Diabetech® Research Summary

Active Disease Management (ADM)
Pilot Results

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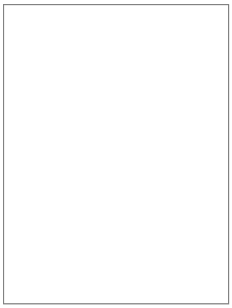

ADM Pilot Final Results

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Research Hypothesis
Through a combination of mobile diagnostic devices, a sophisticated real-time informatics rules engine and the establishment of patient-centric social networks, a DCCT/UKPDS style diabetes program can cost-effectively enable improved outcomes as an enhancement to the traditional provider-centric care delivery model.

Primary Outcome Measures
- Hemoglobin A1c was assessed prior to, during and at the conclusion of the pilot as a proxy for fewer complications, decreased health care cost and fewer work days missed.
- Participant Satisfaction measures to ensure that participants would be willing to voluntarily continue their use of the program over many years.

Research Methods
Non-Randomized, Control Group
Interventional
Phase 2 Translational Research

  - Given the interactive community based hypothesis to be tested, the Screening Group protocol provides some degree of control group insight.

Three protocols were designed to measure the impact of Diabetech's technology enhanced DCCT/UKPDS-style diabetes intervention programs:

  - Protocol #1 - type 1 Active Diabetes Management + social networking
  - Protocol #2 - type 2 Active Diabetes Management + social networking

- Protocol #3 - A1c Screening for type 1 and type 2 diabetes participants

** a $75 Incentive was given to all participants.*

Eligibility & Recruiting

The pilot was open to participation by up to 100 company employees and their adult and child dependents. Participants had to live in one of three cities in the Southeastern USA. The original goal was to recruit and enroll the first 50 consecutive participants (11 participants with type 1 and 39 participants with type 2). The Screening Group would be filled following complete enrollment of the type 1 and type 2 Active Group protocols with planning to accommodate up to 50 participants in the Screening Group.

- 148 responses to internal company newsletter announcement
- 50 Active Group participants enrolled
- 19 Screening Group participants enrolled

Enrollment

Active Group

- Enrollment included completion of the participant's health profile including the Problem Areas In Diabetes (PAID) behavioral psychology profile and their social network profile including contact information for their lay supporter and diabetes physician/nurse.
- Following Enrollment, the type 1 and type 2 Active Group participants were mailed a program Care Kit including:
  - 1 x GlucoMON® wireless glucose meter reporting device
  - 1 x OneTouch Ultra glucose meter manufactured by LifeScan, Inc.
  - 1 x HomeCheck A1c aqueous blood sample collection kit including postage paid return mailer for sending to healthcordia labs; one of only 9 level 1 laboratories in the US, for hematology screening and determination and reporting of A1c results to the Principal Investigator.
  - 1 x pedometer
  - 1 x tape measure
  - 1 x Personalized Local Activities Map (City Specific)
  - 1 x Active Diabetes Management Care Guide
  - 1 x Step-by-step Care Kit Instruction Guide

Screening Group

- Following Enrollment, the A1c Screening Group participants were mailed:

- 1 x HomeCheck A1c aqueous blood sample collection kit including postage paid return mailer for sending to healthcordia labs; one of only 9 level 1 laboratories in the US, for hematology screening and determination and reporting of A1c results to the Principal Investigator.

Monitoring

While participants with both type 1 diabetes and type 2 diabetes received the same enrollment packages and tools, the rules engine and interventions are finely tuned to address specific differences.

Participants in the type 1 protocol were requested to check blood glucose levels by finger stick (SMBG) a minimum of 4 times per day. Actual results were analyzed by the system in real-time with resultant feedback options including temporary SMBG frequency tagging and education automatically delivered based on this analysis via the participant's email account and/or cell phone as a text message.

Participants in the type 2 protocol were requested to check SMBG a minimum of once per day for at least 5 days out of each week. Actual results were analyzed by the system in real-time with resultant feedback determinations made which also considered the participant's temporary SMBG frequent or infrequent tag. Relevant education was then automatically delivered to the participant (and in some cases the participant's social network) based on this analysis via the participant's (or social network member's) email account and/or cell phone as a text message.

The educational content that makes up Diabetech's content library has been sourced from various published repositories and directly from an internationally recognized advisory board honoring copyright and established research. The content addresses 3 categories:

- blood glucose monitoring guidelines, training and rationale
- Medical Nutrition Therapy (MNT) – aka: diet and food choices
- activity and its metabolic impact (never exercise)

Both groups of participants used a OneTouch® Ultra meter to check their blood glucose. The specially adapted GlucoMON®-ADMS™ device allows participants to easily transmit glucose values in real-time to the centralized monitoring system (ie-GlucoDYNAMIX™-ADMS) via Diabetech's nationwide wireless network. (*Beginning in October 2007 Diabetech migrated their system to operate over the AT&T GSM/GPRS global network.*)

The GlucoMON® device was also used to ensure accurate timestamps of the blood glucose checks by automatically synchronizing the glucose meter's internal clock with each usage. There was one time change affecting the participants in this pilot. All glucose meter clocks were automatically adjusted for the Fall 2006 time change to Eastern Standard Time.

Interventions

Feedback was delivered to the participants in very similar fashion. The logic behind the interventions were however much different between the type 1 protocol and the type 2 protocol.

Daily	Day-Over-Day Blood Sugar Trending Report
Every 4th Day	Dynamically Derived Educational QuickTips
Monthly	Surveys
Quarterly	Newsletter
Quarterly	A1c Sample Collection Kit mailed to participant's home
Quarterly	A1c Results Reporting to participant
Infrequently	Technical Support phone call and/or email
*Real-time Alerts	Cell Phone Glucose Notification from Child to Parent • 2 child dependents in the type 1 protocol only

Incentive

The original protocol and informed consent included a promise of a $75 gift card to participants who successfully completed the first 90 days of participation according to minimum behavioral participation requirements:

- minimum self-check frequency according to protocol
- timely A1c submission via home kit or via survey response either online or via fax.
- monthly survey completion either online or via fax.

These measures were not outcome dependent.

Research Results & Analysis

Population A1c Change

- Average A1c change across all Active Group Participants was -0.92 Percent A1c (n=33).

- Average A1c change across all Screening Group Participants was -0.07 Percent A1c (n=12).

Segmentation Analysis

The participants were stratified for analysis according to their Entry A1c. In the event that a participant did not have a pre-program A1c, their first A1c in the program was used as their Entry A1c.

Active Group Participation

- At least one A1c was reported for 38 of the 50 participants
- 35/50 (70%) participants self-reported their pre-pilot A1c
- 15/50 (30%) presumably did not remember their last A1c while several were not aware of the A1c diagnostic test and its role in diabetes care.
- 29/50 (58%) reported/completed an initial A1c at the start of the pilot
- 30/50 (60%) obtained a second A1c at the midpoint of the pilot
- 28/50 (56%) obtained a third A1c at the conclusion of the pilot
- 33/50 (66%) reported/completed at least 2 A1c results with at least 180 days of separation between Entry A1c and Exit A1c

Active Group Results

- 50 people enrolled in the Active Group
- 16/50 (32%) did not participate in the program following enrollment
- 34/50 (68%) actively ***participated*** in the Active Group
- 1 person in the Active Group was not able to provide quality A1c data and is therefore not included in the final results analysis.
- 33/50 (66%) of the Active Group had quality entry and exit data leading to the following results:

A1c Results

- 13/33 (39%) had a significant reduction (A1c $\geq$ 1.0)
- 9/33 (27%) had a less significant reduction (0.3 $\leq$ A1c < 1.0)
- 3/33 (9%) had an increase in A1c $\geq$ 0.3

Participant Satisfaction Results

- 29/33 Active Group participants replied to a Satisfaction Survey designed to obtain feedback relating to their impression of the program in a) ease of use, b) sustainability and c) effectiveness:

    - 4/33 (12%) participants did not complete the survey
    - 26/29 (90%) of participants rated the program as ***most likely(that they would continue)*** or ***absolutely*** satisfied in

every category when asked if they would continue in the program over many years.

- 22/29 (76%) gave the highest rating (absolutely) for both ease of use and effectiveness.
- 20/29 (69%) gave the highest rating for sustainability.

Active Group Test Frequency Analysis

- Test frequency turned out to be an outcome enabler rather than a reportable statistic. Increased test frequency was observed in many of the participants with lower A1c but was generally episodic in nature. This may indicate that increased test frequency is useful during the knowledge acquisition phase but that it is not always directly correlated to improved outcomes as measured by the A1c within the same timeframe. In other words, there is a time lag between knowledge gained and our ability to measure the application of the newly obtained knowledge base.
- In some cases, decreased frequency was also observed with corresponding reduction in A1c. Due to guidance from the program, smarter and more strategic time of day testing may be more useful than an increase in the frequency of random time of day testing.
- Further study will be necessary to better understand the relationships between test frequency and improved blood sugar control.

Screening Group Results

- 19 people enrolled in the Screening Group
- 12 people ***participated*** in the Screening Group (HomeCheck-A1c Test only).
- 12/19 (63%) of the Screening Group had quality entry and exit data leading to the following results:

A1c Results

- 1/12 (8%) had a significant reduction (A1c $\geq$ 1.0)
- 6/12 (50%) had a less significant reduction (0.3 $\leq$ A1c < 1.0)
- 2/12 (17%) had an increase in A1c $\geq$ 0.3

Participant Satisfaction Results

- The intent was to minimize interaction with the Screening Group. Therefore, a satisfaction survey was not offered.

Study Conclusions

- The participant satisfaction results show a strong interest by the participants to seek assistance from a program of this design for assistance in managing their diabetes. (Satisfaction, Effectiveness and Sustainability were due to Diabetech's unique programs and technology - not just a diabetes program in general.)

- Studies of this nature are typically based on a sample size starting with +/- 30 subjects. Given that the sample size was 50 and that quality data was collected from over 30 participants (with an additional 12 participants from the screening group adding support for testing the impact of the Active Group pilot design), results obtained from this pilot can be reasonably extended to the greater diabetic population of both type 1 and type 2 diabetes.

- The correlations between reductions in A1c and near term and long term healthcare system costs and lost productivity costs to employers have been extensively studied and documented in previous research. The significant reductions in A1c observed in this study by a vast majority of the active group participants vs the control group indicates that an expansion of this program will in fact deliver significant cost savings to the health plan and significant reductions in lost productivity for the employer.

Study Implications

"These data raise numerous questions as to the role of enhanced patient-centric care in the management of diabetes mellitus. Current paradigms for diabetes management focus on the physician or specialist-health care team.

Eighty percent of all diabetes care in the United States is delivered from primary care providers in this fashion (family practitioners, internists, pediatricians, OB/GYN and generalists). Poor reimbursement for diabetes medical care is viewed as a loss leader by many physicians that lowers provider enthusiasm for aggressively managing diabetes. Reasons for this include 1) the lack of access to behavioral and educational resources for patients, 2) presence of co-morbid conditions that compete for diabetes-specific management in a time limited clinical encounter, plus 3) an expanding array of new pharmacologic and diabetes self management tools to understand, master, and apply.

Ultimately, the rate limiting factor for successful diabetes outcomes lies with the patient and the environment within which they exist.

This pilot study raises exciting questions as to how to approach the management of diabetes as a socially driven (or at least strongly influenced) disorder."

- Stephen Ponder MD, FAAP, CDE
  (Member of the Diabetech Medical Advisory Board)