants, only one offered suggestions for change after this question. The one participant questioned if more focus should be placed on the DSM-IV-TR (2000) criteria for diagnosis of depression and questioned if the PHQ-9 followed the APA's guidelines. It is the understanding of the researcher that the PHQ-9 and other diagnostic criteria included in this paper are directly based on the APA diagnostic criteria. Some participants' comments to this question included, "Good references and documentation," "Excellent and very helpful".

Responses to Applicability of the SPT

The final section of the survey was presented to allow the PCP reviewers a chance to approve or disapprove of the applicability of the tool for practice. This section included the question, "Is the tool applicable for use by primary care providers?" followed by a Yes/No response prompt. The first question was then followed by a why/why not query to allow the participant the ability to elaborate on the closed ended response. Ten out of eleven participants responded yes to the applicability of the SPT for use in Primary care. Comments made about the tool were as follows; "Yes, simple to use, clear and concise tool for busy PC provider," "Yes, I

think that the tool is applicable for use in primary care," "It is accurate and easy to follow. It stresses the importance of a thorough history and close follow up, which I think too often is lacking in the treatment of depression in a primary care setting". The participant who answered no to the applicability of the tool stated,

> I think it is too lengthy. The algorithm that discusses titration is most helpful, and addresses the common problem of not titrating doses up as aggressively or rapidly as they should be, thus getting inadequate treatment. Perhaps your tool could provide some information from the literature regarding that, since it is the most common prescribing mistake with antidepressants.

There was only one participant who thought the tool was too lengthy for use. If the idea was to simplify the process and this participant felt the provided tool was too lengthy then the tool would not be seen as useful to him/her. However, the same participant identified that a specific section of the SPT was useful and how by focusing in on a specific part of treatment, in this case medication titration, the SPT could be very helpful in practice. The participant's response, of all the responses, helps bolster the researcher's hypothesis that more tools for the treatment of mental illness are needed in the primary care setting. A tool that focused more directly on the needs identified by the reviewer mentioned above may have garnered additional positive responses. There were two additional comments offered by participants regarding the applicability of the SPT. The comments were, "I would use this tool! Very helpful!" and "I may try this tool in practice". A major intent of the project was the design and evaluation of the tool. The above two comments show approval and intent to use, which was a goal of dissemination.

Additional Comments

Two participants used the additional comments space at the end of the survey. This section was provided to allow participants space to evaluate the tool in ways not covered by the previous sections. One participant commented, “great topic”. The other participant used the space to offer grammatical corrections found within the body of the SPT. Both comments were helpful to the researcher.

Dissemination

Dissemination of the project happened by making the SPT tool available to the PCP reviewer group for use. The request was made by two of the reviewers and had been planned as the next logical step. Each of the eleven reviewers received an email thanking them for participation in the review and a copy of the SPT and they were informed that they were welcome to use the SPT in their respective practices. The reviewers were informed that if they knew of anyone else who would be interested in its use that the SPT could be made available. Nine cohorts of the author were also given the SPT as interest had been voiced in having the SPT made available after completion of the project. Hopefully, as these recipients interact with other providers, the interest in this tool or other tools like the SPT will spread and lead to improved patient care. As the SPT was designed to help PCPs, any practitioner who wishes can have access to the tool. Personally, the author of this project intends to use the tool in practice if the future practice involves interactions with depressed persons. Three of the PCPs who have received the SPT have indicated they plan to use the tool along with four of the authors cohorts.

CHAPTER 6. DISCUSSION AND RECOMMENDATIONS

Interpretation of Results

The purpose of the project was to improve prescribing practices of PCPs through the introduction of an evidence-based tool that could be used to guide the treatment of depression. To meet the project's objectives, the results of the project would need to show that the tool could be of benefit to PCPs in their treatment of depressed persons. The PCP reviewers were then chosen by a convenience sample method. The PCPs who agreed to participate were sent the SPT and a survey for evaluation of the SPT. The PCP reviewer group's responses were used to validate that the SPT was a useful tool in PC settings. As was seen in the previous evaluation sections, the SPT was received in a generally positive manner. As the survey group positively responded to the applicability of the SPT for use in primary care, provides some evidence that the project goal of creating a tool that was easily used was met. A basic premise of the project was that if an evidence-based tool were provided to PCPs, having access to the tool would increase confidence in the provider, which could lead to improved health and quality of life in persons with depression. This assumption is based on the project's theoretical framework of Joanne Duffy's QCM. In this case, the provider is augmented by a resource, the SPT, and is therefore better prepared to enter into an Interpersonal Relationship with the person suffering from depression. The patient within the Interpersonal Relationship is benefited by improved treatment delivery and will then achieve the intermediate goal of "feeling cared for" and the terminal goal of improved quality of life with more ease. This is only the first step to actually validating the tool. However, for any other steps to be attempted the tool must first find favor with potential users. The survey group responded that the content and flow of the tool were favorable for use.

Limitations

The major limitation of the project was the limited number of PCP reviews. An additional limitation was that reviewers were from a small geographic area. A third limitation was that most of the PCPs in the review group were nurse practitioners. A larger, more diverse group of PCPs would have been helpful.

Recommendations

As the results of the survey were generally positive, there is the future possibility that the tool could be applied in a more direct clinical trial to see if patients received better care with use of the SPT. The idea that treatment would be improved needs not be limited to the use of the SPT alone. To more adequately determine if the tool was valid in its content and truly usable, the number of PCPs reviewing the tool would need to be larger and more diverse. In a future project, more PCPs could be surveyed and a larger geographical area could be included so that more diverse opinions, educational, and professional backgrounds could be added for the evaluation of the SPT. Also, actual data as to outcomes of depression treatment with use of the SPT as a guide could be gathered. This would increase validity of the tool, as positive outcomes would lend credence to the ability of the tool to aid practitioners. As the goal of any medical or psychological treatment is improvement in the patient, seeing improvement would be the best measure of the SPT and its content.

The general acceptance of the SPT and interest in the tool's use also suggests that there might be interest in the use of other tools to help improve care. As the literature reviewed showed deficits in care of depressed persons, strategies should be sought that can overcome these deficits. Both the literature and the surveys obtained covered specific issues that could be addressed in future studies. These issues could be addressed and changes to the SPT could be

made to address in a more detailed way the issues that were presented by participants in the evaluation of the SPT. It is the opinion of the researcher that there is definitely a need to further the availability, development, and dissemination of both the SPT and other tools already developed or in development. As depression is an issue that is occurring more frequently, and is costly in many ways to those affected by and those associated with depressed persons, further research in a variety of areas can be beneficial.

Summary

This project's purpose was to improve the care provided to depressed persons in the PC setting. The project accomplished this through the development of the SPT from existing evidence-based, research, guidelines, and tools. After the SPT was developed, it was delivered to psychiatric specialists to review it for validity and accuracy of the content. Finally, the SPT was sent to a group of PCPs, who evaluated the tool for applicability as related to use in PC settings. The consensus from the reviewing PCPs was that the tool could successfully be applied in the PC setting. Twenty PCPs were provided with the SPT and three have stated both verbally and by email that they intend to use the SPT in the future.

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APPENDIX A. PAGE ONE OF THE SIMPLIFIED PRESCRIBING TOOL

Simplified Prescribing Tool

Depression in Adults: A Guide for Treatment of Depression in the Primary Care Setting

Step 1: Diagnosis of Depression:
Treatment of depression in the outpatient setting should begin with accurate diagnosis. Diagnosis should be focused on patient specific history, direct examination of the patient by the provider. The provider can be aided in both the screening process and in diagnosing aspects of the depression through the use of evidence-based clinical tools during direct interaction with patients.[6] Listed below are links to tools that can be used as a guide to help establish the existence of depression in a patient and guide treatment.[1,5,6,8,9,10,15,16]

- Inventory of Depressive Symptomatology (IDS)
- Quick Inventory of Depressive Symptomatology (QIDS)
  IDS and QIDS forms in multiple languages and variations can be obtained at: http://www.ids-qids.org
- Patient Health Questionnaire-9 (PHQ-9). (See page 3.)
  Multiple Version of this screening tool can be found at: http://www.phqscreeners.com

Step 2: Defining the level of Depression:
The clinician should ascertain the level of depression, through a thorough history and examination.[1,6] The level of depression is important, as it will help guide the clinician when recommending interventions and the intensity of interventions to the patient.[1,6] Evidence-based tools can aid the provider in establishing severity levels. For this tool the levels of depression will be given in accordance with scores from the PHQ-9. (see below) If the PHQ-9 is not the tool of choice, the clinician should find rating methods that correlate scores from the chosen tool to the specific levels of depression. The following is a rating scale for the scores obtained from the PHQ-9 for 5 different depression levels: [5]

- None-minimal Depression: 0 - 4
- Mild Depression: 5 - 9
- Moderate Depression: 10 - 14
- Moderately Severe Depression: 15 - 19
- Severe Depression: 20 - 27

Scores from screening tools are helpful, as they can serve as a guide to possible interventions both pharmacological and non-pharmacological. However, direct interaction with the patient is vital as details of the depression such as: causative factor, duration, comorbid diseases, economical and social factors will be deciding factors in determining interventions.[1,6,8] It is important to note that "scores" do not replace face-to-face evaluation as the primary tool for both diagnosis and treatment of depression.[6] The literature reviewed indicated initiation of pharmacological interventions at the Moderate Depression level.[1,2,4,5,8,11]

Steps 3: Treatment:
A. This tool focuses on pharmacological treatment of depression (see the algorithm on page 4). However it is important to note that many patients with depression will highly benefit from psychotherapy and/or counseling, by itself, or in combination with pharmacological treatment. Multiple sources agreed that for mild to moderate depression psychotherapy can be the only intervention needed.[1,3,4,5,6,7,8,10,14,15,16] Some examples of psychotherapy that have been shown to be effective in the treatment of depression are:

- Cognitive Behavioral Therapy (CBT) [1,2,8]
- Behavioral Therapy/Activity Scheduling (BT/AS) [1,2,8]
- Interpersonal Psychotherapy (IPY) [1,2,8]

The clinician should be aware of available psychotherapy/counseling and be able to recommend this to the patient.

B. Pharmacological Treatment:

Once the clinician has identified the Diagnosis of Depression at a severity level where pharmacological treatment is needed algorithms can be helpful.[1,2,4,8,11,13] However, most algorithms are not specifically designed for use in primary care. The algorithm included in this tool (see pages 4-5) is adapted from evidence-based research, which was synthesized to create a form more readily used in primary care. More detailed versions of depression treatment algorithms can be found through the following resources:

- Texas Medication Algorithm Project Procedural Manual: Major Depressive Disorder Algorithms [8]
- South Carolina Offering Prescribing Excellence: Best Practices for the Treatment of Major Depressive Disorder in South Carolina [2]
- Institute for Clinical Systems Improvement: Health Care Guideline, Major Depression in Adults in Primary Care [11]

Note: Treatment should be part of a plan discussed and agreed on by both the patient and provider and takes into consideration patient factors, medication factors and availability of resources.

Step 4: Management of Depression:

Success in treating and managing depression requires certain benchmarks to be met to achieve the best possible outcome for the patient. Provided below are some items for consideration as depression is being managed:

- Initial treatment with medication should include a trial period of 6-12 weeks.[1,2,8,11]
- Patient should be seen 1 to 2 weeks after the medication is started.[1,2,8,11] Then at weeks: 4,6,9,12. Subsequent visit should include discussion about depression severity, overall patient functioning, side effects of the medication and medication titration.[1,2,8,11]
- Initial medication should be titrated to the target dose and then if needed to the maximum dose throughout this period or until the patient has obtained submission of or remission from symptoms.[1,2,8,11]
- Medication therapy should continue for at least 6 months after remission of symptoms.[1,2,8,11]
- Medications should not be discontinued for any reason, including pregnancy without consulting with prescriber.

Step 5: Other Considerations for Pharmacological Treatment of Depression:

The clinician should be aware of aspects of the treatment of depression and how each can affect treatment, which include, but are not limited to:

1. Patient Age (this tool is designed for the treatment of adults age>18)
2. Patient Gender
3. Pregnancy Status: Is the depression occurring with pregnancy or Post-Partum?
4. Medication: Generic vs. Name brand, Cost, Side effect profiles, Dosage and Frequency of medication administration.
5. Other mental or health comorbidities that could affect medication effectiveness.

The clinician should be aware of how these factors could affect treatment and be prepared to alter treatment to best suit the needs of the patient.

APPENDIX B. PAGE TWO OF THE SIMPLIFIED PRESCRIBING TOOL

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

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
☐	☐	☐	☐

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

APPENDIX C. ALGORITHM FROM THE SIMPLIFIED PRESRIBING TOOL

Treatment of Depression

Evaluate severity of depression
Is the patient at an immediate risk for suicide?

→ **Yes.** Assure safety. Discuss inpatient treatment. Contact Emergency Services

No. Establish details of depression through thorough: History, Examination.
Document Severity of Depression using a Depression Screening Tool (PHQ-9, pg 3).
Depending on level of depression create treatment plan, which should include:

- Non-pharmacological interventions
- Pharmacological Interventions
- Combinations of both

If depression severity is moderate or greater pharmacological interventions should be discussed, continue to **Stage 1 of treatment**

No. Stage 1. Begin medication treatment with one agent from the one of the following categories: (Trial should last from 6-12 weeks)*

1. Selective Serotonin Reuptake Inhibitor (SSRI): (SSRI: First line therapy)

Examples:

	Initial Dose	Dose: Target | Maximum	Titration	Schedule
Fluoxetine	10-20mg	40mg | 40-80mg	10-20mg/q 4weeks	Daily
Paroxetine	10-20mg	20-40mg | 60mg	10-20mg/q 2weeks	Daily
Sertraline	25-50mg	50-150mg | 150-200mg	50-100mg/q 2weeks	Daily
Citalopram	10-20mg	20-40mg | 40mg	10mg/q 2weeks	Daily
Escitalopram	5-10mg	10-20mg | 20mg	10mg/q 2weeks	Daily
Fluvoxamine	50mg	100-200mg | 300mg	50-100mg/q 2weeks	Daily
2. Serotonergic Noradrenergic Reuptake Inhibitors (SNRI):				
Venlafaxine	37.5-75mg	150mg/375mg	37.5-75mg/q week	1-2 daily
Duloxetine	20-30mg	60mg/120mg	30mg/q 1-2week(s)	1-2 daily
3. Other				
Bupropion	75-150mg	300mg/450mg	150mg @ 3-7 day	Daily
Mirtazapine	15mg	15-30mg/45mg	15mg/q 1-2 weeks	Daily

- Stage 1 not complete until medication therapeutic dose has been reached. Frequent visit should be scheduled during trial period to discuss depression severity, medication effectiveness, tolerance, adherence and side effects
- For Side effects and interactions see Medication Information page following this algorithm

Treatment of Depression

Evaluate response to treatment at week: 2,4,6,9,12. Visit scheduling should be set related to patient specific depression characteristics and severity. Repeat PHQ-9 or comparative depression screening. Evaluate safety, discuss adherence to medications and therapy regimens.

Yes, good response. Decreases in scores to below initial assessment score with goal of < 5. Medication titration should continue throughout the 6-12 week trial period until pt reaches score <5.
Follow Step 4: Management of Depression

Partial response. Decrease in scores, but at a less significant rate than with good response. Add a second medication from **Stage 1**: SSRI, or SNRI used augment with Bupropion or Mirtazapine. If Bupropion or Mirtazapine used augment with SSRI or SNRI. (6-12 week trial)* **(Partial response score in range of 7-14)**

No or poor response. Evaluate patient safety. Is the patient at risk for suicide? If no continue to **Stage 2**

Stage 2. Change medication. Treatment with one agent from the following categories that is of a different mechanism of action from the medication used in **Stage 1**: (Trial should last from 6-12 weeks)*

1. (SSRI): Fluoxetine, Paroxetine, Sertraline, Citalopram, Escitalopram
2. (SNRI): Venlafaxine, Duloxetine
3. Bupropion or Mirtazapine (See **Stage 1** for medication dosage)

At this stage a trial of a different SSRI can be used in place of a change in mechanism of action

Yes, good response. Continue treatment. Follow Step 4: Depression Management.

No. Assure pt safety. Begin discussion about referral to psychiatry for treatment.

*****At any of the **Stages** discussion of Evidence-based psychotherapy, healthy lifestyles changes, and stress management should be included in treatment

*****At both **Stage 1&2** side effects of the medication should be addressed and medication changes should initiated if the patient is experiencing side effects.

APPENDIX D. SIMPLIFIED PRESCRIBING TOOL'S MEDICATION INFORMATION

Medication Information

Brand Name

1. Selective Serotonin Reuptake Inhibitor (SSRI):

Fluoxetine: Prozac® (Generic Available)
Drug interactions: Carbamazepine, Clozapine, Cyclosporine. Hydantoins,Linezolid, MAOIs, NSAIDs, St. John's, Wort, Sympathomimetics, Thioridazine, Tramadol, Triptans, Tricyclic antidepressants.

Paroxetine: Paxil/Paxil CR® (Generic Available)
Drug interactions: Cyclosporine, Linezolid, MAOIs, NSAIDs, Phenothiazines, St. John's Wort, Sympathomimetics, Tramadol, Triptans, Tricyclic antidepressants

Sertraline: Zoloft® (Generic Available)
Drug interactions: Carbamazepine, Clozapine, Cyclosporine, Grapefruit, Hydantoins, Linezolid, MAOIs, NSAIDs, Phenothiazines, Pimozide, St. John's Wort, Sympathomimetics, Tramadol, Triptans , Tricyclic antidepressants

Citalopram: Celexa® (Generic Available)
Drug interactions: Clozapine, Cyclosporine, Linezolid, MAOIs, NSAIDs, Pimozide, St. John's Wort, Sympathomimetics, Tramadol, Triptans

Escitalopram: Lexapro® (Generic Available)
Drug interactions: Cyclosporine, Linezolid, MAOIs, NSAIDs, St. John's Wort, Sympathomimetics, Tramadol, Triptans

Fluvoxamine: Luvox® (Generic Available)
Drug interactions: Carbamazepine, Clozapine, Cyclosporine, Grapefruit, Ropivacaine, St. John's Wort, Sympathomimetics, Tacrine, Theophyllines, Thioridazine, Tizanidine, Tramadol, Triptans, Tricyclic antidepressants

Side Effects: Class Specific for SSRIs:
Agitation, Constipation, Diarrhea, Dizziness, Dry Mouth, Fatigue, Headache, Insomnia, Loss of appetite, Nausea, Nervousness, Sexual Dysfunction, Somnolence, Sweating

Patient Considerations: for SSRIs:
Pregnancy test for women of childbearing age should be performed before starting an SSRI
Monitor the patient of new onset suicidal ideations or behavior after initiation of treatment with an SSRI

FDA Warning: "Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of [Insert established name] or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need."

For full FDA warning see:
http://www.nimh.nih.gov/health/topics/child-and-adolescent-mental-health/antidepressant-medications-for-children-and-adolescents-information-for-parents-and-caregivers.shtml
http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM173233.pdf

2. Serotonergic Noradrenergic Reuptake Inhibitors (SNRI):

Venlafaxine: Effexor/Effexor XR® (Generic Available)
Drug interactions: Linezolid, MAOIs, St. John's Wort, Sympathomimetics, Tramadol, Triptan

Duloxetine: Cymbalta®
Drug interactions: Alcohol, Linezolid, MAOIs, St. John's Wort, Sympathomimetics, Tramadol, Triptan

Side Effects: Class Specific for SNRIs:
Anxiety, Decreased Appetite, Dizziness, Dry Mouth, Fatigue, Insomnia, Nausea, Somnolence, Sweating

Patient Considerations:

Venlafaxine and Duloxetine:

Pregnancy test for women of childbearing age should be performed before starting an SNRI

Monitor the patient of new onset suicidal ideations or behavior after initiation of treatment with an SNRI

Blood pressure monitoring should occur at initiation of an SNRI and during the titrations period of treatment

Duloxetine: Hepatotoxicity has been seen with use of duloxetine. The provider should be aware of this possible side effect. Caution should be taken with patients with known history of or current liver issues and/or alcohol use. Testing for liver functioning should be considered.

FDA Warning: "Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of [Insert established name] or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need."

For full FDA warning see:

http://www.nimh.nih.gov/health/topics/child-and-adolescent-mental-health/antidepressant-medications-for-children-and-adolescents-information-for-parents-and-caregivers.shtml

http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM173233.pdf

3. Other

Bupropion: Wellbutrin (SR/XL)® (Generic Available)

Drug interactions: Carbamazepine, Cyclosporine, Linezolid, MAOIs, Ritonavir, Tricyclic Antidepressants

Mirtazapine: Remeron® (Generic Available)

Drug interactions: Alcohol, Linezolid, MAOIs, SSRIs, St. John's Wort, Tramadol

Side Effects:

Bupropion: Seizures, Constipation, Dry Mouth, Headache, Insomnia, Nausea

Mirtazapine: Constipation, Dry mouth, Increased appetite, Nausea, Sedation, Weight gain

APPENDIX E. SIMPLIFIED PRESCRIBING TOOL'S REFERENCE PAGE

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APPENDIX F. EVLAUATION FORM USED BY PCP REVIEWERS

Evaluation of Simplified Prescribing Tool (SPT) for Depression

Thank you for your willingness to participate in the evaluation of the provided tool. The tool was created to be an easily accessible guide for the treatment of depression in the primary care setting. To ascertain that the tool follows accepted, evidence-based guidelines, a literature review was performed. The information was then synthesized to create the tool. Your input will be used in the evaluation portion of my dissertation. The survey is geared to rate the flow of the tool, the accuracy of the content and the applicability of the tool in the primary care setting.

Flow of the Tool

Were the steps in the tool easy to follow?

1) Not easy to follow 2) Somewhat easy to follow 3) Easy to follow

What did you like best about the design of the tool?

_____
_____
_____
_____
_____

What improvements do you recommend?

_____
_____
_____
_____
_____

Accuracy of the Content

Did the content provide accurate diagnostic/treatment options for depression?

1) The tool was **not** accurate 2) One area of the tool was **not** accurate 3) Yes, the tool was accurate

If you found the tool to be inaccurate, what is the area(s) and what would you recommend for correction?

_____
_____
_____
_____
_____

Applicability of the Tool

Is the tool applicable for use by primary care providers? Yes / No Why/why not?

_____
_____
_____
_____
_____

Additional comments: _____
_____
_____
_____
_____

Please feel free to make notes directly on the tool or within the word document. I will make arrangements to pick-up any hardcopies or you may email me the document at the address provided.

Thank You for Your Participation,

Rob Carroll, RN, BSN, DNP-S
(701)540-4503 robbie.carroll@my.ndsu.edu

APPENDIX G. PERMSSION TO REPRODUCE DSM-IV-TR CRITERIA FOR THE DIAGNOSIS OF A MAJOR DEPRESSIVE EPISODE

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APPENDIX I. EVALUATION FORM USED BY PSYCHIATRIC REVIEWERS

Thank you for your willingness to participate in the evaluation of the provided tool. The tool is focused on helping guide treatment of depression in the primary care setting. To ascertain that the tool follows accepted, evidence based guidelines, a literature review was performed and the information was synthesized to create the tool. I would like you to review the tool for accuracy of the content and offer input for improvement. Secondly I would ask you to review the general layout of the document. Your input will help me to make changes that will allow the tool to be used readily within the primary care setting.

Is the tool relevant for use by primary care providers? _____

_____

Evaluation of content:

What did you like best about the tool? _____

_____

_____

Was the information in the tool accurate? What improvements you would recommend?

_____

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Evaluation of Accessibility:

Was the tool easily understood? _____

What improvement in the general layout of the tool would you recommend? _____

_____

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_____

_____

Additional comments: _____

_____

_____

_____

Please feel free to make notes directly on the tool or within the word document. I will make arrangements to pick-up any hardcopies or you may email me the document at the address provided.

Thank You for Your Participation, Rob Carroll, RN, DNP-S,
(701)540-4503 robbie.carroll@my.ndsu.edu