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Improving Rural Primary Care Depression Treatment: Intervention, Implementation, and Evaluation Design

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Abstract

Major Depression is a significant source of disability, often manifesting as a chronic, recurring condition over an affected person's lifetime. Most people receive no care, but those who do are most often treated in primary care. After 12 months of usual primary care treatment only about 20% of patients achieve significant symptom reduction. Collaborative Care is an evidence-based approach to depression treatment in primary care. A mental health care manager and psychiatric consultant extend and support treatment provided in primary care. Using an outcomes-driven, treat-to-target approach common for other chronic health conditions, Collaborative Care more than doubles the likelihood of significant symptom reduction in randomized trials. The main research question for this paper is the extent to which rural Federally Qualified Health Centers implement Collaborative Care to treat depressed primary care patients, the process of implementing this practice change, and the perceived barriers and benefits affecting implementation. Implementation effectiveness was measured by patient-level clinical outcomes and clinic-level processes of care shown to predict better outcomes. Clinics used a five stage implementation process facilitated by a practice change coach. We describe the design of this five-step process, adaptations to Collaborative Care necessary to address the unique needs of rural clinics, and the characteristics of participating clinics. Findings from this implementation initiative could provide important insights regarding methods to improve access and quality of depression care in rural primary care settings.

Keywords: Depression; Primary care; Collaborative care; Integrated mental health; Practice change; Quality improvement; implementation

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Abbreviations

CM: Care Manager; CoCM: Psychiatric Collaborative Care Management; FQHC: US Federally Qualified Health Center; PHQ-9: Patient Health Questionnaire 9 Depression Items; PC: Psychiatric Consultant; PCP: Primary Care Provider; SIF: Social Innovation Fund; SIF-CoCM: Social Innovation Fund Collaborative Care; CPT: Current Procedural Terminology

Introduction

Worldwide, depressions among the five leading causes of disability. The deleterious effects on various domains of functioning can be measured as years lived with disability, a measure that aggregates the amount of time a specific health condition interferes with functioning [1]. Untreated or ineffectively treated depression is costly to affected individuals who experience disruption in functioning, reduced educational attainment, lower earning potential, higher unemployment, and increased work disability [2]. Workplace disability arises from absenteeism or presenteeism, the latter referring to depressed employees who are present on the job but not functioning well. In fact, presenteeism accounts for the majority of costs borne by employers related to depression [3-5]. Depression is often a chronic, recurring condition that first manifests in the teen or early adult years. Most affected individuals experience their first episode by the age of 24, though first treatment is typically much later [6]. Depression is a pervasive, persistent condition that is unremitting over at least two weeks and often much longer. The two cardinal symptoms of depression are (1) feeling down, depressed, or hopeless, and (2) little interest or pleasure in doing things. Other symptoms that may co-occur are motor retardation or agitation, disruptions in sleep, appetite, concentration, energy, and suicidal thoughts [7]. These symptoms cause significant societal impact, yet nearly 60% of people needing mental health treatment in any given year receive no care whatsoever. Among the 40% who access treatment, over half are treated in primary care and other general medical settings

[8]. In fact, only 21% of antidepressant medications are prescribed by psychiatric specialists with most of the remainder prescribed in primary care [9]. This may be the result of a decline in the number of practicing psychiatrists per 100,000 US residents combined with the number of practicing primary care providers slightly increasing during the same timeframe [10]. Treating depression in primary care offers advantages, especially in rural areas. Primary care is more available in rural settings [8-11]. Whereas mental health treatment is rare [8,12-14]. It is possible to get a same-day appointment at most primary care clinics whereas there is often a months-long waiting list for specialty behavioral health services in both rural and non-rural settings. Primary care has the advantage of an established relationship between the provider and patient, which may help mitigate reluctance to engage in mental health treatment and normalize it as part of routine medical care. This can be important in rural communities where patients may be particularly sensitive to issues of privacy and stigma [15-17], especially because stigma regarding mental health treatment is inversely correlated with population density [18]. Treating depression in rural primary care also presents challenges. Although rates of depression in rural areas are not significantly higher than in urban and suburban areas [19], rural residents are less likely to receive treatment of any kind [8,12-14]. This is likely due, in part, to well-documented difficulties recruiting and retaining behavioral health specialists in rural areas [14,20,21]. Primary care settings, both urban and rural, are less likely to meet minimally acceptable care standards [8,11,22] and rarely offer treatments other than medication [21-23]. Although about 30 million Americans receive an antidepressant prescription each year, only about 20% experience substantial improvement in symptoms after 12 months of treatment [24,25]. Collaborative Care (Called Psychiatric Collaborative Care Management or CoCM by the US Centers for Medicare and Medicaid Services, which funds medical care for the elderly, disabled, and poor) is an approach to depression treatment that uses existing evidence-based pharmacologic and psychotherapeutic therapies in a different way. Based on the Wagner Chronic Care Model [26-28], CoCM uses a team-based, outcomes-driven, treat-to-target approach for delivering mental health services in primary care and other non-specialty settings [25,29,30]. As shown in Figure 1, CoCM is collaboration between the primary care provider, mental health providers, and patient. Over 80 randomized controlled trials conducted over the past 20 years demonstrate that CoCM achieves significantly better patient outcomes than usual care across a wide range of treatment settings [31-33], patient populations [34-36], and mental health conditions [31,37,38]. The primary care provider remains the locus of care, prescribing pharmacologic treatments when they are part of the treatment plan and ensuring that physical and mental health treatments are integrated and inform each other. CoCM adds two mental health providers to the existing dyad of the patient and primary care provider. The first is a behavioral health Care Manager (CM) who: (1) proactively follows up with the entire population of patients in active care management, (2) offers evidence-based, brief, structured psychotherapy when that is part of the treatment plan, (3) measures treatment outcomes and uses the data to cue the team when a change in treatment is needed, and (4) creates a relapse prevention plan with patients when they are transitioning out of active care management. The second addition to the treatment team is a Psychiatric Consultant (PC) who speaks with the care manager weekly to review patients who are not at least 50% improved after 10-12 weeks since initiation of treatment or since the last treatment change. The PC assists the primary care team with diagnosis, treatment planning, and changes to treatment. The PC typically performs this role remotely, does not prescribe medications, does not see patients, and is available to primary care providers when they have questions about diagnosis or treatment recommendations. The PC should be a psychiatrist, psychiatric nurse practitioner, or psychiatric physician assistant-someone who has advanced training and experience with psychotropic medications to assist primary care providers in broadening the range of medications, doses, and combinations they feel comfortable using. CoCM is particularly well-suited for the majority of counties in the US with no practicing mental health providers (e.g. psychiatrists, psychologists, psychiatric nurse practitioners, clinical social workers, licensed counselors). All of these counties are rural [20]. They need models of care that leverage mental health specialists wisely to increase access to evidence-based care and improve treatment outcomes. CoCM uses scarce resources (mental health experts) more efficiently. This allows most patients to receive care influenced by the psychiatric consultant even though they do not see this provider directly. Similarly, care managers provide population-based care that balances reach and depth without compromising outcomes. As early as 2006, an editorial in the British Medical Journal exhorted primary care and behavioral health researchers to stop conducting trials of CoCM and turn their efforts to dissemination and implementation [39]. Yet, implementing a health care innovation is neither simple nor quick [40]. Healthcare clinics are complex systems with many factors, both internal and external, exerting influence on the way they approach patient care. Primary care clinics interested in improving mental health services need an implementation process that understands the healthcare context within which they function. This process needs to be concrete, structured, and explicit without being overly prescriptive or inflexible. This is particularly true for rural primary care clinics, which face greater challenges associated with constrained resources and capacity as compared with urban clinics, even when both serve low-income patients [41,42]. Rural workforce challenges are daunting, especially for mental health specialists such as clinical social workers, counselors, psychologists, and psychiatrists [14,20,21]. These challenges require rural healthcare settings to adapt evidence-based practices based on pragmatic considerations, but these adaptations are rarely based on research conducted in rural settings [42]. Louison and Fleming (2016) noted that rural communities "need formal, frequent and supported communication with program developers so that they can understand and test what adaptations are possible" [43]. They further observed that "Stage-based implementation is important regardless of context, but it is particularly critical in rural communicates where funds must be used as judiciously as possible to assure outcomes" [43]. The Social Innovation Fund (SIF) was a public-private partnership matching federal funding with philanthropic funding to implement evidence-based solutions addressing diverse problems in low-income communities. The Social Innovation Fund-Collaborative Care (SIF-CoCM) initiative was designed to increase access to evidence-based depression treatment in rural primary care clinics.

Materials and Methods

Participants

Primary care clinics eligible to participate in SIF-CoCM were located in federally designated "rural" or "frontier" areas within the states of Alaska, Washington, Idaho, Montana and Wyoming. This geographic area represents 27% of the land mass of the United States and includes the 3 states with the lowest population density per square mile- Alaska, Wyoming, and Montana. Other

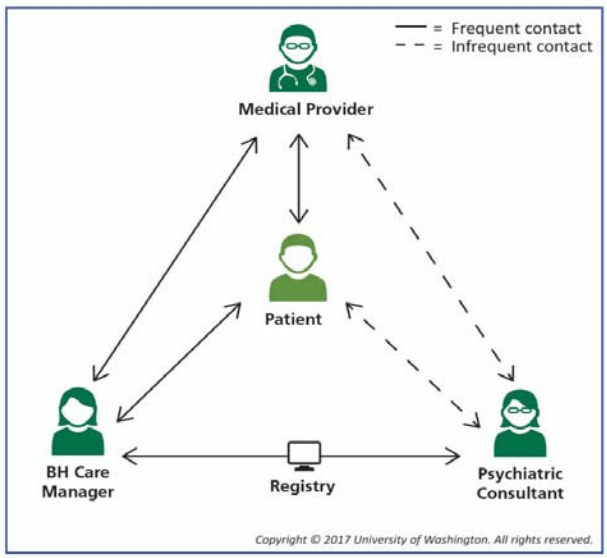

Figure 1: Collaborative Care Team.

eligibility criteria included: (1) non-profit community primary care organization, (2) serving patients from federally recognized medically underserved (e.g. American Indian tribal nation) and/or health professional (primary care and behavioral health) shortage areas, (3) serving patients from low-income communities with a significant number who were uninsured or covered by Medicaid, and (4) serving at least 1,500 unique primary care patients annually. All of the clinics that submitted an application to participate in SIF-CoCM (n=11) were Federally Qualified Health Centers (FQHCs), community-based clinics that provide comprehensive primary care. FQHCs are the largest primary care network in the United States with more than 8,000 clinical delivery locations, over half of which are located in rural areas. FQHCs have some unique features. Their mission is focused on delivery of primary care and preventive health services in underserved and rural communities and to underserved, underinsured, and uninsured individuals. FQHCs provide healthcare services to all people regardless of their ability to pay and, in exchange, receive an annual federal cash grant, cost-based reimbursement for Medicaid patients, and malpractice coverage. Table 1 presents information about the primary care clinics that successfully competed for participation in SIF-CoCM. Of note, two clinics serve a large proportion of non-White patients. One of these clinics predominantly serves Native Alaskans while the other clinic serves a large proportion of American Indian patients. Eligible patients were: (1) enrolled in primary care at one of the participating clinics, (2) diagnosed with an active depressive episode, (3) with or without co morbid behavioral health conditions like anxiety or substance abuse, (4) not currently engaged in depression treatment outside the participating clinic, (5) not currently psychotic, (6) not diagnosed with bipolar disorder, (7) not exhibiting moderate to severe cognitive impairment, and (8) willing to engage in depression treatment.

Materials

The researchers developed a five stage implementation process based on nearly a decade of experience supporting CoCM dissemination that was designed to maximize the likelihood of CoCM implementation success. This implementation process developed in a recursive manner-lesson and insights gleaned from each implementation informed the process for the next one. This culminated in an implementation method shown in Figure 2 consisting of five stages: (1) Initiate, (2) Plan, (3) Launch, (4) Execute, and (5) Sustain. The structure and flow of these five stages is similar to implementation frameworks developed to promote effective dissemination of diverse innovations and recognizes that implementation is a process rather than an action completed at a single point in time [44-46].

Initiate: Each clinic participating in SIF-CoCM identified a person to serve as leader of the implementation and this person dedicated a portion of his or her time to fulfilling this role. The ideal amount of time depended on the size and complexity of the organization but was typically not less than 10% FTE (Full-Time Equivalent) or more than 50% FTE. This role was filled by the clinic manager, medical director, behavioral health director, quality improvement director, or similar person. Necessary qualifications for success in the role included the authority to make decisions and direct resources. Once an implementation leader was selected, the leader focused on developing a shared vision and rationale for undertaking the CoCM practice change. Leaders were instructed by implementation coaches to engage a broad diversity of stakeholders in this process, including clinic leadership, providers, administrative staff, and patients. This process often revealed incongruence among stakeholders or hidden resistance among essential players. Some differences of opinion were expected, but if key stakeholders held drastically different views of the goals to be achieved, leaders were informed this may undermine implementation success if left unresolved. At this stage, clinics also developed the business case for CoCM implementation and used this as an engagement and communication tool with stakeholders. Organizations with more than one clinical delivery location identified one site for initial CoCM implementation.

Plan: The second stage included a CoCM gap analysis at the clinic and clinician levels. Clinics received tools and coaching to facilitate this process. This helped clinics focus their attention on those areas needing the most attention to prepare for CoCM practice change. The second component of this stage was development of a detailed clinical workflow that operationalzed the CoCM treatment pathway for patients and providers and that was tailored to the specific context of the implementing clinic (e.g. existing processes, space constraints). Clinic leaders were instructed to create a concrete and specific workflow, detailing which actions would occur, in what sequence they would occur, where they would occur, who would be involved, and what would happen next. The most effective workflows were a graphical representation of the CoCM pathway that was reviewed by both clinical and non-clinical staff and modified based on their input. At this stage, participating clinics also developed a plan for using a CoCM registry to facilitate efficient, population-based, treatment-to-target depression care. The typical CoCM caseload for a full-time care manager was about 60 patients, making an effective registry critically important for success. Clinics that needed to hire or redeploy staff to fill the care manager and or psychiatric consultant roles did that during this stage. Many SIF-CoCM clinics had an existing, traditional behavioral health service co-located in primary care with varying degrees of integration. These clinics typically redeployed some or all of their existing behavioral health staff into the CoCM care manager role. Clinics not already providing depression treatment in primary care implemented CoCM as a new service and hired staff. These clinics were given example job descriptions and assistance with recruiting to these positions, when necessary. This stage included pre-launch training for the CoCM clinicians (primary

Table 1: Characteristics of Participating Clinics.

	Clinic A	Clinic B	Clinic C	Clinic D	Clinic E	Clinic F	Clinic G	Clinic H	Mean
Unique patients per year[1]	10,000	2,214	13,092	22,934	19,095	2,000	2,756	16,000	11,011
% Non-white in catchment area[2]	8.40%	12.40%	7.20%	16.70%	17.10%	54.80%	40.30%	5.50%	20.30%
% Patients uninsured[1]	13.20%	24%	63.70%	57%	33%	28%	50%	34%	37.90%
% Patients Medicaid[1]	35.70%	32%	12.40%	28%	38%	28.20%	29%	25%	28.50%
Primary Care Provider FTE[1]	5	3	11	18	9	5	6.5	12	8.7
Mental Health provider FTE[1]	3	2.8	3	4	3	2	2	6.7	3.3
Total annual expenditures (in thousands)	$121,703	$24,443	$110,073	$142,753	$92,853	$12,464	$20,964	$106,764	$7,900
Patients at or below 200% of poverty	86.2%[3]	91.2%[3]	98.1%[3]	92.9%[3]	91.1%[3]	84.7%[4]	---[4]	82.1%[4]	78.30%
Depression screening rate	---[3]	---[3]	---[3]	---[3]	---[3]	76.6%[4]	17.2%[4]	52.4%[4]	48.70%

[1] Source: Self report by clinic
[2] Source: US Census Bureau (2010 data)
[3] Source: US Health Resources and Services Administration Data Warehouse (2013 data)
[4] Source: US Health Resources and Services Administration Data Warehouse (2014 data)

care provider, care manager, psychiatric consultant). Primary Care Providers, except the PCP champion, participated in 1.5 hours of training prior to launch. The first component of this training was a 30 minute overview of CoCM completed during Stage 1. The second component of PCP training was a 1 hour training focused on their role in the CoCM clinical workflow. Both trainings were delivered in a group format at the clinic using recorded online modules. Some clinics supplemented this with periodic in-service training for PCPs to reinforce key components of their role in CoCM and to address provider turnover. The PCP champion (one from each clinic), CM(s), and PC participated in a combination of online and in-person training. The online training delivered didactic content focused on each of their CoCM roles. For example, training for Psychiatric Consultants (PCs) emphasized how their role in CoCM differs from traditional consultation learned during residency [47]. Since CoCM is a team-based treatment approach, in-person training for the PCP champion, PC and CM(s) was conducted together and focused on their functioning as a team. CMs also received training and certification in Problem-Solving Treatment, an evidence-based psychotherapy for depression designed for primary care settings [48].

Launch: Each clinic set a specific launch date when the implementation leader and key members of the clinical team would be present and when the clinic would typically be less busy. At this stage, clinics created internal and external communication plans. The internal communication plan was a blueprint for planning the type, amount, and frequency of internal communication with clinic staff about CoCM launch. The external communication plan was designed to consider the effects CoCM implementation could have on community partners and a plan to notify them in advance of CoCM launch. Clinics also started development of a financial sustainability plan for ongoing sustainment of CoCM after grant resources would no longer be available.

Execute: At this stage, clinics activated their internal and external communication plans. Each clinic participated in a monthly one hour implementation coaching call that was structured around reports from the CoCM registry. These reports showed how well the clinic was performing with regard to patient-level clinical outcomes and clinic-level processes of care shown to predict better and faster improvement in depression symptoms [49,50]. Clinics reviewed their progress in relation to peer SIF-CoCM clinics and bench marks based other CoCM implementations. The monthly review of these reports was designed to develop the capacity of each clinic to analyze clinic-level data and use this information for continuous quality improvement. Post-launch training for CMs focused on skill expansion. Each post-launch training topic was delivered over two months-the first month was a one hour didactic webinar followed the next month by a 90 minute case call. Care managers applied the techniques/skills learned during the webinar over the course of the following month and prepared a case to present to their colleagues and the trainer the following month. Post-launch training covered a wide range of CM skills, including anxiety disorders, chronic pain, distress tolerance, and trauma-informed care, among others. Psychiatric consultants participated in quarterly group calls with an expert PC to share best practices and receive peer support for this non-traditional role. Care Managers (CMs) received the most training because they are the nexus of the CoCM team. As clinics prepared to exit implementation coaching, they created an organizational relapse prevention plan designed to help them identify early warning signs indicating that essential components of CoCM may be slipping at their organization. This plan created a process for regular monitoring of these indicators and interventions to get the program back on track.

Sustain: At this stage, clinics were independent. They trained new clinical and administrative staff as turnover occurred. They also used their organizational relapse prevention and financial sustainability plans to monitor processes and make course corrections when needed. Clinics with more than one physical location expanded CoCM to additional sites.

Patient level data: Quantitative patient data was collected from the CoCM registry. The Care Management Tracking System is a HIPAA-compliant web-based registry designed to facilitate CoCM delivery. The registry tracked the entire population of enrolled patients at each SIF-CoCM clinic, including the number of treatment contacts, number of psychiatric consultations, length of time in treatment, *etc*. The registry prompted clinical action based on evidence-based algorithms [51] and documented type, duration, provider, and PHQ-9 score for each visit or phone call. The PHQ-9 is a brief, well-validated measure that screens for depression and tracks symptom changes over time [52,53] and that has become commonplace in most primary care settings. The amount of information required in the CoCM registry was intentionally minimal to reduce duplication with the Electronic Health Record (EHR). Information was entered into the registry by the CM during initial and follow-up contacts using a

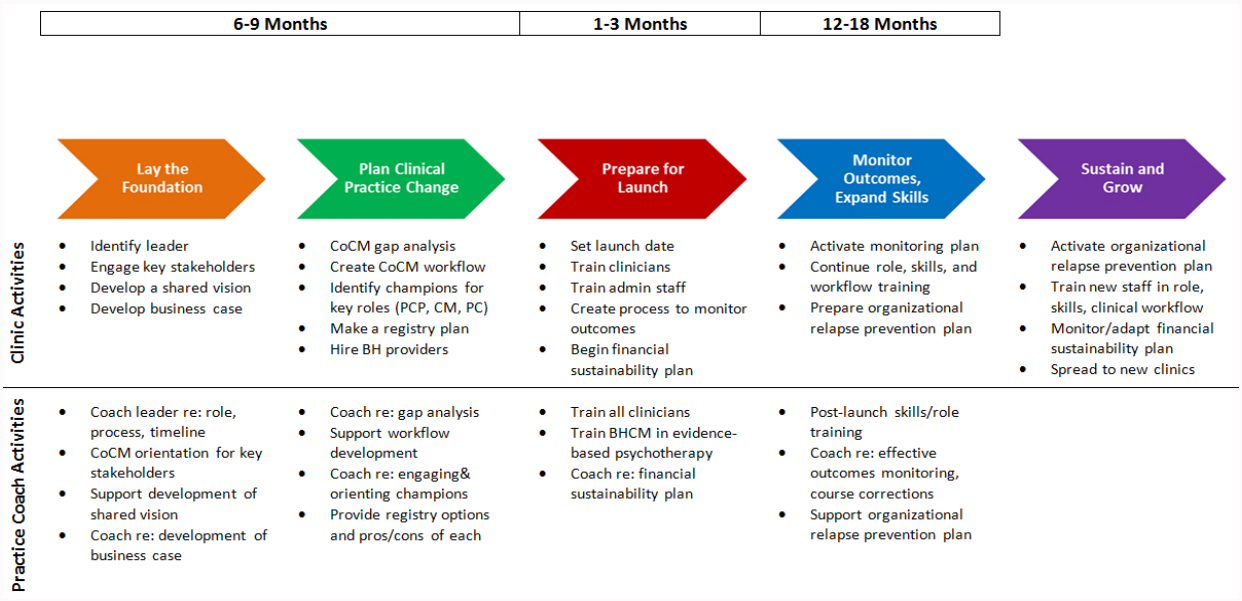

Figure 2: Implementation Process and Activities.

concurrent documentation approach to minimize the amount of data input necessary outside of patient contacts. The CoCM registry also provided clinicians and program leads with several real-time reports for program monitoring and caseload review. These included a sort able caseload report for each care manager that facilitated their ability to quickly identify patients who needed attention most urgently and a report that identified patients whose symptoms had not significantly improved in the past 10 weeks and who hadn't been discussed with the psychiatric consultant during that time. Psychiatric consultants used the registry to prepare for weekly caseload consultation with the care manager's and to document treatment recommendations.

Provider level data: Clinicians, including primary care providers, care managers, and psychiatric consultants participated in a survey of their experience with SIF-CoCM 18 months following launch. Questions included their appraisal of the effectiveness of CoCM in improving access to care and quality of care for their patients, whether they received the support they needed from the clinic to be successful in this new role, level of burnout, and demographic information such as level of training, years of clinical experience, and length of employment at the participating clinic.

Clinic level data: Prior to SIF-CoCM launch, clinics provided quantitative information about their patient population, including number of unique patients treated in the past year, payer mix, FTE of medical care providers, FTE of existing behavioral health providers, and similar information. Clinic leaders also participated in a qualitative interview focused on their goals for the CoCM implementation and outcome of prior quality improvement efforts, among other topics. These clinic-level quantitative surveys and qualitative interviews were repeated at 18 months post-launch and at 2.5 years post-launch, immediately prior to ending active implementation support. In this paper we report qualitative data from pre-implementation interviews with clinic leaders that elucidate perceived barriers and facilitators as they prepared for CoCM implementation. Each clinic provided de-identified demographic data for enrolled patients to supplement data captured in the CoCM registry. When necessary, data regarding total clinic expenditures and demographic information for the geographic area they serve was gleaned from the US Health Resources & Services Administration online Data Warehouse and the US Census Bureau website.

Procedures

Interested primary care clinics responded to a request for proposals with a letter of intent documenting eligibility. Eligible clinics were invited to submit a proposal articulating their rationale for implementing CoCM, the number of patients they intended to treat over a 2.5 year timeframe, prior experience with quality improvement initiatives, proposed staffing plan, and a detailed budget. This budget required clinics to identify a non-federal source of funds to provide a 1:1 match of grant funding. One applicant clinic recruited a local philanthropy as a match partner and another applicant clinic recruited the local public health district as a match partner. All other applicant clinics identified budget reserves as their planned source of match funding. Applications were evaluated and scored by a primary and secondary reviewer according to a weighted rubric. Finalist clinics participated in a one day site visit with the primary and secondary reviewers, who traveled to each primary care clinic. Following the selection site visit, clinics were given the opportunity to provide a written response to questions that came up during the visit. Reviewers met as a group to debrief the site visits, review written responses, and make decisions about which clinics would be invited to participate. The purpose of this screening and recruitment process was to invite clinics demonstrating both interest and readiness to implement CoCM. Table 2 presents information about the clinic selection process. The first cohort of clinics (n=5) did not exhaust the pool of federal and philanthropic funds designated for the initiative so a second cohort of clinics (n=3) was recruited exactly one year later using the same process. The primary philanthropic funder identified other philanthropies interested in supporting CoCM implementation in these communities. Participating clinics that identified budget reserves as their sole or primary source of matching funds were invited to apply to these secondary philanthropies for matching funds. Clinics were unaware of these potential matching funds until after their grants were awarded and all participating clinics

successfully received external matching funds. Each participating clinic had an assigned practice change coach. This coach was a trained clinician experienced with CoCM implementation that helped the clinic navigate the implementation steps, problem-solve challenges, and gave them feedback about their progress. These practice change coaches also assisted clinics with identifying when adaptation of CoCM was necessary to fit the rural context. One adaptation was use of psychiatric nurse practitioners in the PC role to address workforce constraints. The proportion of mid-level providers (e.g. physician assistants, nurse practitioners) to physicians is higher in rural areas than urban, for both general medical care and for specialty care. As expected, SIF-CoCM had a higher proportion of non-physician psychiatric consultants than other CoCM implementations. Another adaptation designed to meet the needs of participating rural clinics was an intentional focus on group and peer-to-peer training and implementation support activities. Rural clinics and clinicians can be isolated and may be the sole provider(s) in their community. Clinics were encouraged to develop peer relationships between organizations and providers to combat isolation and promote sustainment. The most significant adaptation of CoCM for the rural context addressed workforce constraints for the CM role. In most CoCM implementations, this role is performed by a Master's level mental health provider such as a counselor or clinical social worker. These mental health specialists can be difficult to recruit and retain in rural areas, rendering them nearly as scarce as psychiatric consultants. To address this implementation challenge, some SIF-CoCM clinics used a "Shared Care Manager" model. This approach separated care manager responsibilities into those requiring a license (e.g. establishing a diagnosis, developing a treatment plan, providing psychotherapy) and those that did not (e.g. symptom monitoring with the PHQ-9, pleasant events scheduling). This allowed a paraprofessional such as a medical assistant or community health aide to perform care manager tasks that were within their scope of practice, allowing licensed providers to focus on those tasks only they could perform. This gave participating clinics the opportunity to provide maximum population-level benefit to their patients.

Results and Discussion

SIF-CoCM focused on increasing access to depression treatment and improving the quality of that treatment for low-income individuals in non-profit rural/frontier primary care clinics operating in medically underserved and health professional shortage areas. Evaluation of the program will use a mixed methods pre-post uncontrolled design to examine effects on depression response, defined as a 50% or greater reduction in depression symptoms as measured by the PHQ-9 between initial visit and last measurement, and depression remission, defined as a PHQ-9 score less than 5 [54]. Analyses will examine overall and clinic-specific changes in depression response and depression severity from CoCM treatment initiation (baseline) to last recorded visit. CMs measured depression symptoms with the PHQ-9 at nearly every contact with the patient during the course of active treatment, allowing the CoCM team and the patient to monitor the trajectory of treatment. This is the cornerstone of measurement-based care and is necessary to facilitate treatment-to-target. Secondary outcomes include use of evidence-based processes of care shown in previous studies to predict whether patients improve and how fast they improve [49,50], (1) Psychiatric consultation, and (2) two or more contacts within the first four weeks following CoCM initiation. Additional processes of care reviewed during implementation coaching calls included comparison of expected *vs.* actual caseload, the number of patients without any contact for two or more months, the proportion of the active caseload discussed with the psychiatric consultant, and the proportion of contacts without a PHQ-9 measurement. These additional processes of care represent best estimates of intervention effect in other CoCM evaluations [25,30,35]. We will conduct both unadjusted and adjusted mixed model regression controlling for demographic data, clinic variability, and process measures of program implementation. The evaluation is fully powered to test for significant change in depression response and depression remission from baseline to final PHQ-9 with a power level of 80 and an effect size of 40% absolute change. Pre-implementation (baseline) interviews with clinic leaders provided insights about the process of planning large-scale practice change. Several themes emerged from these interviews, including excitement about the opportunity to implement CoCM and concerns about the implementation process.

Theme 1: Importance of behavioral health services to the health of rural communities and the negative effects of prior failed attempts to integrate behavioral health into primary care.

"From the very beginning of the health center we very clearly understood that, in order to make any headway in improving the health of the community, behavioral health had to really be foundational to what we did. And so, really, since day one we've been looking for opportunities and considering how we can do behavioral health. -Clinic F.

Theme 2: Financing behavioral health services.

"Well, before we really didn't have any financing. I want to say it was a $100,000 to $150,000 loss that we were projecting for a year. We knew we needed behavioral health services but we have struggled more to make money from operations. And so that's when you have to start dialing in and say, 'Okay, well, what are we doing that we really can't afford to do any longer?'- Clinic E.

Theme 3: Planning and communicating about implementation planning.

"Well, mostly what we've done is we've used various staff meetings and other venues to talk about the program, give progress reports and translate the program language into language that was more, perhaps, fluent to the group we were talking to And certainly the feedback we're getting is we need to do that even more. It's a matter of constantly being in dialogue and helping manage people's expectations and fears and concerns." - Clinic B.

Theme 4: Ability of CoCM to handle anticipated need for treatment.

"I'm concerned about being overwhelmed. So, one of the things that I don't know is what does it look like? How long does someone stay in treatment? What turnover is expected? So, those kinds of things. And I think probably my concern about that is having been in this setting and having to deal ongoing with the need is so great and [there's] not enough to give to everyone. And so that's always a place where I get uncomfortable." - Clinic E.

Theme 5: Engaging primary care providers in practice change.

"We followed that gap analysis of different roles. The gap that we found is really-the part that is hard is the engagement of providers into understanding this model and getting them into that." - Clinic D.

Theme 6: Incorporating the psychiatric consultant into the clinic

Table 2: Clinic Selection Process.

Selection Stage		Cohort 1 (n)	Cohort 2 (n)	Total (n)
Attended RFA Informational webinar		18	10	28
Submitted Letter of Intent (LOI)		8	5	13
Submitted Grant Application		6	5	11
Participated in Selection Site Visit		6	4	10
Received Subgrantee Award		**5**	**3**	**8**
Clinic Locations	Alaska	1	1	2
	Montana	1	2	3
	Washington	2	0	2
	Wyoming	1	0	1

workflow.

"We had concerns about the providers using the psychiatric consultants, or fear of having a psychiatric consultant onboard. But once the psychiatric consultant met with the providers a lot of those fears were put to rest." - Clinic H.

"I think the new part of it is having a consulting psychiatrist. So I think that's going to be the part that I think is going to be a work in progress, you know how to integrate that and continue to be consistent with a model. So that's kind of where I think it's going to be the challenge, I guess." - Clinic D.

Theme 7: Challenges for behavioral health providers accustomed to working in a traditional specialty setting.

"I think two things we had long intended to bring onto the primary care team behavioral health consultants, and part of the issue there was looking to recruit folks who had had that kind of experience rather than we have some folks here who are eligible by licensure and some experience to do it, but they were coming out of the behavioral health world and we were concerned that they were then just simply going to try and replicate their practice in the primary care environment, when what we were really looking for was a much briefer, problem-focused, brief intervention model along with their beginning to learn and pay attention to medical conditions and helping people with lifestyle changes." - Clinic B.

This program description, including qualitative data from rural FQHCs preparing for CoCM practice change, provides valuable insights about methods for implementing a program designed to increase access to depression treatment and the quality of that treatment in FQHCs and other federally supported primary care settings, including Community Health Centers, Migrant Health Centers, Health Care for the Homeless Programs and Public Housing Primary Care Programs. The impact of SIF-CoCM on patient-level depression outcomes and clinic-level processes of care will be assessed in the 8 participating FQHCs but can be generalized to other clinics wishing to implement evidence-based depression treatment, especially clinics located in rural and other low-resource settings. Findings from SIF-CoCM will provide a clearer understanding of the challenges rural clinics face as they undertake the practice changes necessary to implement CoCM. In particular, the mixed methods used for SIF-CoCM will provide a rich understanding of the experience of clinics and providers as they implement CoCM and this, in turn, may guide other clinics as they plan for CoCM implementation. Clinic leadership identified several important concerns about and barriers to planning implementation of CoCM that contribute to the literature regarding the pre-implementation phase of practice change. Implementation coaches elicited these concerns and barriers as part of pre-implementation (Figure 2, steps 1-3) to assist clinics with addressing and resolving these issues, to the extent possible, prior to program launch. Even if a concern could not be eliminated during implementation planning, acknowledging these and giving clinics the opportunity to share these concerns with their peer clinics improved the process of implementation and, in some cases, may have made implementation easier.

Conclusion

SIF-CoCM has several limitations that may reduce generalizability of the findings. The primary purpose of this initiative was implementation of evidence-based depression care in rural primary care clinics to increase access to care and the quality of that care. The evaluation is a very simple pre-post design that cannot definitively test the clinical program and implementation support processes. Another limitation is the rural focus. Rural primary care clinics are typically less well-resourced than urban and suburban clinics which could make SIF-CoCM less relevant for those non-rural settings. Among rural primary care clinics, FQHCs and other federally supported clinics have more financial resources than rural clinics without such support. This may limit generalizability to settings without this support. However, in January 2017, the Centers for Medicare and Medicaid Services implemented CPT codes (99492, 99493, 99494) allowing all primary care clinics serving Medicare fee-for-service beneficiaries to receive a monthly payment for CoCM services. Many states model Medicaid benefits to align with Medicare and several states already offer CoCM payments for Medicaid recipients. Finally, it is possible that the rural communities participating in this project are different in important ways from other rural areas of the country. Three of the four represented states have the lowest population density per square mile in the US and most of the land mass in these states is designated "frontier". It is possible that clinics in these frontier areas are different in ways that limit generalizability to rural areas in other states. For CoCM to reach individual who need effective depression treatment, especially in rural areas, we need to better understand the process of assisting primary care clinics with the complex task of implementing and sustaining necessary practice changes.

Notes

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