Diabetes Self-Management Education Effects on Hemoglobin A1c

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Abstract

Diabetes, a common chronic condition, effects many individuals causing poor quality of life, expensive medical bills, and devasting medical complications. While health care providers try to manage diabetes during short office visits, many patients still struggle to control their diabetes at home. Lack of diabetes self-management (DSM) is a potential barrier for people with diabetes having to maintain healthy hemoglobin A1cs (HgA1c). In hopes of addressing this concern, an evidenced-based intervention; diabetic education and phone calls, using the chronic care model as its framework was implemented. The intervention targeted people with type II diabetes at a transitional care setting. Measured variables included HgA1c and DSM. Statistically significant improvements were seen in reported physical activity. Average improvements were seen in HgA1c and DSM after three months of diabetes self-management education (DSME). Attrition, cultural sensitivity, and increasing DSME hours should be further evaluated for future projects.

Keywords: diabetes, diabetic patients, chronic care management, care management, hemoglobin A1c

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Chronic care management (CCM) is a significant part of caring for patients with diabetes as it contributes to better patient care and outcomes. Diabetes is a complex disease requiring referrals, continuous education, and frequent medication adjustments. All of which are included in CCM. With the health risks facing people with diabetes, it is important healthcare providers seek alternative methods to care for people with diabetes.

There are approximately 422 million people living with diabetes worldwide, with a predicted increase to 642 million by 2040 (World Health Organization [WHO], 2019; Zou et al., 2018). About one in every five Americans aged 65 and older have been diagnosed with diabetes (Hasche, Ward, & Schluterman, 2017). In Arizona, approximately one-third of people are prediabetic and one in 10 are diabetic, representing 2.1 million and 720,000 people, respectively (Diabetes Action Plan and Report, 2019). With about 34,000 being newly diagnosed yearly (American Diabetes Association [ADA], 2014). Arizona spent an estimated $6.8 billion on diabetes care in 2019 (Diabetes Action Plan and Report, 2019). In 2016, the prevalence of diabetes in Yuma County, located in the southwest corner of Arizona, was 12.9% of the population aged 20 years and older (Centers for Disease Control and Prevention, n.d.). The county has seen diabetes rates double over the last decade (Yuma Regional Medical Center [YRMC], 2016).

Transitional Care Services serves the Yuma Community providing patients with chronic conditions, such as congestive heart failure, chronic obstructive pulmonary disease, and acute myocardial infarctions, who need help transitioning home after a hospital discharge (YRMC, 2019). Their goal is to promote quality of life by enhancing knowledge and management of the patient's chronic conditions (YRMC, 2019). About 90-95% of patients are referred by the only

hospital in Yuma County, which had over 12,000 hospital and emergency room diabetes related discharges (Contreras & Sandoval-Rosario, 2018). Although Transitional Care Services cares for patients with complex chronic conditions, diabetes is not a disease they primarily focus on.

This information led to the clinically relevant PICO question, in adult patients diagnosed with diabetes (P), how does CCM (I) compared to standard care (C) affect HgA1c (O)?

Literature review of current evidence included 10 critically appraised articles chosen from CINHAL, PubMed, and Wiley (see Appendices A and B). Articles selected included five randomized controlled trials, two cohort studies, one quasi-experimental, one observational study with no control, and a case study. Level of evidence ranged from II-IV. All studies chosen had at least one dependent variable (DV) measuring HgA1c. Independent variables showing significant improvements in HgA1c were care coordination, telephone calls and education, especially related to diabetes self-management (DSM).

It was determined the proposed evidence-based practice (EBP) project would use diabetes self-management education (DSME) and telephone calls to implement CCM to type II diabetic patients at Transitional Care Services. The measurable outcomes of the project were DSM and HgA1c. The EBP project was informed by the Chronic Care Model (CCMo) because evidence has shown it may improve diabetic outcomes, such as HgA1c (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], n.d.; see Appendix C). By applying the elements of the CCMo, which are health systems, decision support, clinical information systems, patient self-management support, and community resources, and delivery systems, the project hoped to join informed, active patients and a prepared, proactive practice team to improve diabetic outcomes (Improving Chronic Illness Care, 2019). Rosswurm and Larabee's (1999) model was chosen as the evidence-based model for this project to serve as guidance throughout

the process changes (see Appendix D). The model assists in changes that are healthcare specific and strives for improved quality and outcomes.

Methods

Participants

Adults, 18 years or older, were identified using the electronical health record (EHR) at Transitional Care Services with the target goal being 30 participants. Potential subjects of the project met the following inclusion criteria: ≥ 18 years old, previously documented type II diabetes diagnosis, previously documented HgA1c ≥ 6.5% in last month, English speaking, has access to telephone calls for the duration of project, and able to sign consent. Exclusion criteria includes: history of dementia, participating in other diabetic studies, and non-English speaking. Once identified, a flyer was handed to potential subjects to avoid coercion. If the subject wished to participate, consent was obtained. Ethical consideration for the project was processed and approved by Arizona State University's Institutional Review Board and Yuma Regional Medical Center's Innovation Council Advisory Board.

Study Design

All participants had a HgA1c collected from the EHR and completed a diabetes self-management questionnaire (DSMQ) prior to intervention, which served as pretests. Diabetes education was then initiated during the same visit. All participants were given the same education by the same individual at individual times. Education included glucose management (GM), dietary control (DC), physical activity (PA), and healthcare use (HU). All participants were given a take home folder pertaining to the subject matter. Participants were given three monthly phone calls to serve as a reminder of the lesson content provided at the educational visit. After three months, participants had a new HgA1c collected from the EHR and complete a post-

DSMQ. Participants who did not have a new HgA1c recorded in EHR after three months or did not complete a post-DSMQ were disqualified from the project. Measurable outcomes, HgA1c and DSM, were statistically analyzed using a paired sample *t*-test.

Hemoglobin A1c

HgA1c is a blood test reflecting average blood sugars over three months (ADA, 2019). The ADA (2019) recommends measuring HgA1c levels at least biannually if patients are meeting treatment goals or quarterly if therapy has changed or glycemic goals are not met. HgA1c was chosen as a measurable outcome because the ADA (2019) recognizes the blood test as a standard of care due to its strong predictability value for diabetic complications. Although is it recognized by the Centers for Disease Control and Prevention (2018) and the American College of Physicians (2018) as an appropriate diabetic test, there are some limitations. Conditions that affect red blood cell turnover might cause discrepancies in HgA1c (ADA, 2019). Additionally, HgA1c has shown to have low sensitivity but high specificity. Measuring against a single fasting glucose (≥126 mg per dL), the sensitivity and specificity of an HgA1c ≥6.5% for detection of diabetes was 47% and 98%, respectively (Selvin, Steffes, Gregg, Brancati, & Coresh, 2011). Three years later, repeated fasting glucose (≥126 mg/dL) showed sensitivity increased to 67% and specificity remained high at 97% (Selvin, Steffes, Gregg, Brancati, & Coresh, 2011).

Diabetes Self-Management Questionnaire

DSMQ has 16 questions pertaining to five subscales: GM, DC, PA, HU, and self-care summary (SS) (Schmitt et al. 2013). SS is an overall measurement of perceived self-care. During its evaluation, the DSMQ was found to be reliable with good factorial validity and a strong correlation to HgA1c in patients with type I and II diabetes. It also had good concurrent validity

when compared to Summary of Diabetes Self-Care Activities Measure. Overall, internal reliability was good with a Cronbach's α coefficient of 0.84. Its subscales were mostly acceptable (GM: 0.77; DC: 0.77; PA: 0.76; HU: 0.60).

Statistical Analysis

Statistical analysis began after data collection was finalized using Intellectus Statistics. A two-tailed paired samples *t*-test was conducted to examine whether the mean difference of DVs were significantly different from zero based on an alpha value of 0.05. Based on Shapiro-Wilk test and Levene's test, all DVs' normality assumptions and homogeneity of variances were met.

Results

Demographics

In total, 29 participants were recruited. By final data collection, there were nine subjects who completed the intervention (see Appendix E). The most frequently observed age range was 65 years and older (n = 5, 56%). Most subjects were male (n = 8, 89%). Most subjects identified as Hispanic/Latino/Spanish (n = 8, 89%). Most subjects had been diagnosed with diabetes greater than 10 years ago (n = 5, 56%). The majority of subjects' highest level of education was high school (n = 7, 78%).

Hemoglobin A1c

There were mean improvements in pre- and post-HgA1c for final subjects, 8.57% (SD = 1.92) and 8.29% (SD = 1.77), respectively. The result of the two-tailed paired samples *t*-test was not significant, $t(8) = 0.57$, $p = .587$.

Diabetes Self-Management

Each individual subscale of the DSMQ was statistically analyzed. Each subscale was first given a 10-point scale score. The scale score value was used to calculate the two-tailed paired samples *t*-test of each subscale.

Glucose Management. There were mean improvements in pre-GM and post-GM, 6.30 (*SD* = 3.01) and 7.11 (*SD* = 2.37), respectively. The result of the two-tailed paired samples *t*-test was not significant, $t(8) = -0.70$, $p = .507$.

Dietary Control. There were mean improvements in pre-DC and post-DC, 5.07 (*SD* = 2.34) and 7.12 (*SD* = 1.56), respectively. The result of the two-tailed paired samples *t*-test was not significant, $t(8) = -0.71$, $p = .500$.

Physical Activity. There were mean improvements in pre-PA and post-PA, 6.30 (*SD* = 3.98) and 8.40 (*SD* = 2.02). The result of the two-tailed paired samples *t*-test was significant, $t(8) = -2.56$, $p = .034$.

Healthcare Use. There were mean decreases in pre-HU and post-HU was 9.39 (*SD* = 0.94) and mean of post-HU was 10 (*SD* = 0). The result of the two-tailed paired samples *t*-test was not significant, $t(8) = -1.89$, $p = .095$.

Self-Care Summary. The mean of pre-SS was 9.39 (*SD* = 3.53) and mean of post-SS was 10 (*SD* = 3.11). The result of the two-tailed paired samples *t*-test was not significant, $t(8) = 0.61$, $p = .559$.

Project Impact

By using the CCMo as the project's conceptual framework, the project was able to combine aspects of the community, such as self-management support, and health systems, specifically the EHR, to produce proactive providers. The project encouraged providers to focus

on diabetes. A chronic disease which was not a primary focus for providers at the clinic prior to the project.

The framework supported informed, activated patients. Most results were not statistically significant. Yet, on average, subjects had lower Hg A1c levels and reported better GM, DC, PA, and HU. Furthermore, most subjects had been living with diabetes for 10 or more years and reported never receiving DSME prior to the project. Additional notable reports included: receiving their first diabetic eye exam after 10 or more years of diabetes diagnosis, increasing their daily physical activity, and keeping food and blood glucose logs.

Project Sustainability

Since phone calls were already apart of the clinic's workflow and care management of patients, the project was perceived to have high sustainability moving forward. Nurses at the clinic conduct weekly phone calls with patients, which is more frequent than the project required. In addition, the initial DSME visit was approximately 20 minutes. Fortunately, the clinic's patient volume and schedule flexibility allowed for this block of time. Seldomly providers were delayed seeing their patients. The sustainability of this project would require additional supplies for DSME folder packets, employee hourly pay, and time for education. This additional cost could be sustained by available reimbursement of DSME from entities, such as the Centers for Medicare and Medicaid Services and the CDC.

Discussion

The project did improve HgA1c levels and DSM with the use of DSME as CCM, but statistically significant improvements in HgA1c levels were not yielded. Statistically significant improvement was seen in reported PA. There was a worsening of reported SS.

Findings were congruent to previous literature suggesting significant reduction in HgA1c levels are found in those offered greater than 10 hours of DSME services (Beck et al., 2017). Over the course of the intervention, the project provided about two hours of DSME per subject.

Limitations

The project sample size was small due to large attrition. Subjects were disqualified because they did not have a post-HgA1c value in the EHR to collect, they did not answer phone calls, or they did not perform a post-DSMQ. Social determinants could have played a factor in high rate of attrition. Evidence suggests Latino populations, especially men, struggle with shame of illness and lack of interest in health (Testerman & Chase, 2018).

The project had a short interventional period. Furthermore, the three month period was over several holidays. Some subjects expressed they had overly indulged in culturally traditional foods over the holiday season.

Recommendations

Recommendations to retain subjects include incentivizing the completion of the project. Contacting subjects once a month may have lost the interest of subject's participation without incentivization. Having scheduled phone calls could help retain subjects by avoiding missed phone calls.

Increasing DSME hours to greater than 10 could help yield significant results. Increasing the hours of DSME could give opportunity to measure greater intervals of time, such as six-, nine-, and 12-months. This may give insight to sustainability of the project.

Most subjects were Hispanic with the highest level of education being high school. Subjects could have benefited from culturally centered DSME. In addition, many patients at the

clinic only spoke Spanish, which prevented them from being eligible participants. Further studies could target Spanish speakers.

Conclusion

CCM is a vital part of any chronic disease. In those with diabetes, CCM is an ongoing process that supports individuals with diabetes through the lifelong process of DSM. Tools that help individuals meet their HgA1c goals should be promoted to reduce diabetic complications. DSME, a component of CCM, has been shown to reduce Hg A1c levels. Additionally, DSME has been shown to have a positive impact on diabetes-related costs and complications. While the benefits of DSME have been demonstrated in the literature, low utilization of DSME remains. Efforts to improve DSME should be explored for improving CCM and lowering Hg A1c.

This project showed DSME can be used to help improve HgA1c and DSM. Although statistical significant were not yielded in HgA1c and most subscales of DSM, average improvements were seen in mostly all DV. Attrition rates, cultural sensitivity, DSME hours provided, and length of project intervention should be further evaluated to produce significant results.

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Appendix A

Table 1

Evaluation Table

Citation	Theory/Conceptual Framework	Design/Method/Purpose	Sample/Setting	Major Variables	Measurements/Instrumentation	Data Analysis	Findings/Results	Level or Evidence/Decision for Use/Application to Practice
Holtrop et al. (2017). Diabetic and obese patient clinical outcomes improve during a care management implementation in PC. **Funding:** NIDDK **Bias:** No conflicts recognized **Country:** USA	CCMo	**Design:** Pair-matched cluster randomized trial **Purpose:** To understand how individual practices would implement care management, its successes and effects on those at risk of DM due to obesity.	N – 1,392 IG – 696 CG – 696 **Demographics:** M Age – 54.8 M/F – 50.4%/49.6% **Setting:** PC practices that are physician-owned medical group in southeast Michigan **Inclusion:** active pt at study practices during study period, 18 years or older, diagnosis of type 2 DM or obesity **Exclusion:** had less than 12 month life expectancy, non-English speaking, lived in nursing or group home, had substance	IV1 – care management which includes staffing improvements and new care management software and modifications to EMR DV1 – A1C DV2 – weight DV3 – BP DV 4 – LDL DV5 – BMI DV6 - AU	As pts presented for care, clinical data and laboratory test were collected	Paired *t* test, McNemar's chi-square test, Stuart-Maxwell symmetry test, linear mixed effects model, linear regression	Diabetics: DV1 – <u>Baseline</u> IG – M=8.4, SD = 0.4 CG – M=7.4, SD=0.4 <u>12 months</u> IG – M=7.5, SD=0.1 CG – 7.4, SD=0.5 <u>Unadjusted</u> CI - -0.8 (-1.4,-0.3) <u>Adjusted</u> CI - -0.5 (-1.0, -0.04) DV2 – <u>Baseline</u> IG – M=234.1, SD = 8.3 CG – M=213.7, SD=6.9 <u>12 months</u> IG – M=230.4, SD=6.0 CG – M=209.8, SD=9.0	**LOE –** Level I **Strengths –** RCT design **Weakness –** only 10 practices participated, which 5 received intervention, variability in baseline risks factors vs comparison pt, especially BMI and A1C for diabetics **Conclusions –** Findings add to the growing EB for the effectiveness of CM as an effective clinical practice with regard to improving DM and obesity related outcomes **Feasibility/Applicability –** findings consistent with literature, recommended for diabetic pts because of significant improvements in

Key: A1C – hemoglobin A1C; **ACE –** angiotensin-converting enzyme inhibitor; **ADA –** American Diabetic Association; **ARB –** angiotensin-receptor blocker; **AU –** microalbumin; **BMI –** body mass index; **BP –** blood pressure; **CCC –** chronic care coordinator; **CCMo –** chronic care model; **CHC –** community health center; **CHW –** community health worker; **CI –** confidence interval; **CM –** care management; **CMS –** Centers for Medicare and Medicaid Services; **Com. –** community; **Cr –** serum creatinine; **DM –** diabetes; **DOHMH –** Department of Health and Mental Hygiene; **DSME –** diabetes self-management education; **DSMS –** diabetes self-management support; **DV –** dependent variable; **Dx –** diagnosis; **EB –** evidence based; **EHR –** electronic health record; **EMR –** electronic medical record; **Endo –** endocrinology; **HTN –** hypertension; **IV –** independent variable; **KDIS –** Key Drivers Implementation Scales; **LDL –** low-density lipoprotein; **LOE –** level of evidence; **M –** median; **MCC –** multiple chronic conditions; **MEMS –** medications event monitoring system; **M/F –** male/female; **N –** sample; ***n* –** subgroup of sample size; **N/A –** not applicable; **NIDDK –** National Institute of Diabetes and Digestive and Kidney Diseases; **Opht –** ophthalmology; **PCMH –** patient centered medical home; **PC –** primary care; **PCP –** primary care provider; **PHQ-9 –** Patient Health Questionnaire; **POCT –** point of care testing; **Pt –** patient; **QI –** quality improvement; **RCT –** randomized controlled trial; **SD –** standard deviation; **TP -** telephone

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			abuse, psychiatric illness, or cognitive impairment, had DM or impaired glucose tolerance due to chronic glucocorticoid use, polycystic ovary syndrome, pituitary lesion, or pancreatectomy.				Unadjusted CI – 0.2 (-9.1,9.5) Adjusted CI - -2.2 (-5.3,0.7) DV3 – Baseline IG – M=127.0, SD = 2.0 CG – M=127.5, SD=0.7 12 months IG – M=127.0, SD=2.6 CG – M=125.8, SD=3.7 Unadjusted CI – 1.8 (-2.1,-5.7) Adjusted CI – 2.1 (-2.1, -6.2) DV6 – Baseline IG – M=26.6, SD = 4.0 CG – M=24.3, SD=8.7 12 months IG – M=21.1, SD=4.5 CG – 27.9, SD=11.7 Unadjusted CI - -9.1 (-26.3,8.1) Adjusted CI - -1.3 (-14.0, -11.4)	A1C, but will require training and therefore, funding.

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Solorio et al. (2014). Impact of chronic care coordinator intervention on diabetes of care in a community health center **Funding:** University of Washington Royal Research Fund **Bias:** observational study based on retrospective study and may include bias due to confounding factors **Country:** USA	CCM	**Design:** Retrospective cohort study design **Purpose:** to evaluate the impact of CCC intervention on quality of DM care within the CHC, predominantly low-income Hispanic and non-Hispanic white pt	N – 1,483 IG – 664 CG – 819 **Demographics:** M Age – 50-59 M/F – 48.8%/ 51.2% **Setting:** Sea Mar CHC that provides PC services to predominantly low-income Hispanics and non-Hispanic white pt in the Washington area **Inclusion:** established dx of DM type 2 in EMR in the past 12 months, current Sea Mar pt with clinic visit between 2/1/2009 and 9/30/2009, ages 18-69 years old, have at least 2 visits at the same clinic in last year, speak English or Spanish **Exclusion:** older than 69 years old, DM type 1, pregnant, history of organ transplant, Cr 2.5 mg/dL, dementia, and terminal illness	IV1 – at least 1 CCC visit, that includes case management, care coordination, and self-management DV1 – process of care, including A1C tested at least twice taken 3 months apart, LDL, AU, retinal eye exam, and foot exam DV2 – intermediate outcomes of DM care, including A1C < 7.0 %, LDL < 100 mg/dL, BP < 130/80 mmHg DV3 – health care utilization, including number of PC visits, at least once referral to opht, and at	Data collection through EMR	Propensity score analysis to reduce effect of selection bias, linear mixed effects model during 12 month pre- and postenrollement , *R* statistical software, chi-sqaure test of homogeneity, two-sample *t*-test	A1C – Baseline CG – M=8.0, SD= ±1.6 IG – M=8.4, SD= ±1.6 $p<0.001$ DV1 – A1C measurements: CI - 2.63(1.88, 3.68), $p < 0.001$; AU screen: CI- 2.94 (2.07, 4.17), $p < 0.001$; Retinal exam: CI - 2.27 (1.59, 3.25), $p < 0.001$; Foot exam: CI - 5.22 (3.42, 7.98(, $p < 0.001$ DV2 – A1C < 7%: CI - 0.70 (0.39, 1.27), $p = 0.242$; A1C last value: CI - 0.06 (0.02, 0.13, $p = 0.151$; BP: CI - 0.99 (0.69, 1.42), $p = 0.968$; DV3 – PCP visit: CI -1.39 (1.28, 1.51), $p < 0.001$; Endo referral: CI - 0.88 (0.30 - 2.60), $p = 0.818$; Opht referral: CI - 1.59 (0.86, 2.94), $p = 0.142$	**LOE –** Level IV **Strengths –** large sample **Weakness –** observational study prone to bias, no data on BMI, income, marital status, employment, education, alcohol use and time with DM, missing weight and height on some participants, data of duration of CCC visits is missing **Conclusions –** CCC is suggested and may benefit pt with DM type 2 by improving receipt of DM services **Feasibility/Applicability –** Due to significant findings in increases in DM services with CCC, diabetic pt may benefit from CCC. Therefore, making use for CCC.

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Citation	Theory/Conceptual Framework	Design/Method/Purpose	Sample/Setting	Major Variables	Measurements/Instrumentation	Data Analysis	Findings/Results	Level or Evidence/Decision for Use/Application to Practice
				least 1 referral to endo				
Swietek et al. (2018). Do medical homes improve quality of care for persons with multiple chronic conditions? **Funding:** Agency for Healthcare Research and Quality **Bias:** regression model used to reduce bias **Country:** USA	PCMH	**Design:** quasi-experimental **Purpose:** examine the association between PCMH enrollment and receipt of disease-specific quality measures for nonelderly Medicaid beneficiaries	N – 208,122 IG – 145,145 CG – 62,977 **Demographics:** M Age – 43.91 M/F – 32.4%/ 67.6% **Setting:** Com. Care of North Carolina, regional PC **Inclusion:** ages 18-64 years old; at least 2 chronic conditions that included: DM, asthma, hyperlipidemia, hypertension, major depression and schizophrenia; pt with at least partial Medicaid eligibility; have at least 2 outpatient or emergency department visits or at least 1 inpatient visit for given condition **Exclusion:** Dual Medicare and Medicaid enrollees	IV1 – PCMH enrollment DV1 – A1C testing DV2 – attention for nephropathy DV3 – liver function tests DV4 – eye examinations DV5 – Lipid profile DV6 – ACE or ARB DV7 – SABA overuse, which is 4+ canister equivalents in 3 months DV8 – any psychotherapy	Dataset that links Medicaid claims with other administrative data sources	*t*-test, chi-square, linear probability model, fixed-effects model	DV1 – CG – M=61.5 IG – M=82.1 $p<0.001$ DV2 – CG – M=30.3 IG – M=43.5 $p<0.001$ DV3 – CG – M=20.7 IG – M=25.4 $p<0.001$ DV4 – CG – M=30.0 IG – M=44.2 $p<0.001$ DV5 – CG – M=51.0 IG – M=70.72 $p<0.001$ DV6 – CG – M=53.3 IG – M=78.6 $p<0.001$	**LOE –** Level III **Strengths –** large sample **Weakness –** Not generalized population, PCHM was only defined as any enrollment in a year which may not capture the effects of extended duration of PCMH **Conclusions –** PCMH model may improve quality of care for pt with MCC **Feasibility/Applicability –** Significant findings show PCMH could have benefits to pt with MCC, which shows feasibility.

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				DV9 – assertive community therapy			DV7 – CG – M=7.8 IG – M=10.4 *p*<0.001	
Chamany et al. (2015). TP intervention to improve DM control: a randomized trial in New York City A1c registry. **Funding:** Albert Einstein College of Medicine **Bias:** None identified **Country:** USA	CCM	**Design:** RCT **Purpose:** 1) to evaluate the incremental effect of patient-centered TP intervention on the M A1C levels beyond that achieved with print materials mailed to pts and providers by the DOHMH registry intervention; 2) determine what patient demographic and psychosocial factors mediate the effect of the interventions; and 3) provide estimates of implementation costs of the TP	N – 941 IG – 443 CG – 498 **Demographics:** M Age – 56.3, SD 11.7 M/F – 36.3%/ 63.7% **Setting:** South Bronx **Inclusion:** pts with DM who speak English and/or Spanish and reside in the South Bronx; > 18 years, with DM, who become part of the NYC registry by virtue of having a reported A1C >7% to the DOHMH **Exclusion:** < 18 years; A1C < = 7 %; refuses informed consent and HIPAA consent; cognitive dysfunction as assessed by TP; does not read or speak	IV1 – Telephonic: between 4-8 phone calls each year for health behavior counseling to improve A1C CG – standard registry: letters from the DOHMH to promote improved A1C and give lists of Bronx resources for healthier food and activities DV1 – A1C DV2 – DM self-care activities	DOHMH Registry; self-report; Morisky Medication Adherence four-item scale; Summary of Diabetes Self-Care Activities ; PHQ-9; Well-Being scale of the WHO	Two-tailed z-test; Mann–Whitney *U* test; Sobel test; Stata, version 12.1 MP	DV1 – <u>Baseline</u> IG – M=9.3, SD = 2.1, *n*=443 CG – M=9.1, SD=2.0, *n*=498 <u>12 months</u> IG – M=8.4, SD=1.9, *n*=334, CG – 8.6, SD=2.0, *n*=360 Statistically significant, *p* <0.05	**LOE –** Level II **Strengths –** randomized **Weakness –** missing primary outcome data for 26.3% of participants; not generalized and focuses on low-incomes, mostly Latinos with DM with TP access **Conclusions –** TP intervention delivered by health educators can be an effective tool to improve DM control in diverse populations, specifically for those with worse metabolic control identified using a registry. **Feasibility/Applicability –** The intervention is low cost and low-intensive, making it feasible and applicable.

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		intervention for comparison with the print intervention.	English or Spanish; no DM					
Edelman et al. (2015). Nurse-led behavioral management of DM and HTN in the com. practices: a randomized trial. **Funding:** NIDDK **Bias:** None identified **Country:** USA	CCM	**Design:** RCT **Purpose:** To assess the effectiveness of nurse behavioral management of DM and HTN in com. practices among pts with both diseases.	N – 377 IG – 193 CG – 184 **Demographics:** M Age – 59.6, SD – 10.7 M/F – 45.1%/ 54.9% **Setting:** Practice-based research network of com. PC practices **Inclusion:** adult pts with both DM 2 and HTN and receiving care at 1 of 9 com. fee-for-service practices; A1C ≥ 7.5% but could have well-controlled HTN and had to be taking medications for both **Exclusion:** DM type 1; inability to receive a telephone intervention in English, participations in another diabetes or HTN	IV1 – 12 calls over 2 years: from a nurse experienced in DM and HTN management; calls were tailored to pts's DM- and HTN-behavioral barriers CG – 12 calls not tailored or interactive: calls involved health issues unrelated to DM or HTN DV1 – A1C: measured by fingerstick DV2 – BP: taken at each visit, 2 measures 5 minutes apart and were averaged	Clinical data from visits and POCT	Linear mixed model; covariance model; Wilcox rank-sum test; generalized estimating equation model	DV1 – <u>Baseline</u> IG – M=9.2, SD = 1.5, *n*=193 CG – M=9.0, SD=1.4, *n*=184 <u>24 months</u> IG – M=8.6, CG – 8.5 CI (-0.3%, 0.5%), *p*=0.50 – not significant	**LOE –** Level II **Strengths –** blinded, randomized **Weakness –** intervention was ineffective **Conclusions –** telephonic nurse case management did not lead to improvement in A1c or SBP. **Feasibility/Applicability –** Small gains in clinical outcomes may add up to an important public health impact over a large population, the study of a modest intervention by traditional trial methods may not be feasible.

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			study, or living in an assisted living facility.					
Egede. (2017) Telephone-delivered behavioral skills intervention for African American adults with type 2 DM: an RCT **Funding:** National Institute of Health/NIDDK **Bias:** None identified **Country:** USA	Information-motivation behavioral skills model	**Design:** RCT **Purpose:** To assess the efficacy of a combined telephone-delivered education and behavioral skills intervention in reducing hemoglobin A1C levels in African Americans with type 2 DM	N – 255 IG – knowledge: 63, skills: 65, combined: 63 CG – 64 **Demographics:** M Age – 50-64 M/F – 55.3%/44.7 % **Setting:** Medical University of South Carolina (general internal medicine, endo, family medicine, and com. PC clinics) and the Ralph H. Johnson Veterans Administration Medical Center, both located in Charleston, South Carolina. **Inclusion:** ≥18 years old; dx of type 2 DM and A1C ≥9% at screening visit; self-identified as Black or African American; taking at least 1 oral medication for DM, HTN, or hyperlipidemia and must be willing to use the	IV1 – DM knowledge/information: 12 DM education modules over 12 week period based on guidelines from ADA IV2 – motivation/behavioral: pt activation, pt empowerment, and behavioral skills training delivered via 30 minute phone call ever week for 12 weeks IV3 – combined: receives weekly telephone-delivered DM knowledge/information, pt activation, pt empowerment,	EMR and clinical visits	Chi-square; ANOVA; ANCOVA; longitudinal model	DV1 – <u>Baseline</u> IG – Knowledge: M=9.3, SD = 1.5, *n*=63 Skills: M=9.2, SD = 2.1, *n*=65 Combination: M=9.2, SD = 1.9, *n*=63 CG – M=9.3, SD=2.1, *n*=64 <u>12 months (Differences in levels of A1C)</u> IG – Knowledge: CI – 0.49(-0.13, 1.11), *p*=0.123 – not significant; Skills: CI – 0.23(-0.38, 0.83), *p*=0.456 – not significant; Combination: CI – 0.48(-0.10, 1.07), *p*=0.105 – not significant CG – reference group	**LOE –** Level II **Strengths –** targets vulnerable population; no RCT in this populations; telephone calls are efficacious **Weakness –** eligibility between screening time and baseline visit varied causing drop in eligible pts; staff turnover was high during study, especially among health educators **Conclusions –** combined education and skills training did not achieve greater reductions in A1C at 12 months compared to CG, educations alone, or skills training alone. **Feasibility/Applicability –** Because telephone calls are low cost and nursing staff that are not mastered prepared are doing education makes this study feasible. Modifications must be made to show significant changes in A1C.

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			MEMS cap and bottle for 1 year; speak English; access to a telephone for the 12 week period **Exclusion:** mental confusion; participations in other DM clinical trials, alcohol/drug abuse/dependence; active psychosis or acute mental disorder; life expectancy < 6 months.	and behavioral skills CG – standard care with general health education DV1 – A1C at 12 months DV2 – cost-effectiveness and change in physical activity, diet, medication adherence, and self-monitoring of blood glucose in 12 months				
Halladay et al. (2014) More extensive implementation of the CCM is associated with better lipid control in DM. **Funding:** Agency of Healthcare Research and	CCM	**Design:** observational study **Purpose:** This study examines whether higher KDIS scores are associated with improved diabetes outcomes.	N – 42 practices IG – N/A CG – N/A **Setting:** 42 PC practices in North Carolina **Inclusion:** participated with a practice coach for at least 13 months starting in February 2008 or later; submitted clinical data reports in months	IV1 – 4 key drivers: registries, planned care template, protocols, and self-management support CG – standard practice: without drivers	Clinical data and KDIS data	Logistic regression; odds ratio; extra-binomial variation in linear model	DV1 – <u>Baseline</u> IG – 23 (37%), *n*=42 <u>12 months</u> IG – 4 – not significant	**LOE –** Level IV **Strengths –** innovative approach for QI **Weakness –** Short length of data (2-3 years), was not significant **Conclusions –** Practices that implement key changes may achieve improved patient outcomes in LDL control among their pts with diabetes.

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Quality/National Institutes of Health/National Institute of Environmental Health Sciences **Bias:** Lack of study design may lead to bias. **Country:** USA			10,11,12, and submitted another clinical date report at some point during their second year of participation with their coach. **Exclusion:** Not noted	DV1 – number of practices with pt at with A1C < 9% DV2 – number of practices with pt with BP <130/80 DV3 – number of practices with pt with LDL <100				**Feasibility/Applicability –** Needs stronger study design to be feasible and applicable.
Carrasquillo et al. (2017). Effect of a com. health worker intervention among Latinos with poorly controlled type 2 DM. **Funding:** National Heart, Blood, and Lung Institute, National Center for Advancing Translational Sciences and the National Institutes on	CCM	**Design:** RCT **Purpose:** To compare a CHW intervention with enhanced usual care	N – 300 IG – 150 CG – 150 **Demographics:** M Age – 55.2, SD – 7.0 M/F – 45%/ 55% **Setting:** 2 public hospital outpatient clinics in Miami-Dade County, Florida **Inclusion:** A1C >8.0% **Exclusion:** dx with type 2 DM < 6 months previously, self-reported type 1 DM, dx with type 2	IV1 – A 1-year CHW intervention consisted of home visits, telephone calls, and group-level activities. CG – enhanced usual care DV1 – SBP DV2 – LDL DV3 – A1C	EMR, telephone calls	2-tailed *t* test, generalized estimating equation model, chi-squared test	DV3 – Baseline IG – M=9.3, SD = 2.1, *n*=150 CG – M=9.3 SD=1.9, *n*=150 12 months (Adjusted) IG – CI - -0.51% (-0.94, -0.09) - significant	**LOE –** Level II **Strengths –** single-blinded RCT, correlates with previous evidence **Weakness –** does not provide evidence on which part of the intervention helped lower A1C **Conclusions –** Both groups showed a statistically significant reduction of HbA1c at 6 and 12 months following baseline. **Feasibility/Applicability –** Although CHW are not expensive compared to the average diabetic treatment,

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Minority Health and Health Disparities **Bias:** None noted **Country:** USA			DM younger than 25 years old, were enrolled in intervention studies, planned to move from the county within the next year					insurance plans may not cover their services.
Cykert et al. (2016). Meaningful use in chronic care improved DM outcomes using PC extension center model **Funding:** National Coordinator for Health Information Technology, North Carolina Regional Extension Center Cooperative Agreement, The North Carolina Health and Wellness Trust Fund	Primary care extension center model/CCM	**Design:** cohort study **Purpose:** to evaluate the effectiveness QI of EHR on diabetes	N – 50 practices IG – 50 CG – N/A **Demographics:** N/A **Setting:** **Inclusion:** practices that signed up for Regional Extension Center for Health Information Technology services and agreed to implement a certified EHR system, perform QI through onsite practice facilitation using DM chronic care measures, and work toward achievement of CMS-defined meaningful use of their certified EHR.	IV1 – QI: provided to practices with a coach and practice team engagement at the site, or web-based communication DV1 – percentage of diabetic pts who achieved A1C< 7% DV2 – percentage who remained with HGB A1C > 9% for each practice site	EMR, onsite practice facilitation	Bivariate analysis, linear regression model, KDIS scores	DV1 – Baseline IG – M=41.6, SD = 16.7, *n*=50 6 months (EHR + practice facilitation) IG – M = 51.3, SD = 16.0, *n*=45 6 moths (HER +practice facilitation + Meaningful Use IG – M = 60.0, SD = 11.6, *n*=29 DV2 – Baseline IG – M=21.6, SD = 11.8, *n*=50 6 months (EHR + practice facilitation) IG – M = 20.1, SD = 13.3, *n*=45 6 moths (EHR +practice facilitation + Meaningful Use	**LOE –** Level IV **Strengths –** QI proven to be successful in DM management **Weakness –** No control **Conclusions –** Practice facilitation that provided EHR and QI coaching support showed important improvements in diabetes outcomes in practices that achieved meaningful use of their EHR systems. **Feasibility/Applicability –** if grant money can be rewarded this is feasible. Study is applicable since HER are highly used in practices.

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Bias: None noted **Country:** USA			**Exclusion:** practices that had participated in QI programs				IG – M = 15.4, SD = 6.2, *n*=29	
Sepers et al. (2015). Measuring the implementation and effects of a coordinated care model featuring DSME within 4 PCMH. **Funding:** Bristol-Myers Squibb Foundation **Bias:** None identified **Country:** USA	CCMo	**Design:** empirical case study, retrospective **Purpose:** to measure the implementation and effects of a multisite coordinated care approach that delivered DSME and DSMS for disadvantaged pts	N – 173 IG – 173 CG – N/A **Demographics:** N/A **Setting:** 4 PMCHs in Jacksonville, Florida, Athens County, Ohio, Oklahoma City, Oklahoma, and Nashville, Tennessee **Inclusion:** PCMH had to be a part of Together on DM **Exclusion:** Not noted	IV1 – DSME and coordinated care: accredited DSME program with pt-tailored curricula, DSMS that targets unique needs of underserved populations, enhanced access and linkage to care services, and practice changes aimed at improving quality of DM clinical care CG – N/A DV1 – A1C DV2 – BMI DV3 – BP DV4 - LDL	SPSS Statistics for Windows,	Paired-sample *t* test, Pearson product-moment correlation coefficient	DV1 – Baseline IG – M=9.1, SD = 2.4 6 months IG – M=8.5, SD = 2.1 $p = 0.01$, significant	**LOE –** Level IV **Strengths –** pt and staff satisfaction implementing intervention **Weakness –** no control group **Conclusions –** DSME and DSMS within coordinated care settings have the potential to improve PCMH practice and associated clinical health outcomes for populations experiencing health disparities. **Feasibility/Applicability –** pts and staff shared high satisfaction with DSME within the PCMH setting, making this intervention applicable. Testing of the intervention at multiple sites can be costly.

Key: A1C – hemoglobin A1C; **ACE –** angiotensin-converting enzyme inhibitor; **ADA –** American Diabetic Association; **ARB –** angiotensin-receptor blocker; **AU –** microalbumin; **BMI –** body mass index; **BP –** blood pressure; **CCC –** chronic care coordinator; **CCMo –** chronic care model; **CHC –** community health center; **CHW –** community health worker; **CI –** confidence interval; **CM –** care management; **CMS –** Centers for Medicare and Medicaid Services; **Com. –** community; **Cr –** serum creatinine; **DM –** diabetes; **DOHMH –** Department of Health and Mental Hygiene; **DSME –** diabetes self-management education; **DSMS –** diabetes self-management support; **DV –** dependent variable; **Dx –** diagnosis; **EB –** evidence based; **EHR –** electronic health record; **EMR –** electronic medical record; **Endo –** endocrinology; **HTN –** hypertension; **IV –** independent variable; **KDIS –** Key Drivers Implementation Scales; **LDL –** low-density lipoprotein; **LOE –** level of evidence; **M –** median; **MCC –** multiple chronic conditions; **MEMS –** medications event monitoring system; **M/F –** male/female; **N –** sample; ***n* –** subgroup of sample size; **N/A –** not applicable; **NIDDK –** National Institute of Diabetes and Digestive and Kidney Diseases; **Opht –** ophthalmology; **PCMH –** patient centered medical home; **PC –** primary care; **PCP –** primary care provider; **PHQ-9 –** Patient Health Questionnaire; **POCT –** point of care testing; **Pt –** patient; **QI –** quality improvement; **RCT –** randomized controlled trial; **SD –** standard deviation; **TP -** telephone

Appendix B

Table 2

Synthesis Table

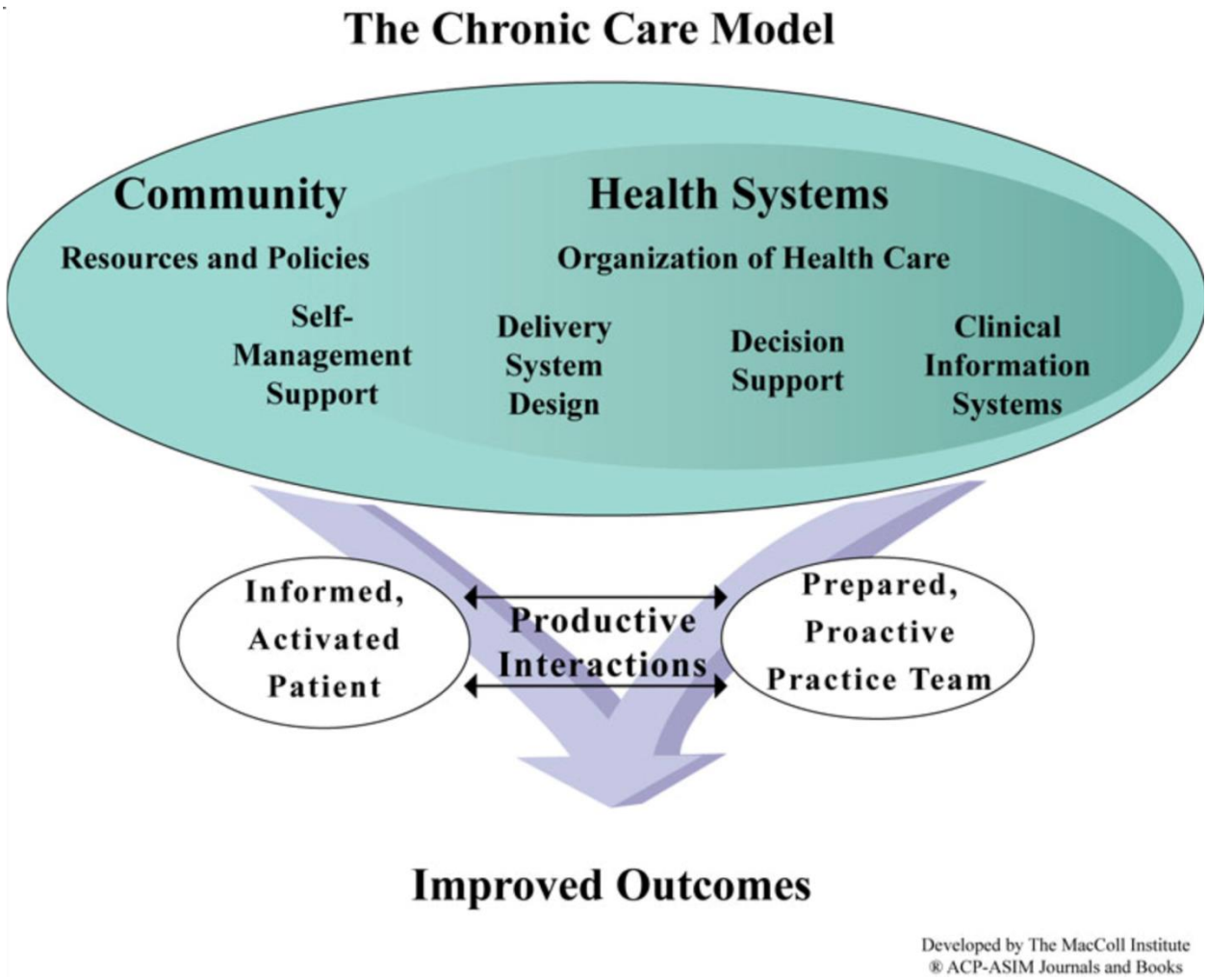
Author	Holtrop	Solorio	Swietek	Chamany	Edelman	Egede	Halladay	Carrasquillo	Cykert	Sepers
Year	2017	2014	2018	2015	2015	2016	2014	2017	2016	2015
LOE	II	IV	III	II	II	II	IV	II	IV	IV
Design	RCT	CS	QE	RCT	RCT	RCT	OS	RCT	CS	CC
Sample Size	1,392	1,483	208,122	941	377	255	42	300	50	173
Demographics										
Age (Mean)	54.8	50-59	43.9	56.3	59.6	50-64	N/A	55.2	N/A	N/A
% Male	50.4	48.8	32.4	36.3	45.1	55.3	N/A	45	N/A	N/A
Findings										
Improve A1C	X	X+	X+	X+	X	X		X+		X+
Interventions										
CCC	X	X	X				X	X		X
Staff Δ	X								X	
EMR Δ	X									
DSME		X					X			X
TP Call			X	X				X		
Education					X					X
Registries							X			
Home Visits								X		
Group Activities								X		
CHW								X		

Key: A1C – hemoglobin A1C; **CC –** controlled case study; **CCC –** chronic care coordinator; **CHW –** community health worker; **CS –** Cohort study; **DSME –** diabetes self-management education; **EMR –** electronic medical record; **LOE –** level of evidence; **N/A –** not applicable; **OS –** observational study; **QE –** quasi-experimental; **RCT –** randomized controlled trial; **TP –** telephone; **+ -** significantly improved; **Δ -** modifications

Appendix C

Figure 1

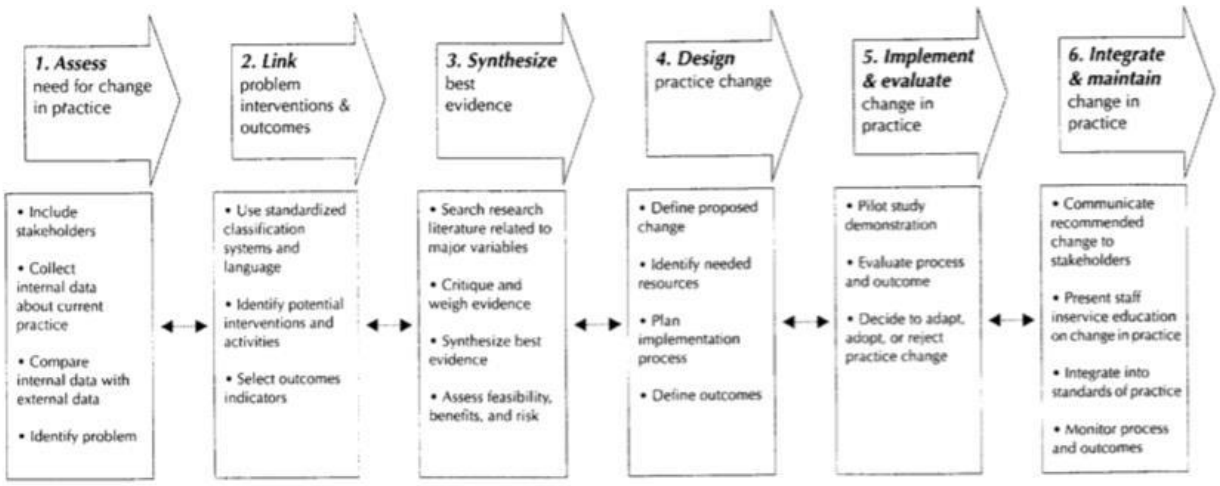
Chronic Care Model



Appendix D

Figure 2

Rosswurm and Larabee's Model



Appendix E

Table 3

Demographics

Variable	*n*	*%*
RACE/ETHINICITY		
HISPANIC/LATINO/SPANISH	8	88.89
WHITE	1	11.11
Missing	0	0
HISTORY OF DIABETES DIAGNOSIS		
>10 YEARS	5	55.56
1-5 YEARS	1	11.11
0-1 YEAR	2	22.22
5-10 YEARS	1	11.11
Missing	0	0
GENDER		
MALE	8	88.89
FEMALE	1	11.11
Missing	0	0
AGE		
45-54	4	44.44
>65	5	55.56
Missing	0	0
EMPLOYMENT		
UNEMPLOYED	2	22.22
RETIRED	7	77.78
Missing	0	0
EDUCATION		
HIGH SCHOOL	7	77.78
NO FORMAL	2	22.22
Missing	0	0

Note. Due to rounding errors, percentages may not equal 100%.

Appendix F

Budget

Phase	Activities	Cost	Subtotal	Total
Preparation	Print copies of project overview for staff (qty 30)	$0.60 x 30	$18	
	Print copies of consent, evaluation, and educational material for participants (qty 30)	$3 x 30	$90	
	Educational session at clinic for staff for 30 min: site snacks time of presenter (project director)	 $0 $15 $15	$30	
Delivery	Site	$0	$0	
	Educational session (project director)	$15 x 20 hours	$300	
	Monthly phone calls by project director (30 min/call x 3 months)	$15 x 30 hours	$450	
Evaluation	Front staff scheduling patient for visit(10 min/call x 30 patients)	$12 x 5 hours	$60	
	Review and analysis of results (10 hours plus software)	$20 x 10 hours + $60	$260	$1,208

Budget Justification: Potential revenue and benefits of project exceeds costs. Decreasing A1c levels could decrease number of diabetes related visits to hospital and emergency room visits. Alongside, meeting quality measures set forth by Yuma Regional Medical Center.

Possible funding: Transitional Care will fund part of the costs, such as site and front staff. Project director will volunteer time and provide funding for all other cost.