Doctor of Nursing Practice Project

entitled

Identifying Depression in Primary Care: An Evidence-Based Intervention.

by

Mary Alice Peters

Submitted as partial fulfillment of the requirements for the
Doctor of Nursing Practice Degree

Temeaka Gray, PsyD, MBA, MSN, CNP, RN
Doctoral Project, Chair

Misty Richmond, PhD, PMHNP-BC
Doctoral Project, Committee Member

Larissa Barclay, DNP, NP-C, PMHNP-BC, CWCN
Doctoral Project, Committee Member

The University of Toledo and Wright State University
May 2018

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An Abstract of

Identifying Depression in Primary Care: An Evidence-Based Intervention

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Identifying depression in primary care is an urgent concern locally and nationally. Due to lack of screening or inquiry by primary care providers, as well as an insufficient number of mental health professionals, depression remains under-detected. This problem has been identified locally as a result of a 2014 population health survey in Huron County, Ohio. The population reported multiple reasons for not seeking out a program or service within the county to address symptoms of depression, anxiety, or emotional problems. The 2016 recommendation by The United States Preventative Services Task Force is to screen the general public as long as there are resources to provide appropriate treatment. Providers should assess risk factors with the patient by discussing the results of the screen and to decide necessary care such as investigating causative factors, monitoring symptoms, pharmacotherapy, and/or referral to mental health professionals. The purpose of this evidence-based practice improvement project was to add to the knowledge of depression screening by evaluating for patient satisfaction of the newly implemented two-step method in a primary care practice in an effort to improve depression identification. The Rosswurm and Larrabee updated version of the Model for Evidence-Based Practice Change was used to guide the project.

In a primary care practice setting, patient satisfaction of a new two-step screening method was assessed over a two-week period of time using a six-question satisfaction survey administered to participants chosen by simple randomization. Of the participants (*n*=86), nearly all (*n*=84) were satisfied with the new method.

Acknowledgements

I would like to express my sincere appreciation to everyone who helped me explore and develop this project. The skills I developed throughout this process will assuredly procure my professional development in evidence-based practice. I would especially like to thank the chairman of my committee, Dr. Temeaka Gray from The University of Toledo. My success with this project is a direct outcome of Dr. Gray's kindness, passion, and perseverance to instruct and guide my understanding to mobilize evidence into knowledge.

Thank you so much to my committee members, Dr. Misty Richmond from Wright State University and Dr. Larissa Barclay from The University of Toledo. Their insightful comments and commitment to evidence-based practice in mental health contributed to my overall success. Your dedication to my learning process is invaluable and I truly appreciated your contributions.

To my husband, Les, and my children Lillian and Lester, Jr., I couldn't have accomplished this success without your daily words of encouragement, sitting with me during long hours of work, and taking care of each other and me. A special thank you to my family and friends who helped me develop and edit this manuscript. Your expertise and kindness was overwhelming.

I would like to thank Fisher Titus Medical Center for the opportunity to explore my patient population in Huron County, Ohio in order to make a difference in the improvement of the mental health of this community.

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Identifying Depression in Primary Care

Introduction and Overview of the Problem

Depression is a common problem associated with disease and pharmacological therapy side effects affecting more than 30 million people worldwide (World Health Organization, 2017). Depression is the leading cause of disability globally (World Health Organization, 2017). According to The United States Preventative Services Task Force (USPSTF), the standard of care in primary practice is to screen annually for depression by his or her primary health provider (USPSTF, 2016). In 2014, there were over 15 million adults or 6.7% of the adult population in the United States affected by depression, having at least one major episode lasting two weeks or longer (Center for Behavioral Health Statistics and Quality, 2015). The National Alliance on Mental Illness (NAMI) (2016) reported 43 million adults or 18.5% experience mental illness in a given year. Of those adults, 41% received mental health services in the previous year. Twenty million adults have some type of substance abuse disorder with 50% of those people having concomitant mental illness. Use of mental health services vary based on the culture of the patient. There is a decreased use of mental health services with Hispanic Americans and African Americans accessing care 50% of the time compared to Caucasians; Asian Americans accessing 30% of the time (NAMI, 2016).

Globally, major depressive disorder ranks first as the leading cause of disability (World Health Organization, 2017). Less than five percent of family practice patients are being screened for depression (American Psychiatric Association, 2017). Therefore primary care has been the target of research for depression screening and treatment outcomes (Smithson, S. and Pignone, M., 2018). The World Health Organization Collaborating Center on Patient Safety (WHO) and The Joint Commission (TJC) recognize the necessity of assessing and treating people with

depression (The Joint Commission, 2014; WHO, 2016). In a report published in 2016, TJC supports the use of screening for depression in an effort to identify patients at risk for suicide. Using a screening tool such as the Patient Health Questionnaire, Nine Questions (PHQ-9) is superior to the providers' clinical judgment of risk of depression and suicide (The Joint Commission, February 24, 2016). Traditionally, USPSTF does not recommended routine screening in all patients. In 2009, USPSTF updated the guidelines for primary care family practice providers to routinely perform screening in individuals not already diagnosed with depression but only if follow up collaborative care is available. As of 2016, the USPSTF revised the guidelines for depression screening to recommend that the general population be screened when adequate systems are in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up (Siu and USPSTF, 2016; USPSTF, 2016). There is no recommendation for frequency of screening. The American Academy of Family Physicians suggests a logical time to screen the patient would be during an annual physical (Savoy, M and O'Gurek, D., 2016). Implementing the PHQ-9 and providing a follow-up interview for those patients who are found to have depressive symptoms is one way to improve screening in a primary care practice setting (Savoy and O'Gurek, 2016).

Screening for depression is defined by Thombs, Arthurs, El-Baalbaki, Meijer, Ziegelstein, and Steele (2011) as:

> Depression screening involves the use of screening tools to identify patients who might have depression but who are not seeking treatment for symptoms and whose depression is not otherwise recognized by their physicians so that they can be further assessed and, if appropriate, treated (Thombs, Arthurs, El-Baalbaki, Meijer, Ziegelstein, and Steele, 2011, p. 1).

The work flow in a primary care office influences the way screening for depression is conducted. Depression screening may not be performed when patients present to the office for acute and chronic problems. Staff responsible for providing health screenings are medical assistants, nurse practitioners, physician assistants, and physicians (Savoy & O'Gurek, 2016). A 2005 Cochrane review revealed use of routine screening tools had little impact on the actual recognition of depression. The best way to screen at that time, was to have a clinical assistant routinely administer the depression tool, and those patients having scores indicative of depression symptoms were given to the clinician for review (Gilbody, Sheldon, & House, 2008).

A population health study conducted in Huron County, Ohio, identified 14% of the population had depression, anxiety, or emotional problems. (Huron County Health Study, 2014). Those experiencing two or more weeks in a row feeling sad or hopeless have increased from 8% in 2007, to 10% in 2014. In Huron County, there were twice as many citizens per mental health providers than for the entire state of Ohio. This equates to being one provider per 2,301 residents in Huron County as compared to one provider per 1,051 for the state of Ohio. Ninety percent of suicides in Ohio were residents that had not been diagnosed or treated for depression, mental illness, and or drug addiction (Huron County Health Study, 2014). This evidence can bring about the conclusion that the problem of depression is under recognized in Huron County. The site of this evidence-based practice (EBP) project is a primary care practice affiliated with a rural north central Ohio hospital. The mental health providers within the organization have expanded services to meet the needs of patients as a result of the Huron County, Ohio, health needs assessment (Huron County Health Study, 2014). The primary care providers within the organization have implemented the latest screening recommendations as their standard of care in

response to a call for action. As a result, their role is to add routine screenings to the primary care patients plan of care.

Purpose and Goals

The purpose of this EBP improvement project is to add to the knowledge of depression screening by evaluating for patient satisfaction of the new two-step method in a primary care practice. Surveying patient satisfaction concerning the screening method using the PHQ tools will provide insight into best screening practice in this population. The investigator of this project identified multiple reasons the target population did not seek out a program or service within the county to address symptoms of depression, anxiety, or emotional problems: "had not thought of it, could not afford to go, fear, co-pay/deductible was too high, did not know how to find a program, stigma of seeking mental health services, didn't feel the services they had received were good, other priorities, transportation, could not get to the office or clinic, and other reasons" (Huron County Health Study, 2014, p. 101). At the time of the Huron County Health Study in 2014, the standard of care in the primary care practice chosen for this EBP project was the use of a simple screening method of asking the patient if they are depressed. The newly implemented standard of care is the use of the two-question PHQ (PHQ-2) asking the patient to rate how often they have little interest or pleasure in doing things and how often are they feeling down, depressed, or hopeless (Kroenke, Spitzer, and Williams, 2003). If indicated, the PHQ-2 will be followed immediately by the PHQ-9 as well as a discussion with the provider when depression is indicated to assess for risk factors and relevance of the findings. It has not been determined if the population is satisfied with this method.

PICOT statement. A PICOT statement is a clinical question in a format that is efficient and searchable, providing relevant information. Melnyk and Fineout-Overholt (2015) define the

elements of PICOT: Population of interest (P), Intervention or issue or interest (I), comparison of interest (C), outcome expected (O), and time for intervention to be implemented (T). This format keeps the problem and intervention focused directly on what the clinician wants to know.

The PICOT format was used to explore identification of depression in primary care. For this project, the following question was postulated: In patients 18 through 64 years of age, seeking care in a primary care practice (P) how does the use of a two- step screening and feedback method (I) compared to a one step depression screening method (C) affect patient satisfaction concerning identification of depression (O) over a two week period (T)?

For the purpose of this paper, the significant concepts of the stated PICOT question are defined as the following:

Depression. Is a serious mental health condition resulting in a loss of interest or pleasure in daily activities for more than two weeks (American Psychiatric Association, 2013).

Primary Care. Healthcare provided by a Nurse Practitioner, physician, or Physician Assistant, for persons with any undiagnosed symptom or concern not limited by biological, behavioral, or social origin (AAFP, 2016).

Primary Practice. First point of entry for a patient in the healthcare system and serves as a focal point for all healthcare services. Each patient has a personal provider as well as a back-up provider when the primary provider is not accessible (AAFP, 2016).

Screen. The selection process of individuals to be high risk of a specific disorder requiring preventive action; systematically offered by medical professionals to individuals of a population who have not sought medical care for the disease in question; benefits the individual (Wald, 2008).

Treatment. Medical care provided by a healthcare provider to a patient; may consist of monitoring, pharmacotherapy, or referral to a specialist such as a mental health professional.

Evidence-Based Practice Model Guiding The Project

The Rosswurm and Larrabee (2009) updated version of the Model for Evidence-Based Practice Change was selected to guide project implementation for this EBP project. Using this model provides insight into successful steps in creating a practice change for use in multiple discipline settings. This model design steers assessment, implementation, and evaluation as the needs of the population change.

The *Essentials of Doctoral Education for Advanced Nursing Practice* (2006) delineates competencies of the advanced practice registered nurse (APRN). The essentials that apply to the problem of identifying and treating depression in a family practice setting are II, V, VI, and VII. Essential II is "Organizational and Systems Leadership for Quality Improvement and Systems Thinking". This applies to direct care of primary care patients to improve the quality of depression screening. Essential V is "Health Care Policy for Advocacy in Health Care". The facilitation of improved screening methods, such as the two-step screening strategy, can improve outcomes and mobilize EBP policy changes. Essential VI is "Inter professional Collaboration for Improving Patient and Population Health Outcomes". This competency describes the primary care team leadership and collaboration with mental health professionals to ensure accurate diagnosis and treatment. Essential VII is "Clinical Prevention and Population Health for Improving the Nation's Health". Dedication to promoting health, utilizing prevention strategies and reducing risk to individuals and families is optimal for stable mental health and reducing comorbid conditions (American Association of Colleges of Nursing, 2006). Understanding these competencies of advanced nursing practice in association with Rosswurm and Larrabee's model

assisted the author of this scholarly project to develop the PICOT statement and population choice.

Literature Review

The literature review consisted of searching to identify high quality articles to answer the PICOT question: In patients 18 through 64 years of age, seeking care in a primary care practice (P) how does the use of a two step screening and feedback method (I) compared to a one step depression screening method (C) affect patient satisfaction concerning identification of depression (O) over a two week period (T)?

The Internet was searched for terms relevant to the problem, organized into a summary and critically analyzed for outcomes. Databases included Google Scholar, PubMed, National Guideline Clearinghouse, and Cochrane Library Online. The University of Toledo Mulford Library Online was used to search the Cumulative Index to Nursing and Allied Health Literature (CINAL Plus), MEDLINE, PyschINFO, and Psychology and Behavior Sciences Collection. Boolean phraseology are words use to combine keywords and phrases with controlled vocabularies within the databases mentioned. Boolean connectors are the words AND, OR, and NOT. (Dearholt and Dang, 2012). Also, articles pertaining to the use of the PHQ-9 screening tool were reviewed. The databases searches and data abstraction table are located in Appendix A.

The CINAL Plus database was searched with Boolean connectors using the combination of depression* AND screening* AND primary care with publication dates from 2006-2016. This yielded 658 results. A narrower search date 2014-2016 of those results yielded 153 results. Of the 153, there were four selected articles pertaining to the PICOT question. MEDLINE used the same search phrase and dates 2006-2016 to produce 1,109 articles. Narrowing the search dates to 2014-2016 produced 385 results with four articles selected. PsychINFO was searched using the

same search phrase and dates 2010-2016 with 693 results. Narrowing the dates to 2014-2016, provided 251 results, of those three were selected. Psychology and Behavior Sciences Collection using the dates 2010-2016 yielded 108 results with two chosen. PubMed, a database that searches MEDLINE as well as other articles in PubMed Central not found in MEDLINE, searched dates 2010-2016 using MeSH terms for systematic reviews: (((((primary[All Fields] AND ("Practice (Birm)"[Journal] OR "practice"[All Fields])) AND ("depressive disorder"[MeSH Terms] OR ("depressive"[All Fields] AND "disorder"[All Fields]) OR "depressive disorder"[All Fields] OR "depression"[All Fields] OR "depression"[MeSH Terms])) AND ("diagnosis"[Subheading] OR "diagnosis"[All Fields] OR "screening"[All Fields] OR "mass screening"[MeSH Terms] OR ("mass"[All Fields] AND "screening"[All Fields]) AND PHQ-9[All Fields]) AND ("Syst Rev"[Journal] OR ("systematic"[All Fields] AND "reviews"[All Fields]) OR "systematic reviews"[All Fields])) AND ("2010"[EPubDate] : "2016"[EPubDate]). This search yielded 351 results with six articles.

The National Guideline Clearinghouse (NGC) provides clinical practice guidelines for use by all healthcare professionals, and was searched using the topic phrase, “depression screening in primary care” further narrowed by adding the date, 2016. This had 132 results, with two relevant guidelines, the 2009 and 2016 recommended updates for depression screening in primary practice. The Cochrane Library is the gold standard for EBP and assesses diagnostic test accuracy. The search terms and Boolean phraseology used include “depression AND screening AND primary care”. This search resulted in three articles and one relevant article. Search terms used were “Depression, emotional,” [MeSH Terms] AND “diagnosis”[MeSH]. Google Scholar is a free resource database for peer-reviewed articles across all disciplines. The search terms

using the date 2016: “screening, depression, primary care, PHQ-9, adults” resulted six articles with two articles selected.

Inclusion and Exclusion

Studies were searched using inclusion and exclusion criteria. Articles must have referenced the use of a depression screening method in the primary care setting, composed in English, presented as scholarly articles from academic journals, and publication dates were within 2006 and 2016. The search was narrowed to capture the most recent articles as the recommendation guidelines changed for depression screening in January 2016. Procuring consistent and reproducible outcomes demonstrates a valid search technique. Article exclusion occurred once a review of abstracts was completed. If the abstract was unclear, the entire reference was reviewed for pertinence to the PICOT statement.

A total of 22 research articles and two guidelines were relevant in answering the PICOT question. Of those studies, 11 articles were selected for critical analysis. The articles are organized into a hierarchal structure. Those towards the top of the order, systematic reviews or meta-analyses of randomized controlled trials (RCTs), have the most robust validity and reliability of design and outcomes (Melnyk & Fineout-Overholt, 2015). Those toward the bottom of the order, qualitative studies or opinion, have the least likelihood to have robust validity and reliability (Melnyk & Fineout-Overholt, 2015). Systematic reviews, clinical practice guidelines based on RCTs, meta-analyses, RCTs, and cohort studies were chosen and critically analyzed to answer the PICOT question. The Rating system for the Hierarchy of Evidence is listed in Appendix B.

Appraisal and Synthesis

Appraisal and synthesis of the literature is the process of evaluating for validity, reliability, and applicability as it relates to the PICOT question (Melnyk & Fineout-Overholt, 2015). Rapid critical appraisal creates value between literature findings and practical application by examining trustworthiness and relevance to a question. Rapid critical appraisal question forms for each level of evidence guides the researcher to determine the level of evidence of each article, results of the intervention or treatment effects with a statistical level of significance, and effect the findings have on clinical practice (Melnyk & Fineout-Overholt, 2015). An example of a rapid critical appraisal question form is located in Appendix C. Once the rapid critical appraisal is completed, a hierarchal numeral can be assigned to the article. The higher the rank, combined with a high grade of quality, determines the level of confidence that the quality is high and relevant to the PICOT question (Melnyk & Fineout-Overholt, 2015). It is best for evidence to have valid and reliable broad application to the clinical question (Melnyk & Fineout-Overholt, 2015). A critical appraisal of the literature is performed for each article identifying the conceptual framework, study design, sample setting, major independent and dependent variables, outcome measures, data analysis, overall findings, and quality of the evidence with a conclusion statement. The critical appraisal of literature is presented in Appendix D.

The quality is determined once the evidence has been critically analyzed and assigned a hierarchal level. The Johns Hopkins Nursing Evidence-Based Practice Model Evidence Level and Quality Guide (JHNEBP) is one way to determine quality. Ratings are assigned from high quality to low quality, or A through C, respectively. Quality grades of A, B, or C are assigned to each level of evidence defined as high, good, or low quality or if the article has major flaws. The quality guide seeks to determine consistency, generalizability of results, sample size sufficiency,

adequate control, definitive conclusions, and consistent recommendations (Dearholt & Dang, 2012). Evidence for this PICOT question was graded and synthesized using the JHNEBP Quality Guide (©The Johns Hopkins Hospital/Johns Hopkins University, Dearholt & Dang, 2012). The JHNEBP evidence level and quality guide is provided in Appendix E.

The JHNEBP Synthesis and Recommendations tool is used to assemble the results of the critical appraisal and the quality guide to answer the PICOT question. The synthesis and recommendations tool organize the total number of sources for each level of evidence with a summary of overall quality of each article into a table. Final recommendations, based on the strength of evidence, are then determined. The JHNEBP Synthesis and Recommendations tool is located in Appendix F. The chosen literature was displayed in a table that compared and contrasted the articles by the level of evidence, sample size, target population and if the study's outcome supported the use of a 2-step screening method. This is known as a synthesis table. The table is provided in Appendix G.

The Appraisal of Guidelines for Research and Evaluation (AGREE) instrument is one way to critically analyze practice guideline development and the quality of the recommendation set forth from the clinical practice guideline. The AGREE II is the current version of the assessment tool and comprised into 23 elements categorized into six domains. The six domains are: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence (Agree, 2014). Applying the AGREE II analysis allows the user to make a final judgment on the quality of the clinical practice guidelines. The Agree II completed for this project is presented in Appendix H.

Clinical practice guidelines are based on evidence developed from best practice outcomes. Historically, screening for depression in the general population was not

recommended. Evidence that screening for depression alone is not reliable or reproducible unless there was a previous history of depression diagnosis and treatment. (Joffres et. al., 2013). New supporting evidence evolved, demonstrating depression screening programs are effective when trained staff assess and collaborate with the primary provider to engage in a multidiscipline treatment approach (O'Connor, Whitlock, Beil, & Gaynes, 2009).

The United States Preventative Services Task Force (USPSTF) updated the 2009 recommendation in January of 2016. This recommendation is to screen for depression in the general adult population in a primary care setting when there is a collaborative referral with mental health professionals in place. The guidelines demonstrate the effect of a two-step screening method. The first step is the screening using a high quality and reliable screening tool. The second step is based on the findings of the screening tool. If warranted, the provider determines risk factors, diagnosis, treatment, and appropriate follow-up with referral to mental health professionals.

Clinicians in primary care may not be accurately selecting which patients should be screened (Thombs et. al., 2011). The risk of bias from inclusion in a screening study demonstrates that patients who already have a diagnosis of or are undergoing treatment for depression, may not be appropriately identified. Therefore, the number of patients who benefit from screening may be skewed. A screening tool should be given to all patients, regardless of presenting problem, and followed with a second step to determine relevance of findings (Thombs et. al., 2011).

It is understood that using a highly specific tool to screen for depression is amenable for use by clinicians. A meta-analysis for heterogeneity of depression screening tools found that depression-specific tools influenced clinicians greater than less-specific tools. Therefore, if the

tool is reliable, valid, and reproducible, as well as easy to interpret due to a high level of specificity, then the clinician is more likely to perform depression screening (Gilbody, Sheldon, & House, 2008).

Improving clinician awareness of the recommendation to screen for depression did not alone improve identification of depression. Romera et. al. (2013) assessed systematic depression screening in high-risk patients attending primary care in a pragmatic cluster randomized clinical trial. In a public healthcare system in Spain, 3,737 patients were screened by 66 primary care providers, who were randomized into an intervention or control group. The intervention group of physicians received depression-screening training and then screened patients for six months. The control group of physicians practiced their normal routine. Results showed no significant differences in screening practices between the two groups after six months for recognition or treatment (Romera et. al., 2013).

Under-detection of individuals with depressive symptoms is not an indicator of lack of training or education of the provider. The patient may be unwilling to accept diagnosis and or treatment (Baas, et. al., 2009). A prospective cohort study conducted by Baas et. al. (2009) in a general medical practice, screened for depression in high-risk patients. A selective screening of 2,005 patients resulted in 780 participants. Patients were grouped according to having mental health diagnoses, unexplained somatic complaints, and those with regular visits with their general practitioner. After completing the screening, there were 71 patients with major depressive disorder, 36 with previous treatment for depression, 14 refusing treatment for depression, and four who failed to attend the appointment. In the end, results included 17 new patients identified and treated for major depressive disorder out of the initial 2,005 selected for screening (Baas, et. al., 2009).

The purpose of using a screening tool is to provide the clinician with subjective information from the patient (Substance Abuse and Mental Health Services Administration [SAMHSA], 2018). The clinician is able to make a clinical judgment to diagnose a state of depression. There are many interdisciplinary screening tools used internationally for the identification of depression. Patient Health Questionnaire (PHQ) tools are useful instruments to identify depression in primary care. Any score above the common threshold of ten, needs additional follow-up, as the current threshold tends to under-detect depressive symptoms. The 9 Question-Patient Health Questionnaire (PHQ-9) has been determined as a highly reliable, reproducible, and valid screening tool (Mitchell, Yadegarfer, Gill, & Stubbs, 2016). The PHQ-9 can also be used to measure severity of depression. In a general population, the normal cut-off score is equal to or greater than ten. At ten, the sensitivity is (.93) and the specificity is (.52) and has been established as adequate. Using a cut-off score of equal to or greater than 13 demonstrated sensitivity of (.83) and specificity of (.72). The PHQ-9 tool assesses two categories of symptoms, cognitive-affective symptoms (feeling down and hopeless) and somatic symptoms (feeling tired, little energy, poor appetite, or overeating). Score results were consistent in both men and women (Beard, Hsu, Rifkin, Busch, & Bjorgvinsson, 2016). Zuithoff et. al. (2010) is a cross-sectional analysis in a larger cohort study (PREDICT-NL), reviewing the reliability, construct validity and accuracy of the PHQ-9 and PHQ-2 to detect major depressive disorder in primary care. Patients in the waiting room, n=1,338, were invited to participate regardless of their presenting problem. They completed a depression specific evaluation tool, the PHQ-9, and mailed it back. This process was again repeated in 14 days. All participants were called on the telephone and given an abbreviated PHQ-9 using only two questions, the PHQ-2. If there was a response of yes to either question, a full depression evaluation was done. Results for the PHQ-9

with a cut-score of 10 showed good internal consistency and test-retest reliability. Those participants with severe depressive symptoms were also associated with having a poorer functional status, increased number of sick days, and increased visits to the general practice.

The classical test theory is a standard method for evaluating rating scales and is the construct premise of the PHQ-9 tool (Horton & Perry, 2016). However, construct assumptions are unable to be formally validated and tested, treats ordinal data as interval level, and formats the evaluations of rating scales as sample dependent. This is a weakness of the PHQ-9 construct premise. Horton and Perry, 2016, applied a new method of psychometric methodology, Rasch analysis, to a PHQ-9 sample of 767 patients with depression. A Rasch analysis formally tests an outcome scale against a mathematical model of measurement invoking a formal measurement. The intention of this study is to show that cut-scores are important based on the clinical question and the desired population. Therefore, as a screening tool the PHQ-9 is reliable, but is not to be used solely for individual outcome evaluation (Horton & Perry, 2016).

Lastly, as the PHQ-9 is not for the sole purpose of outcome evaluation, Picardi et al. (2016) tested the effectiveness of a depression screening program to see if outcomes could be improved and if so, which features of the tool contribute to outcome success. A randomized controlled trial screened participants using two self-administered tools, The Primary Care Screener for Affective Disorders (PC-SAD) and an abbreviated version of the World Health Organization Quality of Life Scale (WHOQOL-Bref). The intervention group consisted of those who screened positive with no suicidal ideation, n=115, and were given their results as well as the offer of a free psychiatric evaluation. The control group, n=59, received no feedback from the screen. After three months, all patients received a telephone interview and were re-administered the screening tools. Severity of depression and quality of life improved for both groups. There

was a significant positive effect by the intervention on the severity of symptoms. The characteristic of the patient perspective is key to success of screening programs.

Summary of the Evidence

Supporting evidence from multiple peer-reviewed research articles support screening in a primary practice patient population. Romera et. al. (2013) and Joffres et. al. (2013) were identified as not supportive of the PICOT statement in the synthesis table located in Appendix G. In 2013, evidence had yet to be established in support of broad screening when additional resources were available for appropriate risk assessment, diagnosis, treatment, and or referral for psychotherapy. Currently, screening should occur for all adult patients when there are resources in place to provide risk assessment, diagnosis, treatment, and or psychotherapy (Baas et. al. 2009; Joffres et. al., 2013; O'Connor, Whitlock, Beil, & Gaynes, 2009; Picardi et al. 2016; Siu & USPSTF, 2016; Thombs et. al., 2011). Evidence findings support the use of a highly specific screening tool rather than the clinical judgment of the provider to determine which patients have depressive symptoms (Gilbody, Sheldon, & House, 2008; Romera et. al., 2013; Thombs et. al., 2011). The PHQ screening tools are appropriate for use in primary care as they are valid, reliable, and reproducible (Beard, Hsu, Rifkin, Busch, & Bjorgvinsson, 2016; Horton & Perry, 2016; Mitchell, Yadegarfer, Gill, & Stubbs, 2016; Zuithoff et. al., 2010) It is imperative to understand the patients' perspective of depression as well as their willingness to accept diagnosis or treatment (Gilbody, Sheldon, & House, 2008; O'Connor, Whitlock, Beil, & Gaynes, 2009; Romera et. al., 2013).

Recommendation for Practice

Screening for depression in adults attending primary care is recommended by the USPSTF. The recommendation is to screen in the general population. Screening should be

performed when there are adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up (Siu & USPSTF, 2016). Monitoring for common risk factors includes identifying disability, poor health status, complicated grief, insomnia, loneliness, and a history of depression. Appropriate screening tests that can be used include the PHQ-2 and the PHQ-9. If the PHQ-9 indicates depressive symptoms are present, it must be followed by a second step to investigate comorbid contributory conditions, severity of depression symptoms, and alternate diagnoses and medical conditions. There is no specific time as to when screening should be completed. A pragmatic approach is recommended to consider risk factors as well as opportunity to screen throughout the care of the patient. Treatment can consist of monitoring, pharmacotherapy with antidepressants, and or psychotherapy.

The best approach is a multidisciplinary approach using case-managers to coordinate care between patients, primary providers, and mental health professionals. The strength of the recommendation is represented in Table 1.

This EBP project surveyed for patient satisfaction of a newly implemented 2-step screening method using the PHQ-2 and the PHQ-9 depression tools in a primary practice setting. The second step was to discuss identified symptoms of depression, risk factors, determine diagnosis, and either monitor, provide treatment with medications, and or refer to mental health professionals

Table 1.

Strength of Recommendation

Recommendation	Strength of Evidence for Recommendation	References in Support of Recommendation
1. Screening adults for depression in primary care is recommended. Screening should be performed when there are adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up	Strong	Beard et al., Gilbody et al, Horton & Perry, Mitchell et al., O'Connor et al, Picardi et al., Siu et al, Thombs et al, Zuithoff et al, Joffres et al., USPSTF

Implementation and Evaluation Plan

Setting and Population.

This EBP project was completed in a primary practice setting in Huron County, Ohio, affiliated with a rural community hospital, Fisher Titus Medical Center (FTMC). A cross-sectional design describes the random selection of subjects who were seen over a two-week period of time, who were not previously unaware of the screening survey, and who verbally agreed to participate in the survey. The population consists of patients ages 18-64. Patients under the age of 18 were not screened using the PHQ-9 due to different needs by this age group. There are other tools that more appropriately reflect the emotional state of children and adolescents. Patients 65 years of age and older are screened using the PHQ-9, however they are screened during their annual wellness visits under the Medicare guidelines (U.S. Centers for Medicare and Medicaid Services [CMS], 2017). The researcher's intention was to evaluate patient satisfaction of the improved method of identification of depression in the selected county. Therefore, this project broadly screened the selected population in order to capture not only the patients who

attend the office regularly and those who do not. In this office, primary care is delivered by physicians, nurse practitioners, and physician assistants. Registered nurses, licensed practical nurses, certified medical assistants, and non-medically trained staff members, provide support. Permission and support from the hospital agency was granted for implementation of this project.

Stakeholders

The key facilitators of change are the stakeholders (Melnyk & Fineout-Overholt, 2015). The stakeholders identified in Table 2 are the multidisciplinary team members: primary care providers, support staff, mental health services, case management, patients, and the local community. Those involved in the depression screening process, diagnosis, and resources for treatment provide valuable insight into a collaborative treatment plan.

Table 2.

Identified Stakeholders

Stakeholders	Rational for Involvement
Primary Care Providers (physicians, nurse practitioners, physician assistants)	Providers evaluate the depression screening and assess the patient to determine need for referral to mental health services
Clinical Support Staff	Support staff can administer depression screenings, communicates with providers and answers patient questions.
Mental Health Services	Mental health services accept referred patients for support of diagnosis, treatment, and offer counseling.
Case Management	Organize and manage resources for patient to sustain treatment plan and follow up.
Primary Care Patients	Patients need to desire screening, communicate with provider about positive screening test scores, and agree to referral and or treatment
Local Community	Community residents need to partake in the screening, utilize resources and referrals, and reduce stigma of mental health diagnoses.

Anticipated Barriers and Facilitators to Implementation

Anticipated Barriers. Barriers to implementation of the EBP project are to be anticipated. Patients attending primary care may not be expecting to be screened for a mental health problem and may resist participating. Fear of the social stigma of depression may interfere with patient responses to screening and discussion. Time constraints may limit providers' opportunity to screen during regular appointments for discussion of co-morbid conditions and treatment. Clinical support staff may feel overwhelmed with multiple screenings and demanding patient workload. Organizational resistance related to time constraints conducting additional screenings may arise. Lack of enthusiasm by providers to discuss depression with patients could also occur. Resistance for patients to accept treatment can occur due to subsequent monitoring practices, social stigma, access to care, disruption of occupational and social routine, and cost burden to the patient. Pharmacotherapy can cause potential adverse reactions due to interactions of medication and strained metabolic processes. Providers may lack knowledge for screening methods and an accurate method to diagnose depression. Additional barriers specific to EBP include a misunderstanding of concepts and relative values as well as a limited number of mentors and champions (Melnyk & Fineout-Overholt, 2015). Barriers to implementation are presented in Table 3.

Barriers were successfully overcome during implementation of the project. Patients did report feeling uncertain when participating due to the element of surprise. The researcher successfully alleviated the participant's unease with discussion of the project's purpose and offering the patient the opportunity to decline participation, while answering the participant's questions. The researcher providing the screenings did not feel limited for time during the implementation period. The clinical support staff working in the environment of the researcher

did not report interference in their normal workload. There was no organizational resistance or unknown hidden costs identified. The researcher did not express any lack of enthusiasm during the implementation of the survey and discussion with the patient.

Anticipated Facilitators. There are many facilitators toward implementation of a two-step strategy. The use of streamlining a screening process and organized use of time and resources in a multidisciplinary approach identifies primary care providers as the anticipated chief facilitators. Organizational administrators have encouraged EBP changes for the purpose of improved efficiency and distribution of resources. Documentation can be a facilitator because it provides concise data for the project with supporting evidence. Mental health providers encourage improved accuracy of depression identification, diagnosis, treatment, and referral processes to improve their efficient use of time. Community leaders desire to improve the state of mental health in an attempt to minimize drug abuse, homelessness, crime, and other problems associated with untreated mental health conditions. Facilitators to implementation are displayed in Table 4.

Outcome Measures

The outcome sought in this project is to provide a baseline for practice change using a two-step method that is satisfactory to patients. Methods for evaluation utilize the PHQ-9 evaluation tool, the PHQ-9 interpretation tool, and a participant evaluation form presented as a self-report survey. The current method for identifying depression is done by using the PHQ-2 and if indicated, followed by a PHQ-9. The PHQ-2 asks the patient to rate how often they have little interest or pleasure in doing things and how often are they feeling down, depressed, or hopeless (Kroenke, Spitzer, and Williams, 2003). The result is scored zero to six with a cut point of three. Exceeding the threshold of three generates the PHQ-9 form for completion.

Table 3.

Barriers to Implementation

Barrier	Rational
Knowledge and Skills of:	Providers may lack skills to evaluate the depression screening, assess the patient to determine need for referral to mental health services, and lack skills to treat depression.
Primary Providers (physicians, nurse practitioners, physician assistants)	
Clinical Support Staff	Staff administering the screening may lack ability to grade the screening; may not understand to notify provider of positive screens
Mental Health Services	May not be aware that referrals may increase, affecting their ability to timely accommodate
Case Management	May not have an updated list of resources for patient to sustain treatment plan and follow up.
Local Community	Community residents may not know the impact that screening and utilizing resources to reduce the stigma of mental health diagnoses has on social hardships
Organizational Influences on:	
Mental Health Services	Lack of mental health services
Clinical Support Staff	Staff may not feel they have time to screen
Documentation	The electronic health record (EHR) may not have the chosen screening tool
Organization Management	Resistance to implement change May not support the implementation of the project
Culture of: Organization	Members of the organization such as providers and staff, may not have empathy skills to assess sensitive topics such as depression.
Attitude of: Primary Providers	Lack of agreement with use of screening tool and or shared decision-making with mental health services; lack of understanding evidence that depression screening and treatment is a need specific to the community.
Resources of: Time	There might not be enough time allotted in the patient appointment to perform the screening tool

An example of the PHQ-9 Patient Depression Questionnaire and a data collection tool are displayed in Appendices I and J, respectively. The patient satisfaction survey is displayed in Appendix K. The patient education handout is displayed in Appendix L. With the exception of the PHQ-9 tools, the project related products have been developed by the author of the paper under the guidance of the project chairperson. Outcomes of the data collection tool identify the number of participants, number of PHQ-9s completed, PHQ-9 scores, number of those diagnosed with depression using an International Classification of Diseases 10th revision (ICD-10) code, the plan of care, and patient satisfaction (WHO, 2017).

Cost Analysis

The cost associated with identifying depression in primary care is primarily associated with the development of the project. The primary provider implementing the project is also the author of this project. As data was collected during normal primary practice work hours, no additional costs were involved in this project in order to implement the intervention. However, a cost analysis has been done to account for salary of primary providers as they would conduct the screening as well as related components. Table 5 provides a demonstration of costs.

Implementation Process

Method. The Model for Evidence-Based Practice Change guides the evidence-based project. Step one is to assess the need for practice change. Step two is locating the best evidence. Step three critically analyzes the evidence. Step four is to design a practice change. Step five is to implement and evaluate the practice change. Step six is integrating and maintaining the practice change (Larrabee, 2009).

Table 4.

Facilitators to Implementation

Facilitator	Rational
Primary Providers (physicians, nurse practitioners, physician assistants)	Streamline screening process in an already burdened system
Mental Health Services	Organizes referral management and improves efficiency for best use of time and resources.
Case Management	Intercommunication with the needs of the population by providing a measurement for monitoring symptoms and disease state.
Local Community	This population has responded that they have under-detected depression symptoms.
Organizational Influences Mental Health Services	Expansion of services to meet the need of the community
Documentation	Screening tool provides concise data on urgency of project and supporting evidence. Deming's PDSA model leads to adoption of practice change and approval by users and organization.
Resources of Time	Strategize time management during project implementation; PHQ-9 provides efficiency.

Step 1. Assess the need for change in practice. The author assessed the need for change based on the 2014 Population Health Survey conducted in the local population. The problem was identified through a self-survey distributed by the county health department. Respondents answered questions about whether or not they had under-recognized and or under-treated symptoms of depression. The outcome demonstrated a 50% increase in those identified with depressive symptoms as compared to the state of Ohio's statistics.

Step 2. Locate the best evidence. Locating the best evidence began with the composition of a clinical question or PICOT statement: In patients 18-64 years of age seeking care in a primary care practice (P) how does the use of a two-step screening and feedback method (I) compared to a one step depression screening method (C) affect patient satisfaction concerning identification of depression and treatment intervention (O) over a two week period of time (T)? A literature search was completed using Google Scholar, PubMed, National Guideline Clearinghouse, and the Cochrane Library Online. The University of Toledo Mulford Library Online was used to search the Cumulative Index to Nursing and Allied Health Literature (CINAL Plus), MEDLINE, PyschINFO, and Psychology and Behavior Sciences Collection.

Step 3. Critically analyze the evidence. Critical analysis of the evidence was performed through critical appraisal and grading the literature. Evidence synthesis discovered support in favor of the recommendation to screen in the general adult public when there are resources in place to confirm diagnosis, provide treatment, and or refer to mental health professionals. The PHQ-9 screening tool is an appropriate choice to use based on reliability, validity, and applicability, with strong specificity and sensitivity in the general adult population. The sensitivity and specificity can change based on special populations. Cut-scores are manipulated to accommodate the special populations.

Step 4. Design the practice change. Currently, practice in the proposed setting is to ask the patient if they are depressed in the form of the PHQ-2. The change implemented a two-step method. The first step is having the patient complete the screening using the standard of care PHQ-2. If the score exceeds the cut point of three, then the patient completes the PHQ-9. The second step is to discuss positive symptoms of depression with the patient to determine relevancy and or a diagnosis. The diagnosis of depression would then warrant a treatment plan. The plan

consists of either monitoring symptoms, providing pharmacotherapy with antidepressants, and or referral to mental health professionals.

Table 5.

Preliminary Cost Analysis

Project Expenses	Cost Relevant to Implementation and Risk as Appropriate	Potential Savings Related to Implementation, Return on Investment (Based on Identified Outcomes)	Determined Cost Figures
Paper, toner, office supplies	$75.00	$0	$75.00
Project Stage 1 (during office visit)	40 provider hours, billed through office visit. Average billed visit code 99214= $160.00, 3 patients per hour.	Generates a response to the community request, increasing return patient visits.	40 hours paid per salary, $2,300. $19,200 billed, average 40% collected = $7,680 income
Project Stage 2 (provider hours necessary for implementation)	10 provider hours, not billed (25% of patients predicted to progress to Stage 2)	Generates a response to the community request, increasing return patient visits	10 hours unpaid, worth $580.
Follow up appointments for patients who need monitoring, treatment, or referral	10 provider hours, billed through office visit. Average billed visit code 99213=$130.00, 3 patients per hour	Generates a response to the community request, increasing return patient visits	10 hours paid per salary, $580. $3,900 billed, average 40% collected = $1,560 income
Total Expense			$4,135
Total potential income, before expenses			$9,240

Step 5. Implement and evaluate the practice change. Implementation of this project was conducted December 18 through December 29, 2017. The outcomes of the project were evaluated January through February of 2018. The process to improve identification of depression was analyzed based on patient satisfaction of the new method. Conclusions and future recommendations were synthesized once data analysis was completed. The facilitation of the

practice change was accomplished by using an application of Deming's PDSA model, The Model for Improvement (Langley et al., 2009; AHRQ, 2017).

Step 6. Integrate and maintain the change in practice. Communicating the recommendation to the stakeholders was done in order to integrate the change into the organization's standard of practice. Quality reviews for monitoring the process and evaluating outcomes were applied. Dissemination of the project results finalizes the results of the EBP project. A final defense and publication concluded the process.

IRB Review Process. The Institutional Review Board (IRB) at The University of Toledo approved this EBP project prior to implementation as a well-designed project that maintained responsible activities involving human subjects. The University of Toledo has established the Human Research Protection Program (HRPP), serving as a guide to the researcher, to assure basic responsibilities have been met concerning human subjects. The HRPP serves as support for administrators associated with Biomedical and Social Behavioral and Educational Institutional Review Boards. The University of Toledo IRB approval letter is located in Appendix M.

The process of application and review utilized an IRB template for expedited review. An Adult Research Subject Informed Consent Form for verbal consent and an Information Sheet was required from each participant before participating in this EBP project. This EBP project was approved from 12/13/2017 through 12/12/2018. The agency that served as the site of this EBP project granted permission for the project to be conducted in the primary practice office, the name of the agency may be identified in the final report, request a conference when project is complete to discuss findings, and names of administrative or consultative personnel in the

agency be withheld. The Adult Research Subject Informed Consent Form and the Adult Research Subject Information Sheet is located in Appendix M.

Human Subjects Concern. Protection of human subjects is a priority and essential in patients being evaluated for mental health concerns, as this is a vulnerable population group. Strict maintenance of privacy and confidentiality was observed throughout the process of the PHQ-9 evaluation tool, the PHQ-9 interpretation tool, and a participant satisfaction self-report survey. Implementing a two-step depression identification strategy required Institutional Review Board (IRB) approval. A data safety and monitoring plan was submitted and approved in December 2017 prior to implementation.

Timeline for Implementation. Planning for implementation serves as the timeline for implementation, and was constructed based on The Model for Evidence-Based Change. All six steps are outlined with specific elements providing the timeline of the project components. The timeline is provided in Table 6.

Evaluation Process

Data Collection. The PHQ-9 screening tool was used to collect data. A second tool to organize patient data has been developed by the author of this project under the guidance of the project chairperson. Data collected included date of participation, age, race, gender, whether or not the person completed the PHQ-9, PHQ-9 screening score, whether or not there was a follow up discussion with the provider, clinical diagnosis, plan of care to be followed, completion of patient satisfaction survey, and if the patient received an educational handout after the screening process.

Table 6.

Planning for Implementation

Planning for Implementation	Timeline
Step 1: Assess the need for change in practice	
Identify problem: Population health survey identified need to detect depression in primary care. PICOT developed.	September 2015
Include stakeholders	March 2016
Collect internal data and about current practice and compare external data with internal data	November 2016
Link problem, interventions, and outcomes	March 2016
Step 2: Locate the best evidence	
Identify types and sources of evidence	April 2016
Review clinical concepts	April 2016
Plan the search	April 2016
Conduct the search	April 2016
Step 3: Critically analyze the evidence	
Critically appraise and weigh the evidence	September 2016
Synthesize the best evidence	October 2016
Assess feasibility, benefits, and risks of new practice	November 2016
Step 4: Design practice change	
Define proposed change, defend proposal, IRB application.	January 2017
Identify needed resources	March 2017
Design the evaluation of the pilot	April 2017
Design the implementation plan	April 2017
Create patient satisfaction survey	April 2017
Step 5: Implement and evaluate change in practice	
Implement project	December 2017
Evaluate processes, outcomes, and costs	January 2018
Develop conclusions and recommendations	February 2018
Step 6: Integrate and maintain change in practice	
Communicate recommended change to stakeholders	April 2018
Integrate into standards of practice	April 2018
Monitor process and outcomes periodically	May 2018
Final defense of project and Graduation	May 2018

Outcomes of project

Presentation of findings

Descriptive statistics were used to organize and convey understanding of data (Kim, M. and Mallory, C., 2014). There were 86 participants chosen by simple randomization. The patients scheduled their appointments without knowing the project was being conducted. The independent variable was the screening process. The dependent variable was the patient satisfaction survey. Participants were described as 81.4% female *n*=70 and 18.6% male *n*=16.

Table 7.

Characteristics of the study participants (N=86)

Gender		Median Age	Race	
Female	*n*=70 (81.4%)	42.67	Caucasian	*n*=82 (95.3%)
Male	*n*=16 (18.6%)		Hispanic	*n*=2 (2.3%)
			Other Hispanic	*n*=1 (1.2%)
			Asian	*n*=1 (1.2%)

Cultural diversity was mostly Caucasian, *n*=82, 95.3%, followed by Hispanic *n*=2, 2.3%, Other Hispanic *n*=1 1.2%, and Asian *n*=1, 1.2%. Participants ranged in ages from 19-64. Table 7 depicts characteristics of the study participants.

Patient Satisfaction

The patient satisfaction survey consisted of six questions designed to assess why patients attended the office, if they felt comfortable answering the depression screening, if they felt comfortable answering the screening honestly, if they were aware that the symptoms mentioned in the screening were symptoms of depression, if they felt the researcher administering the screening cared about their responses, and whether or not they were satisfied with the screening process. Descriptive analysis determined: attendance to have a regular checkup or physical was

most common 70.9% of the time *n*=61; Acute visits were second most common with 15.1% *n*=13; Visits for mental health purposes were third, *n*=9, 10.5%; Hospital follow-ups were least common occurring 3.5% of the time, *n*=3. The number of participants who felt comfortable answering the questions were *n*=82 or 95.3%. Those who felt they could be honest with their answers were 100% *n*=86. Most of the participants were aware that the symptoms were associated with depression with 80.2% *n*=69. Those who were not aware 10.5% *n*=9 and 9.3% *n*=8 were unsure. Those participants who felt the researcher cared about their answers were 97.7% *n*=84 as compared to those who felt the researcher didn't care, 2.3% *n*=2. Overall, the number of participants who answered, "yes that they were satisfied with the way their screening was conducted" was 97.7% *n*= 84, and no 2.3% *n*=2. Table 8 depicts the patient satisfaction survey responses.

Table 8.

Patient satisfaction survey responses (N=86)

Question	Answer options	Results
Why did you come into the office today?	Check up or physical	*n*=61 (70.9%)
	Acute illness	*n*=13 (15.1%)
	Mental health	*n*=9 (10.5%)
	Hospital follow-up	*n*=3 (3.5%)
Did you feel comfortable answering the depression screening?	Yes	*n*=82 (95.3%)
	No	*n*=4 (4.7%)
Did you feel comfortable completing the form honestly?	Yes	*n*=86 (100%)
	No	*n*=0
Were you aware that the questions you answered on the screening form could all be symptoms of depression?	Yes	*n*=69 (80.2%)
	No	*n*=9 (10.5%)
	Unsure	*n*=8 (9.3%)
In your opinion, would you say that the people involved with your depression screening cared about your responses?	Yes	*n*=84 (97.7%)
	No	*n*=2 (2.3%)
Are you satisfied with the way this depression screening was completed?	Yes	*n*=84 (97.7%)
	No	*n*=2 (2.3%)

The collection tool tallied data in order to monitor for consistency of incorporating all elements of this project. Of the 86 participants, 78.3% *n*=63 did not report symptoms of depression to generate a PHQ-9 assessment. Those who completed a PHQ-9 screening totaled 26.7% *n*=23. Almost all of the participants, *n*=83 96.5%, discussed their results with the researcher. All of the patients received a patient education handout and completed a satisfaction survey. If the participants did not report symptoms of depression or it was determined that their symptoms were not indicative of depression, they were encouraged to continue monitoring for new symptoms in the future, equaling 81.4% *n*=70. There were 8.2% *n*=7 advised to continue monitoring while continuing current depression treatment; 3.5% *n*=3 were referred to a mental health provider; and 7% *n*=6 were treated by their primary care provider and referred to a mental health provider. There were 19.8% *n*=17 who had per history or had been diagnosed with depression based on the two-step screening process. Table 9 depicts the data collection categories and results.

Discussion

This EBP project provides insight into patient satisfaction of a two-step depression screening in a primary care setting, providing adequate systems are in place to ensure accurate diagnosis, treatment, and follow-up. All participants allowed the researcher to perform the screening and completed the survey. Nearly all of the patients reported satisfaction with the two-step method.

The National Ambulatory Medical Care Survey: 2010 Summary Tables indicate only 4% of primary care patients in the United States are being screened for depression in primary care settings (Akincigil, A., 2017). The USPSTF has undergone criticism for their recommendation to screen for depression.

Table 9.

Data collection categories and results. (N=86)

Category	Variable	Results
Was there a PHQ-9 completed?	Yes	*n*=23 (26.7%)
	No	*n*=63 (73.3%)
PHQ-9 score	0	*n*=61 (70.9%)
	1-4	*n*=5 (5.9%)
	5-9	*n*=8 (9.5%)
	10-14	*n*=7 (8.2%)
	15-19	*n*=2 (2.4%)
	20-27	*n*=3 (3.1%)
Discussion with provider.	Yes	*n*=83 (96.5%)
	No	*n*=3 (3.5%)
Diagnosed with depression today or previously?	Yes	*n*=17 (19.8%)
	No	*n*=69 (80.2%)
Plan of care	Monitor	*n*=70 (81.4%)
	Monitor and Treat	*n*=7 (8.2%)
	Refer	*n*=3 (3.5%)
	Treat and Refer	*n*=6 (7%)
Patient satisfaction survey completed?	Yes	*n*=86 (100%)
	No	*n*=0
Educational handout given to patient	Yes	*n*=86 (100%)
	No	*n*=0

The critics suggest that evidence to support screening is not rigorous enough due to not having RCTs that compare screening for depression against not screening for depression. Supporters defending the USPSTF declare that evidence used to support recommendations is peer-reviewed, which reduces bias and addresses methodological limitations (Lenzer, J., 2017). Systematic reviews are outsourced by the USPSTF to evidence-based practice centers, which could increase risk for indirect conflicts of interest. Therefore, emphasis should be placed on independent clinical researchers using evidence-based data in their quest to improve quality of care (Lenzer, J., 2017).

This EBP project has been successful. Weaknesses that have emerged include the limitation of surveying over a two-week period of time. Better representation of the population affected by this screening process could have been identified in a larger sample size. At the time of the population health study in 2014, there were 43,128 persons age 18 and older living in Huron County, Ohio. A sample size was determined by power analysis using 95% confidence level totaling 381 adults (Huron County Health Partners, 2014). A chart review for patient history of previous screening or problems with depression may have provided additional comprehension of survey responses. Strengths of this project include patient familiarity with primary care practice, the brevity of the survey explanation and process, the researcher with mastery of the information performed the process, and there were adequate systems in place to ensure accurate diagnosis, treatment, and follow-up as needed.

Altering the cut-score threshold for diagnosis, treatment or referral accommodated vulnerable members in the target population. Those classified as vulnerable include intellectually disabled, those whose primary language is not English, the hard of hearing, visually impaired, or those with impaired thought processes. When it is deemed that a patient may not be able to provide reliable feedback, the provider should take extra measures to assure the patient is cognizant of the intention of the screening questions. The researcher who provided the screening was able to identify vulnerable participants and took extra time to assure valid and reliable feedback.

The researcher who administered the survey also served as a primary care provider in the primary care practice where the project was implemented, thereby raising the concern for conflict of interest or bias. The researcher had familiarity with some participants and had screened them for depression previously. Patients may have reported improved comfort levels or

may have been more likely to report that the researcher cared about their answers. To limit bias and conflict of interest, the researcher was more inclined to refer for treatment if deemed necessary. There were seven participants who were treated by the researcher with pharmacotherapy due to the request of the participant and due to necessitating prompt treatment. It would have been unethical to withhold treatment due to the proceeding project and it would have been unfair and unsafe to ask another primary provider in the office to prescribe without doing their own assessment. There is a waiting period for referrals of approximately 3 months to access mental health professionals for pharmacotherapy without emergent circumstances.

Deming's Plan-Do-Study-Act (PDSA) change theory is an effective change management model for performance improvement adopted and approved by this researcher and the organization. The Model for Improvement is an application of PDSA and is an ideal cycle for continuous improvement (Langley et al., 2009). This model was chosen to integrate findings of this project into clinical practice of this primary care office. The outcome of this project determined that patients were satisfied with the new method of screening. The "plan" was to improve identification of depression in a primary care setting. The "do" implemented the two-step screening method. "Study" occurred by surveying a sample of the population for satisfaction of the new screening method. Finally, "act" is the action of changing clinical practice to address the initial problem. The researcher of this project was invited to become a member of the Medical Care Executive Council for the purpose of quality improvement and guiding best practice for the associated primary and specialty medical practices within the organization. With this opportunity, the PDSA cycle may continue to provide a constant loop for quality improvement change. Figure 1 displays the PDSA cycle.

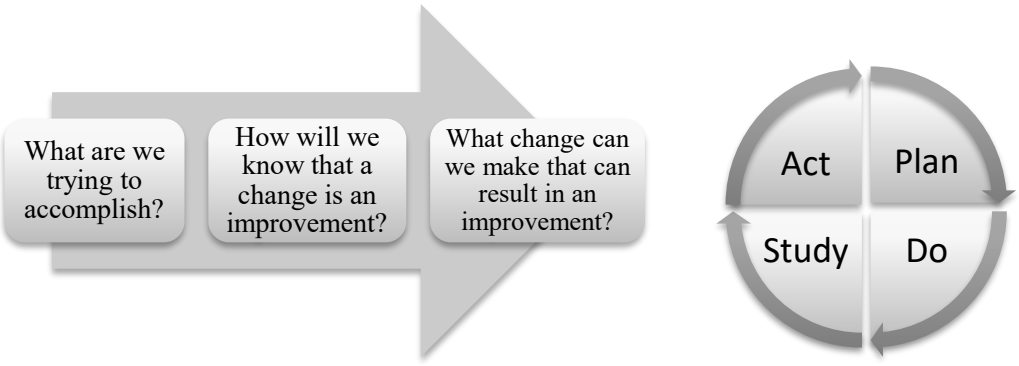

Figure 1. Model for Improvement: Deming's Plan-Do-Study-Act. (Agency for Healthcare Research and Quality (2017). Health literacy universal precautions toolkit, 2nd ed: Plan-Do-Study-Act (PDSA) directions and examples. https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2-tool2b.html)

Future Recommendations and Conclusion

Screening for depression using a two-step method is recommended by the USPSTF, WHO, and TJC. Implementing a two-step method to screen was found satisfactory by patients in an effort to improve recognition of depression in this primary care practice. Implementing the current recommendation to screen, increases the likelihood of assessing those community members who attend the primary care office infrequently. Screening for depression continues to remain controversial. The act of screening is meant to improve awareness of conditions and problems that lead to disease, and lessen overall financial burden of lifetime illness. Primary practice lends patients the familiarity of providers, setting, staff, and routine enactment of medical services. Patients become comfortable with their medical providers and may have reduced discomfort while discussing problems like depression. In a rural county with limited access to mental health professionals, the primary care provider becomes a critical element in identifying depression and mental health disorders while providing continuity of high quality care.

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Appendix A

Databases Searches and Data Abstraction

Date of Search	Keyword(s), Subject headings, MeSH terms Used	Database/Source Used (CINAHL, PubMed, Medline, PsychINFO,Proquest, Google Scholar, NGC, etc.)	Limits Applied	Study Selections		
				# of Hits	# Reviewed	# Keeper Studies for critical appraisal & evaluation
12/3/16	depression* AND screening* AND primary care	CINAHL Plus	Publication dates 2014-2016, English language.	153	12	4
12/3/16	(((((primary[All Fields] AND ("Practice (Birm)"[Journal] OR "practice"[All Fields])) AND ("depressive disorder"[MeSH Terms] OR ("depressive"[All Fields] AND "disorder"[All Fields]) OR "depressive disorder"[All Fields] OR "depression"[All Fields] OR "depression"[MeSH Terms])) AND ("diagnosis"[Subheading] OR "diagnosis"[All Fields] OR "screening"[All Fields] AND ("Syst Rev"[Journal] OR ("systematic"[All Fields] AND "reviews"[All Fields]) OR "systematic reviews"[All Fields])) AND ("2010"[EPubDate] : "2016"[EPubDate])	PubMed	English language, publication dates 2010-2016.	351	20	6

12/3/16	depression* AND screening* AND primary care	MEDLINE	Publication dates 2014-2016, English Language.	385	14	4
12/3/16	Depression screening in primary care	National Guideline Clearinghouse	Publication dates 2016.	132	2	2
12/3/16	depression* AND screening* AND primary care	PsychINFO	Publication dates 2014-2016, English Language	251	3	3
12/3/16	depression* AND screening* AND primary care	Psychology and Behavior Sciences	Publication dates 2010-2016, English Language	108	5	2
12/3/16	depression* AND screening* AND primary care; "Depression, emotional," [MeSH Terms] AND "diagnosis"[MeSH]	The Cochrane Library	Publication dates "all", English Language	3	3	1
12/3/16	"screening, depression, primary care, PHQ-9, adults"	Google Scholar	Publication dates 2016, English Language	6	6	2

Appendix B

Rating System for the Hierarchy of Evidence

Level I	Systematic review or meta-analysis of RCT's
Level II	Well-designed RCT's
Level III	Well-designed controlled trials without randomization
Level IV	Well-designed case-control or cohort studies
Level V	Systematic reviews of descriptive and qualitative studies
Level VI	Single descriptive or qualitative studies
Level VII	Opinion

Modified from Guyatt, G., & Rennie, D. (2002). Users' guides to the medical literature. Chicago, IL: American Medical Association; Harris, R. P., Hefland, M., Woolf, S. H., Lohr, K. N., Mulrow, C. D., Teutsch, S. M., & Atkins, D. (2001). Current methods of the U.S. Preventive Services Task Force: A review of the process. *American Journal of Preventive Medicine, 20*, 21-35.; Melynk, B., & Fineout-Overholt, E. (2015). *Evidence-based practice in nursing and healthcare (3rd ed.)*. Baltimore, MD: Wolters Kluwer

Appendix C

Rapid Critical Appraisal Question Form

Rapid Critical Appraisal of Systematic Reviews of Clinical Interventions/Treatments

1. Are the results of the review valid?

a. Are the studies contained in the review randomized

controlled trials? Yes No
Unknown

b. Does the review include a detailed description of the search

strategy to find all relevant studies? Yes No
Unknown

c. Does the review describe how validity of the individual studies was

assessed (e.g., methodological quality, including the use of random assignment to study groups and complete follow-up of the subjects)? Yes No
Unknown

d. Were the results consistent across studies? Yes No
Unknown

e. Were individual patient data or aggregate data

used in the analysis? Yes No
Unknown

2. What were the results?

a. How large is the intervention or treatment effect

_____

b. (OR, RR, effect size, level of significance)?

_____

3. Will the results assist me in caring for my patients?

a. Are my patients similar to the ones included in the review? Yes No
Unknown

b. Is it feasible to implement the findings in my practice setting? Yes No
Unknown

c. Were all clinically important outcomes considered, including

risks and benefits of the treatment? Yes No
Unknown

d. What is my clinical assessment of the patient and are there

any contraindications or circumstances that would inhibit me from implementing the treatment? Yes No Unknown

e. What are my patient's and his or her family's preferences and

values about the treatment that is under consideration? Yes No Unk

Melnyk, B. & Fineout-Overholt, E. (2015). *Evidence-based practice in nursing and healthcare, 3rd ed*. China: Wolters Kluwer Health/Lippincott Williams & Wilkins.

Appendix D
Critical Appraisal of Literature

Citations of single study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
Romera, Montejo, Aragones, Arbesu, Iglesius-Garcia, Lopez, Lozano, Pamulapati, Yruretagoyena, & Gilaberte (2013). Systematic depression screening in high-risk patients attending primary care: a pragmatic cluster-randomized trial.	Assess depression screening in daily practice	RCT, cluster	·105 PCPs invited ·39 excluded ·66 included ·N=69 randomized, stratified ·2 gps; ·n=35 IG ·n=34 CG ·3,737pts screened, LR Public healthcare system, Spain; 17 autonomous communities,69 centers	**IV**: ·depression screening **DV**: ·rate of under recognized depression; rate of under treatment; CGI-S scores	·2 question screen ·Feasibility of use ·systematic chart review ·CGI-S ·Depression recognition and treatment	LR modeling, adjusted for clusters using estimated equations Covariance analysis adjusted for clustering post hoc analysis as an IV in a LR model	Under recognition of depression: IV: 41.4% DV: 33.9% Recognition: IV:48.1% DV:58% ·95%CI:1.40[0.73-2.68] p=0.309 somatic s/s lower recog: 95% CI:0.58 [0.37-0.90] p<0.016	Level 2 **Weakness:** ·PCP bias in chart review ·study powered to 15% or less ·HRPts vs not **Strength:** design allowed for effectiveness vs. efficacy of depression screening **Conclusion/ Feasibility**: Improving provider awareness of screening did not improve identification of depression.

Legend: RCT-randomized controlled trial; PCPs-primary care physicians; gps-groups; IG-independent group; CG-control group; LR-logistic regression; IV-independent variable; DV-dependent variable; pts-patients; USPSTF-United States Preventative Services Task Force; CGI-S-Clinical Global Impression Severity Scale; s/s-signs and symptoms; recog-recognition; HRPts-high risk patients; vs-versus.

Citation of single study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/ Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
Gilbody, Sheldon, & House (2008). Screening and case-finding instruments for depression: a meta-analysis.	Analysis of depression recognition screening tools	Cochrane systematic review of RCTs in non-mental health settings Meta-analysis for heterogeneity using meta-regression techniques	·16 studies ·7,576 patients	IV: Primary care use of screening tools alone DV: ·Primary care use of screening tools with enhanced assessment ·circumstance and pt population	• Cochrane systematic review of RCTs • heterogeneity of screening tools • rates of recognition as indicated by medical chart review • rates of intervention • outcome of depression intervals <6mo, 12mo, >12mo.	• meta-analysis of variables using random effects analysis • heterogeneity determined by I^2 statistic	• Random effect pooling, screening tools borderline positive impact RR1.27, 95% CI 1.02-1.59 • moderate heterogeneity between studies, 69% • no difference between hospital or primary care • specific tools not related to rate of intervention	Level 1 **Weakness:** only relevant to stand alone screening programs **Strength**: reviewed screening strategy alone **Conclusion/Feasibility**: screening alone does not increase recognition or treatment.

Legend: IV- independent variable; DV-dependent variable; RCTs-randomized controlled trials; pt-patient; <-less than; >-greater than;

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
O'Connor, Whitlock, Beil, & Gaynes (2009). Screening for Depression in Adult Patients in Primary Care Settings: a systematic review.	Analytic framework of 5 key questions	Systematic evidence review	Jan 1998-Dec 2007; 2007-2009 ·Adult Patients in Primary Care ·Abstracts reviewed n=4088 ·Total Articles reviewed n=412 ·Articles critically appraised and synthesized n=33	**IV**: Depression screening **DV**: adverse effects of screening	**5 KQ** ·direct evidence ↓ morbidity/mortality ·screening results effect on usual care depressed pt ·adverse effects of screening ·elderly tx ↑ outcome ·antidepressant AE	Qualitative data analysis	Primary care depression screening likely effective when support staff participates. ·No harm in screening ·depression tx in older adults effective	Level I evidence **Strength:** updated evidence for USPSTF guidelines **Weakness:** failed to capture rare conditions; new evidence being generated may not been included due to deadline of study **Conclusion/Feasibility**: screening does not improve recognition;

Legend: IV-independent variable; DV-dependent variable; KQ- key questions; pt-patient; tx- treatment; AE-adverse effects; USPSTF-United States Preventative Services Task Force.

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
Siu, USPSTF (2016). Screening for depression in adults US preventative services task force recommendation statement.	evidence-based clinical practice guidelines based on systematic RCT reviews	Clinical practice guidelines	• update of 2009 guidelines • 9 studies of 18 years and older; n=3,814 • 6 studies of pregnant and pp women; n=11,869	IV: • screening for depression in adults DV: • benefits and harms of screening • accuracy of screening tools • pop specific benefits and harms	• grade recommendations for practice • levels of certainty regarding net benefit	• pooled results for pregnant and pp pts • pooled results for potential screening harm in adults	• 35% increase in remission with CBT for pregnant and pp pts. 95%CI, 1.19-1.50, K=10, I^2=7.9% • no difference in pregnant vs. pp • no evidence found against screening in adults	Agree II **Weakness**: no identified barriers to effectively implement screening **Strengths**: removed selective screening; included pregnant and pp pts **Conclusion/Feasibility**: screen for depression in adult pop. including pregnant and pp pts. with accurate dx, follow up and tx.

Legend: USPSTF-United States Preventative Services Task Force; RCT- randomized controlled trials; n-individual participants; pp-postpartum; pts-patients; IV-independent variable; DV- dependent variable; pop-population; CBT-cognitive behavioral therapy; dx- diagnosis; tx-treatment.

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
Thombs, Arthurs, El-Baalbaki, Meijer, Ziegelstein, & Steele (2011). Risk of bias from inclusion of patients who already have diagnosis of or are undergoing treatment for depression in diagnostic accuracy studies of screening tools for depression: systematic review.	Investigate original studies included in SR and MA for accuracy of the dx screening tools that appropriately exclude pt with dx or tx of depression and determine if they evaluate bias from inclusion of these pt.	Systematic review	• Jan 1, 2005-Oct 29, 2009 • Medline, PsycInfo, CINAHL, Embase, ISI, SCOPUS, Cochrane databases searched • 17 SR and MA • 197 publications • 8 studies excluded pt with known Dep	IV: • screening for Dep DV: • pt ID with Dep • MisDX pt • OverDX pt	• Inclusion or exclusion of pt with dx or receiving tx for Dep • Tx of spectrum bias in SR and MA	• electronic database search • Incl and excl decisions by reviewers assessed with Cohen's □=95%	• 17 SR & MA did not exclude pt with Dep dx or tx. • 8 unique Pub and 8 cohort studies excl pt with Dep dx or tx • 10 SR and MA assessed spectrum bias • None of the SR and MA noted spectrum bias on pt with Dep dx or tx included	Level 1 **Weakness**: unk #pt with Dep dx or tx included in SR and MA **Strength**: All primary care screening trials produced negative results for depression recognition outcomes **Conclusion/Feasibility**: screening results may have other applications such as monitoring tx or ID relapse of Dep.

Legend: RCTs-randomized controlled trials; Dep-depression; pt-patients; IV- independent variable; DV- dependent variable; MisDX-misdiagnosed; OverDX- over diagnosed; tx- treatment; SR- systematic review; MA- meta analyses; Incl-inclusion; Excl- exclusion; Pub-publications; unk- unkown; #- number; ID-identification

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
Baas, Wittkampf, VanWeert, Lucassen, Huyser, Van den Hoogen, Lisdonk, Bindels, Bockting, Ruhe, & Schene (2009). Screening for depression in high-risk groups: prospective cohort study in general practice.	Screening for depression in high risk groups	Cohort study	• Jan 2005-Mar 2006 PC pt ages 18-70 • PCP n=12 • Health Centers n=3 **3 HR groups**: • pt w/mental health prb; n=970 • Unex somatic c/o; n=107 • pt □ attend their PCP; n=1258 • pt in 2 or 3 grp n=311 **Other**: Excl pt n=318;pt with Dep dx or tx n=146	IV: screening for Dep in primary care DV: high risk groups: • pt with mental health prb • pt with unexplained somatic c/o • pt who frequently attend their PCP	• Effectiveness of selective screening in each group • Assess tx initiation when tx is freely and easily accessible	• PHQ self report questionnaire • Scorers ≧10 were given telephone clinical interview SCID-1, dx with MD	• PHQs returned n=826 or 49% with n=780 or 94.4% giving IC • PHQ ≧10 n=229 • SCID-1 n=173 or 76.5% interviewed, MD Dx n=71 or 41%. • MD dx pt, 36 already had tx, 14 refused tx, 4 no-showed • 17 pt were eligible for MD tx	Level IV **Weakness**: lower rate than normal for mailed responses of PHQ **Strength**: recognizing key to improving care is convincing pt to initiate and continue with EBT for MD **Conclusion/Feasibility**Screening for HRG in PC is feasible when # of newly detected pt is the outcome

Legend: Jan-January; Mar-March; PC-primary care; pt-patients; PCP-primary care providers; n-number of subjects; w/-with; c/o-complaints; Excl-excluded; Dep-depression; dx-diagnosis; tx-treatment; IV-independent variable; DV-dependent variable; prb-problems; PHQ-patient health questionnaire; IC-informed consent; SCID-1- semi-structured interview for diagnosing mental health disorders; MD-major depression; EBT-evidence based treatment; HRG-high risk groups; #-number; ↑- increased; grp- groups; Unex- unexplained.

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
Zuithoff, Vergouwe, King, Nazareth, Van Wezep, Moons, & Geerlings (2010). The patient health questionnaire-9 for detection of major depressive disorder in primary care: consequences of current thresholds in a correctional study.	Validation of PHQ-9 and PHQ-2 in primary care for MDD: • Is the PHQ-p reliable and valid of MDD in PC? • Does threshold score 10 for PHQ-9 yield accurate classification ? • PHQ-2 accuracy for MDD in PC?	cross sectional analysis of large prospective cohort study, PREDICT-NL	General practice in Netherlands, n=7 • waiting room pts invited to participate regardless of presenting problem, n=1338 • Completed PHQ-9 & returned; repeated in 14 days • all pts called & PHQ-2 given if responded yes to either question, full MDD eval done	IV: PC pts DV: PHQ-9 questionaire PHQ-2 interview	PHQ-9 PHQ-2 mean age gender	PHQ-9 internal consistency measured with intraclass correlations and Pearson correlation. Differences in PHQ-9 and PHQ-2 measured with Mann-Whitney U SPSS for imputation and analysis	mean age 51 years; gender female 63% Pts w/ MDD had ↑ PHQ-9 scores (p<.000) PHQ-2 (p< .000) compared with Pts w/o MDD. SSD in quality of life observed with different levels of MDD symptoms; ↑ MDD symptoms=↓ QOL	Level IV **Weakness**: Dutch PC; MDD Dx relatively high **Strength**: well trained interviewers improved validity **Conclusion/Feasibility:** Current thresholds can lead to under detection; High score on PHQ requires additional interview for best detection of MDD

Legend: IPD-individual patient data; dx-diagnostic; PHQ-patient health questionnaire; MDD-major depressive disorder; PC-primary care; ↑- higher; w/-with; w/o-without; SSD- statistically significant difference; QOL-quality of life; SPEC-specificity; SENS-sensitivity; ↓-lower

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
Joffres, Jaramillo, Dickinson, Lewin, Pottie, Shaw, Connor Gorber, Tonelli, & Canadian Task Force on Preventive Health Care (2013). Recommendations on screening for depression in adults.	The purpose of this guideline is to provide evidence-based recommendations on screening for Dep in adults in Canada	This design is a clinical practice guideline	• Asymptomatic adults ages 18 and older • Primary care setting	IV: • depression screening • primary care practice DV: • asymptomatic pt • pt who screen positive	• Quality of life • Rates of suicidality (attempts or ideation) • All-cause mortality • Dep-related mortality • Rates of hospital admission • Changes in symptoms of dep (treatment response or remission)	• Peer review • Meta-Analysis of RCTs andMAs • SR with evidence tables	• NO routine screening in adults w/ average risk of Dep. Weak recommendation; very-low-quality evidence • NO routine screening for Dep in subgroups of the Pop who may be at ↑risk of Dep. Weak recommendation; very-low-quality evidence	Guidelines are applicable to practice. Screening alone is not recommended AGREE II score 6/7.

Legend: Dep-depression; IV- independent variable; DV- dependent variable; pt-patients; RCTs- randomized controlled trials; MAs- meta analyses; SR- systematic review; w/- with; Pop- population; ↑ - increased.

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
USPSTF (2016). Screening for depression for adults : U.S. Preventative Services Task Force recommendation statement.	The purpose of this guideline is to provide evidence-based recommendations on screening for Dep in adults in the United States	This design is a clinical practice guideline, updated from 2009.	• General population, adults ages 18 and older	IV: • depression screening • primary care practice DV: • asymptomatic pt • pt who screen positive	• Quality of life • Harms related to screening • Does tx improve outcomes • Does screening improve outcomes	• Peer review • Meta-Analysis of RCTs and MAs • SR with evidence tables	• Yes, routine screening in adults improves quality of life and can improve outcomes if appropriate follow up is provided: treatment with medications, monitoring, or referral to mental health professionals	Guidelines are applicable to practice. Screening with appropriate follow up measures is recommended AGREE II score 7/7.

Legend: Dep-depression; IV- independent variable; DV- dependent variable; pt-patients; RCTs- randomized controlled trials; MAs- meta analyses; SR- systematic review; w/- with; Pop- population; ↑ - increased.

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
Mitchell, A., Yadegarfer, M, Gill, J., & Stubbs, B. (2016). Case finding and screening sclinical utility of the Patient Health Questionnaire (PHQ-9 & PHQ-2) for depression in primary care: A diagnostic meta-analysis of 40 studies..	The purpose of this MA is to determine accuracy in diagnosis of major depression using he PHQ-9 and PHQ-2 screening tools.	This design is a MA of 40 studies	• All articles up until 2015 that reported accuracy of PHQ tools for diagnosing dep.	IV: • PHQ-2 • PHQ-9 DV: • Accuracy of use	• Sensitivity and specificity • Cut-off scores	• Meta-Analysis and meta-regression • Moderator and sensitivity analysis	• PHQ can be used as initial first step, PHQ-2 and PHQ-9 appropriate for this • Neither tools are appropriate to confirm diagnosis of dep.	Level I **Weakness**: did not review severity assessment or sensitivity to change **Strength**: 40 studies accounted for over 50,000 participants. Strong sensitivity and specificity. **Conclusion**: Applicable to practice

Legend: Dep-depression; IV- independent variable; DV- dependent variable; pt-patients; RCTs- randomized controlled trials; MAs- meta analyses; SR- systematic review; w/- with; Pop- population; ↑ - increased.

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
Beard, C., Hsu, K., Rifkin, L., Busch, A., & Bjorgvinsson, T. (2016). Validation of the PHQ-9 in a psychiatric sample.	The purpose of this is to explore psychometric properties of the PHQ-9	This design is a single qualitative study.	• Adults ages 18 and older • Patients completing PHQ-9 upon admission and discharge from a hospital.	IV: • depression screening • self-report measures DV: • asymptomatic pt • pt who screen positive	• PHQ-9 • Self report measures of dep, anxiety, well-being, structured diagnostic interview	• Peer review • Analysis of sensitivity and specificity of PHQ-9 results • Cognitive affective symptoms • Somatic symptoms	• PHQ tools useful • Any high score above the common threshold needs additional follow up as the current threshold tends to under detect depressive symptoms	Level IV **Weakness**: PHQ-9 sensitivity to change based on the population **Strength**: large, heterogenous sample in psychiatric setting **Conclusion:** Good evidence to apply when using PHQ-9

Legend: Dep-depression; IV- independent variable; DV- dependent variable; pt-patients; RCTs- randomized controlled trials; MAs- meta analyses; SR- systematic review; w/- with; Pop- population; ↑ - increased. PHQ-(9 or 2)- patient health questionnaire (9 questions or 2 questions).

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
Horton, M. & Perry, A. (2016). Screening for depression in primary care: A Rasch analysis of the PHQ-9.	The purpose of this article is to apply a RASCH analysis when exploring psychometric properties of the PHQ-9	This design is a single qualitative study	• Adults ages 18 and older with dep. • Primary care setting	IV: • depression screening • primary care practice DV: • Pt dx with Dep • pt who screen positive	• Rasch analysis to test PHQ-9 outcome scale against a mathematical model of measurement	• Psychometric properties of the PHQ-9 are appropriate, though Question 1 and 2 could be redundant.	• cut-scores are important based on the clinical question and the desired population. Therefore, as a screening tool the PHQ-9 is reliable. It is not to be used for individual outcome evaluation	Level IV **Weakness**: may not represent the entire population **Strength**: identified that the PHQ-9 is appropriate tool for screening and does detect psychometric symptoms **Conclusion**: PHQ-9 is reliable.Not to be used for individual outcome evaluation

Legend: Dep-depression; IV- independent variable; DV- dependent variable; pt-patients; RCTs- randomized controlled trials; MAs- meta analyses; SR- systematic review; w/- with; Pop- population; ↑ - increased.

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence

Citation of Single Study	Theoretical/ Conceptual Framework and Purpose	Study Design	Sample/Setting	Names & Definitions of Major Variables	Outcome Measures	Data Analysis	Findings	Level & Quality of Evidence
Picardi, A., Lega, I., Tarsitani, L., Caredda, M., Matteucci, G., Zerella, M., Miglio, R., Gigantesco, A., Cerbo, M., Gaddini, A., Spandonaro, F., Biondi, M., &the SET-DEP Group (2016). A randomized controlled trial of the effectiveness of a program for early detection and treatment of depression in primary care.	The purpose of this article is to see if depression screening programs effect outcomes in a primary care setting.	This design is a RCT.	• Adults ages 18 and older • Primary care setting	IV: • depression screening • primary care practice DV: • pt who screen positive	• PCSAD5 • WHOQOL-Bref	• Intent-to – treat analysis • Per-protocol analysis • Complier average causal effect analysis.	• Dep severity and quality of life improved in both groups • Intent-to-treat showed no effect • Per-protocol analysis showed significant positive effect on severity of dep symptoms. • Complier average causal effect similar results	Level I **Weakness**: may not represent the entire population **Strength**: identified that the design of the screening should be based on the population and setting **Conclusion**: Screening may be effective to improve outcomes with appropriate follow up.

Legend: Dep-depression; IV- independent variable; DV- dependent variable; pt-patients; RCTs- randomized controlled trials; MAs- meta analyses; SR- systematic review; w/- with; Pop- population; ↑ - increase

Appendix E

Johns Hopkins Nursing Evidence-Based Practice

Evidence Level and Quality Guide

<table>
<tr><th>Evidence Levels</th><th>Quality Guides</th></tr>
<tr><td>Level I
Experimental study, randomized controlled trial (RCT)
Systematic review of RCTs, with or without meta-analysis</td><td rowspan="3">A <u>High quality:</u> Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence

B <u>Good quality:</u> Reasonably consistent results; sufficient sample size for the study design; some control, fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence

C <u>Low quality or major flaws</u>: Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn</td></tr>
<tr><td>Level II
Quasi-experimental study
Systematic review of a combination of RCTs and quasi-experimental, or quasi-experimental studies only, with or without meta-analysis</td></tr>
<tr><td>Level III
Non-experimental study
Systematic review of a combination of RCTs, quasi-experimental and non-experimental studies, or non-experimental studies only, with or without meta-analysis
Qualitative study or systematic review with or without a meta-synthesis</td></tr>
</table>

Level IV Opinion of respected authorities and/or nationally recognized expert committees/consensus panels based on scientific evidence Includes: • Clinical practice guidelines • Consensus panels	**A <u>High quality:</u>** Material officially sponsored by a professional, public, private organization, or government agency; documentation of a systematic literature search strategy; consistent results with sufficient numbers of well-designed studies; criteria-based evaluation of overall scientific strength and quality of included studies and definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years **B <u>Good quality:</u>** Material officially sponsored by a professional, public, private organization, or government agency; reasonably thorough and appropriate systematic literature search strategy; reasonably consistent results, sufficient numbers of well-designed studies; evaluation of strengths and limitations of included studies with fairly definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years **C <u>Low quality or major flaws:</u>** Material not sponsored by an official organization or agency; undefined, poorly defined, or limited literature search strategy; no evaluation of strengths and limitations of included studies, insufficient evidence with inconsistent results, conclusions cannot be drawn; not revised within the last 5 years

Appendix F

Johns Hopkins Nursing Evidence-Based Practice Synthesis and Recommendations Tool

Category (Level Type)	Total Number of Sources/Level	Overall Quality Rating	Synthesis of Findings Evidence That Answers the EBP Question
Level I · Experimental study · Randomized Controlled Trial (RCT) · Systematic review of RCTs with or without meta-analysis			
Level II · Quasi-experimental studies · Systematic review of a combination of RCTs and quasi-experimental studies, or quasi-experimental studies only, with or without meta-analysis			
Level III · Non-experimental study · Systematic review of a combination of RCTs, quasi-experimental, and non-experimental studies, or non-experimental studies only, with or without meta-analysis · Qualitative study or systematic review of qualitative studies with or without meta-synthesis			
Level IV · Opinion of respected authorities and/or reports of nationally recognized expert committees/consensus panels based on scientific evidence			

Level V · Evidence obtained from literature reviews, quality improvement, program evaluation, financial evaluation, or case reports · Opinion of nationally recognized expert(s) based on experiential evidence			

Directions for Use of This Form

Purpose: This form is used to compile the results of the evidence appraisal to answer the EBP question. The pertinent findings for each level of evidence are synthesized, and a quality rating is assigned to each level.

Total Number of Sources per Level: Record the number of sources of evidence for each level.

Overall Quality Rating: Summarize the overall quality of evidence for each level. Use the "Evidence Level and Quality Guide" (Appendix C) to rate the quality of evidence.

Synthesis of Findings: Evidence That Answers the EBP Question

- Include only findings from evidence of A or B quality.
- Include only statements that directly answer the EBP question.
- Summarize findings within each level of evidence.
- Record article number(s) from individual evidence summary in parentheses next to each statement so it is easy to identify the source of the finding.

Develop Recommendations Based on Evidence Synthesis and the Selected Translation Pathway: Review the synthesis of findings and determine which of the following four pathways to translation represents the overall strength of the evidence:

- Strong, compelling evidence, consistent results: solid indication for a practice change.
- Good and consistent evidence: consider pilot of change or further investigation.
- Good but conflicting evidence: no indication for practice change; consider further investigation for new evidence or develop a research study.
- Little or no evidence: no indication for practice change; consider further investigation for new evidence or develop a research study or discontinue project

Dearholt, S. & Dang, D. (2012). *Johns Hopkins nursing evidence based practice: Model and guidelines, 2nd ed*. Indianapolis, IN: Sigma Theta Tau International.

Appendix G

Synthesis Table

	LOE	SS	TP	SU
1^0	II	3,737	Y	N
2^0	I	7,576	NA	Y
3^0	I	9,212	Y	Y
4^0	I	15,683	Y	Y
5^0	IV	2,005	Y	Y
6^0	IV	1,338	Y	Y
7^0	I	197	Y	Y
8^0	NA	NA	Y	N
9^0	NA	NA	Y	Y
10^0	I	26,920	Y	Y
11^0	IV	1,023	Y	Y
12^0	IV	767	Y	Y
13^0	I	230	Y	Y

1^0= Romera et. al. (2013); 2^0= Gilbody et. al. (2008); 3^0= O'Connor et. al. (2009); 4^0= Siu et. al. (2016); 5^0= Baas et. al. (2009);
6^0= Zuithoff et. al. (2010); 7^0= Thombs et. al. (2011); 8^0 = Joffres et. al. (2013); 9^0= USPSTF (2016); 10^0=Mitchell et al. (2016); 11^0=Beard et al. (2016); 12^0=Horton & Perry (2016); 13^0=Picardi et al. (2016).
LOE= level of evidence; SS= sample size; TP= target population; SU= evidence supports use of 2 step screening
I= meta-analysis of all relevant randomized control trials; II= randomized control trial; III= controlled trials without randomization; IV= well designed cohort study; NA= not applicable
Y= yes; N= no

Appendix H
AGREE II Instrument

A critical appraisal of: Screening for Depression in Adults

Created with the AGREE II Online Guideline Appraisal Tool.

No endorsement of the content of this document by the AGREE Research Trust should be implied.

Appraiser: Mary Peters

Date: 4 December 2016

Email: mapeters0812@aol.com

URL of this appraisal: http://www.agreetrust.org/appraisal/38774

Guideline URL:

http://www.guideline.gov/content.aspx?id=45688&search=screening+for+depression

Overall Assessment

Title: Screening for Depression in Adults Overall quality of this guideline: 7/7

AGREE Advancing the science of practice guidelines. 1

Guideline recommended for use? Yes.

Domain Total	
1. Scope and Purpose	21
2. Stakeholder Involvement	21
3. Rigour of Development	56
4. Clarity of Presentation	21
5. Applicability	28
6. Editorial Independence	14

1. Scope and Purpose

1. The overall objective(s) of the guideline is (are) specifically described.

Rating: 7

2. The health question(s) covered by the guideline is (are) specifically described.

Rating: 7

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Rating: 7 general adult population, pregnant, and postpartum women included

2. Stakeholder Involvement

4. The guideline development group includes individuals from all relevant professional groups.

Rating: 7

5. The views and preferences of the target population (patients, public, etc.) have been sought.

Rating: 7

6. The target users of the guideline are clearly defined.

Rating: 7

AGREE Advancing the science of practice guidelines. 2

3. Rigor of Development

7. Systematic methods were used to search for evidence.

Rating: 7

8. The criteria for selecting the evidence are clearly described.

Rating: 7

9. The strengths and limitations of the body of evidence are clearly described.

Rating: 7

10. The methods for formulating the recommendations are clearly described.

Rating: 7

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

Rating: 7

12. There is an explicit link between the recommendations and the supporting evidence.

Rating: 7

13. The guideline has been externally reviewed by experts prior to its publication.

Rating: 7

14. A procedure for updating the guideline is provided.

Rating: 7

4. Clarity of Presentation

15. The recommendations are specific and unambiguous.

Rating: 7

16. The different options for management of the condition or health issue are clearly presented.

Rating: 7

17. Key recommendations are easily identifiable.

Rating: 7

5. Applicability

18. The guideline describes facilitators and barriers to its application.

Rating: 7

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

Rating: 7

20. The potential resource implications of applying the recommendations have been considered.

Rating: 7

21. The guideline presents monitoring and/or auditing criteria.

Rating: 7

6. Editorial Independence

22. The views of the funding body have not influenced the content of the guideline.

Rating: 7

23. Competing interests of guideline development group members have been recorded and addressed.

Rating: 7Created online at www.agreetrust.org 4 December 2016

AGREE Advancing the science of practice guidelines. 4

Appendix I

Patient Health Questionnaire (PHQ-9)

Patient Name: _____ **Date:** _____

	Not at all	Several days	More than half the days	Nearly every day
1. Over the *last 2 weeks*, how often have you been bothered by any of the following problems?				
a. Little interest or pleasure in doing things	☐	☐	☐	☐
b. Feeling down, depressed, or hopeless	☐	☐	☐	☐
c. Trouble falling/staying asleep, sleeping too much	☐	☐	☐	☐
d. Feeling tired or having little energy	☐	☐	☐	☐
e. Poor appetite or overeating	☐	☐	☐	☐
f. Feeling bad about yourself or that you are a failure or have let yourself or your family down	☐	☐	☐	☐
g. Trouble concentrating on things, such as reading the newspaper or watching television.	☐	☐	☐	☐
h. 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.	☐	☐	☐	☐
i. Thoughts that you would be better off dead or of hurting yourself in some way.	☐	☐	☐	☐
2. If you checked off any problem on this questionnaire so far, 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 ☐

The John D. & Catherine T. MacArthur Foundation (2009). Depression management tool kit: Initiative on depression and primary care and 3CM, LLC. https://www.integration.samhsa.gov/clinical-practice/macarthur_depression_toolkit.pdf

PHQ-9* Questionnaire for Depression Scoring and Interpretation Guide For physician use only

Scoring: Count the number (#) of boxes checked in a column. Multiply that number by the value indicated below, then add the subtotal to produce a total score. The possible range is 0-27. Use the table below to interpret the PHQ-9 score.

Not at all (#) _____ x 0 = _____ Several days (#) _____ x 1 = _____ More than half the days (#) _____ x 2 = _____ Nearly every day (#) _____ x 3 = _____

Total score: _____

Interpreting PHQ-9 Scores

Actions Based on PH9 Score **Action**

The score suggests the patient may not need depression treatment

Physician uses clinical judgment about treatment, based on patient's duration of symptoms and functional impairment

Warrants treatment for depression, using antidepressant, psychotherapy and/or a combination of treatment.

Minimal depression Mild depression Moderate depression Moderately severe depression Severe depression

0-4

5-9 10-14 15-19 20-27

Score

<4 5 - 14

> 15

* PHQ-9 is described in more detail at the McArthur Institute on Depression & Primary Care website www.depression-primarycare.org/clinicians/toolkits/materials/forms/phq9/

Appendix J

Data Collection Tool

Client	Age	Race	Gender (F/M)	Completed PHQ-9? (Y/N)	PHQ-9 Score	Discussion With Provider (Y/N)	Diagnosed with Depression? ICD code	Plan of care: Monitor/ Treat/Refer (M/T/R)	Patient satisfaction survey completed?	Handout Given to Patient?
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

Appendix K

Patient Satisfaction Survey: Please Circle Best Response

1. Why did you come into the office today?

   - A regular check up or physical
   - A visit recently made because you are ill
   - A visit to talk about your mental health
   - You have recently been in the hospital and today is your follow-up

2. Did you feel comfortable answering the depression screening?

   - Yes
   - No

3. Did the provider who gave you the form help you feel comfortable completing the form honestly?

   - Yes
   - No

4. Were you aware that the questions you answered on the screening form could all be symptoms of depression?

   - Yes
   - No
   - Unsure

5. In your opinion, did you feel that your provider cared about your responses?

   - Yes
   - No

6. Are you satisfied with the way this depression screening was completed today?

   - Yes
   - No

Appendix L
Patient Education Handout

DEPRESSION

There is nothing more important than your mental health wellness.

If you are currently well, consider other people you may know that could benefit from understanding common symptoms of a depressed mood.

- Little interest or pleasure in doing things
- Feeling down, depressed, or hopeless
- Trouble falling or staying asleep, or sleeping too much
- Feeling tired or having little energy
- Poor appetite or overeating
- Feeling bad about yourself or that you are a failure or have let yourself or family down
- Trouble concentrating on things, such as reading the newspaper or watching television
- Moving or speaking so slowly that other people could have noticed. Or, being so fidgety or restless that you have been moving around a lot more than usual
- Thoughts that you would be better off dead, or of hurting yourself

There are many types of depression:

- **Major depression:** Severe symptoms that interfere with the ability to work, sleep, study, eat, and enjoy life. An episode can occur only once in a person's lifetime, but more often, a person has several episodes.
- **Persistent depressive disorder:** A depressed mood that lasts for at least 2 years. A person diagnosed with persistent depressive disorder may have episodes of major depression along with periods of less severe symptoms, but symptoms must last for 2 years.

Some forms of depression are slightly different, or they may develop under unique circumstances. They include:

- **Psychotic depression,** which occurs when a person has severe depression plus some form of psychosis, such as having disturbing false beliefs or a break with reality (delusions), or hearing or seeing upsetting things that others cannot hear or see (hallucinations).
- **Postpartum depression,** which is much more serious than the "baby blues" that many women experience after giving birth, when hormonal and physical changes and the new responsibility of caring for a newborn can be overwhelming. It is estimated that 10 to 15 percent of women experience postpartum depression after giving birth.
- **Seasonal affective disorder (SAD),** which is characterized by the onset of depression during the winter months, when there is less natural sunlight. The depression generally

lifts during spring and summer. SAD may be effectively treated with light therapy, but nearly half of those with SAD do not get better with light therapy alone. Antidepressant medication and psychotherapy can reduce SAD symptoms, either alone or in combination with light therapy.

- **Bipolar disorder** is different from depression. The reason it is included in this list is because someone with bipolar disorder experiences episodes of extreme low moods (depression). But a person with bipolar disorder also experiences extreme high moods (called "mania").

Sometimes it can be difficult to distinguish grief from major depression. Grief after loss of a loved one is a normal reaction and generally does not require professional mental health treatment. However, grief that is complicated and lasts for a very long time following a loss may require treatment.

If you think you may have depression, start by making an appointment to see your health care provider. Certain medications, and some medical conditions, such as viruses or a thyroid disorder, can cause the same symptoms as depression.

References

U.S. Department of Health and Human Services, National Institutes of Health, National Institute of Mental Health. (2015).Depression (NIH Publication No. 15-3561). Bethesda, MD: U.S. Government Printing Office. Retrieved from: https://www.nimh.nih.gov/health/publications/depression-what-you-need-to-know/index.shtml#pub

Appendix M

University of Toledo IRB Approval Letter

UNIVERSITY OF TOLEDO IRB
APPROVAL DATE: 12/13/2017
EXPIRATION DATE: 12/12/2018
This space for IRB Approval Date Stamp

Health Science Campus
Collier Building, RM 4405
3000 Arlington Ave
Toledo, Ohio 43614
Mail stop 1026

RR050

UNIVERSITY OF TOLEDO IRB
APPROVAL DATE: 12/13/2017
EXPIRATION DATE: 12/12/2018
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ADULT RESEARCH SUBJECT INFORMATION AND CONSENT FORM

IDENTIFYING DEPRESSION IN PRIMARY CARE: AN EVIDENCE-BASED INTERVENTION

Principal Investigator: Dr. Temeaka Gray, PsyD, MBA, MSN, CNP, RN

Other Staff (identified by role): Mary A. Peters, MSN, CNP, RN, DNP Student

Contact Phone number(s): (419) 464-8875 Dr. Gray
(419) 656-7782 Mary Peters

What you should know about this research study:

- We give you this consent/authorization form so that you may read about the purpose, risks, and benefits of this research study. All information in this form will be communicated to you verbally by the research staff as well.
- Routine clinical care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.
- We cannot promise that this research will benefit you. Just like routine care, this research can have side effects that can be serious or minor. There is a possibility during the survey that you may feel stress.
- You have the right to refuse to take part in this research, or agree to take part now and change your mind later.
- If you decide to take part in this research or not, or if you decide to take part now but change your mind later, your decision will not affect your routine care.
- Please review this form carefully. Ask any questions before you make a decision about whether or not you want to take part in this research. If you decide to take part in this research, you may ask any additional questions at any time.
- Your participation in this research is voluntary.

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PURPOSE (WHY THIS RESEARCH IS BEING DONE)

You are being asked to take part in a research study of ***finding out if you are satisfied with the way you are being screened for depression.***

You were selected as someone who may want to take part in this study because ***you attend a primary care office that is trying to improve the way patients are being screened for depression. The study is being conducted in the Norwalk and Milan offices only. There will be approximately 160 people being surveyed.***

DESCRIPTION OF THE RESEARCH PROCEDURES AND DURATION OF YOUR INVOLVEMENT

If you decide to take part in this study, you will be asked to ***complete a short survey, that will last about 5 minutes or less, about your satisfaction with the depression screening that was given to you as part of the normal standard of care in this office. The depression screening used in this office is called the PHQ-9. The DNP student will be with you during your survey in case you have any questions or concerns about the survey. This will complete the research. Then, your regular scheduled appointment will begin with your provider.***

RISKS AND DISCOMFORTS YOU MAY EXPERIENCE IF YOU TAKE PART IN THIS RESEARCH

Reasonably foreseeable risks or discomforts or inconveniences to persons choosing to take part in this research that are associated with the survey include:

- ***Feelings of stress that may occur while completing the survey.***

The survey is being done solely for research and will not be part of your patient chart or accessible by Fisher Titus Medical Center.

There is no known additional risk to pregnant women.

POSSIBLE BENEFIT TO YOU IF YOU DECIDE TO TAKE PART IN THIS RESEARCH

We cannot and do not guarantee or promise that you will receive any benefits from this research.

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COST TO YOU FOR TAKING PART IN THIS STUDY

There is no cost to you for completing this research survey.

PAYMENT OR OTHER COMPENSATION TO YOU FOR TAKING PART IN THIS RESEARCH

If you decide to take part in this research you will not be compensated in any way**.**

ALTERNATIVE(S) TO TAKING PART IN THIS RESEARCH

Potential participants will receive standard care whether or not he/she participates in the research study. Participating in this study is completely voluntary.

CONFIDENTIALITY - (USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION)

By agreeing to take part in this research study, you give to The University of Toledo (UT), the Principal Investigator and all personnel associated with this research study your permission to use or disclose health information. **This information will NOT be identifiable with you that we obtain in connection with this study.** The researcher will assign each patient a number in chronological order of arrival during the research period. All data gathered about you will remain free from any information that could possibly identify you or link the information to you.

The University of Toledo is required by law to protect the privacy of your health information, and to use or disclose the information we obtain about you in connection with this research study only as authorized by you in this form. There is a possibility that the information we disclose may be re-disclosed by the persons we give it to, and no longer protected. However, we will encourage any person who receives your information from us to continue to protect and not re-disclose the information.

A more complete statement of University of Toledo's Privacy Practices is set forth in its Joint Notice of Privacy Practices. If you have not already received this Notice, a member of the research team will provide this to you. If you have any further questions concerning privacy, you may contact the University of Toledo's Privacy Officer at 419-383-6933.

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IN THE EVENT OF A RESEARCH-RELATED INJURY

In the event of injury resulting from your taking part in this study, treatment can be obtained at a health care facility of your choice. You should understand that unless compensation is available from the sponsor as described below, the costs of such treatment will be your responsibility. Financial compensation is not available through The University of Toledo or The University of Toledo Medical Center.

VOLUNTARY PARTICIPATION

Taking part in this study is voluntary. You may refuse to participate or discontinue participation at any time without penalty or a loss of benefits to which you are otherwise entitled. If you decide not to participate or to discontinue participation, your decision will not affect your future relations with the University of Toledo or The University of Toledo Medical Center.

CONSENT

Verbal consent is the only consent needed for this research. Once verbal consent is given to the researcher, you may move forward to complete the survey. Thank you for your time.

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UNIVERSITY OF TOLEDO IRB
APPROVAL DATE: 12/13/2017
EXPIRATION DATE: 12/12/2018
This space for IRB Approval Date Stamp

The University of Toledo
Department of Psychology
2801 W. Bancroft St.
Toledo, Ohio 43606

ADULT RESEARCH SUBJECT INFORMATION SHEET
FOR THE STUDY TITLED
IDENTIFYING DEPRESSION IN PRIMARY CARE: AN EVIDENCE-BASED INTERVENTION

Principal Investigator: Dr. Temeaka Gray, PsyD, MBA, MSN, CNP, RN (419) 464-8875

Purpose: You are invited to participate in the research project entitled, IDENTIFYING DEPRESSION PRIMARY CARE: AN EVIDENCE-BASED INTERVENTION, which is being conducted at the University of Toledo under the direction of Dr. Temeaka Gray. The purpose of this study is to find out if you are satisfied with the way you are being screened for depression.

Description of Procedures: This research study will take place at Fisher Titus Medical Center's primary care offices in Norwalk and Milan, Ohio.

Potential Risks: You may feel stress during the satisfaction survey. It is known that some people feel stress when completing surveys.

Potential Benefits: None.

Confidentiality: The researchers will make every effort to prevent anyone who is not on the research team from knowing that you provided this information, or what that information is.

Voluntary Participation: Participation is entirely voluntary. If you decide not to participate, the refusal will involve no penalty or loss of benefits to which you are otherwise entitled and will not affect your relationship with The University of Toledo or the University of Toledo Medical Center. In addition, you may discontinue participation at any time without any penalty or loss of benefits.

Contact Information: Before you decide to accept this invitation to take part in this study, you may ask any questions that you might have. If you have any questions at any time before,

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APPROVAL DATE: 12/13/2017
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during or after your participation, you should contact a member of the research team or the investigator: Dr. Temeaka Gray (419) 464-8875 or Mary Peters (419) 656-7782.

If you have questions beyond those answered by the research team or your rights as a research subject or research-related injuries, the Chairperson of the Biomedical Institutional Review Board may be contacted by calling (419) 383-6796.

This Adult Research Subject Information Sheet has been reviewed and approved by the University of Toledo Biomedical IRB for the period of time specified in the approval box below.

Approved Number of Subjects:**240**

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APPROVAL DATE: 12/13/2017
EXPIRATION DATE: 12/12/2018
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