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Depression Screening and Care Management in Diabetes Patients at Rural Health Clinics in Primary Care: Quality Improvement

Marcy Doyle
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Marcy Doyle, *University of New Hampshire, Durham*

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in Primary Care: Quality Improvement

Marcy Doyle, MS, MHS, RN, CNL

University of New Hampshire

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College of Health and Human Services
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Doctor of Nursing Practice

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Student Name: Marcy Doyle, MS, MHS, RN, CNL

Depression Screening and Care Management in Diabetes Patients at Rural Health Clinics in Primary Care: Quality Improvement

In partial fulfillment of the requirements for the degree of Doctor of Nursing Practice in the
Doctor of Nursing Practice Program

DNP Project Team: **Signature**

Dayle B Sharp PhD, DNP, McPH, FNP

Dayle B Sharp PhD, DNP, McPH, FNP   _Dayle B Sharp_
Nursing Faculty, Credentials

Emily Beaulieu, MSN, APRN, CDE

Emily Beaulieu APRN   _Beaulieu_
Agency Stakeholder, Credentials

Jeanne Ryer, MSc, EdD

_____   _Jeanne Ryer_
Content Expert, Credentials

Donna Pelletier DNP, APRN, FNP-BC

_____   _Donna Pelletier_
Director DNP Program, Credentials

Marcy S. Doyle MS, MHS, RN, CNL

Marcy Doyle MS MHS CL   _Marcy Doyle_
Print Name of Student, Credentials

Dedication

To my husband Jimmy and son Noah your love and support through this entire process have

been invaluable. Love you to the moon and back.

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To the staff of the Rural Health Clinics, this quality improvement project would

never have been possible without your commitment to learning, testing and reflecting upon small

changes that improve patient care.   To Dr. Jeanne Ryer, your encouragement to "lean in" and

learn as much as I could about behavioral health integration made this quality improvement

project possible. To my project chair, Dr. Dayle Sharp, thank for the journey and supporting

my efforts from day one, all is possible with a great mentor.

Abstract

Depression is one of the leading causes of disease and disability, often found in patients with long-term chronic physical conditions such as diabetes. Collaborative care, which includes care managers, has shown to improve depression outcomes in patients; usual care has been shown to be inadequate. This quality improvement project screened patients with diabetes for depression. Patients with an elevated depression screening score were provided care management support and rescreened every two weeks to evaluate depression symptoms. A small cohort of patients from two rural health clinics participated in the improvement project. The practices noted improvement in depression screening; patients who participated and received care management services had an overall improvement in Patient Health Questionnaire-9 (PHQ-9) scores and glycated hemoglobin (A1c) rates over the project period. The practice findings indicated that focusing on improved systems for rural health clinic patients with diabetes and depression may impact health outcomes, however, additional work needs to be done to determine sustainability in rural health clinics beyond the quality improvement project period. The quality improvement project limitations included study design and size.

Introduction

Problem Description

Depression is the second leading cause of disability worldwide affecting one in five United States adults over the course of a lifetime (Acee, 2015; Moussavi et al., 2007). Increasing with age and co-morbidities, the rate of depression doubles in people with diabetes (Acee, 2015). Sixty-eight percent of patients with mental illness have a medical condition leading to functional impairments that result in an inability to adhere to healthy lifestyle choices, for example, maintaining a balanced diet, exercising or taking required medications (Moussavi et al., 2007). Despite widespread evidence supporting the benefits of depression screening and updated 2016 United States Preventive Task Force (USPTF), depression screening recommendations that standardize screening until remission or reduction of symptoms are often not conducted (Siu et al., 2016).

Studies have demonstrated that "usual care" for depression has resulted in only half of depressed adults receiving treatment in the United States (Kessler RC, Chiu W, Demler O, & Walters EE, 2005). The term "usual care" means that patients diagnosed with depression are treated by their primary care providers and no additional organizational modifications are made within the context of treatment. Patients may receive medication and/or a referral to specialty behavioral health care practices, however, the coordination, advocacy and knowledge acquisition of the services are the responsibility of the patient (Coventry et al., 2012; Kessler RC et al., 2005; Trangle et al., 2016). Depression care is more often reactive versus proactive in nature. IJff et al., (2007) found that only 20% to 40% of depressed adults showed improvement after twelve months of receiving usual care. Evidence-based treatments are available; however, they are adopted sporadically often due to knowledge, cost, operational obstacles, and workforce

shortages. Strategies that merely focus on guideline implementation have been shown to be

ineffective compared to clinician education with enhanced care management roles (Gilbody S,

Whitty P, Grimshaw J, & Thomas R, 2003). Detection of depression in patients is complicated

by physical disease, often leading to a poor treatment and response (Iosifescu et al., 2003).

Barriers to treatment are magnified by the time-limited nature of primary care encounters, the

prioritization of competing needs, limited access to services and lack of evidence-based

standardize guideline implementation (Gilbody et al., 2003). New Hampshire's experience with

diagnosing and treating depression reflects national trends (New Hampshire Citizens Health

Initiative, 2016). For the better part of the last two decades, behavioral health care in New

Hampshire has often been fragmented, episodic and poorly coordinated (Cherokee Health

Systems, 2014). Patients have been unable to navigate timely care for prevention and treatment

of chronic illness.   Workforce shortages, gaps in health information technology, lack of the full

adoption of standardized evidence-based clinical care guidelines and deficient person-centered

systems have further delayed appropriate care within the state.

Currently, New Hampshire ranks 17th nationally per capita for mental health expenditures

and 9th for overall health care expenditures ("Mental Health Spending," 2018; "Health Care

Expenditures per Capita by State of Residence," 2017). New Hampshire has a large proportion

of rural communities that have limited access to services (Appendix A) ("Rural and Non Rural

Public Health Regional Networks 2017/2018," 2017). Nationally, rural locations with lower

socioeconomic status (Table 1) have a disproportionate share of residents reporting symptoms of

depression (Dittrich et al., 2015). The New Hampshire Accountable Care Learning Network used

claims data and reported that over 40% of under age 65 members had depression or anxiety and a

chronic condition, the number rose to 80% in the Medicare population (New Hampshire Citizens

Health Initiative, 2016).

Table 1. United States adults with current depression by Socioeconomic Status 2006
Behavioral Risk Factor Surveillance System (BRFSS) Data

Variable	Factors	Socioeconomic Status		
		% Lower SES	% Middle SES	% High SES
Geographic Locale	Non-Rural	55.0	37.7	7.3
	Rural	65.6	31.1	3.3

Several large-scale efforts have brought together New Hampshire's health care

community and key stakeholders including insurers, federal, state and local government,

businesses, patients and families to improve patient care. The first, a landmark class action

settlement agreement allowed for the implementation of new services for the severe and

persistently mentally ill (SPMI). The second, on January 5th, 2016 the Centers for Medicare and

Medicaid Services (CMS) approved New Hampshire's section 1115(a) Medicaid demonstration

entitled Building Capacity for Transformation, a Delivery System Reform Incentive Payment

(DSRIP). The NH DSRIP demonstration aimed "to transform the way physical and behavioral

health care are delivered to Medicaid beneficiaries with behavioral health disorders, and/or

substance use disorders (SUDs) and/or substance misuse" (New Hampshire Department of

Health and Human Services, 2017, p. 3). Finally, the New Hampshire Behavioral Health

Integration Learning Collaborative (BHI Learning Collaborative), a project of the New

Hampshire Citizens Health Initiative Accountable Care Learning Network (NHACLN)

developed by New Hampshire Citizens Health Initiative (NHCHI) brought together more than 60

organizations since 2015. The focus of this collaboration was behavioral health integration in primary care and payment reform. Providers of all types and specialties, including all of the state's community mental health centers, major private and public insurers, and government worked together to learn and share best practices. As part of these key efforts, standardized evidence-based depression treatment algorithms were identified and shared. Despite these efforts consistent depression screening and treatment varies widely. Where depression screening has been conducted, few efforts have been successfully undertaken to link care management efforts to improved patient outcomes.

Given the significance of depression and diabetes, two New Hampshire Rural Health Clinics (RHCs) were recruited to participate in a quality improvement (QI) project focused on depression screening and treatment. Table 2 describes the number of patients at the practice with diabetes and the county prevalence ("NH Health Wisdom," n.d.). Although both practices screened patients for depression during annual exams, based on patient complaint or clinical judgement, neither practice had a standardized workflow that incorporated care management and rescreening for patients with diabetes or documentation that included the use of a registry. Both RHCs varied in their clinical staff and operational design which reflected the variation seen across the state in practice type. One practice included behavioral health within their health care system; the other relied predominately on referrals to access behavioral services.

Table 2. Number of Patients with Diabetes by Practice and County Prevalence

	Percent Adult Patients Diagnosed with Diabetes	2015 County Diabetes as Percent of Population
Practice A	n/a	7.40
Practice B	9.2	7.97

Note: Practice A was unable to determine accurate prevalence

Available Knowledge

A systematic search strategy was used to assess the available knowledge regarding diabetic patients identified with depression within the primary care setting who were offered care management services based on depression screening results. The search terms included: diabetes, depression, nurse, primary care, care management, screening, and collaborative care. The search was comprised of electronic databases, limited to adult human subjects between 2000 to August 2017 and written in English. The following journal article searches resulted in: CINAHL (1), Cochrane Library (5), Medline (2), PsychINFO (2), PubMed (5), Trip Medical Database (5) and ProQuest (20). A total of seven databases were reviewed, which included grey literature, and resulted in 30 journal articles. After the articles were reviewed for inclusion criteria and evaluated for bias, three non-duplicative research based randomized control trials were identified.

The studies were conducted in the United States, Canada and Australia at primary care clinics (Johnson et al., 2012; Katon et al., 2010; Morgan et al., 2013). Katon et al., (2010) was constructed as a single blinded randomized control and was of the highest quality. The study in Austria and Canada attempted to replicate Katon's et al., (2010) findings. Morgan et al., (2013) had a two-arm open randomized cluster trial with wait-list control for 6 months. Johnson et al., (2014) design was the weakest in terms of bias with two control groups and active control and a usual control group. All three studies were 12 months long. An important note is that the Australian and Canadian studies were subsequent to the published Katon et al., (2010) study and attempted to replicate the intervention. All three studies differed slightly in methodology. The structure of the study was impacted by the practice, resources and settings. All studies

monitored depression and diabetes outcomes using an evidence-based tool. Katon et al., (2010)

used the Symptom Checklist-20 (SCL-20) to measure depression outcomes. The control group

had a statistically significant decrease at 12 months (0.40 points, P<0.001) in depression

symptoms using the Symptom Checklist–20 (SCL-20). The Australian study (Morgan et al.,

2013) showed mean depression scores after 6 months of intervention for patients with moderate-

to-severe depression decreased by 5.7±1.3 compared with 4.3±1.2 in control, a significant

(p=0.012) difference with a 95% confidence range. Johnson et al., (2014) found that intervention

patients had greater 12-month improvements in PHQ-9 (7.3[SD5.6]) compared with control

subjects (5.2[SD5.7], P= 0.015). Recovery of depressive symptoms (i.e., PHQ-9 reduced by

50%) was greater among the intervention group (61%vs.44%, P=0.03). Compared with trial

patients, non-screened control subjects had significantly less improvement at 12 months in the

PHQ score (3.2 [SD 4.9]) and lower rates of recovery (24%, P < 0.05 for both). Only one study,

reported statistically significant changes in the glycated hemoglobin level (Katon et al., 2010).

Rationale

The quality improvement project was based on the framework of the Expanded Chronic

Care Model (CCM) originally developed in the 1990's by Edward Wagner, Director Emeritus,

MacColl Center for Health Care Innovation (Figure 1) and revised in 2003 (Barr et al., 2003;

Bodenheimer, Wagner, & Grumbach, 2002). CCM has long been used to provide a framework

for considering how to deliver population and patient level care. CCM is aligned with behavioral

health integration within primary care. The CCM model can be used to address macro, meso and

micro changes in the delivery of health care for patients with depression and improve overall

outcomes. Using the model, screening and rescreening can be implemented with adequate

systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up

while remaining patient centered and developing scalable care management solutions. Treatment

and follow-up would include diagnosis, patient engagement and education based on the nature of

the disease, risks and benefits of treatment and patient preference. In the CCM model ongoing

contacts would be systematic and include documented encounters over the first 12 months of

care (schedules appointments, phone calls, portal interactions, etc.) including documented

tracking of treatment and response (O'Conner, E., Rossom, R.C., Henninger, M., Groom, H.C.,

Burda, B.U., Henderson, J.T., Bigler, K. D., & Whitlock, E. P., 2016).

Figure 1. The Expanded Chronic Care Model

Image created by Victoria Barr, Sylvia Robinson, Brenda Marin-Link, Lisa Underhill, Anita Dotts and Darlene Ravensdale (2002) Adapted from Glasgow, R., Orleans, C., Wagner, E., Curry, S., Solberg, L. (2001) "Does the Chronic Care Model also serve as a template for improving prevention?" The Milbank Quarterly, 79(4), and World Health Organization, Health and Welfare Canada and Canadian Public Health Association. (1986). Ottawa Charter of Health Promotion. SOURCE: Vancouver Island Health Authority, derived from http://www.viha.ca/NR/rdonlyres/5ACFER09-3FA4-49F1-8F08-C98544F32A36/858/RFCCModel1.pdf

Specific Aims

The QI project's workflow modifications are based upon evidence that supports moving towards improved patient outcomes via an evidence-based systematic screening and rescreening for depression and structured biweekly proactive care management and outreach. The PHQ-9 (Appendix B) is one of the most highly regarded screening tools for depression. The quality improvement project established a standardized evidence-based screening workflow in rural health clinics to evaluate, treat and track treatment response in diabetes patients with PHQ-9 scores that are >=10.

Appropriate and reasonable treatment and follow-up would include diagnosis, patient engagement and education based on the nature of the disease, risks and benefits of treatment and patient preference. Specifically, each practice:

1. Established the level of behavioral health integration.

2. Established the baseline depression screening rate in patients with diabetes.

3. Developed an evidence-based clincal workflow and a pathway for patients identified as depressed.

4. Initiated comprehensive treatment planning with a care managment component in patients with diabetes and a PHQ-9 score ≥10.

5. Bi-weekly rescreening of patients with the PHQ-9 to determine response to treatment.

6. Tracked care management activities as part of the clincal workflow

7. Captured and aggregated physical health metrics (HbA1c, blood pressure and body mass index) at baseline and each health care incounter to determine response to treatment.

Methods

Context

The quality improvement interventions took place at two rural health clinic practices located within New Hampshire. Practice A was independently owned, Practice B was part of a critical access hospital system. The practices employed primary care providers (medical doctors, doctors of osteopathy, nurse practitioners and physician assistants). Both practices had been actively engaged in national or state-wide quality improvement efforts focused on improving the care for chronically ill patients. Each practice utilized an electronic health record (EHR) to document, track, record results and develop treatment plans. Practice team composition varied. A recommended core team at the RHC included at least one provider, a behavioral health clinician (if employed at the practice), a nurse, a care manager (if different from the nurse), a data analyst, and leadership.

Interventions

To be included in the intervention, adult (18 years of age and older) patients who presented for a diabetes follow-up appointment, were screened using the PHQ-9. Patients that had a PHQ-9 $\geq$ 10 were asked if they were willing to participate in the quality improvement project and receive additional care management services. A signed informed patient consent was required prior to participation (Appendix C).

Each practice followed a defined standardized evidence-based depression screening protocol (Figure 2) (Trangle et al., 2016). Study participants with a PHQ-9 $\geq$ 10, mild, moderate or severe depression had a person-centered individualized care plan developed. The care plan may have included depression management with antidepressants and/or psychotherapy, diabetes management including Diabetes Self-Management Evaluation (DSME) classes, stepped

care/treat-to-target algorithms and/or lifestyle modifications (Trangle et al., 2016). Every two weeks the patient was contacted and rescreened with the PHQ-9, this occurred at an office visit or during telephone follow-up calls. The PHQ-9 screening was done by the provider, care management nurse or behavioral health clinician. Treatment adjustments were made in collaboration with the care team, individualized care plan modified as deemed necessary.

Figure 2. Collaborative Care Interventions for Patients with Diabetes and Depression Screening and Rescreening Protocol

Collaborative Care Interventions for Patients with Diabetes and Depression Based on Screening and Rescreening Results
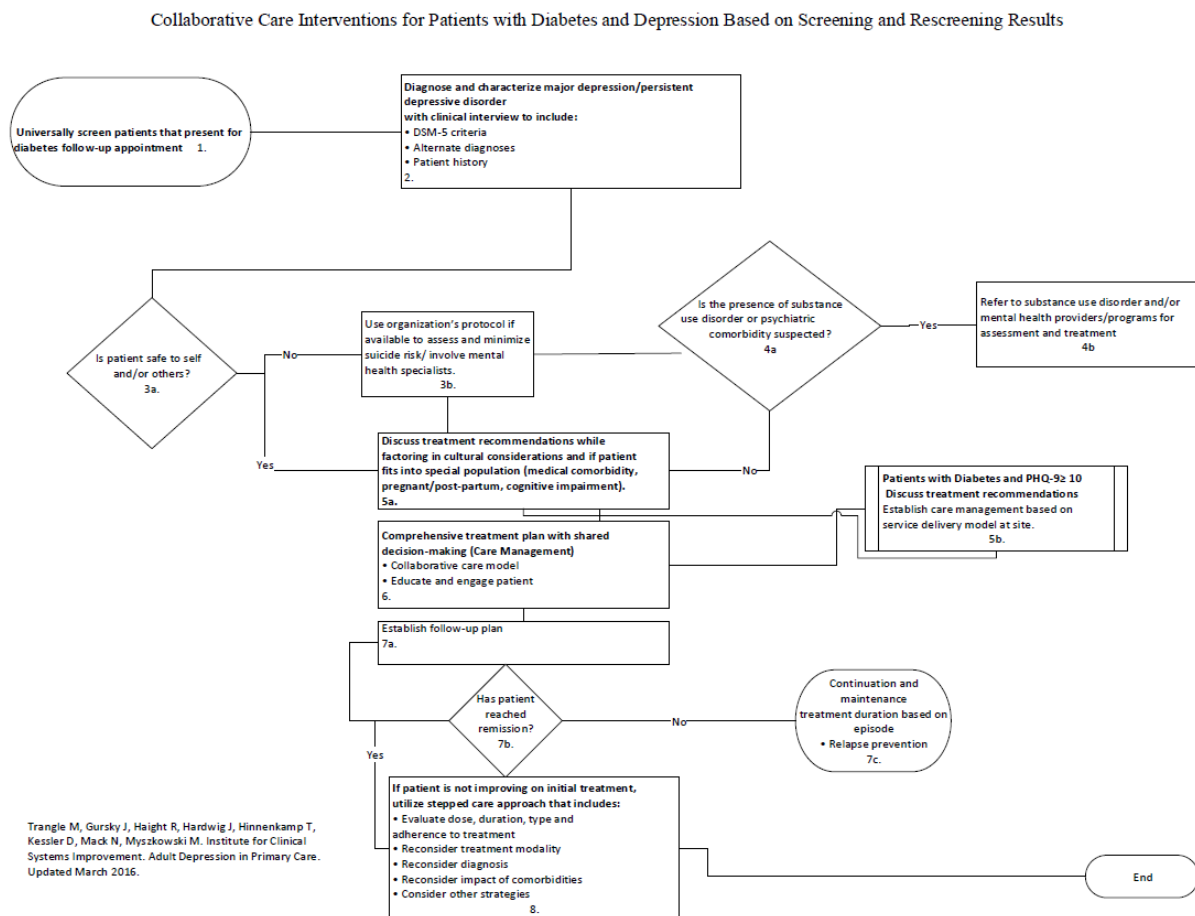
The proposed timeline was 6 months, with a goal of getting a minimum of three months of data for each participant to measure response to the intervention. The frequency of data submission to the researcher was to occur monthly. Although data was reported monthly, the

PHQ-9 was conducted every two weeks for each participant enrolled for a total of 6 times if the participant was in the study for three months.

Each practice took a baseline analysis using the Site Self-Assessment (SSA) (Appendix D), an instrument that measures the level of behavioral health integration occurring within a practice (Scheirer, Leonard, Ronan, & Boober, 2015). Based on the SSA results, practices were asked to track care management services, registry development, self-management support, team-based care, team huddles, staff training as part of the quality improvement framework and process. Each practice was provided a standardized evidence-based workflow from the Institute for Clinical Systems Improvement of Adult Depression in Primary Care guidelines (Trangle et al., 2016). The practice staff were asked to review the nursing job descriptions for the key staff that would be involved in providing care management interventions.

Study Interventions

The Model for Improvement, is a widely used framework for accelerating system change within health care organizations (Berwick, 1996). The model consists of setting aims, establishing measures, selecting change ideas and conducting tests of change (Figure 3). The model provided a framework for the iterative quality improvement process undertaken to target practice level and patient level improvement (Taylor et al., 2014). Corresponding changes were made using Plan-Do-Study-Act (PDSA) cycles. Focused learning occurred during each cycle. The *Plan* for this quality improvement project was to screen adult patients for depression who presented for diabetes follow-ups using a defined standardized evidence-based workflow. All patents who had a PHQ-9 ≥ 10 were offered care management services. The *Do* was to provide the patients structured care management services and proactive follow-up. Every two weeks the practice*s Studied* the patients' PHQ-9 results to evaluate the care management

component at that practice level (Figure 3). Modifications were made to the process during the

Act phase to include adoption or abandonment.

Figure 3. Model for Improvement

Model for Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?

Act | Plan

Study | Do
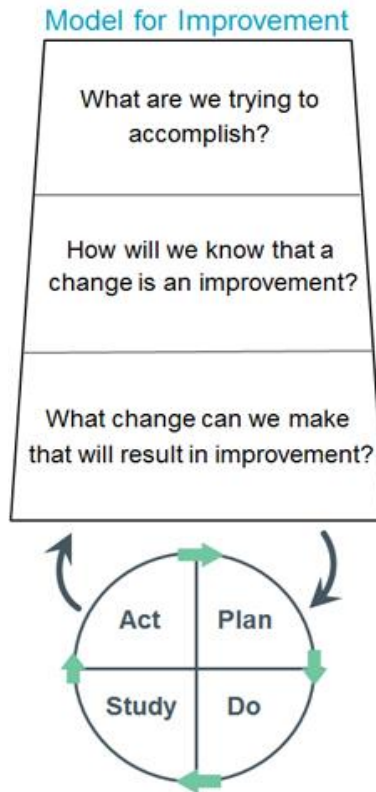
Measures

Each practice began the quality improvement work reviewing their current level of

behavioral health integration by completing a baseline Site Self-Assessment (SSA). The practice

was asked to take the SSA as a team and discuss the answers to each question and come to a

consensus. Each dimension or question is based on a 1-10 scale. Usual care is indicated by a

score of 1, and a fully transformed practice would score a 10. There are 18 questions with a

minimum score of 18 and maximum score of 180. The SSA is the approved tool measuring

behavioral health integration throughout NH. The tool has also been used widely throughout the

United States. The format of the Site Self-Assessment instrument is based on the format of the

Assessment of Primary Care Resources and Supports for Chronic Disease Self-Management

(PCRS) developed by the Diabetes Initiative of the Robert Wood Johnson Foundation (Brownson

et al., 2007). The SSA is used by primary care teams to evaluate the current delivery system

practices and identify quality improvement opportunities. The SSA consists of two domains;

Integrated Services for the Patient and Family and Organizational Supports and 18 dimensions

(Scheirer et al., 2015).

As part of the assessment, current state of depression screening and follow-up was

evaluated at the practice level. Each practice was provided a standardized evidence-based

workflow that utilized the Institute for Clinical Systems Improvement for Adult Depression in

Primary Care guidelines (Trangle et al., 2016). The practice staff were asked to review the

nursing job descriptions for the key people that would be involved in providing collaborative

care interventions. For intervention participants, all data was de-identified, information was

collected on blood pressure, body mass index (BMI), hemoglobin A1C and screening for

depression using the PHQ-9, care management and education activities. A variety of instruments

can be utilized to screen for depression. In primary care settings, the PHQ-2 and the PHQ-9 are

the most widely used depression screening tools in the United States. A recent study found that

only 5% of patients with an elevated PHQ-2 were screened with the PHQ-9 (Fuchs et al., 2015).

The PHQ-9 is a valid instrument for depression detection and monitoring in primary care

settings. Further, it has been validated for measurement depression severity (Kroenke, 2010;

Spitzer, 1999). It has a sensitivity (false negative) of 0.77 and specificity (false positive) of 0.85

when using the screened item scoring method (Trangle et al., 2016). Many practices diagnose a

patient as depressed following a positive PHQ-9 however, a rescreening is often not performed

to determine if the condition has improved following treatment. Presumably, patients and staff would benefit from a structured workflow based on results of screening and rescreening which would trigger treatment recommendations. Patients with diabetes identified with depression had individualized treatment plans developed and received follow-up by the health care team based on a standardized protocol. The practice used and/or developed shared decisions aids and flow charts.

Analysis

IBM® SPSS Statistical Software was used for data analysis and descriptive statistics. The sample size was too small for hypothesis testing.

 Ethical Considerations

Each practice signed a letter of commitment (LOC) outlining project activities and requirements (Appendix E). The University of New Hampshire's Institutional Review Board for the Protection of Human Subjects in Research (IRB) reviewed and approved the protocol as described in Title 45, Code of Federal Regulations (CFR), Part 46, and Subsection 110 (Appendix F). Minimal risks were identified regarding participation in the QI project. One identified risk was that an individual would be identified as suicidal during the evidence-based depression screening.

As with any research or quality improvement project, the participants were made aware both verbally and via a written consent form that there may not be any direct benefits to patients from study participation. At an organizational level, the practice established the organization's stage of behavioral health integration and clinical outcomes, and identified areas for quality improvement. The outcome of this research was provided to the practice, if the data was shared it would be done so in aggregate.

Results

Practice A team members included one provider, a nurse practitioner and new nurse care manager and data analyst (Table 3). Practice A had limited behavioral health services which focused predominantly on providing substance use disorder treatment. The nurse, functioned as the care manager at the practice and followed-up with the patient's bi-weekly.

Practice B included a nurse who was to provide care management, three primary care providers and a master's prepared social worker who provided generalist behavioral health services. The social worker was based at the hospital and made regular visits to the practice based on need. The social worker provided extensive care management plan development and was responsible for bi-weekly patient follow-up.

Both RHC practices experienced staffing interruptions that impacted the intervention team during the October-April time frame. Team members were either replaced or diverted to cover clinic areas that were experiencing staffing shortages. Practice Team A had one consistent team member, a nurse practitioner who was also the QI director. The QI director functioned in the leadership role. Prior to the start of the project the behavioral health clinician left the practice and the position was not replaced, the data analyst retired and a new individual was trained and began working on the project at month four. A new nurse care manager was hired and dedicated to chronic care management four hours per week. Practice B did not have staffing changes in the practice team during the improvement effort (November through April). However, Practice B did experience attrition in other positions which impacted the nurse care management function. Further, Practice B did relocate to the main hospital for a short period while remodeling occurred. All patients were seen at the temporary hospital location approximately 20 minutes from the original RHC location. Throughout the project, Practice A had weekly quality

improvement meetings at the practice and the work was incorporated into the standard QI

meetings. Practice B held a brief training for all clinical staff to discuss the evidence behind the

project, the new screening algorithm and care management services. Following the initial kick

off session, Practice B had monthly meetings held at the main hospital.

Table 3. Practice Team Composition

Practice	Providers Nursing	Behavioral Health	IT
A	NP[ac] RN [de]		Data Analyst [be]
B	NP[b], DO[b], PA [b] RN[a e]	LICSW[ac]	Data Analyst [b]

[a] Primary team member
[b] Support team member
[c] Team member present for entire project
[d] Team member addition mid project
[e] Workforce changes during project
Nurse practitioner (NP)
Registered Nurse (RN)
Doctor of Osteopathy (DO)
Physician's Assistant (PA)
Licensed Social Worker (LICSW)

Prior to implementing the intervention, each practice took the SSA. Practice A took the

SSA as a team and discussed the answers to both domains and all 18 questions. Practice B had

one individual take the SSA. The results were 57/180 for Practice A and 147/180 for Practice B.

Three months after baseline the practices retook the SSA, Practice A's results improved by 93%

and Practice B improved by 12.2% (Table 4). Both practices took the follow-up SSA as a team

and discussed their responses. The overall percent difference over baseline for both practices

combined was 80.8%. The SSA dimension "data system records" was the only dimension that

had an overall percent decrease due to Practice A's -37.5% change over baseline. Practice B had

only one dimension with a decrease which was "follow-up assessment and treatment referral" by

10%. The largest increases in SSA scores were in the dimensions "patient care based on best

practice evidence", "communication with patients about integrated care" and "continuity of care". The largest changes, over 100%, were attributed to Practice A, which at the beginning of the project did not have care management services, developed pathways for behavioral health referral, a registry, or clinical algorithms embedded in the EHR. For Practice B, which had a drop in behavioral health services at the RHC practice, the largest gain was in the dimension of "treatment planning" at 27.5%. Both practices had increases in the dimension "practice team", an increase of 600% for Practice A and 12.5% for Practice B.

Figure 4. Quality Improvement Timeline and Improvement Ramp
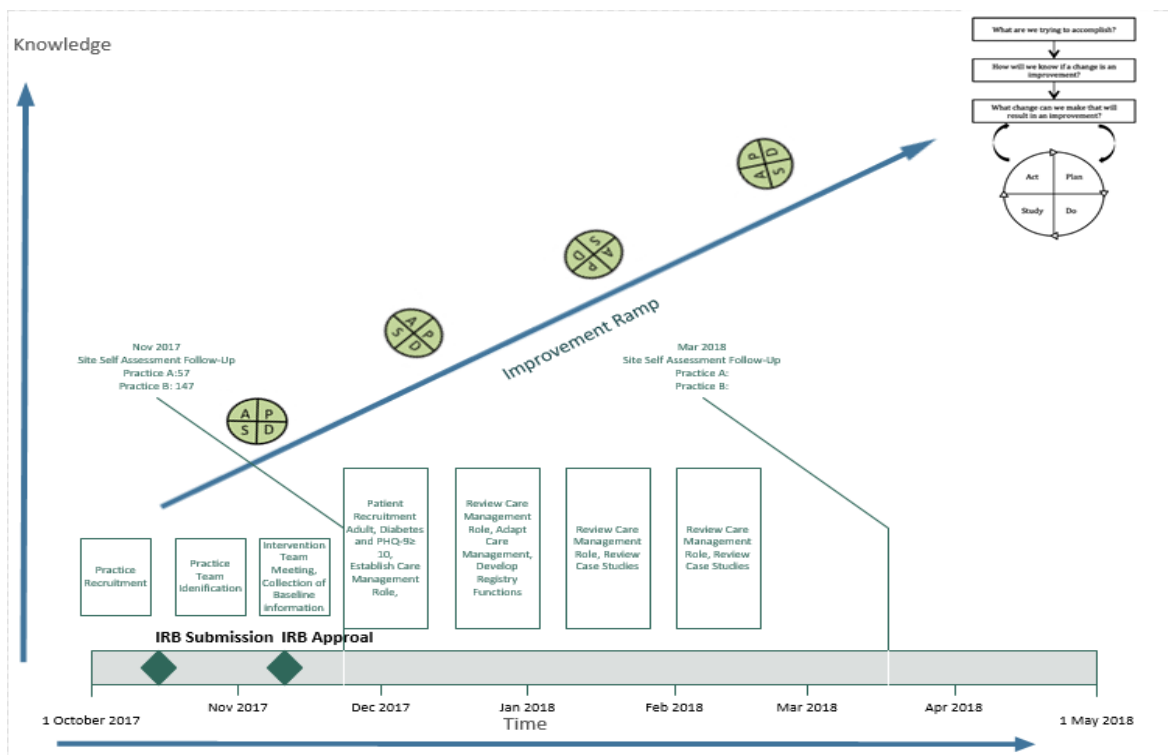
Table 4. Comparison between Private and Hospital Based RHC Site Self-Assessment Results

Site Self-Assessment Dimension	Practice A (%)	Practice B (%)	Difference Between Practice A and Practice B (%)
Level of Integration	0.0	0.0	0.0
Screening and Assessment	100.0	0.0	100.0
Treatment Plans	66.6	27.5	39.1
Patient Care Based on Best Practice Evidence	300.0	0.0	300.0
Patient and Family Involvement	50.0	14.3	35.7
Communication with Patient about Integrated Care	300.0	0.0	300.0
Follow up assessment – Treatment Referral	200.0	10.0	210.0
Social Support	40.0	0.0	40.0
Linking to Community Resources	75.0	0.0	75.0
Organizational Leadership for Integrated Care	33.0	0.0	33.0
Patient Care Team	600.0	12.5	587.5
Providers Engagement with Integrated Care	75.0	11.1	63.9
Continuity of Care (PCP and BMH)	600.0	0.0	600
Coordination of Referral and Specialists	150.0	11.1	161.1
Data System Records	37.5	11.1	48.6
Patient and Input to Integration Management	300.0	14.3	285.7
Staff Education and Training for Integrated Care	100.0	12.5	87.5
Funding Sources and Resources	150.0	0.0	150.0
Total Score: Site Self-Assessment	93.0	12.2	80.8

At baseline, neither practice could identify a standardized written protocol consistently used to screened for depression and rescreen for response with a structured care management and follow-up component (Appendix G-I). Each practice did have an annual depression screening protocol; however, Practice A did not have a discrete data field in the EHR to capture responses. Pre- and post- QI adult diabetes screening rates can be found in Table 5.

Table 5. Adult Patients Diabetes Patients Screened for Depression

	Quarter 2 2017	Quarter 1 2018

	Baseline			Follow-up		
	n	# screened	Screening Rate	n	# screened	Screening Rate
Practice A						
PHQ-9	286	0	0%	279	97	27%
Practice B						
PHQ-9	143	73	51%	141	79	56%

Note: Data was pulled using electronic health records reports, if screening was not in a discrete data field, the result was not captured

Table 6. Baseline and Follow-up Patient Outcome Comparisons

	Baseline		Follow-up		Difference
	n	M	n	Mean	
Practice A					
A1c	4	8.93	4	7.55	1.38
PHQ-9	4	15.25	4	8.25	7.00
Practice B					
A1c	4	7.90	2	7.40	0.50
PHQ-9	4	16.7500	4	12.25	4.50
Practice A and Practice B					
A1c	8	8.41	6	7.50	0.91
PHQ-9	8	16.00	8	10.25	5.75

n=sample size
M=mean
SD = standard deviation
A1c = Hemoglobin A1c
PHQ-9=Patient Health Questionnaire

Further, each practice identified gaps in their protocol for suicidal ideation/suicide risk identified in the PHQ-9 screening, which prompted further review and modification. One site provided additional training for all staff on managing patients at risk for suicide and providing immediate assistance.

The QI project timeline was fairly aggressive, and both practices were slow to identify patients that had a PHQ-9 $\geq$ 10. Practice A reported that patients were reluctant to sign the

consent form. Eight patients, four from each practice participated long enough to have a baseline

PHQ-9 and four follow-up screenings and care management appointments. The overall mean

A1c and PHQ-9 scores when patients were aggregated across practices reduced from 8.41 to 7.50

and 16.00 to 10.25 respectively. Analyzing each practice independently, each practice had a

decline in mean A1c and PHQ-9 scores. Practice A, the practice with the lowest baseline SSA

score at baseline, reported more improvement in both mean A1c and PHQ-9 scores over

baseline.

Qualitative information was captured as part of the quality improvement project.

Patients provided formal feedback regarding the care management initiative. A patient who

recently achieved sobriety during the QI project period commented, "It is nice to be called to see

how you are". The care management activities allowed for reinforcement of relapse prevention

strategies and continued encouragement to continue with psychiatry visits and perhaps insight-

orientated therapy. During the course of the study, the patients PHQ-9 decreased from a baseline

score of 15 to 6. Another patient commented, "I would not have made this much progress if I

did not have the extra help". Several of the patients who participated had depression, diabetes

and substance use disorders. Further, at least two of the patients had family members that had

recently committed suicide.

Staff feedback was positive, one staff member commented, "I cannot believe the

improvement in the health outcomes; however, it takes time to do this work and often we are

short staffed". Behavioral health staff providing counseling and care management stated that,

"Providers did not fully appreciate what I could bring to the table until we started this QI

project". All QI team members in both practices reported improvement in communication

between the provider-patient and clinical staff regardless of position. Both practices also noted

that the EHR was at times a barrier to collect population health data and required time.

Discussion

Summary

The QI project's aim and workflow modifications were based upon evidence that supports moving towards improved patient outcomes via an evidence-based systematic screening and rescreening for depression and structured biweekly proactive care management and outreach. Each RHC practice moved towards the adoption of the evidence-based depression screening guidelines focused on targeting patients with diabetes for the QI project. The QI project results cannot be extrapolated due to the small sample size and limited time-frame. The findings are important at the practice level and within the population of the practice. Further, the individual work spent with each patient began to identify community resources and support services that were needed to address exercise, social isolation, cost of extracurricular activities and transportation.

Utilizing an interdisciplinary team, each practice sought to advance the incorporation of evidence-based knowledge and treatment in depressed patients with diabetes. The engagement of the RHC's in the quality improvement activities provided immediate evaluation of each practice's delivery care setting and responsiveness to patients diagnosed and treatment of depression. The SSA results were used as an inventory of focused areas to improve chronic care management and aligned with Barr et al., (2003) Expanded CCM. Specifically, the care management supported the individual's development of enhanced life skills by identifying patient's readiness for change, and linked them with community resources. Biweekly patient contacts allowed for PHQ-9 rescreening with the patient and individualized care management modification. The focused and consistent use of the PHQ-9 at the care management in-person

visits or phone contacts made each RHC contemplate patient specific results. Further, staff felt a great sense of pride in the ability to see rapid improvements with patients.

Initially, the practices had some degree of concern regarding the PHQ-9 question (9) related to suicide or harm to others. Both practices adopted education and policy modifications to education staff members regarding suicide prevention and established protocols as it relates to community support to treat at risk patients needing additional services.

Interpretation

The RHC's reported improvements in multiple SSA dimensions indicating that the practice team taking the SSA noted changes in the dimension during the QI periods. Four dimensions that both practices improved were the use of treatment plans, patient and family involvement in care, the use of patient care teams and provider engagement. By the end of the project period, the inter-professional teams had developed a system to evaluate the service delivery at the patient level by using care management plans. The use of data to capture population changes remained a challenge. Although each practice was able to obtain population data, it was a struggle. The dimension "data system records" was the only area where an overall decrease was noted when the outcomes of both practices were combined.

The overall SSA score for both practices increased, indicating that core components of behavioral integration advanced during the QI period. Practice A had a large increase in the screening rate and self-reported SSA dimension "screening and assessment" over the QI period. The SSA score for Practice B, the practice reported higher levels of overall integration and the use of screening instruments for patients with behavioral health conditions had no change in the SSA dimension for screening and minor increases in the screening rate, this practice reported a very small increase in screening patients with diabetes. This indicates that the new workflow has

not been fully adopted, which likely impacted the number of patients identified with a PHQ-9

≥10. Aggregate PHQ-9 scores and A1c decreased for both practices, similar to the findings in

the research-based literature.

Large scale research studies have demonstrated improved outcomes that are similar to the

small sample improvements that the RHC clinics experienced. Dissemination and scalability is

often undermined by a scarcity of resources, competing demands and professional resistance

(Coventry et al., 2012). Time and staffing impacted the practice's ability to collect and monitor

population base data, specifically, the "study" component of the PDSA was a challenge and

impacted the formation of rapid recommendations to improve outcomes. As a result, cycles were

prolonged as workforce shortages continued throughout the QI period.

Limitations

The QI project was very small; randomization did not occur and there was no comparison

group. A major strength of the SSA is that it comes directly from the practice, that said,

response bias contributes to measurement error. Study enrollment was triggered by a patient

with diabetes filling out a PHQ-9 at an office visit which can result in selection of a particular

group of patients. For example, would severely depressed patients be motivated to present for a

 diabetes follow-up visit and take the PHQ-9? Additionally, low patient response rates may

select for certain patient characteristics. Further, a developing detailed training plan for the

nursing care management role was part of the QI effort; additional work needs to be done to

explore the specific items related to care management that were effective making replication

difficult without additional PDSA cycles and data collection.

Conclusions

Improved systems for patients with chronic care is essential and care management

has been shown to impact outcomes, however, additional work needs to be done to determine sustainability in rural health clinics beyond the quality improvement project period (Wells, 2000). Training as it relates to evidence-based guidelines and development of workflows are essential for consistent adoptions and improvements to take place in the clinical and community settings, overcoming the strong pull of providing "usual care". Further, quality assurance processes are paramount to ensure that regression to old habits does not occur in the clinical setting. Additional work needs to be done to understand how the use of technology support the movement away from usual care and provide the resistance needed to force the sustained changes needed to improve population health. Further study should be done to evaluate the qualitative findings that suggest the QI project may have impacted the patient's social isolation and support. Lastly, staff satisfaction, engagement and activation should be explored.

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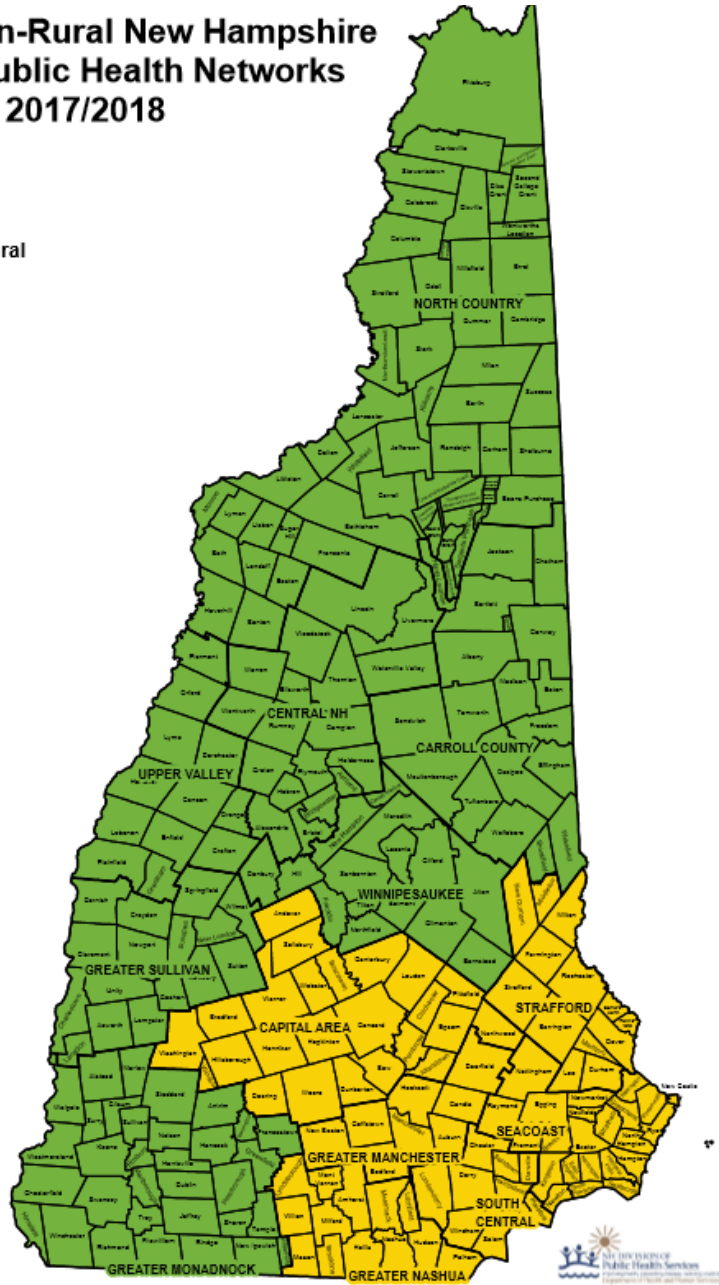Trangle, M., Gursky, J., Haight, R., Hardwig, J., Hinnenkamp, T., Kessler, D., … Myszkowski,

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Appendices

Appendix A

("Rural and Non Rural Public Health Regional Networks 2017/2018," 2017)

Appendix B

PHQ-9 Screening

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 figety 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, please refer to accompanying scoring card*).   TOTAL: _____

Appendix C

Care Management for Patients with Diabetes and Depression Based on Screening and Rescreening Results in Primary

Letter of Commitment
Between [Insert practice name here] and Ms. Marcy Doyle, MHS, MSN, RN, CNL
University of New Hampshire Doctorate of Nursing Practice Candidate
This is a letter of commitment (LOC) between the "University of New Hampshire" hereinafter called UNH and "[*practice*]".

I.   Background

- Depression is one of the most common treatable and underdiagnosed global disorders. By 2030 it is predicted to be the second leading cause of disease and disability worldwide (Mathers & Loncar, 2006).
- Individuals with one or more chronic illness have on average between 9.3% and 23.0% increased risk of having comorbid depression (Moussavi et al., 2007).
- Sixty-eight percent of patients with a mental illness have a medical condition such as diabetes leading to functional impairments which results in an inability to adhere to healthy lifestyle choices, such as, maintaining a balanced diet, exercising or taking required medications (Moussavi et al., 2007).
- IJff et al., (2007) found that only 20 to 40% of depressed adults showed improvement after twelve months of receiving usual care.
- On average, twice as many patients significantly improved when they receive team-based care collaborative care versus usual care (Unützer et al., 2002).

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II.   Project Aims

- Establish the level of behavioral health integration at each practice.
- Establish the practic'sbaseline depression screening rate.
- Establish the practice's depreesion screening rate in the diabetic practice population.
- Develop an evidencebased clincal workflow/pathway for patients identified as depressed.
- Initiatie comprehensive treatment planning under with a care mangment component in patients with diabetes and diabetes and a PHQ-9 ≥10
- Capture and aggregate physical health metrics (HbA1c, blood pressurme and body mass index)

III.   Responsibilities

The below tasks will be the responsibility of [*insert practice name here*].
- Obtain patient consent
- Complete pre-work activities, including identifying QI team members and project lead collection of baseline evaluation data, and completion of a baseline office system survey.

- Hold bi weekly check ins with the practice QI team and DNP candidate
- Support both the practice and DNP candidate in undertaking the QI project time
- Collect and submit monthly data.
- Complete a final self-assessment review.
- Assist with the development and organization of educational sessions for the project

IV.   Benefits of Participation

- Learn evidence-based best practices
- Develop tools, trainings, technical and quality improvement support to aid in implementation.
- Develop an evidence-based clinical pathway for the practice
- Provide staff with additional education on depression and diabetes care and follow-up

We, the undersigned, have read and agree with this Letter of Commitment.

_____   _____

UNH Doctoral of Nursing Practice Candidate   *[Practice] Team Leader*

Date: October 3, 2017   *Date:*

Appendix D Site Self-Asseessment

I. Integrated Services and Patient and Family-Centeredness (Circle one NUMBER for each characteristic)

Characteristic	Levels			
1. Co-location of treatment for primary care and mental/behavioral health care	. . . does not exist; consumers go to separate sites for services 1	. . . is minimal; but some conversations occur among types of providers; established referral partners exist 2 3 4	. . . is partially provided; multiple services are available at same site; some coordination of appointments and services 5 6 7	. . . exists, with one reception area; appointments jointly scheduled; one visit can address multiple needs 8 9 10
2. Emotional/behavioral health needs (e.g., stress, depression, anxiety, substance abuse) 2. (ALTERNATE: If you are a behavioral or mental health site, respond in terms of medical care needs)	. . . are not assessed (in this site) 1	. . . are occasionally assessed; screening/assessment protocols are not standardized or are nonexistent 2 3 4	. . .screening/assessment is integrated into care on a pilot basis; assessment results are documented prior to treatment 5 6 7	. . . screening/assessment tools are integrated into practice pathways to routinely assess MH/BH/PC needs of all patients; standardized screening/ assessment protocols are used and documented. 8 9 10
3. Treatment plan(s) for primary care *and* behavioral/mental health care	. . . do not exist 1	. . . exist, but are separate and uncoordinated among providers; occasional sharing of information occurs 2 3 4	. . .Providers have separate plans, but work in consultation; needs for specialty care are served separately 5 6 7	. . . are integrated and accessible to all providers and care manager; patients with high behavioral health needs have specialty services that are coordinated with primary care 8 9 10
4. Patient care that is based on (or informed by) best practice evidence for BH/MH and primary care	. . . does not exist in a systematic way 1	. . . depends on each provider's own use of the evidence; some shared evidence-based approaches occur in individual cases 2 3 4	. . .evidence-based guidelines available, but not systematically integrated into care delivery; use of evidence-based treatment depends on preferences of individual providers 5 6 7	. . . follow evidence-based guidelines for treatment and practices; is supported through provider education and reminders; is applied appropriately and consistently 8 9 10
5. Patient/family involvement in care plan	. . . does not occur 1	. . . is passive; clinician or educator directs care with occasional patient/family input 2 3 4	. . . is sometimes included in decisions about integrated care; decisions about treatment are done collaboratively with *some* patients/families and their provider(s) 5 6 7	. . . is an integral part of the system of care; collaboration occurs among patient/family and team members and takes into account family, work or community barriers and resources 8 9 10

6. Communication with patients about integrated care	. . . does not occur 1	. . . occurs sporadically, or only by use of printed material; no tailoring to patient's needs, culture, language, or learning style 2 3 4	. . . occurs as a part of patient visits; team members communicate with patients about integrated care; encourage patients to become active participants in care and decision making; tailoring to patient/family cultures and learning styles is frequent 5 6 7	. . .is a systematic part of site's integration plans; is an integral part of interactions with all patients; team members trained in *how* to communicate with patients about integrated care 8 9 10
7. Follow-up of assessments, tests, treatment, referrals and other services	. . . is done at the initiative of the patient/family members 1	. . . is done sporadically or only at the initiative of individual providers; no system for monitoring extent of follow-up 2 3 4	. . . is monitored by the practice team as a normal part of care delivery; interpretation of assessments and lab tests usually done in response to patient inquiries; minimal outreach to patients who miss appointments 5 6 7	. . . is done by a systematic process that includes monitoring patient utilization; includes interpretation of assessments/lab tests for all patients; is customized to patients' needs, using varied methods; is proactive in outreach to patients who miss appointments 8 9 10
8. Social support (for patients to implement recommended treatment)	. . . is not addressed 1	. . . is discussed in general terms, not based on an assessment of patient's individual needs or resources 2 3 4	. . . is encouraged through collaborative exploration of resources available (e.g., significant others, education groups, support groups) to meet individual needs 5 6 7	. . . is part of standard practice, to assess needs, link patients with services and follow up on social support plans using household, community or other resources 8 9 10
9. Linking to Community Resources	. . . does not occur 1	. . . is limited to a list or pamphlet of contact information for relevant resources 2 3 4	. . . occurs through a referral system; staff member discusses patient needs, barriers and appropriate resources before making referral 5 6 7	. . . is based on an in-place system for coordinated referrals, referral follow-up and communication among sites, community resource organizations, and patients 8 9 10

II. Practice/Organization   (Circle one NUMBER for each characteristic)

Characteristic	Levels			
1. Organizational leadership for integrated care	. . . does not exist or shows little interest	. . . is supportive in a general way, but views this initiative as a "special project" rather than a change in usual care	. . . is provided by senior administrators, as one of a number of ongoing quality improvement initiatives; few internal resources supplied (such as staff time for team meetings)	. . . strongly supports care integration as a part of the site's expected change in delivery strategy; provides support and/or resources for team time, staff education, information systems, etc.; integration project leaders viewed as organizational role models
	1	2 3 4	5 6 7	8 9 10
2. Patient care team for implementing integrated care	. . . does not exist	. . . exists but has little cohesiveness among team members; not central to care delivery	. . . is well defined, each member has defined roles/responsibilities; good communication and cohesiveness among members; members are cross-trained, have complementary skills	. . . is a concept embraced, supported and rewarded by the senior leadership; "teamness" is part of the system culture; case conferences and team meetings are regularly scheduled
	1	2 3 4	5 6 7	8 9 10
3. Providers' engagement with integrated care ("buy-in")	. . . is minimal	. . . engaged some of the time, but some providers not enthusiastic about integrated care	. . . is moderately consistent, but with some concerns; some providers not fully implementing intended integration components	. . . all or nearly all providers are enthusiastically implementing all components of your site's integrated care
	1	2 3 4	5 6 7	8 9 10
4. Continuity of care between primary care and behavioral/mental health	. . . does not exist	. . . is not always assured; patients with multiple needs are responsible for their own coordination and follow-up	. . . is achieved for some patients through the use of a care manager or other strategy for coordinating needed care; perhaps for a pilot group of patients only	. . . systems are in place to support continuity of care, to assure all patients are screened, assessed for treatment as needed, treatment scheduled, and follow-up maintained
	1	2 3 4	5 6 7	8 9 10
5. Coordination of referrals and specialists	. . . does not exist	. . . is sporadic, lacking systematic follow-up, review or incorporation into the patient's plan of care; little specialist contact with primary care team	. . . occurs through teamwork & care management to recommend referrals appropriately; report on referrals sent to primary site; coordination with specialists in adjusting patients' care plans; specialists contribute to planning for integrated care	. . . is accomplished by having systems in place to refer, track incomplete referrals and follow-up with patient and/or specialist to integrate referral into care plan; includes specialists' involvement in primary care team training and quality improvement
	1	2 3 4	5 6 7	8 9 10

6. Data systems/patient records	. . . are based on paper records only; separate records used by each provider	. . . are shared among providers on an *ad hoc* basis; multiple records exist for each patient; no aggregate data used to identify trends or gaps	. . . use a data system (paper or EMR) shared among the patient care team, who all have access to the shared medical record, treatment plan and lab/test results; team uses aggregated data to identify trends and launches QI projects to achieve measurable goals	. . . has a full EMR accessible to all providers; team uses a registry or EMR to routinely track key indicators of patient outcomes and integration outcomes; indicators reported regularly to management; team uses data to support a continuous QI process
	1	2 3 4	5 6 7	8 9 10
7. Patient/family input to integration management	. . . does not occur	. . . occurs on an *ad hoc* basis; not promoted systematically; patients must take initiative to make suggestions	. . . is solicited through advisory groups, membership on the team, focus groups, surveys, suggestion boxes, etc. for both current services and delivery improvements under consider-ation; patients/families are made aware of mechanism for input and encouraged to participate	. . . is considered an essential part of management's decision-making process; systems are in place to ensure consumer input regarding practice policies and service delivery; evidence shows that management acts on the information
	1	2 3 4	5 6 7	8 9 10
8. Physician, team and staff education and training for integrated care	. . . does not occur	. . . occurs on a limited basis without routine follow-up or monitoring; methods mostly didactic	. . . is provided for some (e.g. pilot) team members using established and standardized materials, protocols or curricula; includes behavioral change methods such as modeling and practice for role changes; training monitored for staff participation	. . . is supported and incentivized by the site for all providers; continuing education about integration and evidence-based practice is routinely provided to maintain knowledge and skills; job descriptions reflect skills and orientation to care integration
	1	2 3 4	5 6 7	8 9 10
9. Funding sources/resources	. . . are only from MeHAF grant; no shared resource streams	. . . separate PC/MH/BH funding streams, but all contribute to costs of integrated care; few resources from participating organizations/agencies	. . . separate funding streams, but some sharing of on-site expenses, e.g., for some staffing or infrastructure; available billing codes used for new services; agencies contribute some resources to support change to integration, such as in-kind staff or expenses of provider training	. . . fully integrated funding, with resources shared across providers; maximization of billing for all types of treatment; resources and staffing used flexibly
	1	2 3 4	5 6 7	8 9 10

Appendix E

CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

RESEARCHER AND TITLE OF STUDY

My name is Marcy Doyle and I am a candidate for Doctor of Nursing Practice at the University of New Hampshire. I am inviting you to participate in the research study *Care Management for Patients with Diabetes and Depression Based on Screening and Rescreening Results in Primary Care* that I am conducting with other researchers.

WHAT IS THE PURPOSE OF THIS FORM?

This consent form describes the research study and helps you to decide if you want to participate. It provides important information about what you will be asked to do in the research study, about the risks and benefits of participating in the research study, and about your rights as a research participant. You should:

- Read the information in this document carefully.

- Ask any questions, particularly if you do not understand something.

- Not agree to participate until all your questions have been answered, or until you are sure that you want to.

- Understand that your participation in this study involves allowing the research team to use information from your participation in an individualized care management plan for patients with diabetes and depression. Your information will not be linked to your name; thus no one will know it is your information.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn whether individualized care management plans and more frequent follow-up with a care team can have positive effects on a patient's depression and diabetes. We expect approximately 40 people will participate in the research study. In order to participate you must be 18 years or older, have diabetes and have symptoms of depression.

WHAT DOES YOUR PARTICIPATION IN THIS STUDY INVOLVE?

In order to participate in the care management program, your depression screening results must be greater than or equal to a score of 10 which means you have mild to severe major depression. As part of the care management program, you will be asked to complete the Patient Health

DEPRESSION SCREENING, DIABETES and CARE MANAGEMENT

Questionnaire -9 (PHQ-9) every two weeks for between three to six months. You can complete the questionnaire, which should take less than two minutes, in the doctor's office or over the phone. You may be offered additional care management services based on your individualized care plan and depression symptoms.

If you choose to participate in the research study, we will use in the study the results from your PHQ-9 responses and your health measures (blood pressure, body mass index, and hemoglobin A1c). Each month for between 3 and 6 months, the medical practice will provide me with this information. Your information will be sent to me without any information that would identify you.

WHAT ARE THE POSSIBLE RISKS OF PARTICIPATING IN THIS STUDY?

Participation in this study is expected to present minimal risks to you.

WHAT ARE THE POSSIBLE BENEFITS OF PARTICIPATING IN THIS STUDY?

There are no anticipated direct benefits to you from participating in this research study. The research this study may answer the question whether offering short-term case management services in primary care will improve patient outcomes.

IF YOU CHOOSE TO PARTICIPATE IN THIS STUDY, WILL IT COST YOU ANYTHING?

There are no costs to participate in the research study.

WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATING IN THIS STUDY?

Compensation will not be provided as part of the research study.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in the research study is completely voluntary. You may choose not to take part at all. If you decide not to participate in the research study, you will not be penalized or lose any benefits for which you would otherwise qualify. Your plan of care and treatment will not change based on whether you chose to participate in the study.

CAN YOU WITHDRAW FROM THIS STUDY?

If you agree to participate in this study and you then change your mind, you may stop participating at any time. Any data collected as part of your participation will remain part of the study records. If you decide to stop participating at any time, you will not be penalized or lose any benefits for which you would otherwise qualify. Your plan of care and treatment will not change based on whether you chose to participate in the study.

HOW WILL THE CONFIDENTIALITY OF YOUR RECORDS BE PROTECTED?

We plan to maintain the confidentiality of all data and records associated with your participation in this research. To help protect the confidentiality of your information all research staff will be

required to comply with the University of New Hampshire and the primary care practice's procedures for the storage of data. Data will be de-identified by practices before it is submitted to the researchers. De-identified data will be stored on UNH Box, (cloud storage). The information will only be accessible to authorized UNH staff. This staff includes Marcy Doyle, Jeanne Ryer, EdD, MSc and Dayle Sharp, PhD, DNP, McPh, FNP. A UNH statistician, yet to be named, will access the de-identified data.

The data from the research study will be reported as a group. Findings may be reported in publications, presentations or reports. Practices will not be named in any publications or presentations. The results will be used to understand how to best provide care to patients with diabetes and depression in rural areas in New Hampshire.

WHOM TO CONTACT IF YOU HAVE QUESTIONS ABOUT THIS STUDY

If you have any questions pertaining to the research you can contact Marcy Doyle at 603-513-5288 to discuss them.

If you have questions about your rights as a research subject you can contact Dr. Julie Simpson in UNH Research Integrity Services, 603/862-2003 or Julie.simpson@unh.edu to discuss them.

Yes, I, _____consent/agree to participate in this research project.

No, I, _____do not consent/agree to participate in this research project.

_____   _____

Appendix F

University *of* New Hampshire

Research Integrity Services, Service Building
51 College Road, Durham, NH 03824-3585
Fax: 603-862-3564

13-Nov-2017

Doyle, Marcy
Nursing, Hewitt Hall
49 Brick Mill Rd
Bedford, NH 03824

IRB #: 6797
Study: Care Management for Patients with Diabetes and Depression Based on Screening and Re-Screening Results in Primary Care
Approval Date: 07-Nov-2017

The Institutional Review Board for the Protection of Human Subjects in Research (IRB) has reviewed and approved the protocol for your study as Expedited as described in Title 45, Code of Federal Regulations (CFR), Part 46, Subsection 110.

Approval is granted to conduct your study as described in your protocol for one year from the approval date above. At the end of the approval period, you will be asked to submit a report with regard to the involvement of human subjects in this study. If your study is still active, you may request an extension of IRB approval.

Researchers who conduct studies involving human subjects have responsibilities as outlined in the document, *Responsibilities of Directors of Research Studies Involving Human Subjects.* This document is available at http://unh.edu/research/irb-application-resources. Please read this document carefully before commencing your work involving human subjects.

If you have questions or concerns about your study or this approval, please feel free to contact me at 603-862-2003 or Julie.simpson@unh.edu. Please refer to the IRB # above in all correspondence related to this study. The IRB wishes you success with your research.

For the IRB,

Julie F. Simpson
Director

Appendix G

Depression Screening Protocol

Depression Screening
«PHQ-2 SCREEN»
«PHQ-9 SCREEN»
Or Insert copy of phq-9 if you wish «DEL»

.CE: Adolescent Depression Screen: «DEL» «Positive» «Negative»
.CE: Adult Depression Screen: «DEL» Positive «Negative»

CE:PHQ 9 Score: «REQ...»16

«Suicide assessment results must be filled in if the phq is 10 or higher»
Suicide Assessment Results «DEL» Positive «Negative»
If Positive Plan: «DEL» Patient contracts for safety follow up in office in 4 days «Weeks»
If any increase in symptoms patient agrees to go to ER or call 911. «Suicide Plan Positive Unstable»

Handout on Mental Health Providers given to patient with instructions.
Check with their insurance to see who on the list takes their insurance and then they need to call themselves to set up an intake appointment.

Mental Health Referral
.CE: MHR Depression: «DEL» x «click this when you are putting someone on the case management list don't forget to do referral form»
.CE: MHR Counseling: «DEL» x
.CE: MHR Counseling Declined: «DEL» «X»

.CE: MHR Psychiatric Consult: «DEL» yes

Appendix H

Care management protocol and treatment planning notes

.D: 03/27/18 : 07:57am
.T: «*»**Mental Health Case Management**

.CC: 31 «37» «39» «41» «47» «45» «30» «50»

Reason for Referral:
.CE: MHR DEPRESSION: «DEL»x
.CE: MHR MAT: «DEL»
.CE: MHR SBIRT: «DEL»
.CE: MHR MAT: «DEL»

.CE: PHQ 9 Date: «DEL»0310/2018
.CE: PHQ 9 Score: «DEL» 16

NOTE/COMMENT: «DEL» Pt is starting setraline 50mg daily **needs help setting up counseling has handout mental health providers but is having hard time getting an appointment**

Pt was advised to follow up with PCP: «DEL» 3-4 weeks
.CE: MHR Counseling Set Up: «DEL» «X»
.CE: MHR DECLINED COUNSELING: «DEL» «X»
.CE: MHR Psychiatric Referral Done: «DEL» «X»
.CE: MHR PSYCHE CONSULT DECLINED: «DEL» «X»
.CE: MHR CASE MGMT COMPLETED: «DEL»   «this needs to be entered as a date»
.CE: MHR CASE MANAGMENT DECLINED: «DEL» «X»
.CE: MHR UNABLE TO CONTACT: «DEL» «X»

Instructions: call in 3-4 days if has not heard from counseling office.

Appendix I

Registry tracking

MHR DEPRESSION Date of Referral	MHR MAT Date of Referral	MHR SBIRT Date of referral	PHQ 9 Date	PHQ 9 Score	Date	MHR Counseling Set Up	MHR Declined Counseling	MHR Psychiatric Referral Done	MHR PSYCHE CONSULT DECLINED	MHR Case Management Completed	MHR CASE MANAGMENT DECLINED	
			03/05/2018	3								
03/20/2018											No	
03/26/2018	03/26/2018	03/26/2018	03/26/2018	22	03/26/2018	x	03/26/2018	x	x	03/26/2018	x	
											no	

Age	Primary Provider	Date of last appointment	Date of next appointment	Date of HBA1C	HBA1C	DSME Ordered	DSME Completed	Mental Health Referral	Medical Nutritional Therapy	PHQ 9 Score	PHQ9 Date	CGM Date	BMI	Weight
		02/28/2018	05/30/2018	11/29/2017	5.4								2	220 lbs
		11/10/2017	03/15/2018	05/11/2017	5.7								5	311 lbs
		12/01/2017		12/01/2017	6.0								3	273 lbs
		12/19/2017	03/21/2018	12/19/2017	6.2									276 lbs
		01/29/2018	05/01/2018	01/29/2018	6.3								2	184 lbs
		12/26/2017	03/20/2018	12/01/2017	6.3								3	202 lbs
		02/27/2018	03/13/2018	02/02/2018	6.7					15	02/02/2018		3	176 lbs
		03/06/2018	06/27/2018	03/06/2018	6.8					2	03/06/2018		3	270 lbs
		01/05/2018		12/01/2017	6.8								2	129 lbs
		01/19/2018	04/11/2018	01/19/2018	6.9								3	259 lbs
		03/05/2018	04/02/2018	01/02/2018	7.0								2	198 lbs
		03/12/2018	03/15/2018	11/06/2017	7.1								3	188 lbs
		02/28/2018		11/29/2017	7.1								5	312 lbs
		02/20/2018		08/21/2017	7.2								4	249 lbs
		01/16/2018	04/20/2018	10/12/2017	7.3								3	219 lbs
		02/13/2018	05/29/2018	02/13/2018	7.3					2	02/13/2018		3	230 lbs
		01/16/2018		01/16/2018	7.3							01/16/2018	3	190 lbs
		01/30/2018	03/20/2018	01/30/2018	7.4								1	125 lbs
		02/14/2018	05/18/2018	02/02/2018	7.4				02/02/2018	9	02/02/2018		4	225 lbs
		02/20/2018	05/08/2018	01/05/2018	7.5								2	221 lbs
		01/26/2018	04/27/2018	10/24/2017	7.6								4	314 lbs