

IMPLEMENTATION OF AN EVIDENCE-BASED PROTOCOL  
TO IMPROVE DEPRESSION IDENTIFICATION  
IN PRIMARY CARE

by

Melissa Noel Blixt

A scholarly project submitted in partial fulfillment  
of the requirements for the degree

of

Doctorate of Nursing Practice

in

Family and Individual Health

MONTANA STATE UNIVERSITY  
Bozeman, Montana

April 2017

©COPYRIGHT

by

Melissa Noel Blixt

2017

All Rights Reserved

AUTHOR NOTE

Melissa N. Blixt, College of Nursing, Montana State University.

Research reported in this publication was supported by the National Institute of General Medical Sciences of the National Institutes of Health under Award Number P20GM103474. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Correspondence concerning this article should be addressed to Melissa Blixt, c/o College of Nursing, Montana State University, P.O. Box 173560, Bozeman, MT 59717-3560. Contact: [melissablixt@gmail.com](mailto:melissablixt@gmail.com)

## TABLE OF CONTENTS

1. DESCRIPTION OF THE PROBLEM.....	1
An International Public Health Concern.....	2
State and Local Impact.....	3
2. EXAMINATION OF THE EVIDENCE .....	4
Gap in Depression Identification .....	4
Barriers to Depression Identification .....	4
Missed Opportunities to Prevent Suicide.....	6
An Evidence-Based Screening Tool .....	6
Project Question.....	8
Setting of Interest.....	9
Theoretical Underpinning .....	10
3. METHODOLOGY .....	13
Ethical Considerations .....	13
Administration of PHQ-2.....	14
4. OUTCOMES.....	17
Overview of Project Context .....	17
Characteristics of Sample Population .....	18
Outcomes of Depression Screening.....	22
Statistical Analysis.....	23
5. DISCUSSION .....	24
Implementation of the Intervention .....	24
Limitations .....	26
Implications for Nursing.....	29
Conclusion .....	31
REFERENCES CITED.....	33
APPENDICES .....	38
APPENDIX A: Patient Health Questionnaire (PHQ-9).....	39
APPENDIX B: Patient Health Questionnaire-2 (PHQ-2) .....	41

TABLE OF CONTENTS - CONTINUED

APPENDIX C: Subject Consent Form for Participation  
in Human Research at Montana State University .....43  
APPENDIX D: Evidence Table for Applicability .....46

LIST OF TABLES

Table	Page
1. ICD-9 Diagnosis Codes Used in Generating Report of Patients with Depression Diagnosis .....	19

## LIST OF FIGURES

Figure	Page
1. Sample patient panel population demographics by age and gender .....	18
2. Insurance coverage of patients with diagnosis of depression .....	20
3. Sample depression patient population demographics by age and gender .....	21
4. Sample depression patient population gender frequency.....	22

## ABSTRACT

This research project addressed a practice gap in the identification of patients experiencing depression in primary care. Depression is a significant cause of morbidity and mortality worldwide, including one million suicide deaths annually. One rural Western state has a depression rate more than three times the national rate, and the highest rate of suicide in the U.S., nearly double the national rate. The setting of interest was a primary care clinic in this state, and the following research question was asked: among adult patients, does the routine administration of the Patient Health Questionnaire-2 (PHQ-2) during wellness visits improve depression identification as compared to routine care? The project sample was gathered between May 2 and July 25, 2016, and consisted of 33 patients meeting the inclusion criteria gathered from a total patient panel of 1,479. Patients were screened for depression with the PHQ-2 during their wellness visits. Two new cases of depression were identified in the study group, compared to none in the control group. A randomization test, based on 5,000 trials, was done to assess statistical significance. The rate of new diagnosis with the depression screening tool was observed to be 0.062 with an associated 95% confidence interval of between 0 and 15.6%. Associated p-value was 0.243. Although 6.2% was not a statistically meaningful difference, this project holds clinical relevance. By implementing routine depression screenings, discussion of depression was found to be initiated more often, and patients' perceived barriers to seeking help for depression were addressed.

*Keywords:* depression screening, primary care, patient health questionnaire

## CHAPTER 1 - DESCRIPTION OF THE PROBLEM

### An International Public Health Concern

Depression is a common, yet underdiagnosed, chronic disorder encountered in primary care and is responsible for substantial impairment in individuals' quality of life and their ability to function in society. The impact of depression is substantial worldwide. According to the World Health Organization (2012), depression affects an estimated 350 million people, and is the leading cause of worldwide disability. Depression is associated with a decrease in workplace productivity and increased absenteeism. Taking into account the 27 days of work lost per depressed employee each year, this translates to a \$36.6 billion loss per year in the U.S. alone (Kessler et al, 2006).

Depression is a mental disorder that presents as depressed mood and/or loss of interest or pleasure, along with decreased energy, feelings of guilt or low self-worth, disturbed sleep or appetite, recurrent thoughts of death, and poor concentration (American Psychiatric Association, 2014). It often is accompanied with symptoms of anxiety and can become chronic or recurrent, leading to substantial impairments in individuals' activities of daily living (WHO, 2012). Major depressive disorder affects approximately 14.8 million Americans over the age of 18, or about 6.7% of the U.S. population (Depression and Bipolar Support Alliance, 2016). In addition, depression leads to approximately one million deaths per year to suicide, translating to 3,000 suicide deaths every day. For every person who completes a suicide, 20 or more may attempt to end their life (WHO, 2012).

At the World Health Assembly in 2013, the Comprehensive Mental Health Action Plan for 2013-2020 was adopted. This action plan recognized the importance of mental health issues including depression, as well as the important role primary care plays in effective identification and treatment. The World Health Assembly's action plan emphasized the importance of prevention, supported integrated mental health and social care services, and recognized that mental health has an essential role in achieving health for all people (WHO, 2015).

#### State and Local Impact

Data from 2013 reported that a rural Western state of interest has a depression rate of 21.1% (Centers for Disease Control and Prevention {CDC}, 2013). This is more than three times the reported national depression rate of 6.7% (Depression and Bipolar Support Alliance, 2016). The Community Needs Assessment Executive Report (Professional Research Consultants, Inc. 2015) reported that 24.8% of those interviewed in the county of interest were diagnosed with depression, and 27% in the city of interest.

Due to the high overall depression rate, this particular state's residents are at an especially high risk for suffering the consequences of under-diagnosed and under-treated depression, including completed suicide. The state has the highest rate of suicide in the U.S. (Department of Public Health & Human Services {DPHHS}, 2014). Additionally, the state has ranked in the top five for suicide rates nationwide for the past forty years (DPHHS, 2014) and has a suicide rate nearly double the national rate. Nationally, 12 people per 100,000 complete suicide, compared to 21.4 people per 100,000 in the state

(DPHHS, 2014). The state's Office of Vital Statistics reported a suicide rate of 16.3 per 100,000 between 2010 and 2011 in the county of interest; lower than the state rate but still higher than nationally (DPHHS, 2014).

In 2013, the Governor implemented the state's own action plan, outlining health improvement priorities and strategies to improve the health of state citizens (DPHHS, 2014). Included as a health indicator in the action plan was the goal of decreasing the proportion of adults who report days of poor mental health in the last 30 days from 33% to 27% (DPHHS, 2014). The importance of screening for depression was specifically mentioned within the plan's action areas of public health policy strategy as well as clinical preventive service.

## CHAPTER 2 - EXAMINATION OF THE EVIDENCE

### Gap in Depression Identification

Depression is the second most common chronic disorder seen by primary care providers (Sharp & Lipsky, 2002). Despite this, those health care providers are not reliable at identifying cases of depression without the help of screening tools (Mitchel, Vaze, & Rao, 2009). Mitchel et al. (2009) found that primary care providers correctly identified depression without the use of a screening tool in only 47.3% of cases. Lyness and colleagues (2015) suggested depression is complex and often requires numerous office visits to accurately diagnose. Effective identification of depression requires reliable screening methods, as well as interventions that encourage patients to disclose their depression symptoms and providers to ask about depression. Early identification and effective treatment significantly decrease the negative impact of depression in most patients (Sharp & Linsky, 2002).

### Barriers to Depression Identification

Screening for depression in primary care is a controversial topic among the medical community, with some studies claiming that harms outweigh the benefit (Thombs, Ziegelstein, Roseman, Kloda, & Ioannidis, 2014). This controversy may also be due to findings that screening alone without ancillary staff, such as counselors to provide depression care support does not result in improved outcomes in the successful recognition or management of depression (O'Connor, Whitlock, Bell, & Gaynes, 2009).

Narayana & Wong (2014) described four conditions needed for screening asymptomatic patients for a medical condition: 1) the condition causes a significant burden in the population; 2) an easy to administer, effective screening test exists; 3) early treatment is more effective than later treatment; and 4) the benefits of the screening test/treatment outweigh its potential harm. Considering the evidence as a whole, the U.S. Preventive Services Task Force (USPSTF, 2016) recommended screening for depression in the general adult population, including pregnant and postpartum women. Screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up. This recommendation is given a grade “B”, defined as there being high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.

Contributing to the problem of the under-identification of depression is that patients will rarely discuss emotional struggles with their primary care providers. Instead of discussing emotional issues, patients are more likely to present with somatic symptoms such as fatigue or other persistent vague physical symptoms (Sharp & Lipsky, 2002). In addition, many adults subscribe to beliefs likely to inhibit explicit requests for help from their primary care physician during a depressive episode (Bell, et al., 2011). A systematic review of qualitative studies revealed patients fear potential stigma associated with psychological diagnosis as one of the most powerful barriers (Schumann, Schneider, Kanert, Lowe, & Linde, 2012). Some believe their mental health concerns fall outside the scope of primary care or doubt the primary care providers’ knowledge of mental health issues (Kravitz, et al., 2011). A similar pattern exists regarding patients’ beliefs

that clinicians would think them “unbalanced” or “neurotic”, with the greatest stigma expected from primary care providers (Barney, Griffiths, Jorm, & Christensen, 2006, p. 53). Despite these barriers, however, the likelihood of patients seeking help from their primary care provider is greater than that of other clinicians (Barney et al. 2006).

### Missed Opportunities to Prevent Suicide

Between 85% and 90% of individuals with major depression remain largely untreated, placing them at high risk for suicide (Gilbody, Whitty, Grimshaw, & Thomas, 2003). Additionally, a significant number of those who complete suicide (40% to 60%) have seen a primary care provider within a month of their deaths (Luoma, Martin, & Pearson, 2002). Other researchers have found that 90% of those across all age groups who complete suicide will seek help mainly from physicians and nurses in primary care settings three months prior to their deaths (DeLeo, Draper, Snowdon, & Kolves, 2013). Because the majority of patients with depression are likely to seek help initially in the primary care setting, improved efforts in this area regarding depression screening and diagnosis could potentially lead to more effective treatment of depression overall. Clearly, examination of the evidence reveals a gap in applying the best evidence. This led to identification of the best instrument to address this clinical gap.

### An Evidence-Based Screening Tool

The Patient Health Questionnaire-9 (PHQ-9) was originally constructed for the screening of major depression (Adler, Hetta, Isacson & Brodin, 2012), but can be used

for screening/diagnosis and monitoring treatment progress (APA, 2015). The PHQ-9 (see Appendix A) is comprised of nine questions based on DSM-IV criteria for depressive episodes: 1) little interest or pleasure in doing things; 2) feeling down, depressed, or hopeless; 3) trouble falling or staying asleep, or sleeping too much; 4) feeling tired or having little energy; 5) poor appetite or overeating; 6) feeling bad about yourself – or that you are a failure or have let yourself or your family down; 7) trouble concentrating on things, such as reading the newspaper or watching television; 8) moving or speaking so slowly that other people could have noticed, or the opposite – being so fidgety or restless that you have been moving around a lot more than usual; thoughts that you would be better off dead or of hurting yourself. These nine criteria are scored by the test taker to be a problem for them “not at all” (no points), “several days” (one point), “more than half the days” (two points), or “nearly every day” (three points). The total score for the PHQ-9 can range from 0-27, with a total greater than ten indicating the possibility of the presence of major depressive disorder (MDD). The PHQ-9’s validity has been established in primary care studies with 88% sensitivity (ability to correctly identify those with depression), and 88% specificity (ability to correctly identify those without depression) for scores greater than ten for MDD, and has high internal consistency (APA, 2015).

Thombs et al. (2014) stated that, while sensitivity and specificity are most often reported, a screening test’s predictive values are more clinically relevant. Positive predictive value is the probability a patient with a positive screen actually has the illness, while a negative predictive value is the probability a negative test accurately rules it out. According to Williams and Nieuwsma (2014), in a population with 10% prevalence of

MDD, a score of greater than ten on the PHQ-9 has a positive predictive value of 45% of and a score of less than ten has a negative predictive value of 90%. Because of this, the test is a particularly strong screen for ruling out the presence of depression.

To be diagnosed with MDD, a patient must score two points or greater on the first two criteria questions: 1) little interest or pleasure in doing things; and 2) feeling down, depressed, or hopeless. These two questions make up the PHQ-2 (see Appendix B), a shorter version of the PHQ-9 that has been validated in three studies with wide sensitivity variability and can serve as a first contact screening tool (Maurer, 2012). The PHQ-2, with its two questions about mood and anhedonia, is as effective as longer screening instruments, such as the Beck Depression Inventory or Zung Depression Scale (Maurer, 2012). The PHQ-2 has been found to be up to 97% sensitive and 67% specific in adults, and has a 38% positive predictive value and a 93% negative predictive value (Maurer, 2012). Positive screens would then be followed up with administration of the PHQ-9.

### Project Question

Untreated depression has a substantial negative impact on an individual's quality of life, and leads to increased suicide rates (WHO, 2012). Patients suffering from depression can only be treated appropriately if diagnosed, and diagnosis begins with accurate identification. Most people will seek help from their primary care provider (Barney et al. 2006), but recognition of depression in the primary care setting is poor without effective screening tools (Mitchel et al. 2009). Early identification of depression results in significant reduction of its negative impact upon a patient's quality of life

(Sharp & Linsky, 2002), therefore the important question for this project was: among adult patients, does routine administration of the PHQ-2 during wellness visits improve identification of depression compared to routine care in one primary care clinic in a Western state? It should be noted that this state has a suicide rate nearly double that of the nation as a whole (DPHHS, 2014).

### Setting of Interest

A practice gap exists at the setting of interest, a primary care clinic in a small urban center where health care staff consists of six physicians and eight nurses. The setting also included additional clinical staff to aid in the treatment of depression. Three PhD-prepared psychologists are available for counseling referrals and consult. However, while efforts to support routine screening during wellness visits is being done for adolescents and those over sixty five, patients between those ages receive less attention. For patients between the ages of 18 and 64, a routine depression screening is not currently implemented. This current practice served as a control against which outcomes of implementing a depression screening tool during wellness visits for these patients were compared.

The organizational culture is one that strives for excellence in improving the overall health and well-being of the community. Among employees, there is value placed on the continuous improvement of quality and safety. Health care staff are often involved in quality improvement projects. During discussion with one of the clinic's primary care physicians, who had practiced in the group for over twelve years, he agreed that

implementing efforts to increase depression recognition among this population in this setting was “the right thing to do” (Anonymous, personal communication, April 17, 2015). This particular physician’s patient panel, consisting of 1479 patients, served as the population of interest for this project. In the event that he became unable to participate, a colleague was to serve as an alternate and her patient population was to be sampled in the same manner.

### Theoretical Underpinning

Jean Watson’s Theory of Human Caring is a grand theory that values the patient-provider relationship and places the patient at the center of practice (Current Nursing, 2012). Watson’s model is based in the context of caring as both a tool and a philosophy for nursing practice and contains core principles and concepts directly relevant to the identification of patients with depression. Her theory supports ten primary carative factors:

1. The formation of a humanistic-altruistic system of values.
2. The installation of faith-hope.
3. The cultivation of sensitivity to self and others.
4. The development of trust
5. The promotion and acceptance of the expression of positive and negative feelings.
6. The use of scientific problem-solving method for decision making.
7. The promotion of interpersonal teaching-learning.

8. The provision for a supportive, protective and/or corrective mental, physical, socio-cultural and spiritual environment.
9. Assistance with the gratification of human needs.
10. The allowance for existential-phenomenological forces.

(Current Nursing, 2012, The Ten Primary Carative Factors section).

Overall, Watson's belief in the value of holistic health care was a reminder to recognize the importance of both the scientific and the personal realms; the marriage of the art and science that is nursing.

Three out of Watson's ten carative factors in particular were used to guide project decision making, the first being "cultivation of sensitivity to self and others" (Current Nursing, 2012, The Ten Primary Carative Factors section). Administering a screening tool for any mental health issue requires sensitivity on the part of the provider to understand that it may be difficult for patients to discuss such personal subjects. Sensitivity to self is also needed for accepting that as providers, sometimes diagnostic assistance is needed in the form of a screening tool.

Watson's carative factor of "developing and sustaining a helping, trusting, authentic, caring relationship" (Current Nursing, 2012, The Ten Primary Carative Factors section) was also relevant. Her theory placed high value on honoring the relationship and trust between a patient and a provider, thus enhancing open communication. Another aspect of this component is to practice non-judgmental attitudes (Current Nursing, 2012). This practice is particularly important when dealing with a health care problem associated with a stigma, such as depression. This factor is closely related to "the promotion and

acceptance of the expression of positive and negative feelings” (Current Nursing, 2012, The Ten Primary Carative Factors section), without which identification of patients suffering from depression would not be possible.

## CHAPTER 3 – METHODOLOGY

Ethical Considerations

Review by the University Institutional Review Board (IRB) review was sought prior to conducting both the retrospective data collection and intervention to ensure ethical guidelines were met. Additional clinic site IRB review was not required. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule states that, in the course of conducting research, the researcher may obtain, create, use, and/or disclose protected health information (PHI) without authorization if documented IRB approval has been granted to do so (U.S. Department of Health & Human Services, {DHHS}, 2013). In order for an IRB to approve waiver of participant authorization, the following three criteria must be satisfied: “use of PHI involves minimal risk to individual privacy; the research could not practicably be conducted without waiver; and the research could not practicably be conducted without access to and use of the PHI” (U.S. DHHS, How the Rule Works section, paragraph 3, 2013). These criteria were met in order to collect retrospective data to use in this project without the authorization of those patients of interest.

This project had the potential to affect participants’ well-being psychologically more than physically, due to the psychological subject matter being addressed. The nature of the project had very limited potential to cause physical or psychological harm to its participants, and this was supported by IRB approval. Participants’ anonymity was protected by not including any form of PHI in published outcomes other than site

location. It should be noted that all geographical subdivisions smaller than a state are considered PHI under HIPAA (University of Berkeley, 2015). In the case that severely depressed patients who were at risk of harm to themselves or others were identified, immediate referral would have been made available to either the emergency department or mental health crisis team for assessment and inpatient admission if appropriate.

### Administration of PHQ-2

Due to its proven ability to serve as a first contact screening tool (Maurer, 2012) the PHQ-2 was given to patients between 18 and 64 without a current diagnosis of depression during their wellness visits. This intervention had the potential to lead to an increase in the number of patients identified with a new diagnosis of depression; furthermore, it opened a dialogue between patient and provider regarding the importance of identifying and treating mental health issues. Watson's carative factor of *developing and sustaining a helping, trusting, authentic, caring relationship* (Wagner, 2010) places value on enhancing open communication such as this.

The current rooming process at the chosen setting for wellness visits is done by nursing staff with the same nurse always paired with a provider. The nurse involved is the author of this project. This process consisted of updating medication lists, reviewing allergies, medical, family, and surgical histories, and taking vitals. Nursing staff also reviewed any appropriate preventive care (i.e. screenings and immunizations) with the patient based on age, risk factors, and current best practice guidelines. During the

appointment, the provider discussed with the patient the preventive cares that have yet to be addressed and made decisions regarding which items to pursue.

The nurse provided each patient, meeting inclusion criteria, a PHQ-2 at the end of the rooming process, prior to their time with the provider but while the nurse was still present. In the event the PHQ-2 was positive, the PHQ-9 was then given to assess the severity of their depression. Considering Watson's carative factor of *cultivation of sensitivity to self and others* (Wagner, 2010), administering the PHQ-9 at this time gave the patient time to complete it in privacy while the hand-off from nurse to provider was taking place outside the room. The provider checked the PHQ-9 result at the beginning of the visit, allowing them to plan adequate time to discuss depression with the patient, or schedule a follow up visit if needed. Watson's carative factor of *promoting and accepting expression of positive and negative feelings* served as a reminder that sometimes more time than was available at the wellness visit was needed for patients to fully express the extent of their depressive symptoms.

Wellness exams consisted of 30 minute appointments for patients under 50, and 60 minute appointments for those over 50. All outcomes were entered into the patient's chart in the electronic medical record, which contained a specified place for the PHQ-2 and PHQ-9 screenings. Using a single provider and nurse pair reduced the possibility for differences in both the presentation of the PHQ-2 by the nurse and the diagnostic style of the provider.

The PHQ-2 was implemented at wellness visits for a total of 33 patients meeting inclusion criteria beginning May 2, 2016 and ending July 25, 2016. To create a control

group of equal size, retrospective data was gathered via chart review from the 33 patients meeting inclusion criteria that had wellness visits immediately prior to the implementation period. Data collected for the control group came from a sample spanning from to February 12 to May 1, 2016.

## CHAPTER 4 – OUTCOMES

Overview of Project Context

The design of this study involved investigating whether a statistically significant difference existed between the percentages of patients with depression identified during their wellness visits when given the PHQ-2 as opposed to those given usual, customary care. The identification of depression was defined as: referral to behavioral health staff for counseling for depression, initiation of a prescription for antidepressant medication, and/or other mention by the physician of depression in the office visit note. Descriptive statistics for such a model consisted of a proportion in each category. Inferential statistics for this nominal, independent measures data involved a chi-square test for independence to evaluate the group differences (Gravetter & Wallnau, 2014).

The null hypothesis was that there would be no difference in the proportions of adults with newly identified depression between those given the PHQ-2 and those who had not received the PHQ-2 at their wellness visits. The alternative, and expected hypothesis, was that these population proportions will not be equal and, in fact, the group screened with the PHQ-2 depression screening tool would have an increased proportion of identified depression. Outcomes were stated with the chi-square test for independence evaluating the statistical significance. Because this study was not a repeated-measures design, but rather an independent measures design, strong time-related or order effects were not expected (Gravetter & Wallnau, 2014).

### Characteristics of Sample Population

Using the most recent reports from the electronic health record (EHR) system, the patient panel population as a whole is summarized as follows in Figure 1:

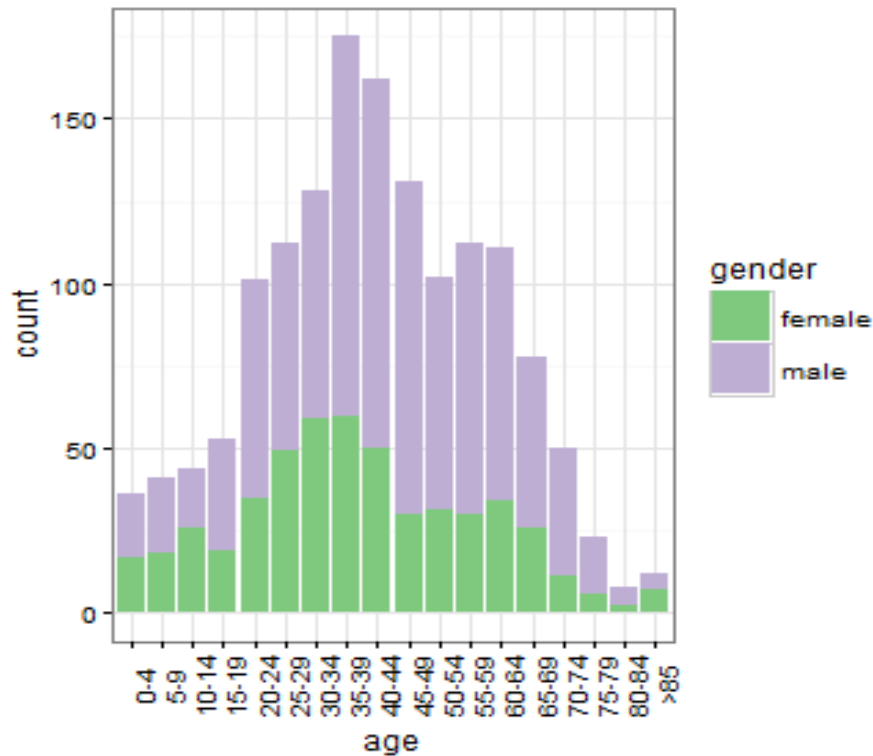


Figure 1. Sample patient panel population demographics by age and gender (Mack & Lin, 2016).

To calculate the depression rate among the patient panel investigated, a report was generated using the existing electronic health record system including all patients with current depression diagnoses with an office visit over an 18 month period from July 2, 2014 to September 28, 2015. The ICD-9 diagnosis codes used are summarized in Table 1.

<u>ICD-9 Code</u>	<u>Diagnosis</u>
300.4	Dysthymic disorder
296.34	Major depressive affective disorder, recurrent episode, severe, specified as with psychotic behavior
296.35	Major depressive affective disorder, recurrent episode, in partial or unspecified remission
298.0	Depressive type psychosis.
296.32	Major depressive affective disorder, recurrent episode, moderate.
296.33	Major depressive affective disorder, recurrent episode, severe, without mention of psychotic behavior convert
311.0	Depressive disorder, not elsewhere classified
296.20	Major depressive affective disorder, single episode, unspecified
296.21	Major depressive affective disorder, single episode, mild convert
296.22	Major depressive affective disorder, single episode, moderate convert
296.23	Major depressive affective disorder, single episode, severe, without mention of psychotic behavior convert
296.24	Major depressive affective disorder, single episode, severe, specified as with psychotic behavior convert
296.31	Major depressive affective disorder, recurrent episode, mild convert

Table 1. ICD-9 Diagnosis Codes Used in Generating Report of Patients with Depression Diagnosis

This provider sees the patients with depression for annual follow up, so this method should have captured all patients with a diagnosis of depression. Some patients required closer follow up – especially those with newer depression diagnoses or depression that is more severe or associated with other comorbidities. Patients with more than one visit in that 18 month period were only counted once. The total number of patients with depression was 85, which translating to a depression rate of 5.7%.

Various demographic and socioeconomic variables potentially affect a person's likelihood of experiencing depression. This correlated with findings of those patients with a current diagnosis of depression among the sample patient panel. Like the panel overall, most people had some form of private insurance. The next highest category, however, was those having no insurance coverage (represented by "NA" in Figure 2), or a form of

Medicaid, indicating lower income groups. The smallest group had some form of Medicare coverage.

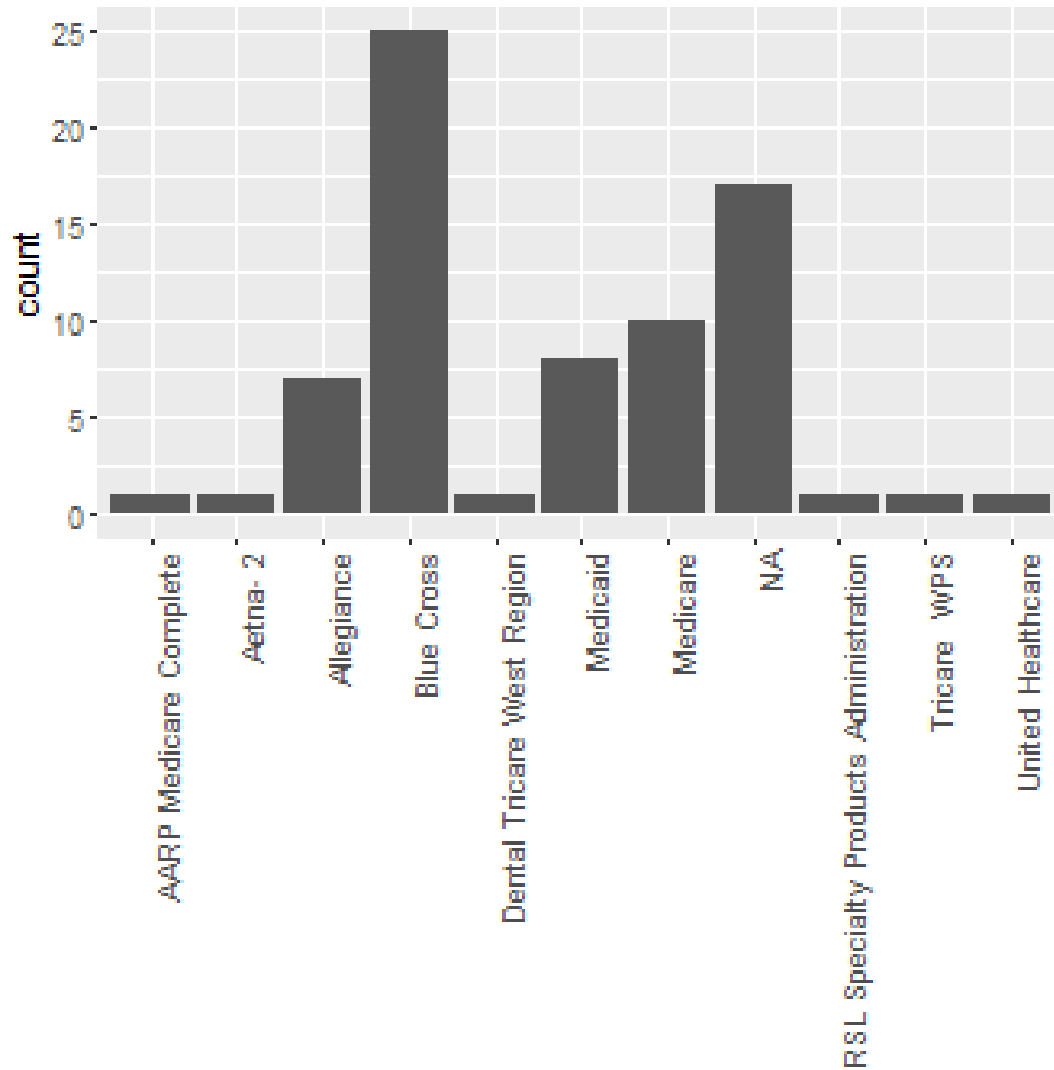


Figure 2. Insurance coverage of patients with diagnosis of depression (Mack & Lin, 2016).

Insurance coverage of the patient panel as a whole differed from the group of patients with depression. Using EHR system data going back to December 7, 2016, a

coverage status report showed that the largest group, once again, had private insurance. However, the next most common forms of coverage were Medicare, Medicaid, then none, respectively. Because of this, perhaps it can be inferred that patients with depression diagnoses consist of a lower income group than the patient panel in general.

Overall, the patient panel consisted of more males than females, as seen in Figure 1. However, more females than males had diagnoses of depression. This is consistent with data supporting higher depression rates among women (Cohen & Martinez, 2015). One reason for this may be that females may be diagnosed with depression, rather than physical issues, more than men.

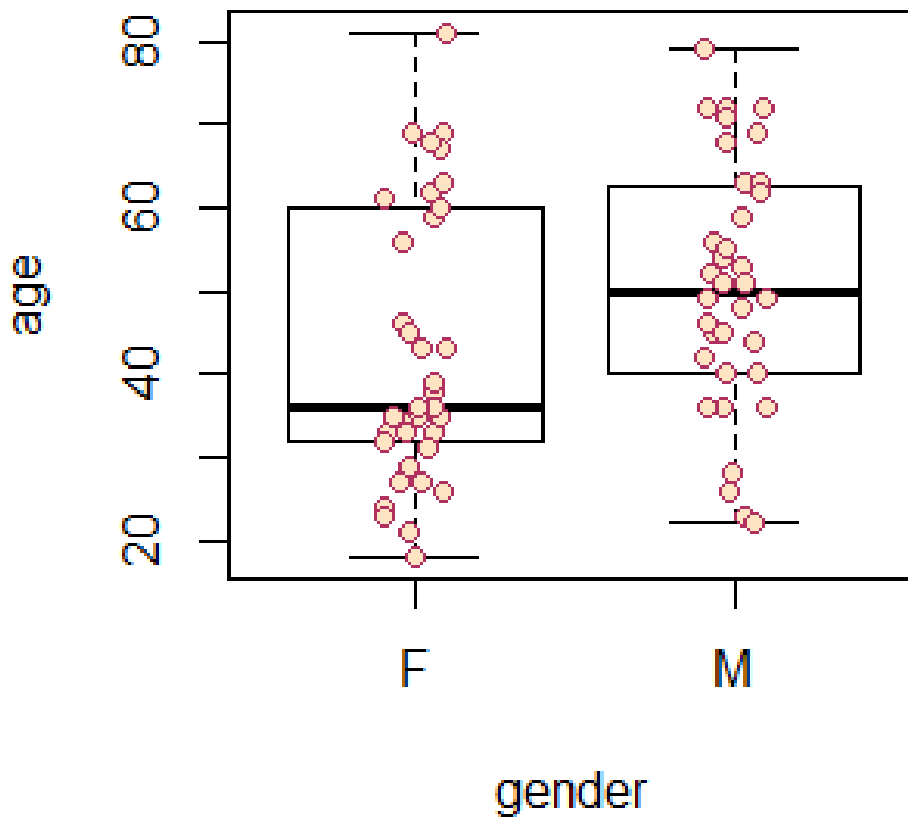


Figure 3. Sample depression patient population demographics by age and gender (Mack & Lin, 2016).

Gender	Frequency
F	0.51
M	0.49

Figure 4. Sample depression patient population gender frequency (Mack & Lin, 2016)

#### Outcomes of Depression Screening

Of the 33 patients that met criteria to be screened with the PHQ-2, one patient declined to participate in the study project. Of the 32 patients screened for depression with the PHQ-2, two positive screenings resulted. Both patients with positive screens were between the ages of 30 and 40, one female and one male. One of these patients did not feel comfortable filling out the PHQ-2 screening form with the nurse in the room. This interrupted the intended work flow of implementing the PHQ-9 due to a positive screen. Although a PHQ-9 was not completed, this patient did discuss the depression symptoms with the provider. The patient's PHQ-2 score was a 2 (positive screen).

The second patient completed the PHQ-2 with a score of 2 (positive screen), and was then given the PHQ-9 where the patient scored a total of 19. This score correlated with a score >10 indicating the possibility of major depressive disorder (MDD). Both of these patients were diagnosed by the physician with depression at their visit. A prescription anti-depressant medication was initiated as well, with instructions to follow up in one to two months; sooner if the patient had any questions or concerns. In both cases, the medication of choice was the selective serotonin uptake inhibitor (SSRI) Wellbutrin, and an offer for referral to counseling was made.

Out of the 32 patients that met criteria for the control group, none were found to have been newly diagnosed with depression at their wellness visit appointments. When this raw data was compared (2 new depression cases in the project group versus none in the control group), these outcomes seemed to be consistent with the expected hypothesis of there being a larger proportion of identified depression cases in those given the PHQ-2 when compared to those receiving usual, customary care. However, statistical analysis did not support this outcome.

#### Statistical Analysis

The chi-squared test for independence and the two sample t-test for a difference in proportions only hold when there are at least 5 successes (depression diagnoses) and at least 5 failures (no depression diagnoses). Unfortunately, both tests could not be used as originally planned due to there being less than 5 successes in the study group (Mack & Lin, 2016). Statistical analysis to provide a confidence interval consisted of a randomization test based on 5,000. The rate of new diagnosis using the PHQ-2 was observed to be 0.062,  $p = 0.243$ , 95% CI [0, 0.156], meaning that 6.2% more people were newly diagnosed with depression with the screening tool.

## CHAPTER 5 – DISCUSSION

Implementation of the Intervention

This project was implemented into the current workflow of the clinic without much change or disruption to the usual, customary care. In a busy primary care setting this is important due to the need to stay efficient and any disruption in work flow can potentially serve as a hindrance to quality care. Because of this, stakeholder buy-in from the involved physician was obtained without difficulty. The implementation of the PHQ-2 was, therefore, an example of a small change that could potentially result in large benefit.

Another benefit obtained by implementing this intervention with minimal disruption to current workflow was that the risk of confounding variables was kept to a minimum. The capabilities of the current EHR system were utilized as the patient scores on the PHQ-2 and PHQ-9 were entered and became a permanent, retrievable part of the patient medical record. Overall, implementation of this project was done in such a way that continued administration of the PHQ-2 at wellness visits as a routine addition to the workflow could be a smooth transition from usual, customary care.

Difficulties in implementation included the patients' reluctance to be screened due to fear of having a potential mention of a mental health issue in their medical record. Out of the 33 patients meeting inclusion criteria to be screened, one of these stated that she did not want to participate because she feared that having information about a mental illness in her medical record would impact her ability to obtain employment as a child

care provider. This instance raised a valid reality regarding society's stigma related to mental health in general, and the specific stigma that exists surrounding depression (Schumann et al., 2012).

Occasionally, participants exhibited hesitance in completing the PHQ-2 with a nurse in the room with them and seemed uncomfortable doing so. However, time would not allow for the nurse to exit the room, and, then return again once the patient was finished to collect the PHQ-2 and administer the PHQ-9 if needed. When the nurse sensed a patient's hesitance, they did leave the room and allowed for the patient to complete the screening form in privacy. However, this did result in a lack of PHQ-9 implementation if needed, as seen in one of the two positive screens. An additional difficulty was related to the administration and length of the consent form used in the project study (see Appendix 3), which contributed to a sense of urgency when giving patients the consent form during their office visit. This potentially resulted in a less than thorough reading of this form on behalf of the participants.

Addressing these issues would promote Jean Watson's carative factors of cultivation of sensitivity and developing trust in communication (Wagner, 2010) by removing barriers for clear communication. A possible solution would be to distribute both the consent form and PHQ-2 to patients via the front desk staff at their time of check-in. The nurse would then follow through with administration of the PHQ-9 in the case of a positive PHQ-2, as this instrument could also be completed in privacy between the time the nurse left and when the provider entered the room. This work flow would allow patients more time to read the consent form in its entirety without feeling rushed

and would increase their privacy while completing both the PHQ-2 and PHQ-9.

However, this strategy would not allow the nurse to explain the forms, which may not be ideal.

### Limitations

A main limitation in this project study was the sample size. A sample size of 150 would have been ideal in both the control and the project groups to assure data quality and adequacy. This number was estimated using G-power analysis for ensuring  $\alpha = 0.05$  and  $\beta = 0.80$  comparing two proportions if group “A” proportion ( $p_A$ ) is estimated at 0.1 and group “B” proportion ( $p_B$ ) is estimated at 0.2 (HyLown Consulting, LLC, 2015). This is based on a generous and optimistic estimation of difference between groups; a much larger sample size may be needed to produce adequate power if actual statistical difference were less.

The number of participants in both the control and the project groups was limited to 33. Time constraints for the implementation of this project as well as the project design did not allow for collection of a larger sample size. A potential result of the small size of the control group was that no new depression diagnoses were captured. A problem exists with no new diagnoses in the control group because, as a result, there was no estimate of the variation in that diagnosis rate. This affected Mack & Lin’s (2016) statistical analysis because the randomization method of creating a confidence interval for the difference in depression identification will always be at or above zero. This is important because it is

misleading to suggest that implementation of the PHQ-2 resulted in at least as many or more patients with depression being identified as without it.

It is also important to recognize that if the sample size in each group had been large enough to capture a positive new diagnosis rate in the control group, the confidence interval may have suggested a lower diagnosis rate using the screening tool than without it. Associated p-value was 0.243, meaning that in the long run, there is a 24.3% chance of seeing 6.2% more new depression diagnoses with the PHQ-2 if there is in reality no difference in diagnosis rate among the two groups. Considering these issues with statistical analysis, it is important to only extend the results to the patients included in the study and not a larger population. (Mack & Lin, 2016).

While a larger sample size may have resulted in statistically significant outcomes, another limitation affecting the generalizability of the findings was that the sample may not have been an accurate representation of the population as a whole. While the depression rate of 5.7% among the particular patient panel that served as the study group is close to the national average of 6.7%, it is dramatically lower than that of the specific county (24.8%) or state (21.1%). The reasons for this difference include the city's status as an affluent college town whose population enjoys both a higher education level and median income in relation to other cities and towns in the county. Both education and income are variables that are known to impact depression rates. The 2014 Community Needs Assessment for counties including the county of interest found that in this area the prevalence of diagnosed depression was notably higher among community members living at lower incomes (Professional Research Consultants, 2015). Including a variety of

primary care clinic sites in different locations would have produced a sample more representative of the population as a whole.

Confounding factors, such as seasonality, are known to affect depression (Keller et al., 2005). Although there was only a difference of four months from the beginning of control group (February to May), and study group (May to July), there may be a difference in depression diagnosis rates overall between of this. Ideally, data from the same time period the year prior would be used to form the control group in an attempt to limit this confounding factor. Due to limitations of data accessibility from the previous EHR system (a new EHR system was implemented in December, 2015), this was not possible and so seasonality may or may not be associated with the resulting diagnosis rates.

There is the potential that implementing routine depression screening in a setting where patients are less well-known to healthcare providers would result in even more cases of depression being recognized. Lyness and colleagues' (2015) suggested that depression is complex and often requires numerous office visits to accurately diagnose. In the sample used for this project, most patients were already well-established with the provider. This could mean that the chances of new cases of depression being diagnosed are lower than if this study would have been implemented in a setting where less established relationships exist between provider and patient. The use of a variety of community health centers as settings would be a valuable addition to the sample pool in this regard.

Outcomes may have also varied had the patients been screened for depression at every office visit instead of only during wellness visits. Patients may be less focused on complaints and more focused on their general and preventive health during the wellness visits, making them less likely to disclose depression symptoms. Including depression screening during all office visits would capture patients with somatic complaints often associated with depression (ie: headaches, pain, abdominal issues) and this could be beneficial. However, because these appointments typically last 15 minutes as opposed to the 30 or 60 minute wellness visits, adequate time for addressing positive screens is scarce. Follow up appointments would need to be made to specifically discuss depression. Considering these limitations, recommendations for further study include: 1) a longer study duration to minimize seasonality and improve sample size, 2) an expanded sample pool including other primary clinic settings to increase generalizability, and 3) implementation of routine depression screening with the PHQ-2 at all appointments, not only wellness visits, to capture depression among patients presenting with specific complaints.

### Implications for Nursing

By implementing routine depression screening using the PHQ-2 in primary care settings, nursing management can address a possible lack of accurate identification of patients suffering from depression by providers (Mitchel, Vaze, & Rao, 2009). Introducing a depression screening during wellness visits could also help to challenge what Kravitz, et al. (2011) found to be a commonly held belief among patients that their

mental health concerns fall outside the bounds of primary care and demonstrate to patients that their mental health is valued as much as their physical in relation to their overall well-being.

Review of the literature showed that patients with depression face a barrier to proper diagnosis and treatment resulting from a fear of stigma surrounding depression and mental health issues in general (Schumann, Schneider, Kantert, Lowe, & Linde, 2012). This fear results in a reluctance to bring up depression with their primary care providers. In order to reduce that barrier, efforts should be made in both undergraduate and graduate nursing education to teach nurses how to therapeutically communicate with patients using Watson's (Current Nursing, 2012) carative factors. Watson emphasizes cultivation of trusting relationships and promoting the expression of feelings. Both are necessary to create an environment in which patients will disclose depression symptoms to their health care providers. This is important, especially in the rural, Western state setting where attitudes regarding depression as a weakness are common (McGreal, 2016).

The subject of depression was brought up in provider/patient conversation during wellness visits much more frequently with the PHQ-2 in place than prior to project implementation. The physician involved estimated that he asked patients aged 18-64 directly about depression symptoms roughly 50% of the time during wellness visits. In those 65+, however, depression is addressed directly 100% of the time due to Medicare requirements/documentation (Anonymous, personal communication, April 28, 2016). By implementing a routine screening tool, the frequency of direct questioning regarding patients' potential to be suffering from depression was improved from 50% of the time to

100% of the time among those between 18 and 64 in this case. This can be considered a key success due to the strong evidence according to Sharp and Lipsky (2002) that patients will rarely discuss emotional struggles with their primary care providers, and routine depression screening could potentially open the door for future conversations regarding mental health. Implementation of the PHQ-2 to screen for depression was seen by the provider/nurse team involved in this project as an overall improvement over the usual, customary care and was continued in the setting of interest going forward as an effort to improve identification of patients with depression.

### Conclusion

Untreated depression has a substantial negative impact on an individual's quality of life, and leads to increased suicide rates (WHO, 2012), while early identification of depression results in significant reduction of its negative impact (Sharp & Linsky, 2002). Depression is the second most common chronic disorder seen by primary care providers (Sharp & Lipsky, 2002) and most people will seek help from their primary care provider (Barney et al. 2006). Despite this, recognition of patients with depression in the primary care setting is poor without effective screening tools (Mitchel et al., 2009), and barriers exist for patients regarding their willingness to discuss depression with their primary care provider such as fear of stigma and the belief that depression falls outside the scope of primary care (Kravitz, et al., 2011).

This scholarly project addressed an existing practice gap regarding depression screening among primary care patients and a solution to address that gap that could be

easily implemented using the PHQ-2 (APA, 2015), an evidence based depression screening tool. This project also attempted to answer the following study question: among adult patients, does administration of the PHQ-2 improve the identification of depression when compared to routine care in one primary care clinic in a rural Western state? Results showed that in this setting, 6.2% additional patients were newly diagnosed with depression when the PHQ-2 depression screening tool was given during wellness visits, compared to usual, customary care. Although 6.2% was not found to be statistically significant, the use of the PHQ-2 has potential to improve the identification within patients visiting their primary care providers. Regardless of statistical outcomes, this project resulted in increased discussion of depression among health care provider and patient, which is significant in its impact on normalizing conversation about depression in the primary health care setting.

REFERNCES CITED

- Adler, M., Hetta, J., Isacson, G., & Brodin, U. (2012). An item response theory evaluation of three depression assessment instruments in a clinical sample. *BMC Medical Research Methodology*, *12*(84).
- American Psychiatric Association (2014). Criteria for major depressive episode: DSM-5. Retrieved from [http://www2.nami.org/content/navigationmenu/intranet/homefront/criteria\\_major\\_d\\_episode.pdf](http://www2.nami.org/content/navigationmenu/intranet/homefront/criteria_major_d_episode.pdf)
- American Psychological Association (2015). *Patient health questionnaire (PHQ-9 & PHQ-2)*. Retrieved from <http://www.apa.org/pi/about/publications/caregivers/practice-settings/assessment/tools/patient-health.aspx>
- Barney, L., Griffiths, K., Jorm, A., & Christensen, H. (2006). Stigma about depression and its impact on help-seeking intentions. *Australian & New Zealand Journal of Psychiatry*, *40*, 51-54.
- Bell, R., Franks, P., Duberstein, P., Epstein, R., Feldman, M., Garcia, E., & Kravitz, R. (2011). Suffering in silence: Reasons for not disclosing depression in primary care. *Annals of Family Medicine*, *9*(5), 439-446.
- Centers for Disease Control and Prevention (2013). *Behavioral risk factor surveillance system: Open data network*. Retrieved from [http://www.opendatanetwork.com/region/0400000US30/Montana/health\\_indicators/depression\\_rate/2013?](http://www.opendatanetwork.com/region/0400000US30/Montana/health_indicators/depression_rate/2013?)
- Cohen, R., & Martinez, M. (2015). *Health insurance coverage: Early release of estimates from the national health interview survey, January-March 2015*. Retrieved from <http://www.cdc.gov/nchs/data/nhis/earlyrelease/insur201508.pdf>
- Current Nursing (2012). *Jean Watson's philosophy of nursing. Nursing theories: A companion to nursing theories and models*. Retrieved from [currentnursing.com/nursing\\_theory/Watson.html](http://currentnursing.com/nursing_theory/Watson.html)
- DeLeo, D., Draper, B. M., Snowdon, J., & Kolves, K. (2013). Contacts with mental health professionals before suicide: missed opportunities for prevention? *Comprehensive Psychiatry*, *54*, 1117-1123. doi: 10.1016/j.comppsy.2013.05.007
- Department of Public Health & Human Services (2013). Big sky. New horizons. A healthier Montana: A plan to improve the health of Montanans. Retrieved from <https://dphhs.mt.gov/Portals/85/publichealth/Publications/Big%20Sky%20New%20Horizons%20final%209.2013.pdf>

- Department of Public Health & Human Services (2014). Montana strategic suicide prevention plan – 2013. Retrieved from <https://dphhs.mt.gov/Portals/85/amdd/documents/AMDD%20Website%20Migration%20Documents/StateSuicidePlan.pdf>
- Depression and Bipolar Support Alliance (2016). *Depression statistics: Who is affected by depression?* Retrieved from [http://www.dbsalliance.org/site/PageServer?pagename=education\\_statistics\\_depression](http://www.dbsalliance.org/site/PageServer?pagename=education_statistics_depression)
- Gilbody, S., Whitty, P., Grimshaw, J., & Thomas, R. (2003). Educational and organizational interventions to improve the management of depression in primary care: A systematic review. *Journal of the American Medical Association, 289*(23), 3145-3151.
- Gravetter, F., & Wallnau, L. (2014). *Essentials of statistics for the behavioral sciences* (8<sup>th</sup> ed.). Belmont, CA: Wadsworth, Cengage Learning.
- HyLown Consulting, LLC (2015). *Power and sample size*. Retrieved from <http://powerandsamplesize.com/>
- Keller, M. C., Fredrickson, B. L., Ybarra, O., Côté, S., Johnson, K., Mikels, J., . . . Wager, T. (2005). A Warm Heart and a Clear Head: The Contingent Effects of Weather on Mood and Cognition. *Psychological Science, 16*(9), 724-731.
- Kessler, R. C., Akiskal, H. S., Ames, M., Birnbaum, H., Greenberg, P., Hirschfeld, R., . . . Wang, P. S. (2006). Prevalence and effects of mood disorders on work performance in a nationally representative sample of US workers. *American Journal of Psychiatry, 163*, 1561–1568.
- Kravitz, R., Paterniti, D., Epstein, R., Rochlen, A., Bell, R., Cipri, C., . . . Duberstein, P. (2011). Relational barriers to depression help-seeking in primary care. *Patient Education and Counseling, 82*, 207-213.
- Luoma, J. B., Martin, C. E., & Pearson, J. L. (2002). Contact with mental health and primary care providers before suicide: A review of the evidence. *American Journal of Psychiatry, 159*, 909-916.
- Lyness, J., (2015) Unipolar depression in adults: Assessment and diagnosis. In P. Roy-Byrne & D. Solomon, (Eds.), *UpToDate*. Available from [http://www.uptodate.com./contents/unipolar-depression-in-adults-assessment-and-diagnosis?source=search\\_result&search=Unipolar-depression-in-adults:-Assessment-and-diagnosis.&selectedTitle=1~150#topicContent](http://www.uptodate.com./contents/unipolar-depression-in-adults-assessment-and-diagnosis?source=search_result&search=Unipolar-depression-in-adults:-Assessment-and-diagnosis.&selectedTitle=1~150#topicContent)

- Mack, A. & Lin, L. (2016). *Depression screening tool evaluation and patient panel summaries*. Bozeman, MT: Montana State University Statistical Consulting and Research Services.
- Maurer, D. (2012). Screening for depression. *American Family Physician*, 85(2), 139-144. Retrieved from <http://www.aafp.org/afp/2012/0115/p139.html>
- McGreal, C. (2016). Financial despair, addiction and the rise of suicide in white America. *The Guardian*. Retrieved from <https://www.theguardian.com/us-news/2016/feb/07/suicide-rates-rise-butte-montana-princeton-study>
- Mitchell, A., Vaze, A., & Rao, S. (2009). Clinical diagnosis of depression in primary care: A meta-analysis. *The Lancet*, 374, 609-619. doi:10.1016/S0140-6736(09)60879-5
- Murray, C., & Lopez, A. (1997). Alternative projections of mortality and disability by cause 1990-2020: Global burden of disease study. *The Lancet*, 349, 1498-1504.
- Narayana, S., & Wong, C. J. (2014). Office-based screening of common psychiatric conditions. *Medical Clinics of North America*, 98(5), 959-980. doi:10.1016/j.mcna.2014.06.002.
- O'Connor, E., Whitlock, E., Bell, T., & Gaynes, B. (2009). Screening for depression in adult patients in primary care settings: A systematic evidence review. *Annals of Internal Medicine*, 151, 793-803.
- Professional Research Consultants, Inc. (2015). Executive report: 2014 community health needs assessment, Gallatin, Madison, & Park counties, Montana. Retrieved from [http://healthygallatin.org/wp-content/uploads/2013/04/2014\\_PRC\\_CHNARreport.pdf](http://healthygallatin.org/wp-content/uploads/2013/04/2014_PRC_CHNARreport.pdf)
- Schumann, I., Schneider, A., Kantert, C., Lowe, B., & Linde, K. (2012). Physicians' attitudes, diagnostic process and barriers regarding depression diagnosis in primary care: A systematic review of qualitative studies. *Family Practice*, 29, 255-263. doi:10.1093/fampra/crm092
- Sharp, L., & Lipsky, M. (2002). Screening for depression across the lifespan: A review of measures for use in primary care settings. *American Family Physician*, 66(6), 1001-1009.
- Thombs, B., Ziegelstein, R., Roseman, M., Kloda, L., & Ioannidis, J. (2014). There are no randomized controlled trials that support the U.S. Preventive Services Task Force guideline on screening for depression in primary care: A systematic review. *BMC Medicine*, 12(13). doi:10.1186/1741-7015-12-13

- U.S. Preventive Services Task Force (2016). Depression in adults: Screening. Retrieved from  
<http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/depression-in-adults-screening1?ds=1&s=depression>
- U.S. Department of Health & Human Services (2013). OCR HIPAA privacy: Health information privacy. Retrieved from  
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/index.html>
- University of Berkeley (2015). Office for protection of human subjects: Research administration and compliance. Retrieved from  
<http://cphs.berkeley.edu/hipaa/hipaa18.html>
- Williams & Nieuwsma (2014). Screening for depression in adults. In Elmore, J. G., Roy-Byrne, P. P., & Solomon, D. (Eds.), *UpToDate*. Available from  
[http://www.uptodate.com/contents/screening-for-depression-in-adults?source=search\\_result&search=Screening-for-depression&selectedTitle=1~150#topicContent](http://www.uptodate.com/contents/screening-for-depression-in-adults?source=search_result&search=Screening-for-depression&selectedTitle=1~150#topicContent)
- World Health Organization Department of Mental health and Substance Abuse (2012). *Depression: A global public health concern*. Retrieved from  
[http://www.who.int/mental\\_health/management/depression/who\\_paper\\_depression\\_wfmh\\_2012.pdf](http://www.who.int/mental_health/management/depression/who_paper_depression_wfmh_2012.pdf)
- World Health Organization (2015). *Mental health action plan 2013-2020*. Retrieved from  
[http://www.who.int/mental\\_health/publications/action\\_plan/en/](http://www.who.int/mental_health/publications/action_plan/en/)

APPENDICES

APPENDIX A

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

*You are being asked to complete a questionnaire. This is voluntary. You are not required to answer any questions & may stop at any time. Information gathered is for the purpose of questionnaire evaluation.*

**PATIENT HEALTH QUESTIONNAIRE (PHQ-9)**

**NAME:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

Over the last 2 weeks, how often have you been bothered by any of the following problems?  
(use "✓" to indicate your answer)

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

add columns  +  +

(Healthcare professional: For interpretation of TOTAL, TOTAL:   
please refer to accompanying scoring card).

10. If you checked off <i>any</i> problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	_____
	Somewhat difficult	_____
	Very difficult	_____
	Extremely difficult	_____

APPENDIX B

THE PATIENT HEALTH QUESTIONNAIRE - 2

*You are being asked to complete a questionnaire. This is voluntary. You are not required to answer any questions & may stop at any time. Information gathered is for the purpose of questionnaire evaluation.*

## **The Patient Health Questionnaire-2 (PHQ-2)**

<b>Over the past 2 weeks, how often have you been bothered by any of the following problems?</b>	<b>Not At All</b>	<b>Several Days</b>	<b>More Than Half the Days</b>	<b>Nearly Every Day</b>
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3

APPENDIX C

SUBJECT CONSENT FORM FOR PARTICIPATION IN HUMAN  
RESEARCH AT MONTANA STATE UNIVERSITY

SUBJECT CONSENT FORM FOR PARTICIPATION IN HUMAN RESEARCH AT MONTANA STATE UNIVERSITY

You are being asked to participate in a research project titled: **Implementation of an Evidence-Based Protocol to Improve Depression Identification in Primary Care**. This may help us obtain a better understanding of how many people have depression. You were identified as a subject because you are between the ages of 18 and 64.

If you agree to participate you will be asked to complete a screening questionnaire. Participation is voluntary and you can choose to not answer any questions you do not want to answer and/or you can stop at any time. If you decline to participate you will still receive care as usual. There are no foreseen risks, and the project is of no benefit or cost to you. Confidentiality of your personal information will be protected in your secured electronic health record. Source of funding of project: N/A

If you have any questions about the research project, you can contact the principal investigator, Melissa Blixt, RN at 406-414-5724. If you have additional questions about the rights of human subjects you can contact the Chair of the Institutional Review Board, Mark Quin, at 406-994-4707 (mquinn@montana.edu).

AUTHORIZATION TO SHARE PERSONAL HEALTH INFORMATION IN RESEARCH

To do this research project, we need to collect health information that identifies you such as your name, medical record number, and date of birth. We will only collect information that is needed for the project. For you to be in this project, we need your permission to collect and share this information. We will collect the results of screening forms and this information will be discussed between your physician and nurse. Results will be included in a project paper without any identifying information.

We may share your health information with people at the hospital who help with the research project, or with people outside of the hospital who are in charge of or work with us on the project. Some of these people make sure we do the project properly. These people include members of the project committee and those who help with statistical analysis of results at Montana State University. Some of these people may share your health information with someone else. If they do, the same laws that the hospital must obey may not protect your health information.

If you sign this form, we will collect your health information until the end of the research project. We may collect some information from your medical records even after your direct participation in the project ends. We will keep all the information for at least **six years**, in case we need to look at it again. We will protect the information and keep it confidential.

Your information may also be useful for other research projects. We can only use your information again if the Institutional Review Board gives us permission. This committee may ask us to talk to you again before doing the project, but the committee may also let us do the project without talking to you again if we keep your health information private.

If you sign this form, you are giving us permission to collect, use and share your health information. You do not need to sign this form. If you decide not to sign this form, you cannot be in the research project. You need to sign this form if you want to be in the project. We cannot do the project if we cannot collect, use and share your health information.

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Melissa Blixt, RN at Bozeman Health Family Medicine, 935 Highland Blvd. Ste. 2200, Bozeman, MT 59715. The letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the project if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research project, not just those people who stay in it.

In the event that your depression screening is positive, your health care provider and/or nurse will discuss this with you and offer more information about depression and what this means for you and your health. If your depression score places you at very high risk, appropriate referral to crisis intervention counseling or emergency care will be made to ensure your and others' safety.

---

AUTHORIZATION: I have read the above and understand the discomforts, inconvenience and risk of this research project. I, \_\_\_\_\_, (participant) agree to participate in this project, I also agree that my health information can be collected and used by the researchers and staff for the project described in this consent form. I understand that I may later refuse to participate and that I may withdraw from the project at any time. I have received a copy of this consent form for my own records.

Signed: \_\_\_\_\_

Investigator: \_\_\_\_\_

Date: \_\_\_\_\_

APPENDIX D

EVIDENCE TABLE FOR APPLICABILITY

Citation	Funding sources/ IRB	Design/ Method	Sample	Measurement	Interventions	Results	Limitations	Rationale/ Comments	LOE
Bell, R., Franks, P., Duberstein, P., Epstein, R., Feldman, M., Garcia, E., & Kravitz, R. (2011). Suffering in silence: Reasons for not disclosing depression in primary care. <i>Annals of Family Medicine</i> , 9, 5, 439-446.	National Institute of Mental Health grant; IRB approval from U of CA, Davis.	Phone interview; qualitative study.	Random sample of 1,054 who had earlier participated in the 2008 California Behavioral Risk Factor Survey. Those with history of depression were oversampled by a factor of 3.	Demographic variables; perceived barriers to care seeking for depressive symptoms; health status single item measures; beliefs about depression with Likert Scales (stigma); anticipated reaction to a future Dx of depression. Descriptive statistics used. Multiple linear regression; $\chi^2$ test of significance.	None (qualitative)	Of the respondents, 43% reported 1 or more reasons for nondisclosure. The most frequent reason was the concern that the physician would recommend antidepressants (22.9%; 95% confidence interval, 18.8%-27.5%). Reported reasons for nondisclosure of depression varied based on whether the respondent had a history of depression. For example, respondents with no depression history were more likely to believe that depression falls outside the purview of primary care ( $P = .040$ ) and more likely to fret about being referred to a psychiatrist ( $P = .036$ ). Respondents with clinically significant depressive symptoms rated 10 of 11 barriers to disclosure as more personally applicable than did those without symptoms (all $P$ values $\leq .014$ ). Number of reported disclosure barriers was predicted by demographic characteristics (being female, Hispanic, of low socioeconomic status), depression beliefs (depression is stigmatizing and should be under one's control), symptom severity, and absence of a family history of depression.	Overrepresented women, older individuals, white race, and individuals of higher socioeconomic status relative to CA population as a whole.	Many adults subscribe to beliefs likely to inhibit explicit requests for help from their primary care physician during a depressive episode. Interventions should be developed to encourage patients to disclose their depression symptoms and physicians to ask about depression.	Level IV
Mitchell, A., Vaze, A, & Rao, S. (2009). Clinical diagnosis of depression in primary care: a meta-analysis. <i>The Lancet</i> , 374, 609-619. doi:10.1016/S	None	Literature search, critical appraisal, & pooled analysis of 118 studies assessing accuracy of unassisted diagnoses of	41 studies; total pooled sample of $n=50,371$ patients. Mean $n=135$ depressed patients; mean	Sensitivity & specificity of diagnostic ability of GPs to identify depression unassisted (sans screening tools; interview only).	Dx of depression; observational study.	GPs correctly identified depression in 47.3% (95% CI 41.7% to 53.0%) of cases & recorded depression in their notes 33.6% (22.4% to 45.7%). 19 studies assessed both rule-in and rule-out accuracy; from these, weighted sensitivity was 50.1% (41.3% to 59.0%); specificity was 81.3% (74.5% to 87.3%). At a rate of 21.9%, positive predictive value 42.0% (39.6% to 44.3%); negative predictive value 85.8% (84.8% to 86.7%).	No standardized method to rate a GPs opinion as to whether a person is depressed or not; GPs may revise opinions later on, at	GPs can r/o depression in most patients who are not depressed; however, modest prevalence of depression in primary care means that misidentification	Level I

0140-6736(09)60879-5.		depression by GPs. 41 of those were included d/t robust outcome standard of structured or semi-structured interview.	n=53.7 GPs.			This suggests that for every 100 unselected cases seen in primary care, there are more false positives (n=15) than either missed (n=10) or identified (n=10). Accuracy improved with prospective exam over extended period (3–12 months) rather than relying on one-off assessment or case-note records.	f/u; data were insufficient to adjust for effect of severity of depression, which is strongly associated w/ detection accuracy.	ons (false positives) outnumber missed cases (false negatives). Diagnosis could be improved by re-assessment of those who may have depression. To increase accuracy of dx, screening tools may be used.	
Schumann, I., Schneider, A., Kantert, C., Lowe, B, & Linde, K. (2012). Physicians' attitudes, diagnostic process and barriers regarding depression diagnosis in primary care: a systematic review of qualitative studies. <i>Family Practice</i> , 29, 255-263 doi: 10.1093/famp ra/crm092	Not reported	Search to identify qualitative studies on PCPs addressing concepts, process, & barriers relevant to diagnosing depression. Thematic synthesis of line-by-line coding of findings for development of descriptive & analytical themes.	13 qualitative studies interviewing a total of 239 PCPs	Systematic review of qualitative studies investigating how FPs diagnose depression, concepts of depression, & perceived barriers when diagnosing depression.	None (qualitative)	3 distinct themes with 9 subthemes specifying attitudes, diagnostic process & barriers while diagnosing depression. Many FPs mentioned patients' fear of potential stigma associated w/ psychological Dx as one of the most powerful barriers. FPs use approaches to diagnose depression usually based on knowledge of the patient's long-term hx, established patient–doctor relationship & a rule-out algorithm of other dx. These strategies markedly differ from the diagnostic criteria for depressive disorders used in psychiatrically oriented classification systems. Vague syndromal character of depressive disorders & individual behavior/expectations of the patient (whether they mask their symptoms, accept or reject a dx & how they react to a diagnosis) are considered other powerful barriers.	Small number of study participants may limit generalizability. Based on clinicians' self-reports so may not accurately represent actual practices. FPs' descriptions may be idealized to reflect socially acceptable answers. No studies provided observation	FPs have sensible strategies for diagnosing depression that are different from concepts operationalized in psychiatrically oriented classifications. Overall this article points out that Dx of depression is a multifaceted process - "Depression is messy".	Level II

							of what FPs were actually doing in routine practice work.		
O'Connor, E., Whitlock, E., Bell, T., & Gaynes, B. (2009). Screening for depression in adult patients in primary care settings: A systematic evidence review. <i>Annals of Internal Medicine</i> , 151, 793-803.	U.S.PSTF	Critical appraisal & synthesis.	33 RCTs or controlled trials; systematic reviews; meta-analyses; & large observational studies.	Benefits & harms of screening adult patients for depression in a primary care setting; benefits of depression treatment in older adults; harms of tx with antidepressant.	Screening; presence of staff assistance	9 fair- or good-quality trials indicate primary care depression screening & care management programs w/ staff assistance (case management or mental health specialist involvement), can increase depression response & remission. Benefit not evident in screening programs w/o staff assistance. 7 regulatory reviews or metaanalyses and 3 large cohort studies indicate no increased risk for completed suicide deaths w/antidepressant tx. Risk for suicidal behaviors was increased in young adults (aged 18 to 29) who received antidepressants, particularly those who received paroxetine, but was reduced in older adults.	Examination of harms was limited to serious adverse events; existing systematic reviews were primarily used.	Good evidence supports health benefits of programs that combine depression screening & feedback w/ support of additional staff to provide depression care in adults who visit primary care. However, evidence does not support screening & feedback of results to the clinician in the absence of additional staff that provides depression care support.	Level I
Kravitz, R., Paterniti, D., Epstein, R., Rochlen, A., Bell, R., Cipri,	Support from National Institute of	15 qualitative focus group interviews in 3 cities.	N = 116 25-64 y.o. w/ firsthand knowledg	Attitudinal & interpersonal barriers to depression care-seeking	None (qualitative)	Participants expressed reservations about ability of PCPs to meet their mental health needs. Specific barriers included problems w/ PCP competence & openness as well as patient-physician	1) Self-selection of participants 2) Depression	Implications for practice; PCPs should continue to develop their	Level III

<p>C., Fernandez y Garcia, E., Feldman, M., &amp; Duberstein, P. (2011). Relational barriers to depression help-seeking in primary care. <i>Patient Education and Counseling</i>, 82, 207-213.</p>	<p>Mental Health grants.</p>		<p>e of depression.</p>	<p>and disclosure in primary care.</p>		<p>trust. Many reflected positively on their primary care experiences, but some doubted PCPs' knowledge of mental health disorders and believed mental health concerns fell outside bounds of primary care. Low-income participants in particular shared stories about the essentiality &amp; fragility, of patient-PCP trust.</p>	<p>hx self-reported &amp; not confirmed 3) Focus groups may foster collective thinking. 4) Sampling may have limited ability to understand experiences of those who never sought help.</p>	<p>depression management skills while supporting vigorous efforts to inform the public that primary care is a safe and appropriate venue for tx of common mental health conditions.</p>	
<p>Barney, L., Griffiths, K., Jorm, A., &amp; Christensen, H. (2006). Stigma about depression and its impact on help-seeking intentions. <i>Australian &amp; New Zealand Journal of Psychiatry</i>, 40, 51-54</p>	<p>Not disclosed</p>	<p>7000 questionnaires sent to random selection of residents.</p>	<p>N = 1312 adults (random sample) from Australian community of New South Wales. 496 men, 796 women. 55% had personally experienced depression.</p>	<p>Help-seeking intention; self-stigma; perceived stigma; current depressive symptoms; depression experience; demographics</p>	<p>None (qualitative)</p>	<p><b>Help-seeking intention:</b> Likelihood of seeking help varied according to the specific source: general practitioners (GPs) were most likely to be sought out for help (73%; 95% confidence interval (CI) 70–75%), followed by other professionals (counsellors, psychologists, psychiatrists, &amp; complementary practitioners. General inclination existed toward help-seeking but distinction in views toward mental health professionals vs. GPs. <b>Self-stigma:</b> Self-stigma varied according to the source of help, w/ greater embarrassment associated w/ seeing mental health professionals (range of 32-44%) &amp; least w/ seeing a GP (29%; 95% CI=26-31%). <b>Perceived stigma:</b> Expectations of negative was greatest expected from GPs (20%; 95% CI=18–23%) followed by other professionals. Similar pattern regarding beliefs that professionals would think them unbalanced or neurotic, w/ the greatest</p>	<p>Help-seeking intention is not a perfect predictor of actual help-seeking behavior; cannot assume people do hold the views they are perceived to hold; voluntary participation restricts generalizability.</p>	<p>Self- &amp; perceived-stigmatizing responses to help-seeking for depression are prevalent &amp; are associated with reluctance to seek professional help. Interventions should focus on minimizing expectations of negative responses from others &amp; negative self-responses to help-seeking,</p>	<p>Level IV</p>

						stigma expected from GPs (18%; 95% CI=16–20%). Many respondents saw seeking professional help as risking stigma from other people. 46% (95% CI=43–48%) believed others would think less of them most greatly for seeing a psychiatrist or psychologist (39%; 95% CI=36–41%) than other professionals.			
Thombs, B., Ziegelstein, R., Roseman, M., Kloda, L., & Ioannidis, J. (2014). There are no randomized controlled trials that support the U.S. Preventive Services Task Force guideline on screening for depression in primary care: a systematic review. <i>BMC Medicine</i> , 12:13. Retrieved from <a href="http://www.biomedcentral.com/1741-7015/12/13">http://www.biomedcentral.com/1741-7015/12/13</a>	None disclosed	Systematic review	11 RCTs; specifically, 9 included in the USPSTF review plus 2 additional.	Objective: to evaluate whether there is evidence that depression screening benefits patients in primary care, using an explicit definition of screening not used previously.	Screening vs. not	No RCTs have compared depression outcomes b/t patients randomized to be screened vs. not screened for depression in trials that met the necessary criteria: determined eligibility & randomized patients prior to screening; excluded patients already known to have depression/already being treated for depression; & provided similar depression management options to patients identified as depressed via screening or via other methods in the comparison group.	Served as a rebuttal to the USPSTF; based on this objective, bias may have been a factor.	Significant study, d/t its findings against benefit of routine depression screening; serves as an alternate stance to current USPSTF recommendation to screen adults for depression in primary care settings when staff-assisted depression management programs are available.	Level I
Kessler, RC., Akiskal, HS., Ames, M., et al. (2006).	Human Subjects Committees of	Regression analysis	N = 3378 respondents from the NCS-R	Major Depressive Disorder (MDD) &	None	1.1% of workers met CIDI criteria for 12-month BPD (bipolar I or bipolar II) and 6.4% for 12-month MDD. BPD was associated with 65.5 and MDD with 27.2	Possible existence of inaccuracy in key	Although this study's goal was to examine how	Level III

Prevalence and effects of mood disorders on work performance in a nationally representative sample of US workers. <i>American Journal of Psychiatry</i> , 163, 1561–1568	Harvard Medical School & U of Michigan			Bipolar disorder (BPD) among workers, & Work impairment using the WHO Health & Work Performance Questionnaire (HPQ)		annual lost workdays per ill worker. Subgroup analysis showed that the higher work loss associated with BPD than MDD is due to more severe and persistent MDE in BPD than MDD rather than to stronger effects of mania/hypomania than depression. Annual human capital loss per ill worker was estimated at \$9619 for BPD and \$4426 for MDD. Annual projections to the US labor force were \$14.1 billion for BPD and \$36.6 billion for MDD.	measures; possible existence of unmeasured common causes of disorders & outcomes.	MDD compares to BPD regarding lost work, it contains valuable information about the human capital loss of those with MDD. Screening of BPD among those with MDE is recommended as well.	
Murray, C., Lopez, A. (1997). Alternative projections of mortality and disability by cause 1990-2020: Global burden of disease study. <i>Lancet</i> , 349, 1498-1504.	Edna McConnell Clark Foundation, Rockefeller Foundation, World Bank, and the World Health Organization (WHO),	Regression equations from dataset based on vital registration data & projection analysis	Data from 47 countries in 1950-1990.	Disability-adjusted life years (DALYs) approach	None	Leading causes of disability-adjusted life years (DALYs) predicted by the baseline model were (in descending order): ischemic heart disease, unipolar major depression, road-traffic accidents, cerebrovascular disease, chronic obstructive pulmonary disease, lower respiratory infections, tuberculosis, war injuries, diarrheal diseases, and HIV. <i>(only relevant information for my causes regarding depression listed here; the article contains a plethora of findings)</i>	Focused, detailed projections of specific disorders/injuries in a given population are likely to be more reliable than the generic methods employed here, simply because more information would usually be available to guide projections.	This work served to put a relevance of depression into perspective of a global scale.	Level IV
Gilbody, S., Whitty, P., Grimshaw, J., & Thomas, R.	None disclosed.	Systematic review; narrative synthesis	19 RCTs; 10 nonRCTs; 5	Effectiveness of organizational and	None; systematic review	Almost all positive-result studies used 2 or more strategies outlined by Wagner et al (1996): explicit plans & protocol such as guidelines; changes in delivery	Studies rarely used just one strategy	There is substantial potential to improve	Level I

<p>(2003). Educational and organizational interventions to improve the management of depression in primary care: A systematic review. <i>Journal of the American Medical Association</i>, 289(23), 3145-3151.</p>			<p>controlled studies; 2 interrupted time-series studies. Most in US primary care practices</p>	<p>educational interventions to improve management of depression in primary care settings.</p>		<p>system design; attention to the information needs of patients; ready access to necessary expertise; information support systems. Most effective strategies included: collaborative care; stepped collaborative care; quality improvement; case management; pharmacist-provided prescribing information &amp; patient education; and guideline implementation strategies embedded in complex interventions.</p>	<p>outlined by Wagner, so an active component of successful intervention was difficult to establish.</p>	<p>management of depression in primary care. Commonly used guidelines and educational strategies are likely to be ineffective alone. Major shifts in the organization &amp; provision of care is needed.</p>	
<p>DeLeo, D., Draper, B.M., Snowdon, J., &amp; Kolves, K. (2013). Contacts with mental health professionals before suicide: missed opportunities for prevention? <i>Comprehensive Psychiatry</i>, 54(7), 1117-23. doi: 10.1016/j.comppsycho.2013.05.007</p>	<p>None disclosed.</p>	<p>Case control study using sudden deaths as controls; psychological autopsy (PA) method for next of kin interviews.</p>	<p>261 suicides; 182 sudden deaths &gt; age 35 from Kingsland &amp; New South Wales, Australia</p>	<p>Percent of sample who visited a general practitioner (GP) within 3 months of their death.</p>	<p>None</p>	<p>No significant differences between suicide and sudden death cases by contact with a GP in the three months prior to death, with 76.9% and 81.9% respectively. However, persons who died of suicide had significantly more contacts with mental health professionals compared to sudden death controls. In suicide group 30.7% had contact with a GP only; significantly lower than the sudden death group (55.1%). Psychiatrist only was seen by 4/1%, however 25% of people who died by suicide had contact with both a GP and a psychiatrist, which was rare in the sudden death group. In total, 89.4% of suicide group and 87.5% of sudden death group had at least one contact with a health professional (all types) in three months prior to death.</p>	<p>Low response rate in both groups (46.6% in suicide, 36.5% control); limitations of PA method including emotional recall bias.</p>	<p>This study addressed the assumption that suicidal patients would visit mental health professionals rather than GPs close to their time of suicide. Findings show that this is not the case, and support the idea that suicide prevention is indeed within the realm of primary care. Furthermore, opportunities for</p>	<p>Level III</p>

								intervention in primary care can be just as likely for potential suicide as they can for other causes of sudden death.	
Luoma, J.B., Martin, C.E., & Pearson, J.L. (2002). Contact with mental health and primary care providers before suicide: A review of the evidence. <i>American Journal of Psychiatry</i> , 159, 909-916	None reported	Systematic review	40 studies; 4 record review, 21 record review w/ supplemental data, and 15 psychological autopsies in the US, UK, and Australia.	Rates of contact with primary and specialty mental health care providers of individuals before their suicide.	None	Overall rate of contact with mental health services w/in 1 month before suicide averaged 19%; 1 year before 32%. Contact w/ PCPs averaged 45% w/in 1 month prior to suicide, 77% w/in 1 year. Greater portion of individuals who committed suicide had contact with PCP in the months prior than with mental health specialists. Approx ½ had contact with PCP w/in 1 month; 75% w/in 1 yr. Only 1/3 of suicide decedents had contact with mental health services w/in the year of their death, while over 75% had contact with PCPs.	Reviewed studies only reported contacts with health providers by suicide decedents; didn't describe all persons who sought care. So, unable to determine if contacts had preventive effects.	This review suggests that contact with health care services in the year before suicide is common. Rates of contact are much higher for primary care providers, relative to mental health services. This is consistent with in the US and the UK, persons with mental health problems are more likely to seek help in the primary care sector rather than mental health.	Level I
Adler, Hetta, Isacsson and Brodin (2012). An item response theory									

evaluation of three depression assessment instruments in a clinical sample. <i>BMC Medical Research Methodology</i> , 12 (84). Retrieved May 5, 2015 from <a href="http://www.biomedcentral.com/1471-2288/12/84">http://www.biomedcentral.com/1471-2288/12/84</a>									
U.S. Preventive Services Task Force (2009). Depression in adults: screening. Retrieved March 3, 2015 from <a href="http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/depression-in-adults-screening?ds=1&amp;s=depression">www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/depression-in-adults-screening?ds=1&amp;s=depression</a>	*UPDATE IN PROGRESS*					Guideline			Level IV
World Health Organization Department of Mental									Level IV

<p>health and Substance Abuse (2012). Depression: A global public health concern. Retrieved February 10, 2015 from <a href="http://www.who.int/mental_health/management/depression/who_paper_depression_wfmh_2012.pdf">http://www.who.int/mental_health/management/depression/who_paper_depression_wfmh_2012.pdf</a></p>						Guideline			
<p>Sharp, L. &amp; Lipsky, M. (2002). Screening for depression across the lifespan: A review of measures for use in primary care settings. <i>American Family Physician</i>, 66 (6), 1001-1009.</p>						Background Article			
<p>American Psychological Association (2015). Patient Health Questionnaire (PHQ-9 &amp; PHQ-2).</p>						Background Article			

Retrieved from <a href="http://www.apa.org/pi/about/publications/caregivers/practice-settings/assessment/tools/patient-health.aspx">http://www.apa.org/pi/about/publications/caregivers/practice-settings/assessment/tools/patient-health.aspx</a>									
Maurer, D. (2012). Screening for depression. <i>American Family Physician, 85</i> , (2), 139-144. Retrieved from <a href="http://www.aafp.org/aafp/2012/0115/p139.html">www.aafp.org/aafp/2012/0115/p139.html</a>						Background Article			
Narayana, S., & Wong, C.J. (2014). Office-based screening of common psychiatric conditions. <i>Medical Clinics of North America, 98</i> (5), 959-980. doi: 10.1016/j.mcn.2014.06.002						Background Article			