Community-Created Programs: Can They Be the Basis of Innovative Transformations in Our Health Care Practice? Implications from 15 Years of Testing, Translating, and Implementing Community-Based, Culturally Tailored Diabetes Management Programs

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Diabetes prevalence is predicted to rise dramatically during the next 20 years, and associated spending is expected to increase threefold.[1–3] Cultural barriers contribute to this burden by preventing optimal care among diverse ethnic groups that are at elevated risk for high-cost complications.[4–10] Culturally appropriate, clinically sound, and cost-effective models are needed to respond to the growing and diverse populations affected by diabetes worldwide.

Chronic disease now accounts for 75% of the $2 trillion in annual medical costs in the Untied States, and adherence to prescription regimens among those with chronic conditions is estimated to range from 20 to 50%.[11,12] Nonadherence to medications accounts for ~ $100 billion in annual health care costs.[13,14] Health care reform is a driving force to identify low-cost and clinically effective interventions to improve health care quality and reduce costs.

Nontraditional care management models, innovative technologies to improve patient adherence to prescribed medical regimens, and use of adherence-enhancing strategies in clinical practice would greatly enhance the health impact of efficacious treatments and prevention efforts and consequently reduce the burden of nonadherence-related health care costs.

The most recognized approach for improving care through the current health care delivery system is the Chronic Care Model (CCM) developed by Ed Wagner et al.[15–18] This model recognizes that a substantial portion of chronic care management takes place outside of formal health delivery settings. Patient self-management, delivery system design (including information systems and decision-support tools), and community resources are crucial components of this model. The CCM has been used successfully in staff-model health maintenance organizations, large group practices, and community health clinics, and its implementation has been shown in numerous studies to improve care in diabetes and other chronic diseases.[19]

The medical home model holds promise as a way to improve health care in America by transforming how primary care is organized and delivered. The Agency for Healthcare Research and Quality defines a medical home as a model of the organization of primary care that delivers the core functions of primary health care: patient-centered, comprehensive, coordinated care; superb access to care; and a systems-based approach to quality and safety.[20]

Integrating the concepts of the CCM into newly created primary care homes would be a valuable undertaking. However, relatively few provider settings are fully prepared to implement the CCM.

Physician organizations, on average, have adopted very few of the components of the diabetes care management index. Similar to the CCM, the care management index includes clinical practice guidelines, care management, physician performance feedback, and disease registries. Research conducted in 2006–2007 that measured the use of care management processes (CMPs) among large physician organizations found that organizations used only 46% of the six CMPs studied. The most prevalent were patient lists or electronic registries (39.1%), feedback to physicians on care quality (30.9%), and use of patient educators (30.5%). Less than 24% used nurse care managers.[21] Usage was even less common in small and medium-sized practices,

with only 20% using patient-centered medical home processes.[22]

These findings are consistent with an Institute of Medicine (IOM) report titled "Crossing the Quality Chasm," which concluded that the gap between scientific knowledge and routine practice in the treatment of chronic conditions such as diabetes remains large. The IOM report also suggested that low quality is primarily the result of a failure at the organizational level, rather than at the individual physician level.[23]

The creation of primary care homes is being recommended as a method to integrate and implement these crucial components. The Accountable Care Act may drive a more rapid adoption of these methods throughout our health care system.[24–26]

Project Dulce was developed in 1997 as part of a collaborative effort in San Diego County, Calif., to improve the health and access to health care of underserved, ethnically diverse people with diabetes. Program partners included the County of San Diego, the Community Health Centers network of clinics and its physicians, San Diego State University behavioral health scientists, and the Scripps Whittier Diabetes Institute, a regional center specializing in diabetes care and education. Project Dulce incorporates elements of the CCM in its underlying design.

In the subsequent 15 years, studies evaluating the various components of the Project Dulce model have demonstrated positive effects on physiological, behavioral, and cost-effectiveness outcomes.[27–34] The results of these studies are presented below. As the United States continues to seek methods to deliver higher quality medical care at lower costs, the concepts tested with Project Dulce in a real-world environment may prove particularly valuable.

Project Dulce Model

The Project Dulce model uses a patient registry to identify and stratify patients with diabetes by risk. Trained diabetes registered nurses (RN/CDEs) follow evidence-based care management protocols to lead a multidisciplinary care team that provides clinical care and management for patients in federally qualified community health centers throughout San Diego County. The team also includes registered dietitians and medical assistants acting as health coaches.

Trained peer educators—individuals with diabetes who have successfully managed their own disease—provide education and support to participants. Peer-led education has been demonstrated as a successful method of delivering self-management education.[35–37] These peer educators, or *promotoras*, hail from the patients' ethnic group and are able to help patients overcome cultural, social, and economic barriers to effective self-management.

Nurse care management approach

The clinical goals of Project Dulce are to meet the American Diabetes Association (ADA) Standards of Medical Care and achieve improvements in A1C, blood pressure, lipid parameters, and health behaviors.[38] The nurse care management (NCM) team uses established protocols and preformatted orders for glucose, lipid, and hypertension management.[39] Participants undergo a 1-hour baseline visit to assess demographic information, history of diabetes, weight/BMI, blood pressure, foot status (including neurosensory and vascular examinations), A1C, chemistry and lipid panels, liver function tests, and proteinuria. The Patient Health Questionnaire (PHQ2) screener for depression has been added as part of the initial assessment.[40]

Participants who are not at target for their clinical parameters are scheduled for quarterly or more frequent visits as needed. At each subsequent visit, an RN/CDE reviews self-monitoring of blood glucose (SMBG) results, provides self-management guidelines, individualizes goals, orders follow-up laboratory studies, and, in collaboration with a primary care provider (PCP), provides recommendations for changes in diabetes medications following standardized management protocols.

Peer education approach

The Project Dulce peer education curriculum "Diabetes Among Friends" builds on the effectiveness of the *promotora* model in reducing Latinos' cultural barriers to care and health education.[41,42] Individuals with diabetes who exemplify the traits of a "natural leader" are identified by peer educators from the patient population in the diabetes group education classes and trained by a team that includes a lead peer supervisor, nurses, and dietitians at the Scripps Whittier Diabetes Institute as *promotoras* during a 3-month period. *Promotoras* spend 40 hours learning the education curriculum, behavior-modification techniques, group instruction and mediation methods, and employee standards. Specific competencies have been created to assess the capabilities and readiness of the trainees and must be met to be placed in the program as a peer educator. The trainees co-teach two series of classes with their trainer and then, finally, teach two series on their own under observation by the trainer.

The Project Dulce curriculum is delivered in the native language of participants and *promotoras* and covers the basics of diabetes and its complications, diet, exercise, medications, SMBG, and cultural beliefs that interfere with optimum

self-management (e.g., fear of using insulin and reliance on home-based remedies as cures). Classes are interactive, so patients may discuss personal experiences and convey support and advice to other group members. The curriculum targets the ADA standards of care to achieve improvements in A1C, blood pressure, lipids, and self-management behaviors.[38]

The value of the *promotora*-delivered education program stems from their direct experience with the community and participants' living and firsthand understanding of the myths, beliefs, and cultural remedies that may interfere with adherence to health recommendations. This type of support and empathy is often difficult for professionally trained individuals from outside the community to provide. Blood pressure and weight are assessed, and participants' SMBG logs are reviewed at the beginning of each class, and the *promotoras* have access to clinical laboratory results throughout the clinical care period. *Promotoras* encourage patients to follow up with their PCP when patients are not meeting ADA treatment goals, but they are not permitted to make any medication management recommendations.

Support groups are offered on a monthly basis by the same *promotora* who teaches the classes. Patients are called before each support group to promote attendance. Group sessions are 2 hours long and include topics of interest to the participants, interactive discussions facilitated by the *promotoras*, and, occasionally, guest speakers to discuss areas of interest (e.g., eye disease, foot care, or nutritional or weight loss approaches).

Project Dulce Results
Project Dulce has achieved remarkable results in improving objective and subjective outcomes, including improvements in health status and quality of life. Project Dulce has enrolled and treated > 18,000 patients in its 15-year history and has achieved significant reductions in emergency room visits and hospital admissions within the first year of implementing the disease management services. Reports published to date on the outcomes of the Project Dulce model include evaluations that incorporate the entire comprehensive care management model and that assess individual components of the model, such as peer education alone.[27–34]

Comprehensive interventions
Since program inception, several studies have been conducted to assess changes in clinical, behavioral, and economic outcomes using this comprehensive care management model. In a 1998–2000 pilot program,[27] 153 high-risk, primarily underserved, Latino patients with type 1 or type 2 diabetes, aged 18–80 years, were recruited from six community clinic sites in San Diego County and enrolled in Project Dulce NCM and peer education. Baseline and 1-year A1C levels, lipid parameters, systolic and diastolic blood pressure, knowledge of diabetes, culture-based beliefs in ineffective remedies, and treatment satisfaction were prospectively measured. Risk progression in the group receiving NCM and peer education was compared to risk factor changes in 76 individuals in a matched control group (i.e., patients referred to but not enrolled in Project Dulce who were followed in the same community clinics over the same time period).

At the 1-year follow-up assessment, Project Dulce participants showed substantial improvements relative to baseline on clinical indicators including A1C (reduced from 12.0% at baseline to 8.3% at 1 year, $P < 0.0001$), total cholesterol (reduced from 224 to 186 mg/dl, $P < 0.0001$), LDL cholesterol (reduced from 130 to 108 mg/dl, $P < 0.0001$), and diastolic blood pressure (reduced from 80 to 76 mmHg, $P < 0.01$). In addition, self-administered surveys in the Project Dulce group showed increases in diabetes-related knowledge ($P < 0.05$), and treatment satisfaction ($P < 0.01$) and reduced endorsement of beliefs in culture-based remedies for diabetes ($P < 0.01$). The control group showed no significant improvements in clinical risk indicators over the same time period. Additionally, between-group comparisons at 1 year showed lower levels of A1C (8.3 vs. 10.4%, $P < 0.0001$), total cholesterol (186 vs. 220 mg/dl, $P < 0.001$), LDL cholesterol (108 vs. 134 mg/dl, $P < 0.05$), and triglycerides (181 vs. 248 mg/dl, $P < 0.01$) in Project Dulce compared to control group participants (Table 1).[27]

A subsequent study using the Project Dulce comprehensive care management approach replicated these improvements in clinical outcomes and also demonstrated an economically significant reduction in hospital expenditures.[28] Participants

Table 1. Between-Group Comparisons in Metabolic Parameters in the Project Dulce and Comparison Groups at 1 Year

Measures	Project Dulce	Comparison	*P*
A1C (%)	8.3	10.4	< 0.0001
Total cholesterol (mg/dl)	186	220	< 0.001
LDL cholesterol (mg/dl)	108	134	< 0.05
Triglycerides (mg/dl)	181	248	< 0.01

included 348 people with diabetes covered under the San Diego County Medical Services Program, who were receiving care in community health centers in San Diego County. Changes in clinical outcomes and medical care costs over 1 year were compared between Project Dulce participants and individuals in a historical control cohort.

Project Dulce participants evidenced statistically and clinically significant reductions in A1C (0.8%, $P < 0.001$), systolic blood pressure (5.4 mmHg, $P = 0.001$), diastolic blood pressure (8.0 mmHg, $P < 0.001$), total cholesterol (28.1 mg/dl, $P < 0.001$), and LDL cholesterol (15.6 mg/dl, $P < 0.001$).

A comparison of total costs, which included hospital, emergency department, outpatient, pharmacy, and diabetes management costs, was included and suggested higher expenditures for Project Dulce participants during the first year of disease management ($5,711 for Project Dulce patients vs. $4,365 for control subjects, $P < 0.001$). However, more refined analyses demonstrated that, whereas costs for pharmacy, diabetes-related supplies, and disease management increased under Project Dulce, hospital and emergency department care costs declined (although this change was only marginally statistically significant). This decrease in hospital and acute-care costs was attributable to reduced likelihood of admission rather than lowered costs once patients were hospitalized. This suggests a rapid and clinically and economically meaningful benefit for a high-risk population. A similar cohort evaluated as part of the California Medicaid program 1 year earlier demonstrated analogous results.[43]

Further evidence in 2007 documented the cost-effectiveness of Project Dulce and the comprehensive care model. A validated simulation model (the Center for Outcomes Research Diabetes Model) was used to evaluate the relative long-term cost-effectiveness of the Project Dulce model, as provided to four cohorts defined by insurance status in San Diego County as follows: uninsured, county medical services, Medi-Cal coverage (California's Medicaid program), and commercial insurance. Cost-effectiveness was measured by incremental cost-effectiveness ratios, which measure the estimated incremental cost of the Project Dulce, compared to usual care, divided by the estimated incremental improvement in quality-adjusted life-years (QALYs) associated with the intervention.

Incremental cost-effectiveness ratios were estimated at $10,141, $24,584, $44,941, and $69,587 per QALY gained for Project Dulce versus control participants in the uninsured, County Medical Services, Medi-Cal, and commercial insurance cohorts, respectively.[30]

The Project Dulce diabetes care management program was associated with cost-effective improvements in quality-adjusted life expectancy and decreased incidence of diabetes-related complications throughout patients' lifetime. Project Dulce achieved these results across a broad range of payers and was especially cost-effective for under- and uninsured groups.

Subsequently, in 2009–2010, as part of a statewide Health Care Coverage Initiative, low-income adults with diabetes in San Diego County were provided health insurance coverage and access to disease management services, including Project Dulce's NCM and peer education. Health econometric methods were used to compare costs of participants in disease management to those of nonparticipants, both overall and in comparisons between those who were newly insured versus previously insured under an alternative county-sponsored insurance product. Annual inpatient costs were $1,260 lower, and outpatient costs were $723 higher among participants in disease management ($P < 0.001$ each). Similar to the previous study, annual inpatient/emergency room costs were $1,192 lower ($P = 0.010$), and outpatient/pharmacy costs were $703 greater ($P < 0.001$) among participants receiving NCM, demonstrating the program's effectiveness in increasing participants' use of outpatient services.[34]

Peer educator–only interventions
In 2011, a randomized trial evaluated the effectiveness of the Project Dulce peer-led self-management education alone compared to standard diabetes care delivered in community health centers. A total of 207 Mexican-American patients with diabetes and an A1C ≥ 8% were recruited from federally funded community health centers in San Diego County and randomly assigned to the Project Dulce peer intervention or continuation of standard diabetes care. Relative to the standard care control group, the Project Dulce group exhibited greater improvement across time in A1C ($P < 0.05$) and diastolic blood pressure ($P < 0.04$). Moreover, analyses that examined changes within the Project Dulce group showed statistically and clinically significant improvements in A1C from baseline to a 10-month follow-up assessment and significant improvements in secondary clinical indicators, including in total cholesterol, HDL cholesterol, and LDL cholesterol. No significant improvements were noted in the control group over the same 10-month period of time compared to baseline (Table 2).[33]

Discussion
Disease management and comprehensive care management have been

evaluated in many environments and have demonstrated success in randomized and nonrandomized studies. Methods that can be incorporated in building such models of care delivery include telephonic, remote communication; one-on-one care management; group medical visit interventions; home visits; pharmacist-led medical management; and numerous others.[44,45] Variation can exist in the structure and components of these models.[46] In this article, we reviewed a specific approach based on the CCM that has been tested and used in the San Diego community for > 15 years: Project Dulce. This model uses

comprehensive NCM that combines a strong team approach to care delivery with culturally appropriate, peer-led self-management education.

The Project Dulce model was purposefully integrated into a primary care community health center setting with a high prevalence of ethnically diverse, underserved patients to reach populations at highest risk, facilitate easy access for patients, and build preestablished relationships and trust with the providers. Designed to allow team members to work at the top of their scope of practice, the model demonstrates the ability to significantly improve clini-

cal quality for some of the highest-risk community members while achieving the goal of lowering costs and preventing unwanted admissions to hospitals and emergency rooms.

In the cost-analysis data, of particular interest was the fact that the uninsured patients, who were also younger (mean age 47.1 years) compared to the commercial cohort (55.2 years) demonstrated the greatest mean change in A1C, lipid levels, and blood pressure values after the intervention.[30] This suggests that an intervention provided earlier in life has a high potential to provide long-term health gains and may

Table 2. Results of Analyses of Covariance Examining Within-Group Changes in Clinical Indicators From Baseline to Month 4 and Month 10

	Month 4 Assessment [a]			Month 10 Assessment [b]		
	n	Mean (SD) at Month 4	Δ From Baseline	n	Mean (SD) at Month 10	Δ From Baseline
A1C (%)						
Project Dulce	64	9.0 (1.9)	–1.7†	56	9.1 (2.0)	–1.5†
Control	81	9.1 (1.9)	–1.1	74	9.7 (2.3)	–0.8
Total cholesterol (mg/dl)						
Project Dulce	64	183.3 (46.1)	–11.0	57	186.8 (44.4)	–7.2*
Control	81	187.0 (40.9)	–8.5	74	192.1 (51.9)	–2.4
HDL (mg/dl)						
Project Dulce	64	47.3 (12.2)	+1.4*	57	48.1 (11.7)	+1.6*
Control	82	46.8 (13.5)	+0.5	74	47.9 (14.6)	+1.7
LDL (mg/dl)						
Project Dulce	60	99.1 (40.2)	–8.1	56	99.4 (36.3)	–8.1*
Control	80	104.3 (34.2)	–5.8	72	103.6 (37.7)	–7.2
Triglycerides (mg/dl)						
Project Dulce	64	180.2 (103.7)	–28.7	56	182.3 (113.6)	–20.0
Control	82	192.0 (89.1)	–8.4	73	198.6 (28.3)	+7.5

*$P < 0.05$; † $P < 0.01$. Two-tailed P values pertain to tests of within-group changes from baseline.
[a]Values reported for participants with baseline and month 4 values (total n for Project Dulce = 66, for control = 83; the n values for individual analyses were reduced as noted because of missing values.
[b]Values reported for participants with baseline and month 10 values (total n for Project Dulce = 58, for control = 75; the n values for individual analyses were reduced as noted because of missing values.
 Change values were calculated using the baseline mean of the subset of participants who completed the follow-up under consideration. All analyses were controlled for age and sex; however, unadjusted means were reported.

additionally positively affect employment productivity and translate into positive role modeling and lifestyle modifications within the family unit. Additionally, these types of program interventions may have a more significant effect on populations that have previously lacked access to quality care than on their insured, higher-income counterparts. Finally, in the county-wide data analysis, the offsetting costs of the program suggest that comprehensive disease care management should be considered for some newly insured populations, and especially for adults with diabetes.

In a recent publication of the Commonwealth Fund, the United States was noted to have the highest cost of health care delivery in the world, yet the quality of care in several areas has lagged behind other countries.[47] The interventions in the Project Dulce programs use lower-cost providers such as nurses and other certified diabetes educators and peer-educators as part of a team of health care providers to deliver care and meet quality targets set by the ADA, the Healthcare Effectiveness Data and Information Set, Medicare, and others. The findings in these studies suggest the effectiveness of this low-cost, culturally sensitive approach to self-management education for high-risk diabetic populations. The improvements noted in clinical and behavioral indicators can translate into long-term savings by preventing the complications of diabetes and instilling healthier patterns of lifestyle management in the home and community environment. Such models may allow health care systems in the United States to successfully achieve better quality outcomes at a lower cost.

Successful replication and integration of such models in other communities will be required to assess whether the quality and cost-effectiveness can be translated more broadly. A number of key elements are needed to build similar disease management programs in other environments. Senior health system leadership must support the concept and be prepared to make an investment in its underlying infrastructure to ensure success. This includes assigning dedicated personnel to lead the program and staff the disease management teams; allowing training time for the nurses, dietitians, medical assistants, peer educators, and physicians that will be part of the core teams; creating disease registries that will support risk stratification and clinical management; identifying physical space in which to conduct and deliver the program; and ensuring that evidence-based protocols and curriculums are in place to support management and education recommendations. Engaging the community early on in the process through awareness campaigns and including them in steering committees to develop programs can facilitate acceptance as well. Proposed steps for preparation and deployment of teams within a health system and the organizational elements required for a diabetes disease management program are outlined in Figures 1 and 2.

The potential significance of this approach and these outcomes extend far beyond the borders of San Diego County. Incorporating nurse care managers, dietitians, and peer educators into the CCM provides complementary multidisciplinary support that can enhance diabetes care interventions. Economical, effective, and culturally tailored interventions such as the Project Dulce model may be a crucial link in our health care delivery system to achieve improved diabetes and overall health outcomes.
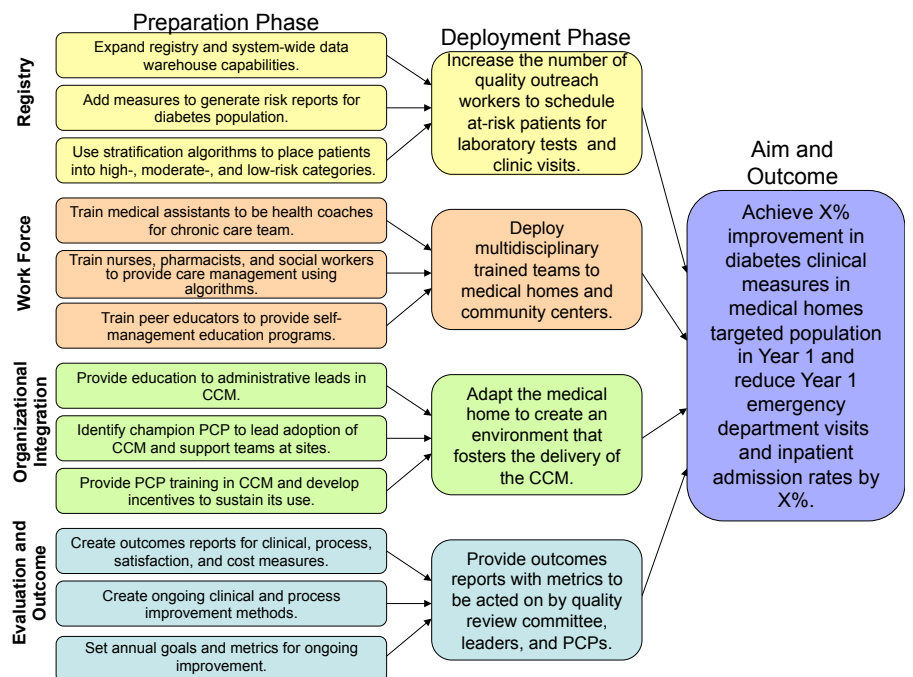

Figure 1. Key elements needed for a health system to prepare and deploy a diabetes disease management program.
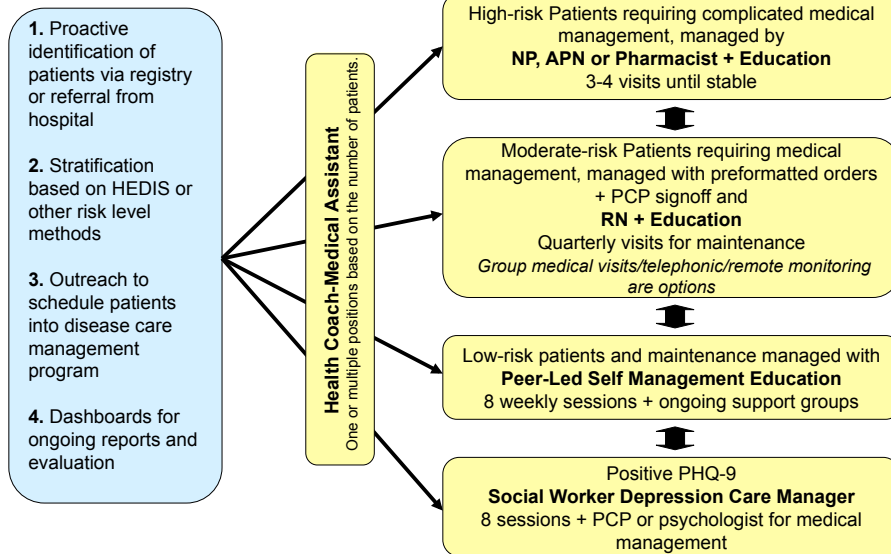
Centralized Function Quality Group

1. Proactive identification of patients via registry or referral from hospital

2. Stratification based on HEDIS or other risk level methods

3. Outreach to schedule patients into disease care management program

4. Dashboards for ongoing reports and evaluation

Health Coach-Medical Assistant
One or multiple positions based on the number of patients.

Linked With PCP Office/Medical Home
Goal is primary, secondary and tertiary prevention of complications and hospital admissions

High-risk Patients requiring complicated medical management, managed by
NP, APN or Pharmacist + Education
3-4 visits until stable

Moderate-risk Patients requiring medical management, managed with preformatted orders + PCP signoff and
RN + Education
Quarterly visits for maintenance
Group medical visits/telephonic/remote monitoring are options

Low-risk patients and maintenance managed with
Peer-Led Self Management Education
8 weekly sessions + ongoing support groups

Positive PHQ-9
Social Worker Depression Care Manager
8 sessions + PCP or psychologist for medical management

Figure 2. Proposed disease care management model for diabetes. APN, advanced practice nurse; HEDIS, Healthcare Effectiveness Data and Information Set; NP, nurse practitioner; PHQ-9, Patient Health Questionnaire 9.

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