TEXAS MEDICAID ADULT TYPE 2 DIABETES PILOT

May 11, 2011

Submitted to:

State of Texas

Health & Human Services Commission

INTRODUCTION

This report was originally written as a way to share preliminary results with lay readers about a multi-year pilot program authorized in accordance with provisions enacted into law by the Texas State Legislature in 2009.

It is made available now via the study's lead investigator to promote the field of telemedicine and telehealth by sharing one of the most comprehensive studies of remote mobile enabled self-care programs for adults with type 2 diabetes ever conducted.

A scientific manuscript is under development and planned for submission to peer review and publication in a respected medical journal in late 2011 or early 2012.

For inquiries please send email to me at kevin.l.mcmahon@[gmail.com]

Sincerely,

Kevin L. McMahon
Sponsor-Investigator

STUDY PURPOSE

This study of adults with diagnosed type 2 diabetes was performed by Healthimo in order to assist the State of Texas Health & Human Services Commission to investigate innovative models of telemedicine and telehealth style care for Medicaid recipients enrolled in the State sponsored Enhanced Care diabetes disease management program.

The research team worked closely with the State's incumbent disease management vendor McKesson Health Solutions (MHS) in determining the effectiveness of the Healthimo social support-based diabetes intervention program. This report summarizes the results obtained over the course of the pilot program, including non-patient identifiable outcome data.

STUDY ANALYSIS

In an attempt to identify the impact of this pilot on patients with well controlled blood sugars vs. poorly controlled blood sugars, all subjects in each of the treatment and control groups were segmented (retrospectively) for analysis representing relative blood sugar control via % A1c equal to or greater than 8 vs those participants at the time of enrollment with % A1c below 8.

Participants with an enrollment % A1C less than 8 (indicating well-controlled) will be included in Group A while participants with an enrollment % A1C of 8.0 or greater (indicating suboptimal-control) will be included in Group B.

STUDY DESIGN

The study protocol was designed by Healthimo and its medical advisors with input from MHS and the State of Texas Department of Medicaid. Two groups were established for analysis; treatment group includes those receiving the MHS and Healthimo's comprehensive diabetes education program including home based collection of A1c data, use of the home blood glucose monitoring device and control group including those with only the MHS program plus home based collection of A1c data. The home A1c collection and exchange method is a unique service component available from Healthimo and can be utilized separately from various other elements of the comprehensive program.

The Intervention

Participants in the treatment group of the study receive a wireless data transmission device shipped to their home including a pre-registered blood sugar meter. Daily or at least weekly connection of the meter to this transmission device is requested as a means of allowing the Healthimo diabetes program to review blood sugar patterns and trends, to make simple suggestions of self-care basics and to mail blood sugar reports to the patient for their own review. Additionally, when persistent hyperglycemia is encountered, the system automatically forwards the patient blood sugar report to the MHS care management staff.

Blood samples were collected from the patient's home at baseline, 3 months and 6 months following enrollment in the study utilizing a home kit with a prepaid mailer for sending to the specialized laboratory. Results were then provided from the lab to the Healthimo program and appended to the patient record. All A1c results were shared with MHS.

Recruiting & Group Assignment

Patients from an MHS provided randomized list of disease management program participants were called initially by phone to fill the treatment group. Following a substantial number of verbal enrollments for the treatment group, additional participants were then contacted from the same list to participate in the control group. Due to insufficient numbers of enrollments the list was utilized various times and in various orders to enroll treatment and control group participants and not in any particular order. Total verbal agreement to participate was secured from 505 Enhanced Care Program participants; 267 treatment group and 238 control group participants. Startup packages including Informed Consent and Healthimo's proprietary mail-in blood sample collection kit were mailed to all Enhanced Care program members who verbally indicated their desire to participate in the study.

Outcomes

Primary Outcome Measures (treatment and control groups)

- Hemoglobin A1c collected at baseline, 3 months and 6 months

Secondary Outcome Measures (treatment group only)

- Problem Areas in Diabetes survey (PAID) collected at baseline and again at 6 months
- Satisfaction Scores collected from surveys
- Sustainability Scores collected from surveys
- Patient Diet and Activity Self-Assessment collected from surveys

- Self Managed Blood Glucose data (time of day distribution, standard deviation, daily mean) collected from participants using the study issued GlucoMON device and OneTouch Ultra2 blood glucose meter.

Challenges Encountered and Solutions

Recruiting During the Holidays

Challenge - The initial recruiting efforts were launched toward patients during November and December of 2009 and continued through January 2010. Only 5/51 treatment group patients in the final completed study treatment group were enrolled and activated during these first 3 months. This low enrollment rate appears to be due to distraction of the Holiday Season as well as including too many enrollment steps as the initial actions required by patients.

Solution - The protocol was redesigned to simplify the initial actions required of the patient. Recruiting was re-launched in March 2010. Enrollment rates based on the revised protocol were more similar to prior studies performed by Healthimo.

Lack of Internet Connectivity by Patients, Supporters and Physicians

Challenge - During the recruiting phone call patients were asked if they had email. Less than 10% confirmed that they had an email address.

Since the initial protocol was designed for a population with approximately 70% having access to email, the intervention was redesigned during a 2 month pause in recruiting and enrollment.

Solution - The entire protocol was redesigned to ensure feedback could be sent to patients either via US Mail or phone calls. For example, several of the surveys that are normally delivered online via the Internet were instead conducted over the phone by Healthimo's care specialists. Blood sugar pattern management were mailed to the participants with quicktip education messages added to the report or delivered by phone call from the care specialist. This lack of connectivity caused the program to engage supporters through the patient participant. In that most supporters lived in the same household with the patient this modification was easily accommodated. Even several physician offices told the care specialists that they did not have a fax machine and very few were willing to share an email address. Physician engagement depended on phone calls from care specialists.

Difficulty in Getting Patients OneTouch Ultra Blood Glucose Test Strips

Challenge - Getting the patient's current DME provider and physician to change the prescription to the study required strip proved very difficult. We learned that due to the profit incentive to the DME for selling various

other meter/strip products, DME companies are incented to move patients frequently to the current most profitable test strip. Worse, patients commonly complained that when they were switched to a new meter there was no instruction provided to ensure that they knew how to use the new meter.

Solution - MHS agreed to fund the cost of providing test strips for several patients in order to get them started which then gave the Healthimo care specialists more time to complete the process of getting the patient's physician to write the script and for the patient to either convince their DME to fulfill their request for the Ultra test strips or to switch DME providers to one that would provide the Ultra test strips.

STUDY DURATION

Patients were recruited for a 6-month duration in Healthimo's program.

INCLUSION CRITERIA

- Active participation in the Enhanced Care Program.
- Previously diagnosed with type 2 diabetes.
- Adults only.
- Oral medication for control of elevated blood sugar (this criteria was subsequently expanded to include patients using insulin).
- Ability to submit at least the baseline blood sample for A1c analysis at study Entry and again at study completion in 6 months in order to facilitate analysis of the intervention's impact via % change in A1c. An additional blood sample was attempted at the study midpoint approximately 3 months following enrollment.

EXCLUSION CRITERIA

- Lack of wireless coverage at the home of the patient
- Loss of coverage for participation in the Enhanced Care Program

INCENTIVE

All enrolled patients were eligible for a $10 Walmart gift card for each blood sample mailed to the laboratory for A1c analysis. Treatment group participants were also eligible for an

additional $10 gift card following return of their study issued wireless GlucoMON device to Healthimo.

STUDY POPULATION

All patients were recruited by Healthimo via telephone from a list provided to Healthimo by MHS. All people on this list were enrolled in the Enhanced Care Program at the time of recruiting.

Treatment Group

40% (107/267) of the enrollees returned a signed Informed Consent agreement.

37% (98/267) of the enrollees returned a baseline mail-in blood sample.

34% (90/267) of the baseline blood samples received were of sufficient quality for returning a valid % A1c result.

→ 8% (8/98) participants were not able to submit a blood sample containing the 3uL required for performing valid analysis.

Control Group

24% (57/238) of the enrollees returned a signed Informed Consent agreement.

21% (50/238) of the enrollees returned a baseline mail-in blood sample.

20% (48/238) of the baseline blood samples received were of sufficient quality for returning a valid % A1c result.

→ 4% (2/50) participants were not able to submit a blood sample containing the 3uL required for performing valid analysis.

RESULTS

No adverse events reported

ANALYSIS

Control Group participants were not offered any surveys nor was daily blood sugar data collected. Therefore, the only Control Group biomarker collected for analysis was A1c.

Treatment Group Participant Use of HomeCheck-A1c Blood Sample Collection & Mailer Kit.

Home Blood Sample Kit Utilization

- 148 (98 treatment / 50 control) participants submitted at least the baseline sample
    - 103 (66 treatment / 37 control) participants submitted at least two samples
    - 63 (47 treatment / 16 control) participants submitted all three samples
- 83 (51 treatment / 32 control) participants provided a valid baseline (entry) and exit (following at least 6 months beyond enrollment) A1c blood samples to the laboratory via the study supplied HomeCheck A1c blood sample collection and mailer kit.

Duration of Participation for those who completed the full study requirements

Treatment Group (n=51).

Days in Study	Mean	Low	High
Group A	**196**	**103**	**369**
Group B	**214**	**160**	**326**

* only 2 participants in Group A participated for less than 153 days.

Control Group (n=32).

Days in Study	Mean	Low	High
Group A	**230**	**139**	**336**
Group B	**238**	**139**	**321**

Migration Across the 7% ADA Threshold Indicating Good Control

A1c < 7.0	Entry	Exit	Final Diff
Treatment (n=51)	33% (17/51)	67% (34/51)	**58% (17/54)**
Control (n=32)	56% (18/32)	63% (20/32)	**6% (2/32)**
Comparison			**52% favorable treatment group**

When analyzing for changes in overall blood sugar control the mean change in A1c for a group does not tell the entire story. The American Diabetes Association target for well controlled diabetes is an A1c below 7%. In this study, the Treatment Group experienced a significant shift in blood sugar control vs. the ADA standard. given that 33% (17 of 51) of the treatment group entered the study with an %A1c below 7 and completed the study with 67% (34 of 51) of the group below the ADA recognized standard of 7. In contrast, a net improvement of only 2 participants in the control group achieved the ADA target.

Mean difference in A1c for Entire Population (Not Stratified)

Statistics Table 1 – Mean Change in A1c – Control vs. Treatment

	Control Group	Treatment Group	*p* value
n	32	51	
Baseline A1c	7.37 ± 2.27	7.64 ± 1.96	0.57
6 month A1c	7.00 ± 1.64	6.83 ± 1.39	0.09
Change A1c	0.37 ± 1.90	-0.81 ± 1.14	0.16

[1] Values are mean ± SD

Independent t-test shows the treatment group participants had a moderately significant lower mean A1c over the duration when compared with the control group. However, the change in A1c was not clinically significant when considered as a unified group.

Baseline Blood Sugar Analysis Stratification

- Participants with entry A1c less than 8%.
    - Treatment Group A = 67% (34/51)
    - Control Group A = 75% (24/32)
- Participants with entry A1c greater than or equal to 8%.
    - Treatment Group B = 33% (17/51)
    - Control Group B = 25% (8/32)

Primary Outcome Measure Comparison – Group A

Mean HbA1c	Entry	Exit	Final Diff
Treatment	6.6	6.2	**-0.4**
Control	6.3	6.5	**0.2**
Comparison			**-0.6 favorable treatment group**

Primary Outcome Measure Comparison – Group B

Mean HbA1c	Entry	Exit	Final Diff
Treatment	9.7	8.1	**-1.6**
Control	10.5	8.6	**-1.9**
Comparison			**-0.3 favorable control group**

Statistics Table 2 – Change in A1c - grouped by Baseline A1c

	CA	TA	CA vs. TA *p* value	CB	TB	CB vs. EB *p* Value
n	24	34		8	17	
Baseline A1c	6.34 ± 0.78	6.60 ± 0.70	0.53	10.45 ± 2.52	9.71 ± 2.05	0.23
6 month A1c	6.48 ± 1.05	6.18 ± 0.76	0.07	8.56 ± 2.13	8.12 ± 1.47	0.32
Change A1c	0.14 ± 0.97	-0.42 ± 0.74	0.61	-1.89 ± 3.06	-1.59 ± 1.40	0.01

[1] Values are mean ± SD; CA = control group with baseline A1c < 8.0%; TA = treatment group with baseline A1c < 8.0%; CB = control group with baseline A1c ≥ 8.0%; TB = treatment group with baseline A1c ≥ 8.0%

Independent t-test shows that participants in the treatment group beginning the study with hemoglobin A1c values of less than 8 had moderately significant lower A1c values at 6 months compared with counterparts in the control group. Individuals in the control group who began the study with A1c ≥ 8.0 had significantly larger decreases in A1c than any other group. This may be explained by analysis of 'dosing of care' which is data that was not captured. Future studies of this nature should be careful to capture and analyze differences in dosing of care.

Primary Outcome Measure Comparison – Group C

Another observation when analyzing the data indicated a possible difference between treatment vs control when looking at that group of members who entered the study with an A1c between 7.0 and 8.9. Given that the study protocol required special treatment for patients with an A1c of 9 or above regardless of treatment or control group enrollment, this group is especially interesting since the control group would have been less likely to receive additional dosing of care. For the purpose of illustration we shall call this analysis Group C.

Group C - Changes in Mean %A1c

Mean HbA1c	Entry	Exit	Final Diff
Treatment (n=19)	8.0 (+/- 1.9)	7.2 (+/- 3.0)	**-0.8**
Control (n=9)	7.7 (+/-1.4)	7.5 (+/- 5.9)	**-0.2**
Comparison			**-0.6 favorable treatment group**

Group C - Movement Across the 7% ADA Threshold Indicating Good Control

A1c < 7.0	Entry	Exit	Final Diff
Treatment (n=19)	0 of 19	11 of 19	**58% (11/19)**
Control (n=9)	0 of 9	4 of 9	**44% (4/9)**
Comparison			**14% favorable treatment group**

When analyzing for changes in overall blood sugar control the mean change in A1c for a group does not tell the entire story. The American Diabetes Association target for well controlled diabetes is an A1c below 7%. In this study Group C, the Treatment Group experienced a slightly more significant shift in blood sugar control vs. the ADA standard. In the treatment group, 58% (11 of 19) of the Group C participants dropped their A1c below the ADA recognized standard of 7 whereas only 44% (4 of 9) in the control group were able to do so.

Group C - Individual Changes in A1c

Change in Mean HbA1c	Improvement A1c Decrease > 0.3	No Change 0.3 ≥ n ≥ -0.3	Deterioration A1c Increase > 0.3
Treatment (n=19)	84%	11%	5%
Control (n=9)	44%	22%	33%

Significantly more treatment group participants were able to improve their blood sugar control as compared to those participants in the control group

Statistics Table 3 – Change in A1c – Control vs. Treatment "Group C: baseline A1c 7-8.9"

	Control Group	Experimental Group	*p* value
n	9	19	
Baseline A1c	7.67 ± .56	7.96 ± 0.57	0.745
6 month A1c	7.49 ± 1.77	7.17 ± 0.87	0.048
Change A1c	-0.18 ± 1.93	-0.79 ± .78	0.020

[1] Values are mean ± SD

For those study participants with a baseline A1c of 7.0 – 8.9 %, an independent t-test shows the treatment group participants had a significantly lower mean A1c at 6 months when compared with the control group. Treatment group participants also had significantly larger change in A1c than the control group.

Secondary Outcome Measures – Treatment Group Only

PAID Scores including corresponding mean A1c results

Mean PAID	Mean A1c Entry	Mean A1c Exit	Mean A1c Diff	Mean Entry PAID	Mean Exit PAID	Mean PAID Diff
Group A (n=11/34)	6.4	6.0	-0.5	18	19	7%
Group B (n=5/17)	10.1	8.6	-1.5	38	23	-41%

Only 31% (16/51) participants from both Groups returned both the entry PAID and the exit PAID. The entry PAID score represents a baseline whereas subsequent PAID scores indicate a change as compared to baseline. A decrease in PAID scores represents improvement whereas an increase indicates a worsening of depression and/or anxiety regarding diabetes self-management. The sample size of surveys returned is small. However, the data does suggest that patients who entered the program with a high level of anxiety and possibly depression may have experienced an improvement in PAID scores as compared to seemingly no difference in the group who entered the study with relatively well controlled blood sugar levels.

Satisfaction Scores

Treatment group participants were asked to rate their experience using a range of 1 through 5 with an answer of 5 meaning most satisfied with the program and 1 meaning least satisfied. The scores represent the mean within each study Group.

Question	Group A (n=24/38)	Group B (n=14/38)
How satisfied are you with your current (this study) diabetes mgmt routine?	**4.88**	**4.86**
How satisfied are you with your doctor?	**4.63**	**4.43**
How satisfied are you with Healthimo, the pilot study provider?	**4.92**	**4.86**
How satisfied are you with the MHS Nurse(s): Enhanced Care Program?	**4.75**	**4.57**
How satisfied are you with your meter test strip supplier (DME)?	**4.75**	**4.71**

Sustainability Scores

Treatment group participants were asked to rate their experience using a range of 1 through 5 with an answer of 5 meaning most likely to continue active participation in the program for years into the future and 1 meaning that they did not believe they could continue doing what was asked of them during their study participation. The numbers represent the mean score within each study Group.

Question	Group A (n=24/38)	Group B (n=14/38)
Were the study issued tools easy to use or hard to use?	**4.96**	**4.86**
Can you do what you did in this study for a long period of time (5) or only a short period of time (1)?	**4.42**	**4.77**

Patient Diet Self-Assessment

Treatment group participants were asked to rate their diet using a range of 1 through 5 with an answer of 5 meaning a high level of understanding/improvement of Diet and 1 meaning a low level of understanding/no improvement with regard to diet. The numbers represent the mean score within each study Group.

Question	Group A (n=24/38)	Group B (n=14/38)
How much has your understanding of your diet improved during your participation in this study?	**4.25**	**4.5**
How much have you improved your eating choices during participation?	**4.42**	**4.5**

Patient Activity Self-Assessment

Treatment group participants were asked to rate their activity using a range of 1 through 5 with an answer of 5 meaning a high level of activity/influence/understanding and 1 meaning a low level of activity/influence/understanding with regard to activity. The numbers represent the mean score within each study Group.

Question	Group A (n=24/38)	Group B (n=14/38)
How much has your activity level increased since you enrolled in the study?	**3.33**	**3.71**
How much has participation in this program influenced your activity levels since you enrolled in the study?	**3.83**	**4.29**
How much has your understanding of the role of increased activity improved during participation in this study?	**4.29**	**4.29**

Analysis of Individual Blood Sugar Data (aka SMBG) obtained via participant use of the GlucoMON ® home telehealth/telemedicine device

78 treatment group participants successfully used their study issued blood sugar meters and transmitted data during the pilot using their study supplied GlucoMON telehealth appliance. The following table illustrates mean results within Group A (n=34) and Group B (n=17) of the 51 patients completing the treatment arm. Additionally, similar data is presented for the 27 patients who utilized the GlucoMON device but were not able to provide at least a valid entry A1c and valid exit A1c.

	Group A	**Group B**	**Incompletes**
	(n=34/78)	**(n=17/78)**	**(n=27/78)**
Mean of Standard Deviation	**34.3 (8.6-88.3)**	**56.9 (15.3-108.6)**	**43.0 (11.2-114.7)**
Average Daily SMBG Frequency	**1.8 (1.0-4.7)**	**1.8 (1.0 - 3.3)**	**1.4 (1.0 - 2.7)**

SMBG Notification Algorithm

31 participants SMBG profiles exceeded the study protocol definition for risk of either persistent hyperglycemia or hypoglycemia resulting in the transmission of a current Day over Day report to the MHS case managers.

	Group A	**Group B**	**Incompletes**
	(n=34/78)	**(n=17/78)**	**(n=27/78)**
Total # of participants triggered Notification	**9 of 34**	**14 of 17**	**8 of 27**
Average # of Notifications	**9.3**	**8.6**	**8.1**
Range in Frequency of Notifications	**1 - 38**	**1 - 39**	**1 - 44**

DISCUSSION

Physician Intervention Request Coordination

In response to a request from State of Texas HHSC, Healthimo designed and implemented a process for direct physician communication with the member's medical provider following the start of the pilot study. The purpose of this process was to identify patients with extended hyperglycemia, collect relevant and useful background information from the patient and notify the patient's provider of the event. Further, Healthimo requested feedback from the provider with the hopes of being able to close the loop regarding actions taken by the comprehensive and coordinated health care delivery team. The process utilized Healthimo's Continuity of Care Record (CCR) for Patient to Provider Request for Intervention.

There were a total of 72 Invitations faxed to the participant's providers. Of these, only 26% (19/72) returned the signed invitation indicating their agreement to work with their patients in the study and only in the event that the member's diabetes was identified as remaining outside of the acceptable range and over an extended time frame.

During the course of the pilot, there were a total of 17 events requiring the initiation of the risk-based Patient to Provider CCR. Two of these events were for members who had previously triggered a Patient to Provider CCR.

Of the 17 CCR events, four of these resulted in a fax to Healthimo from the provider summarizing the actions taken as a result of the CCR.

This facet of the pilot demonstrated that it is possible to leverage the pilot systems and processes as a mechanism for identifying risk, collecting additional data and engaging the

member's primary care provider. It also showed that willingness of physicians to participate is low especially given their lack of reimbursement related to the additional data and work created by the Patient to Provider CCR process.

Physician Interactions Survey

In an attempt to isolate all cause behavior and medication modification confounders on primary and secondary outcomes, Healthimo interviewed the study participants. Treatment group participants were asked to rate their physician interactions using a range of 1 through 5 with an answer of 5 meaning a high level of visits/modification/contacts and 1 meaning a low level of visits/ modification/ contacts. The numbers represent the mean score within each study Group. Some patients were not reachable for completing the following survey (6 in Group A and 1 from Group B).

Question	Group A (n=24/38)	Group B (n=14/38)
How many doctor visits have you "scheduled" during participation in this study?	**3.25**	**3.86**
How many doctor visits have you "attended" during your participation in this pilot?	**3.29**	**3.71**
To what degree has your physician prescribed any changes to your diabetes management since the enrollment survey?	**2.08**	**2.43**
How many times have you contacted your doctor about you having "high blood sugars" since you enrolled in this study?	**1.50**	**1.57**
How many times have you contacted your doctor about you having "low blood sugars" since you enrolled in this study?	**1.21**	**1.07**

Individual patient 'dosing of care' data was not available. Therefore, a survey was conducted to approximate the impact. The numbers represent the mean score within each study Group. Some patients were not reachable for completing the following survey (6 in Group A and 1 from Group B).

Question	Group A (n=18/24)	Group B (n=13/14)
Have the MHS Nurses called you more or less since enrolling in this study?	**2.94**	**3.69**

(1=much less, 3=about the same, 5=much more)

Other key drivers that could have influenced outcomes include the patient's physician including prescribed medication changes and the influence from Healthimo's diabetes education program. Self-reported data was collected for physician encounter frequency and complexity. Healthimo tabulated the frequency and complexity of the program interactions only for the treatment group members.

Home Diagnostic Screening as a Cost Effective Facet of the Pilot

At a very basic level, the random nature of recruiting from a population of Texas Medicaid members with previously diagnosed diabetes resulted in enrollment of nearly 40% of participants with an A1c below 7.0 indicating well controlled blood sugar. Blood pressure and cholesterol levels were not collected (home LDL cholesterol kits are available for a similar cost to the A1c blood sample collection kit as well as urine collection kits for testing micro

albumin levels to indicate early stage problems with the kidneys) during this pilot and could be utilized to assess whether or not these individuals truly warrant participation in a high cost disease management program at all. The cost to screen this population is roughly $50 per year per member as compared to the nearly $20/member per month fee for an enrolled member in the Enhanced Care diabetes program. Therefore, if screening were implemented across all members with diagnosed diabetes, net savings could potentially be on the order of $175/yr for those members with a screening A1c less than 7%. Following the screening step, additional markers can be used as the program is appropriately stair stepped toward ever increasing intensity and the accompanying cost of these more intensive interventions.

CONCLUSIONS

More participants in the treatment group vs. their control group counterparts improved blood sugar control as measured by A1c; the primary outcome measurement of the study. Based on survey data, participants in the treatment group also appeared satisfied with ease of use of the program tools and content indicating that this intervention is something they could utilize for many years thus answering the sustainability question.

The design of this pilot proved that it is possible to engage patients in Healthimo's data intensive program without ever having the patient leave their home or requiring a worker to visit the patient's home. This demonstration of Healthimo's ability to collect A1c data from Texas Medicaid members without leaving their home or visiting a health care provider office appears to have the potential 'to significantly expand access to care' given that the results are utilized in a way that provides feedback to the patient and in some cases their social supporters.

Developing low cost remote screening tools and methods as a facet of the existing disease management program shows the potential to significantly improve cost effectiveness of the overall program. Based on the cost of the screening portion of the study, the pilot was cost-effective.

Due to the dosing of care question it is difficult to assess the specific reason for the reduction in A1c for those participants entering the study with an A1c of 8 or greater. However, there was a clinically significant reduction in A1c for two other treatment groups in the study; those participants who enrolled with an A1c less than 8 (Group A) and those who entered the study

with an A1c between 7.0 and 8.9 (Group C) vs. their Control Group counterparts. Further, when the specific nature of the pilot interventions is considered, Group C (patients who enrolled with an A1c between 7 and less than 9) experienced an even greater clinically significant reduction in A1c favoring the treatment group.

Further studies are warranted and should pay special attention to tracking 'dosing of care' from all providers including the patient's physician, disease management programs or other health condition programs/support groups that the patient may be participating in.

ACKNOWLEDGEMENTS

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REFERENCES TO PRIOR RELEVANT RESEARCH

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