Implementation Barriers of the PHQ-9 in Primary Care: A Quality Improvement Project

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Implementation Barriers of the PHQ-9 in Primary Care: A Quality Improvement Project

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Abstract

Purpose: The purpose of this research translation project was to mitigate the consequences of under-recognition, and under-treatment of depression through use of an evidence-based depression-screening tool, the PHQ-9, in a primary care setting.

Methods: A plan-do-study-act model was utilized for the implementation of this initiative. An informal educational intervention about administration and interpretation of the PHQ-9 first took place at the provider level in a primary care practice. Next, a pre and post-test study design (n=12) was administered to providers, nursing, and ancillary staff. A report was shared at monthly quality meetings with representatives from each practice in the health system. Finally, a system-wide initiative for administration of the PHQ-9 was adopted. A matched pairs t-test was used to analyze the practice-wide educational initiative. Administration of the PHQ-9 was tracked system-wide at quarterly intervals.

Results: The change in depression screening between quarters 1 and 4 was 42.5%. The healthcare system achieved 60% of their target goal in one year. The total knowledge rating of the pre test showed a mean score of 10.8 and post intervention 13.8. The matched pairs t-test revealed the post test knowledge scores (t(11) = -6.8, p <.001).

Conclusions: The large volume of individuals seen in the primary care setting affords a rich opportunity for identifying depression. Current evaluation suggests that the validated PHQ-9 depression-screening tool was effective in the current primary care setting, allowing for purposeful interventions to improve patient outcomes.

Keywords: Depression, primary care, PHQ-9, screening
Introduction and Background

Depressive disorders reach into every area of life affecting individuals, families, and communities in complex and devastating ways (Centers for Disease Control and Prevention [CDC], 2013a). Depression is manifested at all levels of society, with those from lower socioeconomic groups demonstrating the greatest vulnerability (National Center for Health Statistics [NCHS], 2012). The sequelae of this inadequately recognized and under-treated condition encompass personal and professional relationships, employment, physical health, health behavior choices, and a sense of personal well being (CDC, 2012; NCHS, 2012).

The American Psychological Association [APA] (2015) describes depression as a sad mood with decreased interest in participating in practices that were once considered pleasurable. The health burden associated with depressive disorders manifests as hypertension, stroke, and mortality from suicide (CDC, 2012). Additionally, worsening cardiac disease, recurrence of heart attack, and mortality after myocardial infarction are increased in those with depression (McLaughlin, 2011). Co-occurring mental health and addiction disorders have been identified in approximately 10.2 million adults (National Alliance on Mental Illness [NAMI], n.d.) and account for a cascade of risk and complications impacting morbidity and mortality in this population. Depression carries staggering implications for the overall health risk profile of individuals with this diagnosis (CDC 2013a). Depressive disorders are associated with other adverse health behaviors, including: smoking, alcohol use, physical inactivity, and sleep disturbance.

Individuals with depression may experience fluctuations in weight. Their psychomotor function may be slowed (activities of daily life become overwhelming) or excited (displayed as angry outburst, anxiety, and/or agitation). Feelings of fatigue, excessive guilt, inability to focus,
and intrusive thoughts of death may persist. In order to meet the diagnostic criteria for major depressive disorder (MDD), five or more of these symptoms must be present unremittingly for two weeks (APA, 2013). The CDC (2013b) states that there is an urgency to treat the first depressive episode since inadequate treatment results in increased chronicity of depression. They further assert that even a single episode elevates the risk of recurrence by 50%, and with each lapse, subsequent episodes become more likely.

Greenberg et al. (2015) report that the economic burden of depression increased 21.5% between the years 2005 and 2010. They record the total cost to the United States after adjusting for inflation as $210.5 billion per year, with only 38% attributable to MDD itself. Co-morbidities are responsible for the remainder of the financial load. NAMI (n.d.) records depression as the leading cause of disability worldwide. In the United States it accounts for approximately 400 million disability days per year (Greenberg, Fournier, Sissitsky, Pike, & Kessler, 2015).

Depression is the most common mental health disorder in the United States (NAMI, n.d.). The Vermont Department of Health [VDH](2014) identified that in the past year, 18% of the adults in America have been told they have a depressive disorder. Notably, this statistic does not account for those cases that have not been recognized. Given the increased risk of chronicity with MDD, it is surprising to note that many who experience this debilitating illness are not treated, or receive inadequate treatment (McLaughlin, 2011; NAMI, n.d.). A third of those with depression will never receive care outside of primary care practices and 75% who seek initial treatment from these centers are less likely to receive evidence-based interventions (McLaughlin, 2011). Approximately 60% of adults and 50% of those ages 8-15 with mental illness did not receive mental health care at all in the past year (NAMI, n.d.).
The prevalence of depressive disorders in Vermont is 5% higher than the national average (VDH, 2014) and significant disparities in the prevalence of treated depression exist between counties. Less than 400 per 100,000 Windsor and Windham county residents (0.4%) receive treatment for depression (Pandiani & Harrigan, 2012). This very low percentage is evidence that few individuals with depressive disorders are receiving treatment. This is especially tragic since evidence-based treatment practices including medications and psychotherapeutic interventions have a profound ability to lift the burden of this illness (CDCa, 2013).

Barriers to treatment of depression in primary care exist in two domains: those that impede the patient from accessing care, and those that inhibit the provider from delivering appropriate care. Issues that occur at the patient level include concerns about being perceived as weak or incompetent, fear of social implications, fear of referral to a psychiatrist, and fear of medication (Bell et al., 2011). Barriers that originate with the provider include lack of knowledge about screening for depression, time constraints, misunderstanding about how to interpret screening tools, lack of knowledge about treatment modalities, and lack of collaborative support (Dilonardo, 2011; Schumann, Schneider, Kantert, Lowe, & Linde, 2012). Dunn & Blount (2009) suggest that the division of health services into primary care and specialty care is another barrier. Dunn & Blount (2009) maintain that primary care providers are limited in training and time to manage mental health concerns. Yet, the majority of medications for mental health are prescribed in primary care. In addition, 68% of patients with these diagnoses seek care in this setting and 32% of those without a diagnosed mental health issue state they would approach their primary care provider (PCP) first for help with psychological problems. Integrated and collaborative health care systems are the recommended mode of care for all
patients, however, this collaborative environment is not currently available in all practices.

According to the APA (2011), the 9 question Personal Health Questionnaire (PHQ-9) (see Appendix A) is the most efficacious depression-screening tool for the primary care setting. The PHQ-9 screens for mood, energy, sleep, pleasure, and suicidal ideation during the prior two weeks. It was developed to address diagnostic criteria from the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (APA, 2013). Pertinent data used for identification of risk, diagnosis, and treatment of depressive disorders are gathered with this tool. The purpose of this quality improvement project was to mitigate the consequences of under-recognition, and under-treatment of depression through use of an evidence-based depression-screening tool, the PHQ-9, in a primary care setting. In addition, barriers related to use and interpretation of the PHQ-9 depression screening tool were identified and addressed.

**Problem Statement**

Depression is under-treated and under-identified in Vermont as indicated by depression prevalence, rate of under-treatment, and suicide exceeding the national average (VDH, 2014). Lack of depression diagnosis in the primary care settings leads to absent or inadequate treatment; increasing the risk of chronic depression and its devastating consequences. This gap in care exacerbates the consequences of depressive disorders related to the increase in psychological and physical ramifications that have an impact on the overall health and stability of individuals, families, and communities. Furthermore, the absence or ineffective use of evidence-based screening tools by primary care clinicians allows for ineffective and inadequate treatment of depressive disorders (Manea, Gilbody, & McMillan, 2012).
Review of the Literature

A comprehensive search of the literature for evidence addressing the use of the PHQ-9 in the primary care setting for identification of those with, or at risk for depression, included the Cumulative Index of Nursing and Allied Health Literature (CINAHL), PubMed of the National Library of Medicine, and PsycINFO. The terms Depression, PHQ-9, primary care, and screening were the key words, or Medical Subject Headings (MeSH) used individually, or in combination to narrow the investigation. The search yielded over 500 results published between 2009 and 2015. Inclusion criteria were full text articles published in the English language. Of these articles, several related to use of the PHQ-9 in other practice settings resulting in exclusion. In addition, duplicate articles were eliminated. In all, 31 research articles relating to use of the PHQ-9 in the primary care setting were retained for this review, including retrospective and prospective cohort studies, systematic reviews, randomized control trials, cross-sectional and observational analysis, and meta-analysis. These were evaluated for strength, level of evidence, and quality based on the Stetler rating tool (Stetler et al., 1998). Selected research fell into levels I-V for strength of evidence (Stetler et al., 1998).

Depression Identification in Primary Care

Depression is a significant issue in the primary care setting (PCS) for a constellation of reasons (Angstman, Rohrer, & Rasmussen, 2010). First, chronic conditions are commonly treated in this arena. Those with chronic illness have a higher rate of depressive disorders as compared to the general population (Acee, 2010; Dunn & Blount, 2009; Hirsch, Duberstein, & Unutzer, 2009; Sharma, Cheng, Moore, Coffman, & Bazemore, 2013). Hirsch et al. (2009) studied chronic medical issues in primary care and found an association with suicidal thoughts in these patients. Shah et al. (2014) report that half of those who committed suicide had contact
with their PCP prior to completing this devastating act, yet they were not as likely to have seen a mental health provider. They also purport that patients with PHQ-9 scores greater than or equal to 10, are more likely to have a discussion with their PCP about suicidality, thereby, increasing engagement in care of their depression. Further, Simon et al. (2013) looked at 84,418 electronic patient records of those age 13 or higher: they examined the records to evaluate results of the PHQ-9 for those who had made a suicide attempt. They contend that the PHQ-9 is an effective tool for identification of suicide risk in integrated health systems.

The effectiveness of the PHQ-9 in primary care was further endorsed in a study of 11,015 adults in an integrated setting (Bauer, Chan, Huang, Vannoy, & Unutzer, 2012). Bauer et al. (2012) found the PHQ-9 easy to administer and interpret when screening for suicide risk in the PCS. When crucial topics such as ability to experience pleasure, sleep, appetite, and mood were discussed, the clinician had an indication of the complexity of the mental health challenges a patient was experiencing. Further, administration of the PHQ-9 opens a dialogue about suicidal thoughts. MacGregor, Funderburk, Pigeon, & Maisto (2011) did a cross-sectional survey of 111 males which showed a benefit of the PHQ-9. In addition to depression risk identification, the PHQ-9 is useful for uncovering sleep disturbance. They assert that both sleep disorders and depression, which are so significant in primary care, are identified when this tool is utilized appropriately. Manea et al. (2012) conducted a meta-analysis to identify the diagnostic accuracy of the PHQ-9. Their analysis included 7,180 studies (18 validation reports) and concluded that the PHQ-9 is useful in detecting depression. Optimal cut-off scores for depression recognition were defined as between 8-11. These values were used for guiding treatment choices.
Dissenting Views on Use of Depression Screening Tools

The routine screening of patients for depression in primary care is a controversial topic. Thombs et al. (2012) state that there is a risk that these screenings may use already limited resources, and cause harm to patients by generating false-positives, minimal difference with treatment, and marginal care quality for depression treatment in the PCS. Additionally, they state there is not sufficient evidence to support improved outcomes when depression-screening tools are utilized. Specifically, Thombs et al. (2013) claim there is a lack of random control trials (RCT) validating the use of screening tools for depression identification in the PCS. Jerant et al. (2014) conducted an exploratory observational analysis of data from a randomized control trial that looked at interventions for depression in primary care offices including 595 patient records. They concluded that administration of the PHQ-9 is associated with assigning a depression diagnosis, and the treatment of individuals who may not have depression. In 2010, the United Kingdom generated a guideline stating there is not enough evidence to support screening for depression in the PCS (National Collaborating Center for Mental Health, 2010). However, the United States Preventive Task Force (2009) promotes screening for depression by the PCP. Both guidelines support the use of these tools as a component of a collaborative approach for the recognition and treatment of depression in integrated health care systems where both psychiatric and primary care are represented (Mitchell et al., 2012; National Collaborating Center for Mental Health, 2010; Thombs et al., 2012; United States Preventive Services Task Force, 2009).

Inadequate Follow-up of Depression Screening

Guidelines describe appropriate follow up procedures of positive PHQ-9 screenings. Research endorses these procedures. Moore et al. (2012) conducted a retrospective cohort study
examining the records of 604 patients. They found that when the PCP administered a second PHQ-9 in a follow-up visit, they were acting in concordance with treatment guidelines for managing depression in primary care issued by the National Institute for Health and Clinical Excellence (Moore et al., 2013). However, Shim, Baltrus, Ye, & Rust (2011) found of 4836 individuals screened with the PHQ-9, 20.1% reported significant depressive symptoms. Of the patients who were found to have severe depression, 36.9% did not have any type of interventions. Those who did have treatment (45.2%), continued to report mild to severe symptoms. These researchers claim that primary care providers need to focus on evidence-based diagnosis and treatment of depression to improve outcomes.

Kamphuis et al. (2012) conducted a prospective cohort study in a general practice. Of the 1,293 patients, 36% with MDD were diagnosed by their PCP using a depression-screening tool. This research also found that PHQ-9 scores did not differ after 12 and 39 months, and outcomes were comparable for those who had depression identified prior to participation in the study. This may indicate a problem with interpretation of screening tools, application of interventions, and understanding of treatment modalities for depression by PCPs. This is an old problem in primary care. Historically, the focus of education for medical professions has been on specialization. Though 70% of physicians report training in a focused area, the majority of patients with chronic health conditions are managed by PCPs (Sharma et al., 2013).

Unfortunately, implementation of evidence-based practice is lagging in the primary care arena (Molfentor, Copoccia, Boyle, & Sherbeck, 2012). Research has identified factors that impede adherence to treatment protocols: these include the time necessary to complete an intervention, types of interventions used, the nature of the patient’s condition, and how other providers in the same practice treat similar patients (Beehler, Funderburk, Possemato, & Vair,
Other studies indicate that lack of training, time pressures, concerns about billing, and complexity of the patient condition influence the clinician’s ability to provide the highest level of care (Sharma et al., 2013). According to Schwenk, Evans, Laden, & Lewis (2004), patients were generally satisfied with the treatment they received by primary care providers, however they continued to suffer with symptoms of depression, medication side effects, and decreased function related to depression. This continuance of symptoms was attributed to the clinician, systems of care, and patient factors.

**Efficacy of the PHQ-9 for Use in the Primary Care Setting**

The PHQ-9 screening tool was developed from the Patient Health Questionnaire. Kroenke & Spitzer (2002) record that this tool has been validated by two large studies in the outpatient setting. Arroll et al. (2010) conducted a validation study of the PHQ-9 with 2,642 subjects. They found this intervention detects depression when scores are 10 or higher. Sensitivity and specificity were 74% and 91% for scores in this range. More support of the efficacy of the PHQ-9 screening tool is provided by Yawn et al. (2012). They found that for the 654 post partum women identified to have elevated scores on the PHQ-9 screening; outcomes were improved for depression when managed in the PCS through a twelve-month period. They identified that those who were screened were more likely to receive appropriate interventions for depression. A RCT conducted by McMillan, Gilbody, & Richards (2010), to evaluate provider response to patient PHQ-9 scores found close agreement between the standard definition of improvement, and the criteria that has been defined to indicate a reliable and clinically significant improvement in depression. When the PHQ-9 screening tool was utilized, outcomes were noted to show clinically significant improvement. A meta-analysis by Moriarty, Gilbody, Mcmillan, & Manea (2015) looked at overall reliability of the PHQ-9 for screening and
identifying those with depression in the PCS, and established the diagnostic performance of this scale at a cut off of 10. Thirty-six studies with 21,292 patients represented collectively, met criteria for inclusion in this investigation. This analysis found the PHQ-9 to be most useful in the primary care setting as a diagnostic screening measure. There was a confidence interval of 95% for this study; the sensitivity and specificity were 78% and 87%.

Studies conducted to evaluate the use of the PHQ-9 in patients with chronic conditions validate the efficacy of using this tool with this population. Thombs et al. (2013) conducted a thorough review of the recent literature scanning seven databases for PHQ-9 use with coronary heart disease (CHD) and post-myocardial infarction (MI). They included articles that contrasted screening with diagnosis of depression, RCT of placebo, or usual care compared to depression treatment, and RCT that looked at outcomes after depression screening. Results of this review found that with the use of depression screening tools for patients with CHD and those who were post-MI, improved outcomes were identified. A reduction of depressive symptoms post-MI and in those with stable CHD were present when screening tools were used. Hyphantis et al. (2015) studied the use of the PHQ-9 in 349 patients with chronic conditions including diabetes, inflammatory rheumatic diseases, and chronic obstructive pulmonary disease. At the optimal cut-off point of 8, this screening tool had a sensitivity of 90.5% and a specificity of 89.4% in this population.

The PHQ-9 has been investigated for bias. Cameron, Crawford, Lawton, & Reid (2012) studied the PHQ-9 and Hospital Anxiety and Depression Scale (HADS) for bias related to age, gender, and educational background. The screening measures were statistically evaluated with a sample size of no less than 895 for each analysis. They found that there was no bias for educational background or gender, but identified that bias exists in relation to age. Allgaier,
Pietsch, Fruhe, Sigl-Glockner, & Schulte-Korne (2012) also studied the validity of the PHQ-9 related to age. Their sample included 322 adolescents ages 13-16. They concluded that the PHQ-9 has evidence of validity when a dimensional algorithm is used. Overall, the PHQ-9 is reported to be an efficacious tool for improving depression recognition rates in the adolescent population.

To investigate cost effectiveness of depression screening tools, Kendel et al. (2010) administered the PHQ-9 to 1271 patients. The results of the analysis identified the PHQ-9 as both a valid and economically conservative screening tool for depression.

In terms of global use of the PHQ-9 in the PCS, Inagaki et al. (2013) studied the sensitivity of the PHQ-2 and PHQ-9 for 598 patients in rural Japan. In contrast with the PHQ-9, the PHQ-2 consists of the first two questions of the PHQ-9. When a patient answers “yes” to these two questions, the final 7 questions are asked. It is often used when large groups are being screened to increase efficiency of screening, while still capturing those at risk of depression (STABLE National Coordinating Council Resource Toolkit Workgroup, 2010) This study showed that sensitivity and specificity for depression were 86% and 85% (Inagaki et al., 2013). For identification of suicidality the sensitivity and specificity were 70% and 97% with the PHQ-9 screening measure. Their findings validate the use of this tool for recognition of depression and suicidality in primary care.

In summary, the PHQ-9 has been found to be effective in the identification of sleep disturbance, depression, and suicidality in the primary care setting. Additionally, studies endorse improved outcomes for patients treated in primary care. However, there is still a gap in use of and interpretation of depression screening tools, how to respond to results related to level of depression according to age, and appropriate interventions for depression in primary care. This
gap supported the need for an educational quality improvement project to increase competence in these areas.

**Theoretical Framework**

The theoretical framework that served as a guide in the actualization of this PHQ-9 depression screening quality improvement project was the promoting action on research implementation in health services framework (PARIHS). A major tenet of this theory is the concept that practice change has many facets including evidence, context, and facilitation (Stetler, Damschroder, Helfrich, & Hagedorn, 2011). Schaffer, Sandau, and Diedrick (2013) explain that “evidence” is defined as a knowledge base garnered from sources that are endorsed by key stakeholders. The organizational climate or practice site are the “context” where the quality improvement project is implemented. Finally, “facilitation” refers to the element that supports change in individual’s attitudes, abilities, customs, approaches to thought, and work.

The elements of the PARIHS framework can be further delineated: Evidence includes research, clinical expertise, patient experience, or information drawn from the local environment that has been rigorously evaluated. The context may refer to the receptiveness of the setting, culture, leadership, or evaluation process. The role, skills, and characteristics of facilitation may be a specific task such as technical help, teaching, or planned interactions. Facilitation may also refer to a holistic approach to individuals through maintaining relationship, enabling implementation, or providing meaning for the change (Stetler, et al., 2011).

There are two elements that provided the scaffold for the planning of this quality improvement project. The first was the process theory: it identified the practical components necessary to support the project, for example, knowledge base (evidence). Included in this is the capacity for the organization to implement and sustain the project financially, through
information technology, and infrastructure (context). The process theory also addressed how the PHQ-9 would reach the patient population at risk for, or with depression through the service utilization plan (facilitation) (Issel, 2014). The second element was the effect theory: This specifically addressed how the causal factors of depression were affected by PHQ-9 in terms of outcomes and impact in the target population. Further, causal and impact theories were woven into the effect theory providing an explanation of this relationship (Issel, 2014).

**Project Design and Methods**

The design and methods of this quality improvement project followed the Plan-Do-Study-Act (PDSA) model described by Demming (Ransom, Joshi, Nash, & Ransom, 2014). The “plan” for this project was to effectively utilize the PHQ-9 screening tool in the primary care setting for the detection of individuals at risk for, or with depression, including understanding of how to apply interventions in response to patient scores. The “do” was to educate nurses and providers regarding use, interpretation, and response to the PHQ-9 depression-screening tool, including follow-up with patients with significant findings. The “study” portion of this project included analysis of aggregate data and feedback from patients, nurses and providers during the course of the project. Rates of screening for depression in patients without a previous depression diagnosis were collected quarterly from implementation to completion of the project period. The “act” included responses made to the findings of the comparison between quarters and the limitations of the electronic medical record. Additionally, quarterly comparisons were made following the initial informal teaching interaction with nurse practitioners and physicians through resolution of the project to identify if there were increases in use of the screening measure as the project progressed. Adjustments to the PHQ-9 screening process were made based on findings. For example, informal education was given regarding how to speak to
patients about the screening results. During the course of the project, a decision was made regarding the repeatability of the project for application of the PHQ-9 in the other primary care practices within the medical care system (Ransom et al., 2014).

**Setting and Resources**

This project took place in a rural primary care practice that is part of a not-for-profit medical care system servicing two counties in Vermont. It is one of eight primary care practice sites within the medical care system and has a National Committee for Quality Assurance (NCQA) Medical Home designation. Care is patient-centered and evidence-based. Quality, access, and affordability are emphasized by utilization of a sliding scale to accommodate those at varying levels of socioeconomic advantage.

Key stakeholders included the organization, patients, providers, and the primary care practice manager. A needs assessment conducted by the medical system identified that the community is concerned about access to behavioral health. This project directly addressed these interests. Additionally, the project supported efforts to qualify for incentives offered by the State of Vermont for meeting the standards of care outlined in the Vermont Blueprint (VB) for Health (Vermont Agency of Human Services, 2010).

**Description of the group, population or community.** This medical care system serves a rural population of over 90,000 individuals, 95% of which are Caucasian (United States Census Bureau, 2015). Inclusion criteria was patients who had not had a PHQ-9 screening in the past year, and did not have a current depression diagnosis. Exclusion criteria include those under the age of 12, those with a depression diagnosis, and those who had been screened with the PHQ-9 prior to the start date of this project.
**Organizational analysis of project site.** The practice is immersed in an integrated care system that includes primary, preventive, pediatric, behavioral health, dental, diagnostic, and other specialty care. It is comprised of clerical staff, medical assistants, X-ray technicians, nurses, nurse practitioners, and physicians. This busy primary care practice consists of three providers, with a ratio of two nurses per provider. There is one physician, two nurse practitioners, and six nurses that serve the primary care arm of this practice.

**Evidence of stakeholder support.** A stakeholder agreement was signed verifying evidence of their support prior to the initiation of this project. The quality improvement team was charged with the task of implementing screening for depression in the primary care setting within this medical care system. The DNP candidate met with both behavioral health and leadership in the quality improvement arm of the system to discuss implementation of depression screening protocols. This project involved assisting the team in implementing depression screening in a primary care practice, developing a guideline for institution of depression screening, and a teaching tool for new nurses and providers to the primary care practices in the medical care system.

**Facilitators and barriers.** Whenever a new intervention is introduced into practice, there are facilitators and barriers to implementation. The major facilitator of this project was the support of the administration and quality improvement team. The quality improvement team was comprised of a nurse and a provider from each of the primary care practices within the medical care system, supportive administration, and information technology personnel. Additionally, the community health team was represented in this group. Together, they were ambassadors for improving practice within the system. The primary care practice that was chosen for the depression screening initiative had an interest in implementing this measure to practice at the
highest evidence-base. Additionally, the requirements of the VB were motivation for implementing changes in practice.

Efforts to meet these requirements and to fill the need identified in the community for improved behavioral health access added to the weight of support for this project. Specifically, the primary care office manager and clinical staff, medical care system administrative staff, the community health team, and behavioral health services were in support of this project. The quality improvement team had measures in place to track data. They met monthly to discuss progress on compliance with the VB objectives, and brainstorm when barriers arose, adding increased support of this PHQ-9 project. The incentives that are available when requirements addressed in the VB are met were also a significant facilitator of this project. The intention of the VB is that a broad range of health and human services will be offered in a seamless fashion through coordination by health systems to meet the needs of patients and their families (Vermont Agency of Human Services, 2010). The VB (2010) offers enhanced payments to NCQA members when they qualify as an Advanced Primary Health Care Practice (APHCP). To qualify, they must accrue points that are assigned based on achieving treatment standards defined by this designation. In addition to the financial reimbursements already in place to those qualifying as an APHCP, the number of attributed beneficiaries in the practice is multiplied by a dollar amount consistent with the points achieved to generate a per patient per month (PPPM) payment sent directly to the practice. Dollar amounts range from $1.20 to $2.39 PPPM.

Primary barriers to this project included time constraints felt by already stretched clinical staff, short patient visit times, and confusion regarding documentation of PHQ-9 results. Additionally, understanding the response to PHQ-9 scores, interventions, treatment, and follow-up were a concern. Providers and nurses had previously reported uncertainty in administration
requirements, results interpretation, and how to guide patients who are identified as potentially depressed based on PHQ-9 screening. In addition, providers did not feel that they would be able to adequately educate patients on depression and PHQ-9 screening results. These issues were addressed during the educational intervention, individual support offered by the project manager, and the creation of interpretive devices to aid in response to PHQ-9 scores.

Another barrier that was not anticipated was the limitation of the electronic medical record to track the PHQ-9, responses to abnormal scores, and follow up. Additionally, protocols regarding where to record completed screenings and scores was not clear. Interventions were instituted to create uniform documentation standards to improve data collection.

Goals, Objectives, Expected Outcomes

The primary goal of this depression screening initiative was to increase the number of patients screened for depression in primary care and to decrease and mitigate the consequences of under-recognized and under-treated depression in primary care. Since current research supports screening for depression in primary care, an increase in depression screening would likely lead to improved care and treatment of depression in this population. By increasing the identification of patients with, or at risk for depression, the organizational goal to meet VB recommendations and qualify for incentives was attainable. Each patient is to be evaluated with the PHQ-9 screening tool on a yearly basis. Nurses are responsible for administering the PHQ-9 as a part of their initial assessment of the patient. The results are then reported to the provider who assesses the patient and determines the appropriate level of intervention based on both the PHQ-9 screening tool and their observations during the patient visit (See Table 1, Objectives, Expected Outcomes, and Measurements).
Table 1

Objectives, Expected Outcomes, and Measurements

<table>
<thead>
<tr>
<th>Number</th>
<th>Objective</th>
<th>Expected Outcome</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Staff will participate in an PHQ-9 training session</td>
<td>95% of staff will attend the PHQ-9 orientation and training</td>
<td>Percent of staff who attend session</td>
</tr>
<tr>
<td>2</td>
<td>Increased staff knowledge of depression screening in primary care settings</td>
<td>Post intervention scores will be significantly higher than pre-intervention scores</td>
<td>Pre-post assessment</td>
</tr>
<tr>
<td>3</td>
<td>Increase number of patients screened</td>
<td>More patients will be screened post intervention</td>
<td>Pre-post difference in patients screened</td>
</tr>
<tr>
<td>4</td>
<td>Accurate use of screening tool</td>
<td>Post intervention scores will be significantly higher than pre-intervention scores</td>
<td>Pre-post difference in patients screened</td>
</tr>
</tbody>
</table>

Objective 1: staff participation. An explanation of how staff training was completed is described below in the implementation section. Staff who were not available to participate in the training were sought out and individual training was provided. The majority of the staff were trained in a single educational intervention venue.

Objective 2: staff knowledge. To assess change in knowledge after the intervention, an intervention specific questionnaire was developed to assess knowledge change in each of the intervention content areas. Questions were asked immediately prior to, and immediately following the training session to evaluate knowledge change in each training content area (see Appendix B, PHQ-9 Pre-Post Assessment).

To evaluate pre-post change, a total score was compiled for both assessments. Score values were compared using matched-pair t-tests. To ensure that the same staff member’s data was compared pre and post assessment, study codes were assigned to each staff person. The staff person created the code and there was no information tying the staff person to their code.
Objective 3: patients screened. For this objective, the data that was provided to the DNP candidate in aggregate form was evaluated. The number of patients screened for depression were contrasted from when the PHQ-9 screening was adopted to the end of the project period. Depression screening was tracked quarterly for one year. Each quarter was compared with the previous quarter for change in number of patients screened for depression. Then the overall change in level of depression screening during the project period was calculated.

Objective 4: screening tool use. Since the PHQ-9 is a validated screening instrument, it was assumed that PHQ-9 screenings that were completed were accurately interpreted. For this objective, the PHQ-9 screening data was provided to the DNP student in a de-identified data set for the same project period as described in Objective 3. The changes between quarters and the overall change in depression screening assumes accurate intervention was provided to the screening results. Additionally, the change pre/post intervention was evaluated to determine if understanding of the screening tool improved.

Ethics and Human Subjects Protection

The use of educational materials to describe and demonstrate the use and interpretation of the PHQ-9 were used to address the low utilization of this evidence-based screening tool. This project did not involve patients as human subjects. Rather, the subjects of this study were the nurses and providers. To verify patient safety and ethical considerations, a letter of support was obtained from the medical care system. A description of the project was submitted to the University of Massachusetts Institutional Review Board (IRB). The board indicated that this was not a human subjects protocol and received an exempt status (see Appendix C, Human Subjects Determination Memorandum).
Implementation and Data Collection

The project timeline covered the months of August 2015-May 2016 (Appendix D, Project timeline). Initial groundwork for the project took place starting in May of 2015. The DNP candidate met with the clinical director of behavioral health, and the community health team coordinator to discuss the goals of the organization for this project. Additionally, the DNP candidate attended and participated in monthly quality improvement team meetings to discuss and track progress of the PHQ-9 screening initiative.

The quality improvement team engaged with information technology staff to establish a tab within the health maintenance section of the electronic medical record to simplify and standardize documentation, and ensure that the data was captured for evaluation of use to meet VB incentive requirements.

In the early stages of use of the depression screening tool, an informal educational initiative with the physician, nurse practitioners, and nurse manager in the primary care practice took place. A written reference sheet was introduced to improve understanding of PHQ-9 scoring, response, and how to explain the results of the screening to patients (see Appendix E, Depression Screening Protocol In Primary Care). The written reference was developed in conjunction with the clinical director of behavioral health and PHQ-9 interpretation guidelines (Center for Quality Assessment and Improvement in Mental Health, 2015). This information was distributed by the nurse manager to nursing staff during a nursing meeting.

A formal educational intervention was conducted by the DNP candidate at a staff meeting. During this session, providers were educated on depression, evaluating depression in the primary care setting, documentation practices, interpretation of the PHQ-9, patient education, data captured in the electronic medical record for tracking purposes, and depression screening
guidelines in practice. Training addressed when administration of the PHQ-9 should occur, how often screening is recommended, to whom results are reported, and VB incentives available to this practice. Additionally, discussion of how PHQ-9 results were to be communicated between nurse and provider, understanding PHQ-9 scores, therapeutic response to scoring, and documentation of appropriate interventions and follow-up were facilitated.

The majority of the staff attended this educational program. A pre-test was administered prior to the formal educational intervention, and a post-test was given directly after the educational intervention for those present at the meeting. Evaluation of understanding of the guideline by nursing staff will be determined by the nurse manager. To evaluate pre-test/post-test change in those at the educational initiative, a total score was compiled for both assessments. Score values were compared using matched-pair t-tests as described in objective 2. A summary of all intervention content includes:

1. Brief overview of depression in primary care patients

2. Screening patients for depression in a primary care setting
   a. Why is this needed?
   b. Why are providers doing this?
   c. What is the PHQ-9?
   d. When should screening occur
   e. How often should you screen
   f. Interpretation of screening score
   g. Therapeutic response to scoring

3. Benefits of screening patients for depression in a primary care setting
   a. How does this benefit patients?
   b. How does this benefit the medical care system?

4. Documentation:
   a. Where should this information be documented?
   b. To whom should the results be reported to?
   c. Documentation of referral and intervention
   d. Incentives available to this practice for proper screening and reporting
The nursing representative from the pilot practice in collaboration with the quality improvement team wrote a guideline for administration, documentation, and follow up of PHQ-9 in the primary care setting of the medical care system. During the course of this quality improvement project, this evidence-based intervention was adopted by the entire medical care system. Members of the quality improvement team acted as educators and ambassadors to support implementation of this initiative. Educational sessions were held at practices within the medical care system who specifically solicited additional help, had further questions, or were in need of additional support.

Those who did not attend the formal education session were provided information in the form of a guideline, kept in a location that is known to all staff, containing information regarding how all procedures are carried out in the practice. In addition, informal education was shared individually with staff who did not attend the session. Time was provided for asking questions, reviewing the educational material, and evaluation of PHQ-9 administration. Per diem staff were directed by the nurse manager to the guideline and understanding and use of the PHQ-9 was evaluated by her.

The DNP candidate in cooperation with the quality improvement team tracked utilization of the PHQ-9 screening tool quarterly through examination of aggregate data. Feedback was provided to nursing staff and providers by the office manager through staff meetings, informal conversations, and written communications. A quarterly comparison of PHQ-9 use was shared with nurses and providers in a written communication to demonstrate progress toward meeting VB goals.

It was expected that there would be an increase in those identified with depression and referrals to behavioral health related to increased screening of this at risk population. However,
when information technology was trying to collect useful data to share with the quality improvement team during a monthly meeting midway through the project, it was found that this outcome could not be determined related to limitations in the electronic medical record.

**Evaluation**

**Results, Findings, and Data Analysis**

A primary care practice consisting of a physician, two nurse practitioners, and six nurses were asked to use the PHQ-9 screening tool with patients ages 12 and older. Twelve staff members consisting of one male and 11 females participated in the formal teaching intervention. The group included one physician, one nurse practitioner, seven nurses, and five ancillary staff. The average age of the group was 46.4 years. Three of the participants were under the age of 40 and half were over the age of 50. The average number of years worked was 19.6 with nine having 10 or more years of experience in patient care. Only three of the participants reported no experience with the PHQ-9 screening tool, while three others stated some experience. Two participants reported having a lot of experience with the PHQ-9 and four answered that they used the PHQ-9 all the time. Three providers and one RN participated in the informal teaching initiative at the start of the quality improvement project. During the early phases of this project, all of the primary care practices in the medical care system except one chose to participate, thus a total of seven practices were included in this initiative. The eighth practice, newly acquired by the medical care system during the course of this project, was not able to participate because they had not started utilizing the electronic medical record system. At the project’s end, the medical care system had met 60% of its two-year goal of screening patients not previously diagnosed with depression in the primary care practice setting. All patients screened met the inclusion criteria of being over the age of 12, and had not been previously diagnosed with depression.
The data from the first three quarters of implementation of PHQ-9 in eight primary care practices were examined to determine the level of change in depression screening. By the end of the 2nd quarter (Q2), 16.1% of patients were screened in these practice settings. In the 3rd quarter (Q3), 30% were screened, and by the 4th quarter (Q4), 42.5% were screened for depression using the PHQ-9. The percent change between quarters (ΔQ) was then calculated. Between quarters 1 and 2 (ΔQ2), there was a 16.1% change. The percent change between quarters 2 and 3 (ΔQ3) was 13.9%, while the percent change between quarters 3 and 4 (ΔQ4) revealed a 12.5% change. The overall change in level of depression screening between quarters 1 and 4 (Q1-Q4Δ) was 42.5% (See Table 2, PHQ-9 Screening Tools Completed by Quarter in 2015).

Table 2

*PHQ-9 Screening Tools Completed by Quarter in 2015*

<table>
<thead>
<tr>
<th>Practice</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>ΔQ2</th>
<th>ΔQ3</th>
<th>ΔQ4</th>
<th>Q1-Q4Δ</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>9</td>
<td>20</td>
<td>47</td>
<td>9</td>
<td>11</td>
<td>27</td>
<td>47</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>30</td>
<td>41</td>
<td>47</td>
<td>30</td>
<td>11</td>
<td>6</td>
<td>47</td>
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<tr>
<td>3</td>
<td>0</td>
<td>23</td>
<td>29</td>
<td>37</td>
<td>23</td>
<td>6</td>
<td>8</td>
<td>37</td>
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<tr>
<td>4</td>
<td>0</td>
<td>3</td>
<td>33</td>
<td>42</td>
<td>3</td>
<td>30</td>
<td>9</td>
<td>42</td>
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<tr>
<td>5</td>
<td>0</td>
<td>12</td>
<td>25</td>
<td>51</td>
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<td>13</td>
<td>26</td>
<td>51</td>
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<tr>
<td>6</td>
<td>0</td>
<td>47</td>
<td>61</td>
<td>69</td>
<td>47</td>
<td>14</td>
<td>8</td>
<td>69</td>
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<tr>
<td>7</td>
<td>0</td>
<td>5</td>
<td>31</td>
<td>47</td>
<td>5</td>
<td>26</td>
<td>16</td>
<td>47</td>
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<tr>
<td>8</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mean</td>
<td>0.0</td>
<td>16.1</td>
<td>30.0</td>
<td>42.5</td>
<td>16.1</td>
<td>13.9</td>
<td>12.5</td>
<td>42.5</td>
</tr>
</tbody>
</table>
Twelve staff persons, including clinical and clerical staff, completed the face-to-face educational intervention. The total pre-intervention knowledge mean score was 10.8, while the post-intervention mean score was 13.8; mean knowledge difference score was 3.0. A matched pairs t-test was used to determine that the t-statistic was significant at the 0.05 critical alpha level, $t(11)= -6.8$, $p = < .001$. Results identified that the post-test scores were significantly higher than pre-test scores (see Table 3, Pre and Post Test Matched Pairs T-Test).

Table 3

*Pre and Post Test Matched Pairs T-Test*

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-test</td>
<td>10.8</td>
<td>1.5</td>
<td>-6.8</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Post-test</td>
<td>13.8</td>
<td>1.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Following the administration of the pre-post tests the elements of the educational intervention were evaluated and compared for each participant. These included knowledge about depression screening in the primary care setting, state initiatives to improve care for depressed patients, and the PHQ-9 depression screening tool. Comparison showed an increase in knowledge about depression and depression screening in primary care.

The project data supports that the overall goal and objective of this practice intervention to increase screening of patients in the primary care setting at risk for depression were achieved. In addition, the educational intervention increased staff knowledge about depression and depression screening, meeting the objective to better equip PCPs and nurses to meet the mental health needs of their patients.
Discussion

Though patients may have been evaluated and treated for depression in this setting prior to instituting the PHQ-9 depression screening project, a standardized evidence-based practice was not in place. The lack of uniform use of ICD codes and documentation practices in the electronic medical record created a barrier to collecting data, impeding the evaluation or understanding of how this issue was being addressed in their patient population. They were unable to capture percentages of patients evaluated for depression prior to this project.

After piloting use of the PHQ-9 in practice, several advantages were identified: ease of use, minimal barriers, low cost, and interest exhibited by the other practices. These advantages influenced the quality improvement team to initiate use of the PHQ-9 for depression screening at all primary care practices in the system. This sparked informal educational initiatives within other primary care practices to aid in adoption of the depression screening program. The overall impact resulted in screening of a large segment of the population which had not previously been evaluated for depression. This move toward closing the gap in depression identification supports the VB’s goal of weaving behavioral health care into the primary care setting. Recognition, intervention, and appropriate treatment of depression are significant issues faced by primary care providers. The integrated approach addresses this gap with a wholistic method of patient care (Mitchell et al., 2012; National Collaborating Center for Mental Health; Thombs et al., 2012; United States Preventive Services Task Force, 2009).

Depression screening in the primary care setting is imperative. The co-morbidity of depression with other chronic diseases managed by PCPs is well documented (CDC, 2012). The PHQ-9 is a valid tool for depression screening that is inexpensive and easy to use (Kendel et al., 2010). The routine screening of depression in patient care centers that have heavy use provides a
rich opportunity to capture patients at risk for, or with depression. This is demonstrated by the speed at which the quality health team met 60% of their 2-year screening goal in 1-year.

The PARIHS framework was a strong facilitator of this evidence-based practice implementation project. The first level of support of evidence-based practice was identified at the state level through financial incentives put in place by the VB initiative. This motivated and enabled the administrative staff to allocate resources for improving patient care. The obvious support of administration (facilitation) allowed for the quality improvement team to identify evidence-based practice measures to improve depression screening in primary care (evidence). The commitment to evidence-based practice became collaborative when financial/time allocation supports were firmly established by administration. This allowed for the quality improvement team to form and function. Furthermore, the primary care practices had a culture of growth (context) that allowed for adoption of the PHQ-9 in an efficient and professional manner. Participants at all levels were active and engaged in the initiative, providing a backdrop for successful implementation and superior patient care.

**Limitations**

The major limitation of this project was the electronic health record. Capturing data within the system was prohibited by non-uniform use of ICD-10 codes for depression diagnosis, and limited search technology. Monitoring screening practices by month was diminished by data collection barriers. The ability to track patient outcomes and response to abnormal depression screening was relegated to individual chart audits which were prohibited by the IRB agreement. Even if the IRB had allowed for chart audits, this is a time consuming method of data collection that is prohibitive in large patient populations.
In comparison to the structured teaching intervention, the informal education sessions did not have pre/post testing to identify if the teaching was helpful in improving knowledge of PCPs and nurses. The rapid rate at which the PHQ-9 was adopted in other practices did not allow for the same level of education and intervention as in the pilot practice.

Recommendations for future projects include establishing a data collection plan prior to project implementation. It would be advised to trial data retrieval before implementation with test patients in the electronic health record system. Also, future work should include follow-up practices by PCPs, and identification of patient outcomes to depression treatments that are instituted as a result of the PHQ-9 screening.

Conclusions

Under-recognition and under-treatment of depression remains a daunting obstacle to meeting the mental health needs of individuals at risk for, or with depression in Vermont. The cost of the health burden to individuals and communities is substantial. The primary care practice setting is an ideal safety net that can be utilized to capture those who have not sought care in traditional mental health care settings. This project was designed to fulfill the objectives set out by the VB of establishing a depression screening protocol within a rural medical care system in Southern Vermont. The overall goal was to initiate screening of patients within a pilot primary care practice as a vehicle to repeating the project at the seven other primary care locations owned by the medical care system. This medical care system will continue to screen patients with the goal of achieving 70% of patients screened within two years of the start of this project. When this goal is met, screening will continue of all patients in the primary care panel on a yearly basis. Ongoing education of new staff members will be accomplished through the treatment guideline created during the course of this evidence-based intervention.
Dissemination of project results includes sharing with the quality improvement team, and through a poster presentation at a professional day hosted by University of Massachusetts-Amherst.
References


Appendix A

PHQ-9 Screening Tool

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

<table>
<thead>
<tr>
<th>Problem</th>
<th>Not at all (0)</th>
<th>Several days (1)</th>
<th>More than half the days (2)</th>
<th>Nearly every day (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Little interest or pleasure in doing things.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Feeling down, depressed, or hopeless.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Trouble falling/staying asleep, sleeping too much.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Feeling tired or having little energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Poor appetite or overeating.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Feeling bad about yourself, or that you are a failure, or have let yourself or your family down.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Trouble concentrating on things, such as reading the newspaper or watching TV.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>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 more than usual.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. Thoughts that you would be better off dead or of hurting yourself in some way</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

**FOR OFFICE CODING**  

Total Score = + + + +

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

Not difficult at all  Somewhat difficult  Very difficult  Extremely difficult

☐ ☐ ☐ ☐

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

PHQ-9 Pre-Post Assessment

(Note: Questions 1 – 5 will not be repeated in the post-assessment)

1) Gender (circle one):  Male       Female

2) What is your age (enter # of years) __________________________

3) What is your current position?
   a.  Physician
   b.  Nurse Practitioner
   c.  Physician’s Assistant
   d.  Nurse
   e.  Medical assistant

4) How many years have you been in this role (enter # of years)? __________

5) How much experience have you had using the PHQ-9?
   a.  No experience
   b.  A little experience
   c.  Some experience
   d.  A lot of experience
   e.  I use it all the time

6) What percent of patients are identified as needing further screening for depression in primary care?
   a.  < 30%
   b.  > 60%
   c.  < 50%
   d.  <40%

7) What is the rate of co-morbid diagnoses in patients with depression?
   a.  50%
   b.  90%
   c.  60%
   d.  80%

8) Among conditions that account for the most disability days taken per year, how does depression rank?
   a.  First
   b.  Second
   c.  Third
   d.  Fourth
9) What percent of antidepressants are being prescribed in primary care?
   a. 40-50%
   b. 50-60%
   c. 60-70%
   d. 70-80%

10) It is recommended that anyone over the age of 12 be screened for depression in clinical practices that have an integrated management system.
   a. True
   b. False
   c. 

11) Which item is not monitored or documented when caring for patients with depression in a primary care setting?
   a. Diagnosis
   b. Education
   c. Follow-up
   d. Outcomes

12) The most widely recommended depression screening tool recommended for use in primary care settings in Vermont is the PHQ-9.
   a. True
   b. False

13) The PHQ-9 monitors for symptoms of depression that have been present for:
   a. 1-month
   b. 1-week
   c. 2-months
   d. 2-weeks

14) The Vermont Blueprint for Health focuses on specialized health systems for patients to improve population health and manage costs.
   a. True
   b. False

15) Incentives are available for primary care practices that institute depression screening.
   a. True
   b. False

16) Results of the PHQ-9 are recorded in the electronic medical record in:
   a. Lab results
   b. Standards of care
   c. Social history
   d. Medical history
17) Who is responsible for administration of the PHQ-9?
   a. nurse or medical assistant
   b. receptionist
   c. Physician
   d. Nurse practitioner

18) Who is responsible for interpretation and response to PHQ-9 scores?
   a. The Provider
   b. Nurse or medical assistant
   c. Receptionist
   d. Behavioral Health

19) Who is responsible for documentation of PHQ-9 scores?
   a. nurse or medical assistant
   b. receptionist
   c. Physician
   d. Nurse practitioner

20) Patients in primary care who are screened for depression have better outcomes.
   a. True
   b. False
MEMORANDUM

To: Angela Miller  
From: Human Research Protection Office  
Date: September 29, 2015

Project Title: Implementation barriers of the PHQ-9 in primary care: A quality improvement project

IRB Number: 15-019

The Human Research Protection Office (HRPO) has evaluated the above named project and has made the following determination:

☐ The activity does not involve research that obtains information about living individuals.

☐ The activity does not involve intervention or interaction with individuals OR does not use identifiable private information.

☒ The activity is not considered research under the human subject regulations. (Research is defined as “a systematic investigation designed to develop or contribute to generalizable knowledge.”)

☐ The activity is determined to meet the definition of human subject research under federal regulations, but may qualify for exemption. If uncertain as to whether the scope of the research falls within an exempt category, please contact the HRPO for guidance. Exempt determinations must be made by the IRB.

☐ The activity is determined to meet the definition of human subject research under federal regulations and is not exempt. The research must be reviewed and approved by the IRB and requires submission of applicable materials.

Information regarding Types of Review for human subject research protocols may be found at http://www.umass.edu/research/irb-guidelines-levels-review
Appendix D

Project timeline

<table>
<thead>
<tr>
<th>Task</th>
<th>August/Sept</th>
<th>Oct</th>
<th>Nov-Jan</th>
<th>Jan</th>
<th>Feb</th>
<th>March-May</th>
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<tbody>
<tr>
<td>Meet with key stakeholders</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Educational intervention</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supportive interventions and monitoring</td>
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<td></td>
<td>✔</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Gather data to compare</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In depth analysis of results</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>Written documentation of project, evaluation, and interpretation submitted to appropriate agencies for approval</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Presentation to professional audience at the University of Massachusetts Amherst campus</td>
<td></td>
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<td></td>
<td>✔</td>
<td></td>
</tr>
</tbody>
</table>
Appendix E
Depression Screening Protocol In Primary Care

1. **Scores of 1-4 fall in the normal range-minimal depression**
   a. Reassurance with supportive counseling and validation of coping skills
   b. Recommend physical activity
   c. Patient self-manages
   d. Educate patient to call if symptoms worsen

2. **Scores of 5-9 suggest mild depression elevated level of stress and/or at risk for depressive disorder**
   a. Clarification of duration of symptoms and current stressors
   b. Brief Intervention with HEALTH and/or consultation with Behavioral Health
   c. Watchful waiting (allow time to pass to assess for improvement or decompensation before offering pharmacological or behavioral health interventions)
   d. Repeat PHQ-9 at next visit
   e. Educate to call PCP if symptoms worsen

3. **Scores of 10-14 suggest moderate depression, elevated level of stress and likely depressive disorder diagnosis**
   a. Clarification of duration of symptoms and current stressors
   b. Brief Intervention with HEALTH
   c. Review of treatment options w/ PCP/watchful waiting
   d. Follow up in 4 weeks with office visit or phone call
   e. Educate to call PCP if symptoms worsen

4. **Scores of 15-19 suggest moderately severe depression with very elevated level of stress, depression and a risk for self-harm**
   a. Clarification of duration of symptoms, current stressors and available support systems to assure safety
   b. Safety assessment w/ regards to Suicidal and/or Homicidal Ideation
   c. Review of treatment options w/ PCP including antidepressant medication and referral to behavioral health
   d. Educate to call PCP if symptoms worsen

5. **Scores of 20-27 endorse severe depression**
   a. Clarification of duration of symptoms, current stressors and available support systems to assure safety
   b. Safety assessment w/ regards to Suicidal and/or Homicidal Ideation
   c. Antidepressant medication recommended
   d. Immediate referral to be behavioral health/expedite for collaborative management of depression

6. **Positive Endorsement of item 10 (Suicidal Ideation)**
   a. Safety assessment w/ regards to Suicidal and/or Homicidal Ideation
b. Educate about available resources: Local Crisis Team, Emergency Room, Crisis hotline
c. Availability of practice behavioral health provider

**Script for PHQ-9 Screening Tool for provider**

**Scores 1-4:**
- Score indicates mild stress in your life that may be getting in the way of your ability to function.
- Recommend getting some regular aerobic exercise. (best walking outside in the morning. If not, that is okay.
- Find something you enjoy that keeps your heart rate up for 20-30 minutes
- Call if you are feeling worse to discuss other options
- We will check in with you again at your next routine exam unless we hear from you.

**Scores 5-9:**
- Score is at a level that indicates you have mild-moderate stress
- Follow up in a month or earlier if your symptoms worsen.
- In the meantime, increase the focus on your overall HEALTH (Refer to HEALTH intervention sheet)
- If you notice an improvement in your mood and increase ability to do what you like and need to do, call and let us know. We can have a phone conversation to assess where you are at and make a different follow up plan if you are feeling better.
- Please call if you are feeling worse.

**Scores of 10-14:**
- You are experiencing a significant level of stress at this time.
- It is clear that these feelings are getting in the way of you being able to fully enjoy your life.
- If not feeling better in a month, we should consider medication options with referral to behavioral health providers.
- In the meanwhile, let’s start with (Refer to HEALTH intervention sheet).
- Follow up in 4 weeks or earlier if your symptoms worsen.
- Please call if you are feeling worse.

**Scores of 15-19:**
- Responses indicate you are experiencing a significant amount of stress right now
- At this time, it makes sense to consider multiple approaches to reduce your stress levels including medication and behavioral health intervention.
- Are you feeling safe? Do you feel like you want to hurt yourself or anyone else? (If yes, immediate referral to crisis) Who are the supportive people in your life? Can you let them know you are not feeling well so they can support you?
- Follow up in 2-3 weeks after you have been on the medication for a while.
• Please call if you are feeling worse. If after hours, contact crisis

Scores of 20-27:
• **Your stress levels are clearly elevated at this time.** Nobody should have to feel this bad.
• At this time, we will consider multiple approaches to reduce your stress levels including medication and behavioral health intervention.
• Are you feeling safe? Do you feel like you want to hurt yourself or anyone else? (If yes, immediate referral to crisis) Who are the supportive people in your life? Can you let them know you are not feeling well so they can support you?
• Follow up in 2-3 weeks after you have been on the medication for a while.
• Please call if you are feeling worse.

Suicidal Ideation:
• Are you feeling safe now?
• Do you have a plan to hurt yourself or anyone else?
• I want to give you some phone numbers to call if you do feel this way. These people are available 24/7 to help you.
• Since you are feeling so badly, we want to get you into see someone on the behavioral health team.

**Script for PHQ-9 for nursing**

Scores 1-4:
• Your score indicates that you have mild stress in your life that may be getting in the way of your ability to function.
• Recommend regular aerobic exercise. (best walking outside in the morning. If not, that is okay.
• Find something you enjoy that keeps your heart rate up for 20-30 minutes.
• Please call if you are feeling worse. There are options to help with these feelings.
• We will screen you again at your next routine exam unless we hear from you.

Scores 5-9:
• Your score indicates that you have mild-moderate stress in your life.
• I am going to let your PCP know about these results.
• In the meantime, something that you can do to help you feel better is the HEALTH acronym.
• Please call if you are feeling worse.

Scores of 10-14:
• You score indicates that you have a significant amount of stress at this time
• We want to monitor these feelings.
• I am going to share this with your PCP so you can talk a bit further about what we can do to help you feel better.
In the meantime, something that you can do to help you feel better is the HEALTH acronym.

Please call if you are feeling worse.

**Scores of 15-19:**
- Your score indicates that you have moderate-severe stress in your life right now.
- Are you feeling safe? Do you feel like you want to hurt yourself or anyone else? (If yes, immediate referral to crisis) Who are the supportive people in your life? Can you let them know you are not feeling well so they can support you?
- I am going to tell your PCP about these results so you can discuss options to get you feeling better.
- Please call if you are feeling worse.

**Scores of 20-27:**
- Your score indicates that you are experiencing severe stress at this time. Nobody should have to feel this bad.
- I’m going to tell your PCP about this, so we can make a plan to help you.
- Are you feeling safe? Do you feel like you want to hurt yourself or anyone else? (If yes, immediate referral to crisis) Who are the supportive people in your life? Can you let them know you are not feeling well so they can support you?
- If you start to feel suicidal, call the crisis numbers that we are giving you.
- Please call if you are feeling worse

**Suicidal Ideation:**
- Are you feeling safe now? Do you have a plan to hurt yourself or anyone else? I want to give you some phone numbers to call if you do feel this way. These people are available 24/7 to help you.
- Since you are feeling so badly, your PCP will likely want to get you in to see someone on the behavioral health team.
- I am going to let your PCP know we talked about this so we can decide what steps to take to help you feel better.