Measuring the Implementation and Effects of a Coordinated Care Model Featuring Diabetes Self-Management Education within Four Patient-Centered Medical Homes

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Abstract

Purpose: The purpose of this study is to measure the implementation and effects of a multi-site coordinated care approach that delivered diabetes self-management education (DSME) and diabetes self-management support (DSMS) for disadvantaged patients within four patient-centered medical homes (PCMH).

Methods: A total of 173 patients (69.9% African American, 26.0% Caucasian, and 4.1% other) experienced elements of the intervention, which featured DSME and coordinated care. Key informant interviews with PCMH site staff were used to capture, code, and characterize activities related to implementation and sustainability of the intervention. Outcome measures collected at baseline and at 6 months included clinical health indicators: A1C, body mass index (BMI), blood pressure, and lipids; as well as the AADE7 Behaviors™.

Results: A statistically significant decrease occurred in A1C and BMI within 6 months for participants within one PCMH. This improvement among clinical health outcomes was associated with the frequency of services provided (eg, DSME, patient support).

Conclusion: Integrating and delivering DSME and DSMS within coordinated care settings have the potential to improve PCMH practice and associated clinical health outcomes for populations experiencing health disparities.

Some populations, such as African-American women, are disproportionately affected by diabetes and associated health consequences.[1] Underserved populations also represent a disproportionate number of uninsured or underinsured Americans,[2] making access and linkage to needed care for managing diabetes particularly challenging. The Affordable Care Act, if fully and effectively implemented, holds promise for wider availability of evidence-based strategies for diabetes prevention,[3] as well as greater access to primary care for those who can enroll in insurance coverage.[4] Success will depend on innovative approaches to ensuring access to diabetes care, particularly for those experiencing health disparities.

Only a small portion of those diagnosed with diabetes, about 7%, are at recommended clinical values for A1C, blood pressure, and low-density lipoprotein (LDL) cholesterol.[5] The Patient-Centered Medical Home (PCMH) has been shown to be a promising approach to improving the quality of diabetes care.[6] The PCMH offers a common set of components for delivering primary care: a) care coordination, b) quality and safety, c) whole person orientation, d) personal physician, e) physician leadership, and f) enhanced access and payment.[6] Taken together, the PCMH may be an effective framework for delivering the Chronic Care Model[7] in treating chronic diseases with complex illness trajectories like diabetes.[8] Results from pilot demonstrations across 1,400 practice clinics, all delivering diabetes care through the PCMH model, showed improvements in patient health outcomes (eg, A1c, blood pressure, LDL cholesterol), population health indicators (eg, hospitalization use, inpatient admissions, pharmacy utilization), and return on investment.[7] Further, the delivery of patient support through community health workers (CHW) has improved A1c among patients as a part of a coordinated care approach among community clinics.[9] CHWs extended the delivery of diabetes care beyond the primary care clinic for these clients; and they may be particularly effective at addressing health inequality experienced by vulnerable, minority and economically disadvantaged populations. Diabetes self-management education (DSME) has been effective at improving A1C; and it becomes more effective with increased time of contact with people experiencing diabetes.[10,11] Often delivered by certified diabetes educators, DSME has also been effective when administered by those without certified credentials (eg, CHWs) when supervised by credentialed education professionals.[12] Improving patient access to DSME is necessary to fully address the disease burden. Yet, access to certified diabetes educators may prove challenging as the prevalence of diabetes increases[13] and their use within coordinated care becomes more widespread.[12] Adopting a coordinated care approach to diabetes education and support may be helpful in meeting the demand for diabetes education in treatment settings.

This empirical case study examined the implementation, associated outcomes, and sustainability tactics used in the delivery of the DSME and DSMS coordinated care model within participating PCMHs. To this end, this report examines three specific research questions:

1) How were the elements of the coordinated care model implemented across a multi-site diabetes self-management and support initiative?

2) Was implementation of the coordinated care model associated with improvement of clinical health indicators for diabetes and behavioral indicators for diabetes self-management?

3) How were the elements of the coordinated care model of the diabetes initiative sustained beyond the initial grant funding?

Method

Research Design

This study used an empirical case study design to examine these questions. This design was best suited for this study for several reasons. The study was primarily interested in investigating how the interventions naturally unfolded at each site.[14] Three of the four sites implemented interventions that affected all diabetes patients, which made finding control comparisons difficult. Investigators also had little control over the implementation of interventions or the context in which they were implemented.[14] A within-subject experimental design was used to evaluate clinical and behavioral effects.

Context

The current study was conducted as part of the overall participatory evaluation of the Bristol-Myers Squibb (BMS) Foundation's Together on Diabetes (ToD) initiative, an evaluation led by the University of Kansas Work Group for Community Health and Development (KU Work Group). The American Association of Diabetes Educators (AADE) demonstration project was one of 22 separate projects funded by the ToD initiative to address type 2 diabetes among populations experiencing health disparities. The overall aim of the participatory evaluation is to help understand and improve the impact of projects within the ToD initiative.

AADE contacted several relevant stakeholders in the field (i.e. Am Osteopathic Assoc, National Minority Quality Forum, and AADE Research Committee) to identify quality organizations interested in working on this project to serve the diabetes needs of disparity populations in their local area within the context of the PCMH model.

Study Settings and Participants

This AADE project supported work of the ToD initiative in four geographically-distributed PMCHs.

Site 1 in Jacksonville, Florida. The Jacksonville Urban Disparity Institute (JUDI) is part of a PCMH network comprised of nine clinics located throughout Jacksonville, Florida that have adopted the CCM for delivering diabetes care. This network serves both insured and uninsured patients, as well as those served through designated provider services (ie, uninsured, Medicaid, and impoverished patients). This site's capacity for comprehensively addressing diabetes began in 2006 with implementation of an ongoing, ADA-accredited Diabetes Rapid Access Program (D-RAP). The D-RAP, tailored to work within the PCMH model, focuses on the needs of patients with prediabetes as well as those with uncontrolled diabetes. At the time of site selection, JUDI had an accredited DSME program. A total of 83 JUDI patients were included in the present study (see Table 1). Jacksonville is located in Duval County where more than 74,000 residents (11.5%) have been diagnosed with diabetes.[15]

Site 2 in Athens County, Ohio. The Diabetes Institute at Ohio University (DIOU)—in partnership with their clinical care team, University Medical Associates, and Live Healthy Appalachia—was selected by AADE to deliver the integrated diabetes model to low-income Appalachian patients within Athens County, Ohio. Athens County residents experience diabetes at a rate higher (10.4%)[16] than the national average (8.3%).[17] To meet AADE eligibility requirements, DIOU achieved PCMH status and adopted an accredited DSME program. A total of 20 patients participated in the study (see Table 1).

Site 3 in Oklahoma City, Oklahoma. The Harold Hamm Diabetes Center (HHDC), a University of Oklahoma practice clinic in partnership with the School of Pharmacy, is focused on innovative strategies for enhanced diabetes treatment, education, and prevention (eg, on-site specialists, behavioral health) in Oklahoma City, Oklahoma. Oklahoma residents experience diabetes at a rate higher than the national average; and Oklahoma ranks among the 10 worst states for diabetes prevalence.[16] At the time of site selection, HHDC already had an accredited DSME program and achieved PCMH status; thus meeting AADE's participation criteria. For this project, HHDC staff recruited 42 patients, all of whom were African American (see Table 1).

Site 4 in Nashville, Tennessee. The Vanderbilt Diabetes Research and Training Center (DRTC) is a comprehensive diabetes care provider serving six locations in Nashville, Tennessee. The Vanderbilt DRTC uses a coordinated team approach to provide personalized care. Patients have full access to specialist services including

endocrine, gestational, and foot care. Tennessee residents experience diabetes at a rate higher than the national average; and Tennessee is ranked with the sixth highest rate for the disease nationally.[16] At the time of site selection, the Vanderbilt DRTC already had an accredited DSME program and achieved PCMH status. This site engaged 28 diabetes patients in the study (see Table 1).

Intervention

Implementation of the coordinated care approach was conducted by each PCMH's respective staff; it included delivery of four main intervention components: a) an accredited DSME program with patient-tailored curricula; b) DSMS that targeted the unique needs of underserved populations; c) enhanced access and linkage to care services; and d) practice changes aimed at improving quality of diabetes clinical care (see Table 2). All sites began delivery of the intervention components by October, 2011; and this continued approximately 6 months, with a rolling recruitment from September, 2011 to July, 2012. Although program funding concluded by July, 2012, some intervention elements continued and were ongoing at some sites at the time of data collection. See Table 2 for the specific intervention components, elements, and modes of delivery implemented.

Data Collection and Measurement

Key informant interviews. Data on implementation were captured primarily using key informant interviews. Semi-structured interviews were conducted with project directors of each of the four implementation sites using an established protocol. These qualitative data were used to systematically capture, code, and characterize activities associated with planning and implementing the intervention; all displayed within an online documentation system. Authors from the KU Work Group conducted key informant interviews with project staff via telephone over a 2-week period, in May, 2013, each lasting 90 minutes. Authors from AADE distributed a context survey to project leads at each of the PCMH site's key informants to help prompt the recall of specific activities related to the development, implementation, or communication of the project prior to the key-informant interviews. Site leads (key informants) identified a number of specific programs, policies, practices, and service activities to promote the goals of the program in response to the context survey. Key informants then provided further detail describing each activity named during the structured interview (ie, who, did what, when, with whom, and toward what goal). These responses were coded by type of activity (eg, community/systems change, services provided) and characterized (eg, type of strategy used; goals addressed) by KU Work Group staff.

Document review. Documents submitted by both the PCMHs and AADE staff (eg, interim and final reports, protocol descriptions) provided additional data on project activities for capturing, coding, and characterization.

Measurement of implementation. To capture implementation of the Chronic Care Model, the authors used an online documentation and support system.[18] This enabled recording of the discrete activities of each site participating in the AADE demonstration project. This monitoring and evaluation (M&E) system allowed for the creation of graphic data displays from the accomplishments entered into the database. Measurement consisted of: a) Capture of activities (eg, "The staff at Harold Hamm Diabetes Center at the University of Oklahoma provided a training session on foot exams for their Diabetes Self-Management Education program for their enrolled patients with diabetes."); b) Coding (eg, instances of services provided); c) Characterization (eg, Behavior change strategy of providing information/enhancing skills); and d) Communication of discrete activities as data displays (eg, graphs of number of sessions of services provided over time) and written reports.

Documented activities included: a) Development activities related to the project (eg, hiring community health workers); b) Community advocacy (eg, creation of new partnerships to bring about a specific community or system changes); c) Community/system changes (ie, new or modified policies, programs, and practices); d) Services provided (eg, instances of diabetes self-management education); e) Resources generated or leveraged (eg, the use of AmeriCorps workers as CHWs); and f) Dissemination efforts as a result of the project (eg, scientific publications). Specific activities related to the implementation of the coordinated care approach varied by site, see Table 2.

Inter-observer agreement. Staff from the KU Work Group served as primary and secondary documenters. The first documenter entered and coded a total of 151 entries captured during data collection. The second documenter independently coded a sample of 45 (29.8%) of the entries. The authors calculated interobserver agreement between the primary and secondary coders by dividing the number of entries coded the same by both (44) by the total number of entries both documenters observed (45). The resulting interobserver agreement was 97.8%. The Cohen's κ statistic for interobserver reliability was .90.

Clinical and behavioral indicators. Staff from each implementation site collected a shared set of clinical diabetes indicators at baseline; and again at a 6-month follow-up assessment. Clinical assessments included measurement of A1C, body mass index (BMI), blood pressure, cholesterol (ie, HDL, LDL, and total), and triglycerides. Clinical values were recorded by site staff at baseline and at 6 months, relative to the time of patient

enrollment from September, 2011 to July, 2012. Additionally, patients received the AADE7 Self-Care Behaviors™ instrument at baseline and at a 6-month follow-up to assess changes in patient diabetes self-management behavior. Self-reported behaviors included healthy eating, being active, monitoring, taking medication, problem solving, reducing risks, and healthy coping.[19]

Analysis

This evaluation research project used an empirical case study design.[14] Intervention implementation communicated descriptively and visually using appropriate graphs. Paired-sample *t* tests were performed to examine within-subject clinical outcome data for all participants who completed both baseline and follow-up sessions. To test the relationship between implementation and clinical outcomes, a Pearson product-moment correlation coefficient was calculated between the number of services provided during the implementation period and the mean clinical outcomes. Data are presented in aggregate and by site. Data analyses were completed using IBM SPSS Statistics for Windows, Version 22.0. An α of .05 was used on all statistical tests.

Results

Data on Implementation

A total of 151 implementation activities were documented across all sites; of these, the majority of activities (*n* = 132) were services provided related to implementing the model of coordinated care. Illustrative examples of service provided included the delivery of DSME, diabetic cooking classes, and community events aimed at diabetes education and linkage to care. The next most frequently documented type of activities were community/system changes (*n* = 15). Examples of community and system changes (ie, new or modified programs, policies, or practices) included implementation of the AADE DSME curricula in one-on-one sessions with program participants, implementing a patient-facilitated diabetes support group, and implementing the new practice of using a nurse care coordinator to manage diabetes patient workflow.

Project implementation at JUDI in November 2011 and continued through July 2012, resulting in 293 services provided. The intervention at HHDC began in September, 2011 and was ongoing at the time of data collection, which resulted in 156 services provided. Project implementation at DIOU lasted from December, 2011 until September, 2012 that resulted in 18 services provided. The Vanderbilt DRTC's intervention was implemented in March 2012 and concluded by December, 2012 with 9 services provided.

Figure 1 displays the delivery of services provided across all sites by type of goal. The largest number of services provided was for the goals of improving access/linkage to care (n = 350; 32.8%) and improving clinical health outcomes (n = 348; 32.6%). Moderate levels of services provided were delivered for the goals of increasing preventive health behaviors (n = 146) 13.7%) and improving diabetes self-management (n = 128; 12.0%). The fewest services provided were for the goal of improving quality of care (n = 75; 7.0%). A total of 20 activities (1.9%) were in the category of "other."

Figure 2 shows the pattern of implementation for a particularly active partner, the JUDI site. The results show a steady delivery of services provided during the implementation period; with a marked and continued acceleration beginning in September, 2012, that was attributed to a single practice change known as SEAT. Prior to the practice change, those patients missing primary care visits received a home visit. Since this missed many patients with work or other obligations, this service practice was modified to include visits to any non-clinical setting designated by the patients themselves (eg, employment settings, homes). JUDI's new Site Evaluation and Assessment and Treatment (SEAT) Program resulted in a marked increase in services delivered; services that included blood glucose monitoring, insulin titration, and blood pressure assessment.

Data on Clinical Outcomes

Table 3 displays data on patient clinical health outcomes. Site and aggregate indicator means and standard deviations are displayed for time points at baseline and 6 months intervention. Within-subject mean difference scores were computed for each patient who completed both baseline and 6 month testing (N = 86). Paired t tests were performed within each site and across all participants. The implementation of the coordinated care approach was successful at decreasing A1C (M = −0.43, SD = 1.60, p = .01) among diabetes patients (see Table 3). Additionally, significant decreases in A1C (M = −1.07, SD = 1.90, p = .01) and BMI (M = −0.58, SD = 1.00, p = .01) were observed at one of the sites (HHDC), see Table 3. Effect sizes ranged from 0.90 to −0.57, see Table 3. During the funded intervention period from September, 2011 to July, 2012, a total of 128 services provided were delivered across all sites (JUDI = 18, DIOU = 14, HHDC = 90, and DRTC = 6). There was a strong, negative correlation between services provided during the intervention period, the primary measure of implementation of the intervention, and the mean change in A1C, r = −.962, p = .038. Increased delivery of the intervention components were associated with improvement in blood glucose. There was not a correlation between services provided during the intervention period and the remaining clinical outcomes (p > .05).

Data on sustainability

Table 4 displays intervention elements sustained and associated tactics used for sustainability. A total of 11 elements of the intervention were sustained or continued following the grant period. Four different tactics for sustainability were used: 1) Becoming a line item in an existing budget of another organization; 2) Incorporating the initiative's activities or services into another organization with a similar mission; 3) Appling for grants; and 4) Soliciting in-kind support[20]. Illustrative examples of specific approaches include: a) the institutionalization of the Jacksonville Urban Disparity Institute's Diabetes Rapid Access Program into their normal diabetes care practice; b) demonstration of AADE's organizational capacity for network engagement to seek CDC funding for a national diabetes prevention initiative; c) and the use of AmeriCorps workers to provide patient diabetes self-management support and access/linkage services (see Table 4).

Discussion

Implementation

This case study demonstrated the capacity of an M&E system to capture, code, and characterize implementation of initiative in multiple, uniquely structured sites. The majority of the 151 documented activities across the four PCMHs were services provided (n = 132) to patients and community residents. These included activities such as diabetes self-management education (DSME), home-based health care, and community outreach and screening events. Two intervention sites (JUDI and HHDC) implemented a relatively high number of services in comparison to the other PCMHs (DIOU and DRTC). The contexts for site implementation were quite different: DIOU and the Vanderbilt DRTC were only testing the feasibility of implementation of the coordinated care model; so their activities were very limited during this brief, pilot period. By contrast, the two remaining sites, JUDI and HHDC integrated the intervention as a practice change within their organizations in addition to evaluating program feasibility. For example, JUDI modified an underperforming approach to expand diabetes care to settings beyond patient homes to include alternate locations designated by patients. Further, JUDI and HHDC continued to deliver elements of the intervention well beyond the funding period.

The types of implementation activities also varied across sites. The documented services provided at DIOU and the Vanderbilt DRTC were nearly exclusive to DSME sessions at a rate of about one session per month which was consistent with the approach testing feasibility and fidelity of the approach. By contrast, JUDI and HHDC offered DSMS (eg, support groups, coping, and peer support) in addition to the education curricula. It is no surprise that

interventions that offered DSME and follow-up support delivered a higher amount of diabetes treatment services to participants than interventions that contained DSME alone.

Clinical Outcomes

The results of this study suggest that using an integrated, coordinated care model that combines DSME within the PCMH model can be effective in reducing A1C. A within-patient analysis detected clinically meaningful[21,22] and statistically significant improvement in A1C within who completed blood glucose testing at baseline and at 6 months. This within-patient clinical improvement of A1C and BMI was detected within one PCMH (HHDC). Improvement to A1C within a relatively short time is of particular interest since similar DSME interventions have produced mixed improvement with A1C after only 6 months.[23-25] Understanding factors related to differential effects seen among the various AADE implementation sites may help identify promising elements of functional interventions.

Three sites failed to detect improvement in any of the clinical health outcomes. There are several plausible explanations. Of the 173 patients who participated in the AADE study, only 49.7% of total patients completed the follow-up clinical assessments at 6 months. The proportion of those that completed both baseline and follow-up at 6 months varied widely between sites leaving open the possibility of selection biases. For example, HHDC, the only site detecting clinical improvement, had the highest rate of completers for A1C (69.0%) compared to the other PCMHs (38.5% to 53.5%). A similar pattern was observed with BMI; a considerably higher rate of patients completed both baseline and follow-up measurements at HHDC (64.3%) than those among other sites (1.4% to 47.4%). Perhaps the participants in HHDC had characteristics that affected both their ability to maintain participation and observed improvements in clinical indicators. It is also possible that HHDC implemented support features that affected both retention and clinical success.

More promisingly, it is possible that the increased opportunity for patients to receive elements of the intervention—highest in HHDC—may have affected improvement in clinical outcomes seen at HHDC, but not the other sites. The number of services provided to the population of patients was associated with improvement to A1C; as services provided increased, A1C decreased. The PCMH site that measured improvement in clinical outcomes delivered a greater number of services provided during the funded intervention period (September 2011, to July, 2012) than the other three sites.

Individual patient data on exposure to specific intervention components were not available in this study. However, previous research has shown a relationship between the amount of community health worker (CHW) contact and improvement in A1C .[26] The HHDC intervention included CHW-led peer support groups, in addition to a certified DSME curriculum, during the study period. The combination of these services—including community health workers in delivery—produced a markedly higher volume of opportunities for exposure to elements of the intervention. The disproportionately higher number of services provided—with CHWs as part of the delivery system—were associated with the site's improvement in A1C at HHDC.

Sustainability

Ultimately, the implementation of the coordinated care model was considered a modest success by AADE and their partners. The project goal of demonstrating the integration of DSME within the PCMH settings was achieved; and both patients and staff indicated high levels of satisfaction with the approach. As a result, several elements of the intervention were sustained. As Table 4 displays, all PCMH implementation sites retained some features from the intervention.

The diversity of contexts yields a variety of goals and tactics for sustainability. As a well-established PCMH addressing chronic disease and diabetes, JUDI was able to integrate the delivery of DSME within their current practice of patient-centered care. The Jacksonville PCMH implemented the AADE coordinated care model as a practice change to their existing Diabetes Rapid Access Program.[27] Similarly, HHDC established the AADE-sponsored coordinated care model as practice change within their existing patient-centered, diabetes treatment program. This led to a practice change in a culturally-competent CHW was integrated into service delivery of its accredited DSME program. Additionally, HHDC created the conditions for the CHW to tailor patient-centered support beyond what was originally planned for or intended. These results are consistent with other studies that suggest that utilizing CHWs can yield a moderate return on investment;[28] particularly in the implementation of DSME programs.[12]

The context for sustainability of the coordinated care model was quite different for these projects aiming to test fidelity of implementation. For the Ohio-based DIOU, the AADE project allowed them to evaluate their capacity for addressing diabetes using a multi-level team approach that included CHWs. Lessons learned were used to inform future research and changes to practice. Similarly, the Vanderbilt DRTC sought to test the feasibility and fidelity of the pilot study by evaluating patient- and program-level outcomes of coordinated care within an existing diabetes

treatment program. By contrast, JUDI and HHDC aimed to apply the approach within an already existing community practice setting. The differences in context and aims that leaned toward primarily fidelity- or practice-level implementation help explain the conditions that supported sustainability, what elements of the intervention persisted, and what new practice and features resulted from the investment.

Several of the intervention elements were sustained beyond the funding period within two of the implementation sites. Carried out in September 2012—2 months after the funding had concluded—JUDI implemented the SEAT Program described above. The result of this practice change markedly increased the volume of services provided to JUDI patients; an increase from 3 to 33 services provided per month. Further, the JUDI team continued to integrate the multilevel patient DSME curriculum within their established D-RAP beyond the conclusion of the grant funding; as an institutionalized practice change. Similarly, the HHDC retained the services of their CHW at the conclusion of the funding period. Clinical improvement to diabetes health outcomes and patient satisfaction through culturally-proficient DSME delivery highlighted the need to sustain the use of CHWs within the coordinated care practice. The elements of the intervention—DSME, patient outreach and support, and a facilitated peer-support group—were institutionalized into the site's standard of care. The efforts taken to sustain these elements beyond the project implementation period by JUDI and HHDC suggest the feasibility of implementing the AADE coordinated care model within well-established diabetes care settings.

The AADE feasibility pilot study also enabled a number of new practice changes and initiatives. By building the capacity to delivery coordinated care to patients with chronic disease, the Vanderbilt DRTC was able to leverage a substantial amount of resources from multiple sources for expanding this coordinated care model. This built capacity was integral for creating an Accountable Care Organization—a network of coordinated care centers aimed at improving patient health outcomes and reducing the cost of healthcare for Medicare beneficiaries.[29] The PCMH and the ACO models, incentivized by the Affordable Care Act, are viable strategies for assuring coordinated quality care.[30] In addition, the Vanderbilt DRTC's PCMH designation and readiness for coordinated care delivery contributed to Vanderbilt University School of Medicine receipt of a MyHealth Team award for improving chronic disease management for high-risk patients within rural Tennessee and Kentucky counties, including those with diabetes. Ohio's DIOU used four AmeriCorps volunteers to deliver diabetes patient support and linkage to care services, including creating environmental arrangements to make healthy lifestyle choices easier and more likely. Positive feedback from patients created the opportunity for one AmeriCorps CHW to provide similar supports for children

with type 1 diabetes beyond the conclusion of the intervention. The type 1 navigator was later hired by the local school district into a newly-created, full-time position.

Collaboration between JUDI and AADE in implementing the coordinated care model led to additional partnerships for preventing and managing chronic disease. Together, they were evaluated as part of the CDC's Million Heart Campaign initiative; to develop and establish practice recommendations for addressing chronic disease, including diabetes. Specifically, this effort aims to lower the prevalence of the leading risk factors for cardiovascular disease.[31] The coordinated care pilot demonstrated AADE's capacity to engage provider networks and implement sustainable diabetes treatment and prevention programs. This demonstration helped position AADE for success with its application for a cooperative agreement with CDC's National Diabetes Prevention Program effort to expand access and qualify the Lifestyle Change Program as an insurance-covered healthcare expense.

Feasibility testing of the coordinated care model within 4 diverse diabetes care settings, using a multi-level care team to integrate DSME within the PCMH practice setting, enabled AADE to refine and further test the approach. The demonstration of built capacity for multi-site diabetes project management enabled further support from the Bristol-Myers Squibb Foundation to fund Together on Diabetes (ToD) AADE Phase 2 project.

Study Limitations and Strengths

There were a number of limitations within the current study. First, the cross-site evaluation was retrospective. This post-hoc data collection restricted the depth of the documentation of activities. It also precluded shared sensemaking; that is, jointly reviewing patterns in the data and implications for adjustment during the unfolding of the intervention. Second, a majority of the data were gathered via self-report during interviews with key informants. This may have also limited the completeness and accuracy of documented activities related to program implementation. Third, small samples of study participants and attrition made this study particularly sensitive to selection bias. Of the 173 patients that completed baseline assessment for all sites, less than half (49.7%) completed 6-month follow-up testing across sites. Perhaps small to modest effects in some sites were masked sue to the small sample size and weak power of this study, with only very large effects able to be detected. It is quite plausible that the effects detected are limited to only a select sub-set of the population whose situations enable them to maintain participation in a study of this kind. Due to the relatively small sample size, the analysis assessing clinical differences between baseline and follow-up did not control for possible covariates (eg, patient A1C levels at baseline, age, gender, and years since diagnosis). Finally, each of the sites utilized a pre-post study design without

comparison; thus, making history a plausible threat. Additionally, the empirical case study design contains some limitations. This design does not include control comparisons. The use of control PCMHs would have assured a higher degree of internal validity than the case study design. The complexity of the natural PCMH setting made the selection of controls not feasible in the current study. Intervention implementation was measured systematically and communicated descriptively. Despite some limitations, the study had a number of strengths. First, this is among the first research of its kind to evaluate the implementation, associated clinical health outcomes, and sustainability of a multi-level coordinated care delivery model of DSME within PCMHs. Second, participation of 4 unique care settings, each serving a different population experiencing health disparities, helped to assess the feasibility and generality of this approach. Third, greater clinical effects observed for a program with higher amounts of implementation activities is a particularly intriguing finding. Fourth, data on project implementation helped to capture, code, and characterize elements of the intervention actually delivered. Quantifying the study's implementation activities communicates the amount of intervention available to participants and may be an important implementation variable that helps explain differential affects and report fidelity. Finally, analyzing the implementation data of the model through visual inspection of cumulative records allowed for the identification of accelerations and decelerations over time and associated factors and changes in implementation.

Conclusion and Implications

This empirical case study examined the varied forms of implementation of a coordinated care model that incorporates DSME within PCMHs. It shows an association between services implemented and improved A1C and BMI, in some contexts. Clinical improvement in A1C was associated with the number of discrete services provided over the implementation period. Additionally, the built capacity among site stakeholders for integrating DSME with coordinated care produced resulted in sustainability of some elements of the intervention. Further research is needed to extend the evidence base for the effectiveness of multi-level coordinated care teams and DSME integration for improving patient outcomes for diabetes. This research suggests the value of systematic measurement of implementation within such an approach. Improvements in the quality and availability of diabetes care—especially among those experiencing health disparities—is essential for improving health equity and abiding by the value of social justice on which it is based.

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Table 1. PCMH and DSME Status at the Point of Site Selection and Patient Demographics

Sites	Established PCMH	Accredited DSME	Primary Patient Ethnicity		Patient Age
Jacksonville Urban Disparities Institute (JUDI)	Yes	Yes	African American Caucasian Hispanic/Latino Other	82% 12% 3% 3%	M_{years} = 57.9 (*SD* = 11.2) *n* = 83
Diabetes Institute at Ohio University (DIOU)	No	No	Caucasian African American	96% 4%	M_{years} = 61.3 (*SD* = 11.7) *n* = 20
Harold Hamm Diabetes Center (HHDC)	No	Yes	African American	100%	M_{years} = 57.0 (*SD* = 13.7) *n* = 42
Vanderbilt Diabetes Research and Training Center (DRTC)	No	Yes	Caucasian African American Other	53% 37% 10%	M_{years} = 60.1 (*SD* = 13.9) *n* = 28

Table 2. *AADE Intervention Components, Elements, and Modes of Delivery*

Intervention Component/ Behavior Change Strategy	Specific Intervention Elements	Modes of Delivery
Diabetes Self-Management Education—*Providing information and enhancing skills*	Behavior-change curricula aimed at addressing patient health behaviors identified in the AADE7 Self-Care Behaviors™: a) Healthy eating b) Being active c) Monitoring blood glucose d) Taking medication e) Problem solving f) Reducing risks for disease progression g) Healthy coping	Certified diabetes educators facilitated both individual and group DSME sessions. Health coaches supplemented DSME with curricula to enhance health literacy and enhanced nutrition education.
	Individual and group-based ad hoc education sessions to increase health literacy; included enhanced nutrition education	
Support for Managing Diabetes and Distress—*Enhancing services and support*	Support group for diabetes patients	Patient-led support groups assisted patients in coping with diabetes-related distress.
	Diabetes self-management support	Health coaches performed follow-up phone calls with patients to review and promote self-management behaviors.
	Cooking classes featuring diabetes-compatible recipes and demonstrating use of healthy ingredients	Project staff delivered cooking classes to participants via a mobile kitchen at a local community center.
Enhanced Access/Linkage to Care—*Modifying access, barriers, and opportunities*	Delivery of home and at-work follow-up care for patients with chronic diabetes who did not meet scheduled medical appointments (eg Home Evaluation Assessment and Treatment Program, Site Evaluation Assessment and Treatment Program)	Medical assistants sought out patients at home or place of employment to provide clinical services.
	Brown-bag outreach meetings at community centers and retirement communities with elderly residents to discuss the importance of diabetes care	Clinic staff conducted these access/linkage to care outreach events at local senior centers to reach elderly residents with diabetes.

	Individualized phone-based linkage-to-care services to patients with diabetes Enhanced supports for patients with diabetes provided by patient supports, including providing transportation to treatment appointments and arranging home visits	Community health workers and health coaches contacted patients via telephone to connect them with community supports for diabetes management and to provide transportation to clinic services.
Improve Quality of Care—*Modifying policies and broader systems*	Incorporation of Level 1 (community health workers) and Level 2 (healthcare workers with limited experience in DSME) educators within the delivery of the DSME curricula to provide culturally-relevant diabetes self-management information and support Electronic patient medical records used to coordinate services Coordinated patient care teams (eg, primary care doctor, nurse care coordinator, certified diabetes educator, and health behavior coach)	Implementation of the coordinated care approach within PCMHs established multi-level DSME delivery, coordinated care teams, and the use of electronic patient medical records for coordination and assurance of diabetes standard of care.

Note. DIOU = Diabetes Institute at Ohio University; SEAT = Site Evaluation Assessment and Treatment Program; JUDI = Jacksonville Urban Disparities Institute; AADE = American Association of Diabetes Educators; CDC = Centers for Disease Control and Prevention.

Table 3. Clinical Outcomes for Enrolled Patients in the AADE Intervention

Measure/Project	Pre-Intervention			Post-Intervention			Within-Patient Difference†				
	M	*±SD*	*N*	*M*	*±SD*	*N*	*M*	*±SD*	*N*	*p*	Cohen's *d*
Total HbA1c (%,mmol/mol)	9.1 (76)	±2.4	173	8.5 (69)	±2.1	86	−0.43	±1.6	86	**.01	−0.27
JUDI	9.0 (75)	±2.7	83	8.5 (69)	±2.5	32	−0.04	±1.9	32	.91	−0.02
DIOU	8.9 (74)	±1.6	20	8.3 (67)	±1.7	10	−0.18	±1.2	10	.65	−0.15
HHDC	9.5 (80)	±2.2	42	8.6 (70)	±2.2	29	−1.07	±1.9	29	**.01	−0.56
DRTC	8.8 (73)	±1.9	28	8.4 (68)	±1.6	15	−0.21	±1.9	15	.67	−0.11
Total BMI (kg/m^2)	36.4	±9.3	160	37.1	±7.0	47	−0.44	±2.1	47	.16	−0.21
JUDI	36.3	±8.5	72	43.4	—	1	−1.26	—	1	—	—
DIOU	37.0	±10.1	19	36.7	±5.1	9	0.53	±2.2	9	.49	−0.24
HHDC	35.2	±8.6	42	35.0	±8.2	27	−0.58	±1.0	27	**.01	−0.57
DRTC	37.1	±11.9	27	33.3	±4.3	10	−0.87	±2.4	10	.28	−0.36
Total SBP (mmHg)	133.5	±18.2	153	134.2	±18.4	67	0.29	±21.5	59	.29	−0.01
JUDI	129.2	±16.9	76	125.7	±19.0	12	3.18	±20.0	11	.61	−0.16
DIOU	134.5	±32.5	11	144.0	±21.8	9	−7.50	±39.7	4	.73	−0.19
HHDC	134.4	±17.1	39	131.5	±18.2	26	−1.40	±17.4	25	.69	−0.08
DRTC	135.8	±15.4	27	135.5	±15.0	20	2.47	±23.8	19	.66	−0.10
Total DBP (mmHg)	78.1	±10.3	153	77.2	±10.1	67	−1.32	±12.4	59	.42	−0.11
JUDI	77.3	±10.0	76	74.5	±7.4	12	−1.82	±8.7	11	.51	−0.21
DIOU	77.8	±13.4	11	80.2	±15.6	9	−3.75	±21.8	4	.76	−0.17
HHDC	79.2	±10.7	39	75.4	±10.2	26	−2.76	±12.4	25	.28	−0.22
DRTC	78.0	±9.9	27	78.8	±8.3	20	1.37	±12.4	19	.64	−0.11
Total HDL-C (mg/dL)	47.7	±22.0	129	44.6	±16.7	63	3.39	±18.5	54	.14	−0.18
JUDI	52.7	±22.0	76	48.1	±17.4	32	1.94	±12.6	31	.40	−0.15
DIOU	47.4	±10.6	8	40.4	±6.9	7	0.67	±4.5	3	.82	−0.15
HHDC	50.0	±26.7	28	48.1	±22.9	14	2.83	±31.0	12	.75	−0.09
DRTC	40.8	±14.6	17	41.6	±6.0	10	10.88	±20.8	10	.13	−0.52
Total LDL-C (mg/dL)	90.8	±39.1	130	95.4	±32.8	61	−4.41	±31.5	49	.33	−0.14
JUDI	97.3	±35.9	75	97.8	±29.0	28	−2.62	±26.0	26	.61	−0.10
DIOU	70.9	±24.8	7	117.7	±45.3	7	28.33	±54.2	3	.46	1.25
HHDC	94.7	±35.8	26	89.3	±32.6	13	−8.00	±22.7	10	.30	−0.35
DRTC	100.4	±53.7	22	76.9	±26.2	13	−15.30	±41.7	10	.28	−0.37
Total CT (mg/dL)	179.8	±46.4	129	173.8	±42.5	63	−9.33	±58.9	51	.26	−0.16
JUDI	175.1	±37.6	76	167.0	±62.2	32	−6.69	±41.0	29	.39	−0.16
DIOU	169.1	±53.1	8	199.0	±51.1	7	29.33	±57.0	3	.47	0.51
HHDC	176.7	±32.6	28	182.2	±37.2	14	8.00	±24.9	12	.29	0.32
DRTC	198.3	±83.8	17	146.9	±28.2	10	−66.57	±116.9	7	.18	−0.57
Total CITG (mg/dL)	171.3	±89.7	127	173.7	±84.0	67	15.45	±86.3	49	.22	0.18
JUDI	139.7	±78.5	76	136.4	±62.2	37	0.25	±77.4	28	.98	0.00
DIOU	222.9	±121.0	8	204.0	±91.8	7	−1.00	±20.7	3	.94	−0.05
HHDC	152.4	±85.3	27	206.6	±115.6	13	53.58	±123.5	12	.16	0.43
DRTC	170.0	±116.6	16	147.7	±62.8	10	18.33	±20.4	6	.08	0.90
Total AADE7 Behaviors™	2.7	±0.3	172	2.7	±0.3	52	0.42	±0.4	52	.50	0.05
JUDI	2.7	±0.2	83	—	—	—	—	—	—	—	—
DIOU	2.6	±0.3	20	2.9	±0.1	7	0.05	±0.2	7	.40	0.12
HHDC	2.7	±0.2	42	2.7	±0.2	28	0.06	±0.3	28	.30	0.15
DRTC	2.5	±0.5	27	2.7	±0.4	17	0.21	±0.6	17	.21	−0.03

Note. HbA1c = Glycosylated Hemoglobin; BMI = Body Mass Index; SBP = Systolic Blood Pressure; DBP = Diastolic Blood Pressure; HDL-C = High Density Lipoprotein Cholesterol; LDL-C = Low Density Lipoprotein Cholesterol; CT = Cholesterol, Total; and CITG = Cholesterol Triglyceride. JUDI = Jacksonville Urban Disparity Institute, DIOU = Diabetes Institute of Ohio University, HHDC = Harold Hamm Diabetes Center, and DRTC = Vanderbilt Diabetes Research and Training Center. **significant at the .01 level. Cohen's *d* effect sizes are defined as small = 0.20, medium = 0.50, and large = 0.80[32]. Negative Cohen's *d* values indicate improvement. †Within-patient analysis was conducted on those individuals that that completed pre- and post-intervention assessments.

Table 4. Intervention Elements Sustained and Associated Tactics Used for Sustainability

Intervention Element Sustained/Related Components	Tactic for Sustainability Used
The type 2 diabetes access/linkage to care navigator that was associated with this project (DIOU) was hired by the local school district to provide similar navigation services to children with type 1 diabetes following the grant period. (Enhanced Assess/Linkage to Care) A mobile kitchen—a practice change planned during the implementation of the intervention—was integrated into DSME enhanced nutrition classes offered at a local community center at the conclusion of the grant funding (DIOU). (Diabetes Self-Management Education) The SEAT Program (JUDI), developed during the period of program delivery, was implemented 2 months after the conclusion of the project funding. (Enhanced Assess/Linkage to Care) The D-RAP Program (JUDI) became the standard of care for DSME among Jacksonville diabetes patients and continued beyond the funding period. (Improve Quality of Care) The community health worker at HHDC was retained to continue education and patient support. (Enhanced Assess/Linkage to Care)	Become a line item in an existing budget of another organization—Convince another organization to pick up part of the expenses of running the initiative (eg, the city provides funding for a school health program).
AADE, in partnership with the University of Florida Health Jacksonville, applied for and was chosen for evaluation as part of the CDC's Million Heart Campaign initiative to establish practice recommendations for addressing chronic disease, including diabetes. (Improve Quality of Care)	Incorporate the initiative's activities or services into another organization with a similar mission
AADE submitted a CDC grant to scale the efforts of improving the availability of diabetes prevention programming. The pilot program funded by the Bristol-Myers Squibb Foundation was used as a demonstration for AADE's capacity for network engagement and the implementation of sustainable programming. (Improve Quality of Care) Bristol-Myers Squibb Foundation Together on Diabetes funded an AADE Phase 2 project. This is focused on implementing and evaluating a model for delivery of integrated DSME and DSMS to high disparity populations. It utilizes a multi-level team consisting of diabetes	Apply for grants—Consider time and resources that will be necessary for success, and the need for reapplication.

educators and patient supporters, similar to those strategies used in the Phase 1 demonstration project. (Support for Managing Diabetes and Distress)	
The Vanderbilt DRTC leveraged funding to expand the implementation of the model across additional PCMHs in Tennessee in the first steps to establish an Affordable Care Organization. (Improve Quality of Care)	
The Vanderbilt DRTC received an award to increase their capacity for coordinated chronic care delivery through inter-professional healthcare teams and advanced health information technology. This award was made possible by becoming a PCMH, a requirement for the AADE coordinated care model. (Improve Quality of Care)	
DIOU sought and used AmeriCorps volunteers as lay health workers to deliver access/linkage to care services. (Enhanced Assess/Linkage to Care)	Solicit in-kind support—Seek goods and services the organization would otherwise have to purchase (eg, donations of office supplies from a local business).

Note. DIOU = Diabetes Institute at Ohio University, SEAT = Site Evaluation Assessment and Treatment Program, JUDI = Jacksonville Urban Disparities Institute, HHDC = Harold Hamm Diabetes Center, DRTC = Vanderbilt Diabetes Research and Training Center, AADE = American Association of Diabetes Educators, CDC = Centers for Disease Control and Prevention, PCMH = Patient Centered Medical Home.

Figure 1. The delivery of services provided across all sites by type of goal.

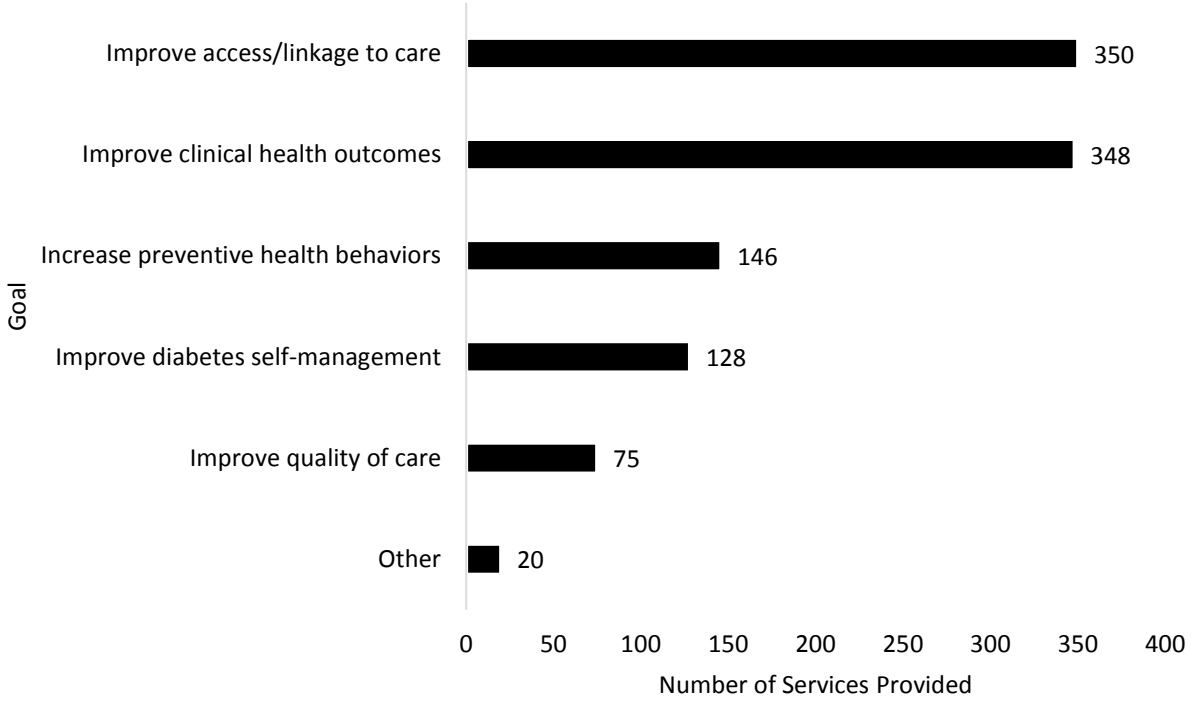
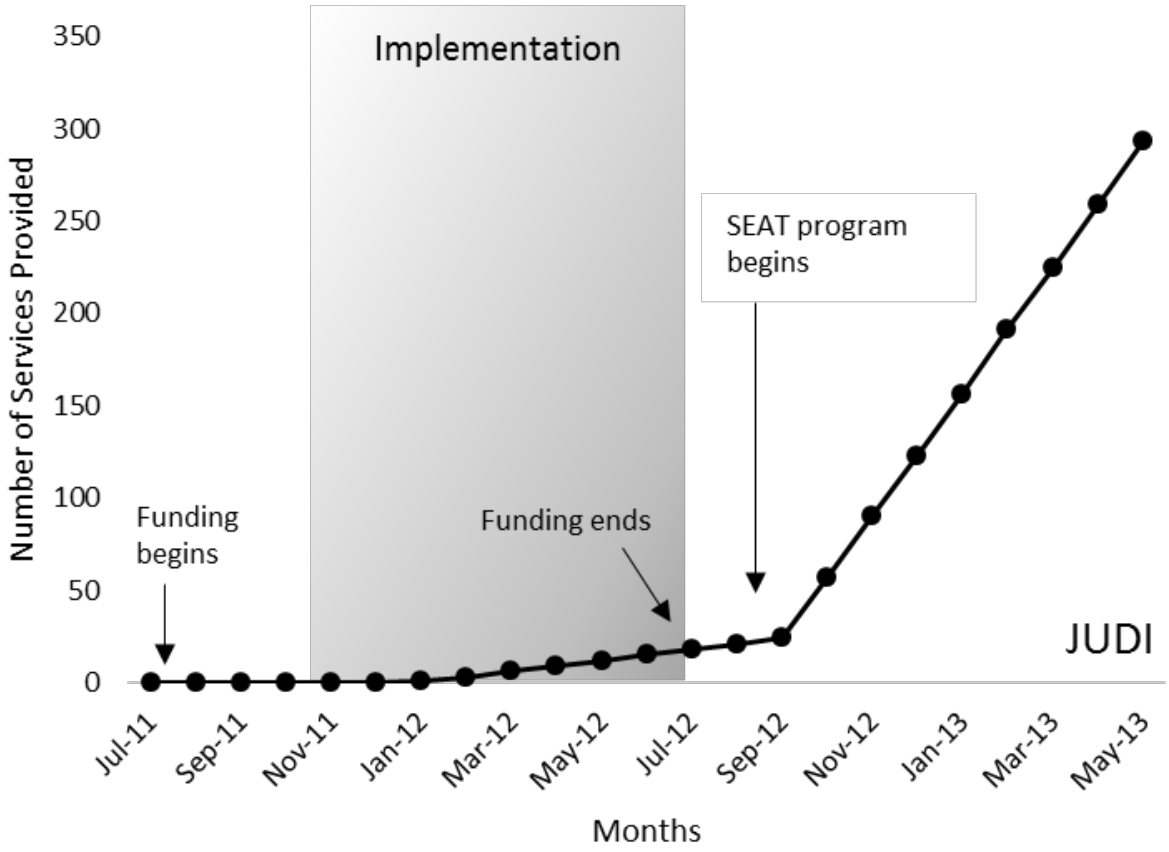


Figure 2. Delivery of services provided over time across the JUDI implementation site



The pattern of the services provided data during the implementation period are illustrative of the steady unfolding of activities measured across all sites, JUDI, HHDC, DIOU, and DRTC.