Original Project Title
Patient-Centered Online Disease Management Using a Personal Health Record System

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Abstract

Purpose

To evaluate an online disease management system managed by a multi-disciplinary health team supporting patients with uncontrolled type 2 diabetes.

Scope

The study included 415 patients from a large, multi-specialty, community-based group practice with type 2 diabetes and baseline A1C values $\geq$ 7.5%.

Methods

The project team conducted a 12-month randomized controlled trial of online disease management compared to usual care. The intervention included: 1) wireless upload of home glucometer readings to the patient's electronic health record with graphical feedback correlated to other parameters; 2) comprehensive patient-specific Diabetes Summary Status Report; 3) nutrition and exercise logs; 4) insulin record; 5) online messaging system with the patient's health team; 6) nurse care manager and dietitian who provided advice and medical management; and 7) patient-specific text and video educational "nuggets" dispensed electronically by the care team. The primary outcome variable was A1C.

Results

Compared to usual care (UC), patients in the intervention (INT) group had significantly reduced A1C at 6 months (-1.32 % INT vs. -0.66% UC; $p<0.001$). At 12 months, the differences were not significant (-1.14% INT vs. -0.95% UC; $p=0.133$). Significantly more patients in the intervention group improved control of their diabetes ($\geq$ 0.5% reduction in A1C) than usual care at 12 months (69.9 (95% CI 63.2, 76.5) INT vs. 55.4 (95% CI 48.4, 62.5) UC; $p=0.006$).

Key Words:

diabetes mellitus type 2, disease management, telemedicine, health information technology, case management, personal health record, electronic health record, glycosylated hemoglobin, computerized medical record system

PURPOSE
We conducted a randomized clinical trial to evaluate whether an online disease management (ODM) system used by a multidisciplinary health care team could improve the control of diabetes in patients with diabetes compared to usual care. The project specifically focused on three aspects of patient-centered care: patient self-management, patient-clinician communication, and providing access to medical information to patients and their care team.

Specific aims: The specific aims of the proposed project were three-fold:

1. To refine a **Customized, Continuous Care Management (CCCM) now called the Personal Health Care Project (PHCP)** model with a particular focus on enhancing the customization capability of the ODM system and ensure a seamless incorporation of ODM into the work flow of clinicians on the Care Management team.

2. To evaluate the PHCP program, relative to usual medical care (UC), in a 2-arm randomized controlled trial (RCT) of 400 patients with A1C$\geq$ 7.5% in a large, community-based, multispecialty ambulatory care setting. We refer to the clinical trial as EMPOWER-D (Engaging and Motivating Patients Online With Enhanced Resources for Diabetes). Our **primary hypothesis** was that patients in PHCP would have lower A1C at 12 months post-randomization than those in UC. We expected an incremental 0.5% decrease or greater in A1C for PHCP compared with UC. Secondary outcomes included blood pressure, lipids, overall cardiovascular risk, processes of care, changes in patient self-management, experience and satisfaction, and psychosocial well-being. Finally, health care utilization of all participants (PHCP and UC) was examined.

3. To disseminate results of the RCT in the scientific literature and to deploy the PHCP program in the Palo Alto Medical Foundation (PAMF) and other ambulatory care settings for use with diabetes and other chronic conditions. We intend to disseminate PHCP internally by transitioning it to an ongoing PAMF-supported program and extend its use with other chronic diseases (*e.g.,* heart failure), and other chronic conditions, (*e.g.,* prediabetes).

SCOPE

Background
Diabetes mellitus is the seventh leading cause of death in the United States and has been identified as a priority area for transforming health care by the Institute of Medicine (http://www.ahrq.gov/qual/iompriorities.htm).[1] An estimated 25.8 million Americans are living with this chronic condition.[2] The prevalence is projected to increase to 39 million by 2050. Most of the expected increase will be in type 2 diabetes mellitus, which accounts for 90 to 95% of all diagnosed cases of diabetes.[3]

Although there has been steady improvement in the proportion of diabetic patients achieving recommended levels of A1C, blood pressure, and LDL cholesterol in the last 10 years, in some studies only 57.1% of adults with diagnosed diabetes achieved an A1C of less than 7%, only 45.5% had a blood pressure less than 130/80 mmHg, and just 46.5% had a total cholesterol of

less than 200 mg/dl, with only 12.2% of people with diabetes achieving all three treatment goals.[4] The potential for further improvements in diabetes care remains substantial.

Patient engagement is fundamental in developing chronic disease management approaches. Without such patient engagement, even the best practitioners or care teams will fail to deliver significant improvements in the desired outcome.[5] Typical self-management education programs incorporate a combination of group classes, one-on-one visits, support groups, and followup visits. Traditional programs rely mainly on in-person visits, and phone contact for patient-provider interactions.[6] Given its clinical significance and societal impact, diabetes presents a model disease in which to study novel paradigms for chronic disease management and to engage patients in better management of their own healthcare.

Personal health records (PHR) are one type of patient enabling technology, presenting an opportunity for patients to access and understand their personal clinical data.[7] We have developed a PHCP model that includes an online disease management (ODM) system that supports a multidisciplinary health care team consisting of a nurse care manager (NCM), a clinical pharmacist, a registered dietitian (RD) and the patient's physician(s). The ODM system is integrated with a comprehensive electronic health record (EHR) system that includes a personal health record (PHR) and secure patient-clinician messaging capabilities. By leveraging information available in the EHR and PHR, the NCM incorporates patient values and needs with clinical guidelines to create and update customized care plans and support patient self-management, which has been identified as a priority area for transforming health care by the Institute of Medicine (http://www.ahrq.gov/qual/iompriorities.htm).

METHODS

Setting, Participant Identification, and Recruitment
This study was conducted at the Palo Alto Medical Foundation (PAMF), a not-for-profit health care organization. PAMF provides care across three health care divisions (Palo Alto, Camino, and Santa Cruz) in 35 locations in the San Francisco Bay Area region of Northern California. The affiliated Palo Alto Foundation Medical Group is the 8th largest medical group in the United States; more than 1,000 physicians in more than 40 specialties practice at PAMF, 52% of who deliver primary care. Annually, PAMF cares for over 700,000 patients. Patients for EMPOWER-D were recruited from 10 of the 35 clinics.

Currently, approximately 70% of adult patients of PAMF have logged in to the PAMF PHR, MyHealthOnline (formerly PAMFOnline). MyHealthOnline includes many features including access to their active medication lists, active problems, and customized decision support alerts about chronic disease management and preventative care maintenance.[7, 8] Proxy access to the PHR of an adult patient at PAMF is available to designated family members when appropriate health care proxy documentation is in place.

PAMF patient records were initially reviewed to identify potential study participants based on the following criteria:
- Age $\geq$ 18 years
- Diagnosis of type 2 diabetes mellitus (T2DM) on current medical problem list

- Hemoglobin A1C ≥ 7.5%
- Patient had been seen by a primary care physician (PCP) or specialist at PAMF at least once in the past 12 months

Patients were excluded based on the following criteria:
- Initial diagnosis of T2DM within the last 12 months
- Inability to speak or read in English
- Lack of regular access to a computer with Internet and email capabilities
- Unwillingness to perform any self-monitoring at home, including blood glucose and blood pressure
- Diagnosis of a terminal illness and/or entry into hospice care
- Pregnancy, planning a pregnancy, or currently lactating
- Current enrollment in a care management program at PAMF or elsewhere
- Family household member already enrolled in EMPOWER-D Study
- Resident of a long-term care facility
- No longer receiving primary care from PAMF or planning to leave within the study period
- Uninsured

Table 1 provides and updated table with the final distribution of our enrolled participants.

Table 1: Enrollment Table for Recruited Participants

SUBJECT ACCRUAL				
Ethnic Category	**Sex/Gender**			**Total**
	Females	**Males**	**Unknown or Not Reported**	
Hispanic or Latino	18	34	0	**52**
Not Hispanic or Latino	146	210	1	**357**
Unknown (Individuals Not Reporting Ethnicity)	2	4	0	**6**
Ethnic Category Total of All Subjects*	**166**	**248**	**1**	**415**
Racial Categories				
American Indian/Alaska Native	1	3	0	**4**
Asian	22	67	0	**89**
Native Hawaiian or Other Pacific Islander	3	3	0	**6**
Black or African American	11	10	1	**22**
White	108	136	0	**244**
More Than One Race	0	0	0	**0**
Unknown or Not Reported	21	29	0	**50**
Racial Categories Total of All Subjects*	**166**	**248**	**1**	**415**

Of the potential study participants identified through the EHR system and approved by their physician to be invited to participate in the study, 1,594 patients were contacted and agreed to participate in the online screening questionnaire. Of the patients screened, 768 (48.2%) met inclusion criteria and 415 patients consented to participate in the study (See Figure 1). Two hundred and two (48.7%) patients were randomly assigned to the intervention group and 213 (51.3%) were assigned to the usual care group. To achieve the statistical power targeted for the study, recruitment continued until the group with the smaller number exceeded 200. See **Table 1** for demographic data on all screened individuals.

Participants were randomly assigned to the PHCP intervention or usual care (UC) group on a 1:1 basis. A randomization program based on Pocock's "minimization" procedure[9] was used to assure better-than-chance group balance for the following key variables: site, age, gender, levels of A1C, systolic blood pressure, LDL cholesterol, and pre-enrollment PAMFOnline status (user vs. non-user).

Figure 1: Recruitment Diagram

EMPOWER-D 2008-2011 Flow Diagram
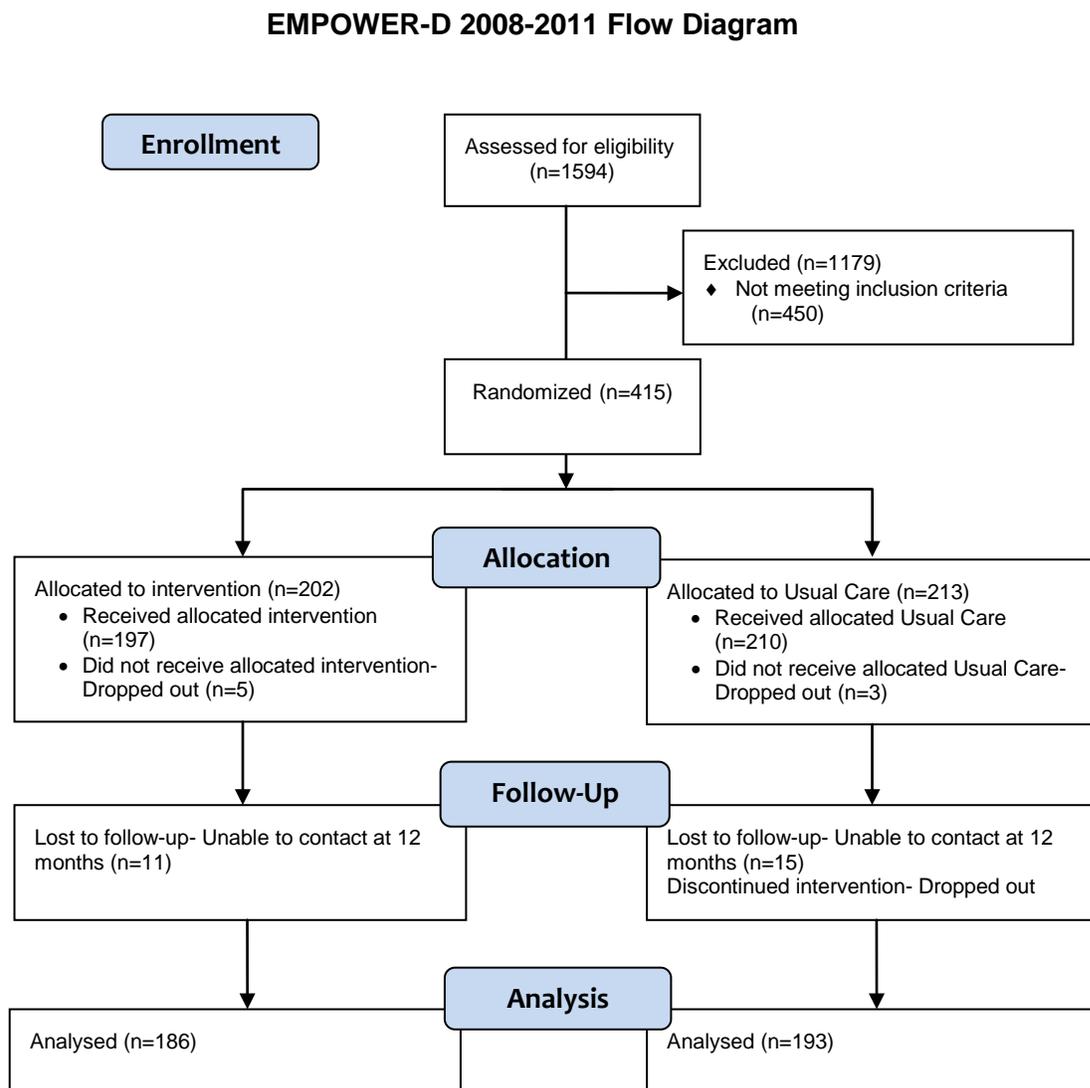
Baseline Patient Characteristics

Overall, more than 70% of PAMF patients are using MyHealthOnline and are well-educated and score highly on health literacy measures. The demographic characteristics and baseline clinical measures were comparable between the two groups (Table 2). The mean A1C for the intervention (INT) group was 9.24% compared to 9.28% for the usual care (UC) group, which was not statistically different (p = 0.79). Secondary outcome measures (e.g., LDL, blood pressure, weight, Framingham risk) were also similar at baseline between both groups (p-values between 0.33 to 0.99).

Table 2: Comparison of Baseline Characteristics by Randomization Group

	Mean (STD) or %		
	UC	Intervention	P-value
Demographics			
Mean Age	53.6 (10.1)	54.0 (10.7)	0.710
% Female	39.0	41.1	0.659
% White	57.8	59.9	0.656
% Hispanic	10.8	14.4	0.274
% Married	76.5	76.2	0.945
% whose PCP opt out of DM program	3.8	4.0	0.914
% any insulin	47.0	45.5	0.774

Data Collection
Data was collected directly from patients during clinical visits, using an online survey completed behind our firewall as well as electronic chart review and data collection processes to record extant data in their electronic health record (EHR) reflecting process of care and completion of preventive health care recommendations. All data was maintained in an ACCESS database and reports were generated weekly to identify data collection required and completed.

Primary outcomes
The primary outcome of the EMPOWER-D study was glucose control over a 12-month period. It was hypothesized that participants managed through the ODM would show greater reductions in their A1C levels over 12 months than those participants randomized to the Usual Care group. We expected an incremental 0.5% decrease or greater in A1C for PHCP compared with UC.

Secondary outcomes
Secondary outcomes of the EMPOWER-D study included cardiovascular risk, processes of care, patient self-management, self-management experience and satisfaction, and psychosocial well-being. It was hypothesized that participants managed through ODM would have lower cardiovascular risk (*e.g.*, blood pressure and lipids) and better processes of care (*e.g.*, medication management) at 12 months than those in UC. In addition, it was hypothesized that participants would have improved self-management practices (*e.g.*, medication adherence, consistent home monitoring of glucose and blood pressure, and healthier decisions re: diet, and exercise), heightened experience and satisfaction (*e.g.*, CAHPS), and enhanced psychosocial well-being

(*e.g.*, diabetes-related emotional distress) at 12 months than those in UC. Finally, health care utilization of all participants (PHCP and UC) was documented for the periods of time directly before, after, and during the EMPOWER-D study using the EHR.

Outcome measures
The biomedical measures of A1C (primary outcome), fasting glucose, lipids, and microalbumin, were obtained using standard techniques at on-site PAMF laboratories. Study blood pressure procedures and equipment followed the recommendations of the American Heart Association for blood pressure measurement in humans. All of these measures were taken at baseline, 6 months, and 12 months during visits with blinded study staff.

Patient self-reported data was collected using a single questionnaire (containing all scales) at baseline and 12 months, and an abbreviated version of the questionnaire was administered at 6 months. The complete questionnaire included questions or scales measuring patient diabetes knowledge, attitudes, behavior, mental health, self-management experience and satisfaction, and demographic information.

Patient knowledge of diabetes was assessed using a variation of the Diabetes Knowledge Test (DKT), which has a 14-item general test of knowledge about diet, glycemic control, glucose testing, and diabetes complications and a 9-item insulin-use subscale. Questions from the 9-item insulin-use subscale were reworded to be applicable to non-insulin users; three questions were removed from this subscale. The *Problem Areas in Diabetes (PAID)* scale was used to measure diabetes-related distress; the instrument had respondents rate the degree to which each of 20 common situations was currently problematic for them.[10] The brief 9-item *Patient Health Questionnaire (PHQ-9)* was used to measure severity of depression in study patients.[11]

To measure patient self-management experience and satisfaction throughout the study, the *Diabetes Treatment Satisfaction Questionnaire (DTSQ)* was used. The 8-item status version (DTSQs) was used to make the initial assessment of total diabetes treatment satisfaction, treatment satisfaction in specific areas, and perceived frequencies of hypo- and hyperglycemia. The 8-item change version (DTSQc) consisted of the same questions but was slightly reworded to assess change in satisfaction rather than absolute satisfaction. Individual questions were included to capture self-management behaviors related to frequency of home glucose monitoring, medication adherence, and diet and exercise habits. This version was administered in the 6-month and 12-month followup questionnaires. The *CAHPS® Clinician & Group Survey* was adopted to assess patient experience in: access to care; clinician communication; shared decisionmaking; and cost of care.

Patients completed this questionnaire at baseline, 6-, and 12-month points in the study prior to meeting with a research assistant (RA) blinded to the group status of each study participant. Once completed, in-person visits were held with an RA at baseline, 6- and 12-month. During these in-person visits the RA collected clinical measurements (i.e. blood pressure, weight, height, and waist circumference) and facilitated collection of the laboratory work. Adverse event information was collected and reported at each of these visits. Following randomization, those in the UC group continued to see their primary care provider (PCP) and received usual care.

INTERVENTION

The Personalized Health Care Program (PHCP) was developed as a model of patient-centered care with many of the components known to be included in effective consumer health IT[12] including, responsiveness to the needs and preferences of individual patients, continuous, convenient, online access to health records, and frequent communication with clinicians.

Clinical Intervention Protocol

Those participants randomized to the intervention group were scheduled for three in-person visits. The first visit oriented participants to the online tools to access their health information using the MyHealthOnline patient portal, the online monitoring tools, and data uploading procedures used in the study. The second meeting was a 90-minute, one-on-one consult with a NCM. At this meeting, the NCM assessed the patient's current diabetes knowledge, assessed the patient's current diabetes control, and then created a plan with the patient to improve diabetes control (via selection of self-management goals related to lifestyle and medication regime). At this visit, the patient's medications and supplements were reviewed extensively with the patient, and adherence was assessed. The third visit was with a registered dietician (RD) where the RD assessed the patient's nutrition knowledge and goals, provided medical nutrition therapy, and supplied the patient with the wireless tools and taught him or her how to use those tools. Depending on individual patient needs, some patients were seen for additional in-person visits with a NCM and/or RD.

During the 12-month intervention period, NCM's followed internal protocols created for the management of type 2 diabetes, hypertension (in diabetes), and dyslipidemia (in diabetes). Medications were initiated and discontinued with PCP or endocrinologist approval only, but NCM's independently titrated existing medications, ordered followup laboratory measures, and monitored effectiveness of the treatment plan.

Between the first and second visits, a PAMF pharmacist reviewed the patient's medical chart. This chart review was used to identify duplicate medications, identify negative drug interactions, and offer potential recommendations on titrating medications related to management of DM, HTN, and dyslipidemia. The pharmacist was consulted by the NCMs as needed throughout the year.

Use of Health Information Technology to Support Patients with Diabetes

PAMF developed an ODM system to provide patients with personalized tools to manage their health. We used the ODM system, which is integrated with our CCHIT-certified, comprehensive EHR and PHR system in the EMPOWER-D clinical trial. The ODM system uses pattern matching technology to process a wide range of patient-specific data inputs, which include clinical parameters (*e.g.*, laboratory results, medications, clinical findings), demographics, disease-related knowledge, attitudes (*e.g.*, distress, self-efficacy), and behavior (*e.g.*, medication adherence, diet, physical activity, self-monitoring), to produce a composite characterization of a patient's state. The EMPOWER-D team used this composite state to create a tailored care plan, *MyPlan*, which includes evidence-based recommendations for treatment and self-monitoring and

provides patient-centered self-management support and surveillance. In addition to customizing the treatment plan, the system enables automation of many labor intensive steps in the care management process.

Key Features of the Online Disease Management (ODM) System
The ODM system was designed to be a sustainable, scalable chronic disease management platform that personalized the care of the patient, supported by technological innovations. Patients were encouraged to develop an online relationship with their care management team to support active communication about their disease processes after initial in-person visits. This framework facilitated close monitoring of these patients, sometimes on a daily basis. For example, patients were given timely, regular feedback about their clinical parameters (such as blood glucose readings, food intake, and insulin doses) and their overall progress in the program.

One of EMPOWER-D's core objectives was to empower patients with a better understanding of their disease processes and prompt them to take a more active role in self-management. To that end, patients were provided both an enhanced personal health record experience and wireless remote monitoring tools to amplify opportunities for teachable moments.

- **Wireless Remote Disease Monitoring**
  In order to simplify data capture of glucometer readings for patients, research staff collaborated with iMetrikus (Mountain View, CA) to develop a Bluetooth® adaptor that wirelessly transmits annotated (e.g., before meals, after exercise) glucose readings from Lifescan OneTouch® Ultra®2 glucometers to a smartphone (Palm Treo™) that subsequently uploaded the information to our EHR, EpicCare, by Epic Systems (Verona, WI). Upon upload, these data are immediately available for viewing by the patient via the PHR and is analyzed by the ODM system according to patient-specific parameters.

- **Lifestyle and Disease Management Self-Monitoring Data Logs**
  The PHR had structured forms in which the patient could enter information relevant to diabetes management (e.g., dietary intake, physical activity, home blood pressure, insulin doses, weight). Data entry logs were customized for individuals (See Figure 2). Other information, such as type of exercise and minutes of exercise, could also be entered. Interactive visual displays of this data allowed patients to visually track progress towards goals (e.g. physical activity targets for a week) and correlate glucose control with medication compliance or successful lifestyle changes.

- **The Diabetes Status Report**
  The diabetes status report illustrated the key parameters of diabetes care so that patients could see the important parameters that affected their risk of long term complications and the medications and preventive services that reduced their risks.

  o **An Action Plan** – The PHCP approach was to dynamically modify the action plan based on the evolving needs of the patient and partnership with the NCM. The action plan could leverage other tools available in the PHR, such as the physical activity log. Patient action plans were prominently displayed at the top of the Diabetes Status Report (See Figure 3).
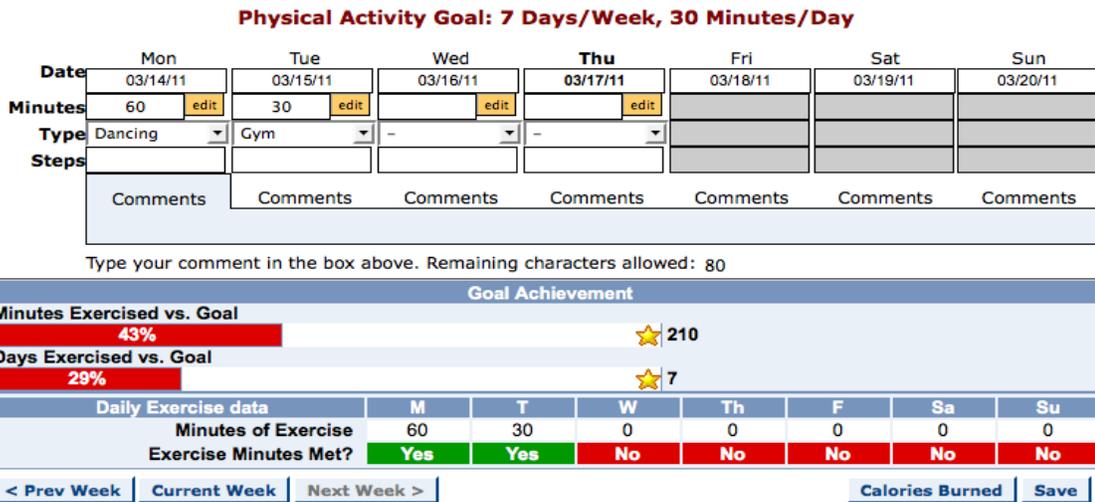
Figure 2: Monitoring Physical Activity – Screenshot of physical activity log and graphical progress towards the patient's goal
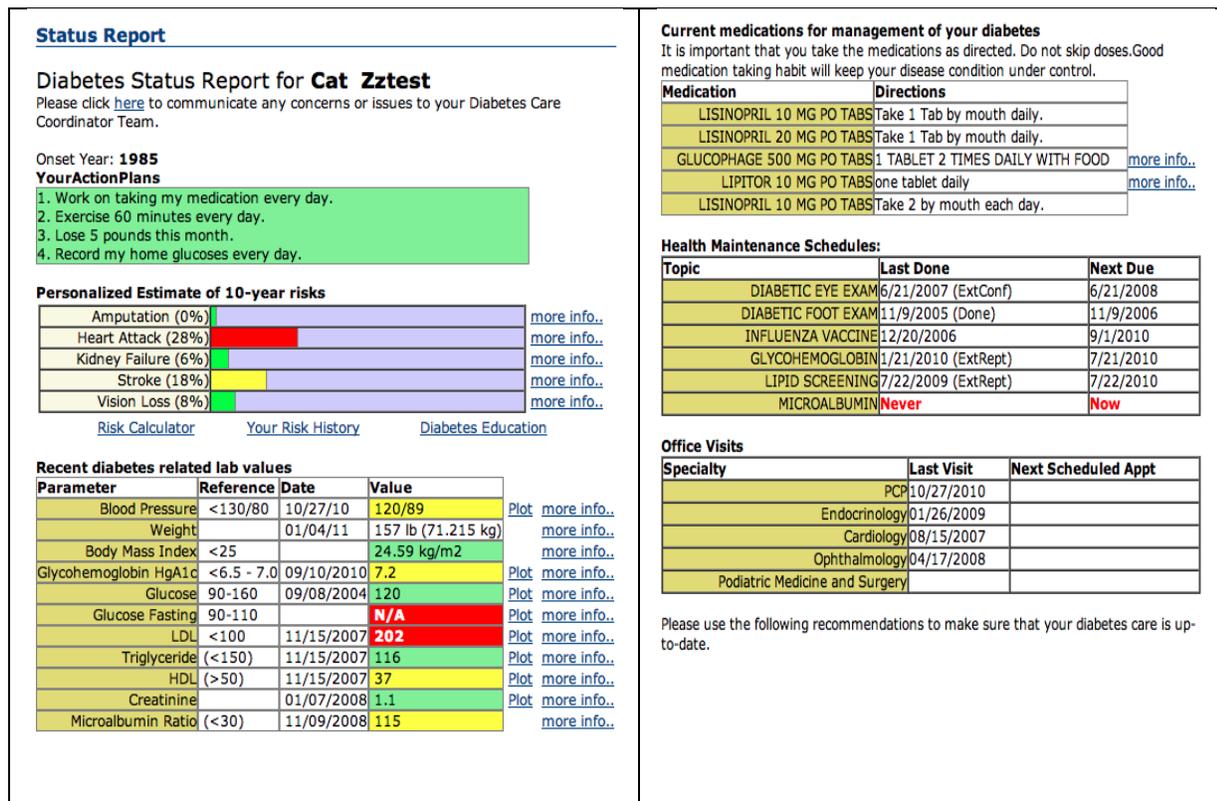

Figure 3: Diabetes Status Report – Screenshot of a summary report of the patient's treatment goals, risk factors, relevant laboratory test results, relevant medications, diabetes-related health maintenance schedule, and medical office visits

- o **A morbidity risk calculator** – Using a verified disease model for complications of diabetes (Diabetes S.E.T. for Success^{TM} Version 2.0, Medicom Digital and GlaxoSmithKline), patients received tailored 10-year risk scores for diabetes-related complications (e.g. cardiovascular events, amputation) based on their personal data in the EHR. Patients could visualize risk reduction in the calculator with projected changes to clinical parameters such as improved A1C or tobacco cessation. The nurse care managers reviewed online tools with each patient, clarifying any features or medical vocabulary that might have been unclear to the patient.
- o **Vital signs** – Blood Pressure, Body Mass Index, Weight
- o **Laboratory values** – hemoglobin A1C, kidney function, lipids
- o **Medications targeting management of diabetes and its cardiovascular complications**
- o **Health care maintenance recommendations with prominent displays of overdue items**
- o **Upcoming clinical visits related to diabetes care**

- **Customized Multi-Media Patient Care "Nuggets"**
  Personalized patient-content, also known as nuggets, were generated by the PHCP platform in response to incoming data from the patient via the PHR or remote monitoring devices and the EHR. PREDICT™ scenario-based technology (Enigma CKM, Inc) was used to incorporate each patient's critical determinants (clinical parameters, demographic characteristics, disease-related knowledge, attitudes and behaviors) to trigger the selection of one of the 500 pre-defined CM scenarios that best matched the patient state. The selected CM scenario included specific, logical rules that prompted NCMs to send custom-tailored, dynamically-generated responses, known as "nuggets," by secure messaging. These responses included text, hyperlinks, graphs, audio messages and videos that were electronically delivered to the patient after a clinical event trigger, providing education, motivation, encouragement or resources, as needed. For example, in response to a hypoglycemic reading submitted via the remote glucometer device, the patient received a short personalized video nugget educating about the dangers and prevention of hypoglycemia. A sample video nugget can be viewed at https://hra.sutterhealth.org/videohosting/launch.cfm?video=AhVxW%2Fqvcmc%3D.

Throughout the intervention period, patients received regular check-ins from the NCM and RD via secure messaging, unless patient strongly preferred phone contacts. Check in times varied from 1 to 4 times per month during the first three months of the intervention, and was individualized thereafter based on patient need for the duration of the project.

Statistical Methods

Two-sample t-tests and Chi-square tests were used to test for differences in demographic and clinical characteristics at baseline between the PHCP and UC groups. For each dependent variable, mixed effects regression models were used with 6- and 12-month followup while adjusting for the baseline value. For each model, a random effect for patient was included to account for within patient correlation. In the models, time was included as a categorical variable; with time, intervention status and their interaction included in the model as fixed effects. Appropriate contrasts were used to estimate and test the intervention effect at each time

point. For several of these comparisons where the data was highly skewed, the Kruskal-Wallis test was applied instead of ANOVA. All analyses were performed using SAS version 9.2.

For certain analyses, we categorized patient outcomes into four groups based on change in A1C values at 6 and 12 months. Improvement was defined as 0.5% decrease in A1C and we performed a sensitivity analysis using 1.0% decrease in A1C to define improvement. Chi-square tests and ANOVA were applied to test for differences in demographic and intervention related measures (i.e. logins, uploads, and glucose readings) between the four improvement groups for the intervention patients.

RESULTS

Primary Outcome

Compared to usual care, participants in the PHCP intervention group had significantly better control of their diabetes as measured by A1C at 6 months (-1.32 % INT vs. -0.66% UC; $p<0.001$). At 12 months, the reduction in A1C in the intervention group was greater than the reduction in the UC group, but was not statistically significant (-1.14% PHCP vs. -0.95% UC; $p=0.133$). In a secondary analysis, significantly more patients in the intervention group improved control of their diabetes (defined as $\geq 0.5\%$ reduction in A1C) than usual care at both 6 months (70.3 (95% CI 63.6, 76.9) INT vs. 53.4 (95% CI 46.3, 60.6) UC; $p=0.002$) and 12 months (69.9 (95% CI 63.2, 76.5) INT vs. 55.4 (95% CI 48.4, 62.5) UC; $p=0.006$). The percentage of patients in each group with greater than 1% reduction in A1C was not statistically different.

Secondary Outcomes

The intervention group patients had significantly better control of their LDL cholesterol at 12 months, compared to usual care (-6.1 mg/dl INT vs. 0.0 mg/dl UC; $p=0.001$). There were no statistically significant differences between the usual care group and the intervention group at 12 months for blood pressure (systolic or diastolic), weight, or Framingham risk. Regarding medication management, there was a significant increase in the number of medication orders (1,312 INT vs. 1,158 UC; $p=0.02$), number of insulin orders (336 INT vs. 170 UC; $p=0.002$), number of times the diabetes medication regimen was intensified (563 INT vs. 401 UC; $p=0.001$), and number of times insulin doses were increased (227 INT vs. 90 UC; $p=0.001$) in the intervention group compared to usual care. There were no significant differences between the two groups in number of insulin orders with decreased doses or changes in lipid medication orders.

There were no significant differences in the number of total physician visits (3.5 INT vs. 3.3 UC; $p=0.53$) or physician visits for diabetes (2.4 INT vs. 2.3 UC; $p= 0.46$) between the intervention group and the usual care group. There was no significant difference among the groups for hypoglycemic home readings (glu < 70) or severe hypoglycemia (glu < 60). From the CAHPS-CG survey, PHCP patients were significantly more likely to report always having better access to care ($p=0.018$). Collected CAHPS-CG survey data were not shared with the National CAHPS Benchmarking Database (NCBD) because we only used relevant subsets of the CAHPS survey.

Intervention patients were also more likely, but not significantly, to report that their clinician always was easy to understand, listened to them, gave easy instructions, was knowledgeable, respectful, and took enough time with them (p=0.092). Responses to other CAHPS questions were similar between the intervention and usual care groups.

Over 61,000 home-monitored glucose readings were uploaded by participants in the intervention group over the course of the study. Patients maintained ongoing care management relationships with the care team, communicating consistently throughout the study. A total of 2,625 MyHealthOnline secure messages and 151 phone calls were initiated by patients over the 12-month intervention. The total time spent by the NCM and RD during the intervention ranged from 1 to 18 hours per patient, with an average of six hours per patient, including all remote contact as well as individual and group sessions (on average, group sessions occupied 4.5 hours of the care team's time).

Patient Questionnaire and EHR Results

Depression scores on the PHQ-9 were not significantly different between the two groups at any point in time during the study. There was a significant difference in Treatment-Related Distress between the control and intervention groups at both six months (1.6 (0.7 SD) INT vs. 2.0 (0.9 SD) UC; p≤0.001) and 12 months (1.7 (0.8 SD) INT vs. 2.0 (0.8 SD) UC; p≤0.001). All other subscale scores of PAID were similar between the two groups. Measurement of treatment satisfaction using the DTSQ questionnaire demonstrated significantly improved outcomes at 12 months for treatment satisfaction (4.51 (1.6 SD) INT vs. 4.04 (1.6 SD) UC; p=0.007), understanding of diabetes (4.92 (1.0 SD) INT vs. 4.30 (1.3 SD) UC; p≤0.001), and willingness to recommend treatment to others (5.11 (1.4 SD) INT vs. 4.19 (1.6 SD) UC; p≤0.001). In addition, intervention patients were less likely to report unacceptably low recent blood sugars (0.75 (1.2 SD) INT vs. 1.07 (1.4 SD) UC; p=0.034). There were no significant differences between the two groups on items related to unacceptably high recent blood sugars or perceived treatment convenience or flexibility. The revised version of the Diabetes Knowledge Test reflected significant increases among the intervention participants related to knowledge about blood glucose testing (1.8 (0.4 SD) INT vs. 1.6 (0.6 SD) UC; p=0.004) and complications related to diabetes (5.0 (0.7 SD) INT vs. 4.9 (0.9 SD) UC; p=0.025) at 12 months. Furthermore, a summation of the 22-item scale showed that knowledge scores significantly improved overall (17.9 (2.3 SD) INT vs. 17.4 (2.7 SD) UC; p=0.013).

Changes in Self-Management and Processes of Care

As an indication of increased self-management activity, at 12 months, the patients in the intervention group reported greater increase in the number of days glucose was tested at home in the week preceding administration of the survey (4.9 (2.6 SD) INT vs. 3.9 (2.9 SD) UC; p=0.001) and greater increase in the number of times tested per day (2.0 (1.4 SD) INT vs. 1.6 (1.4 SD) UC; p=0.003).

Another important component of the patient feedback survey was evaluating patient-perceived behavior change and activation. A majority of patients had an increase or a significant increase in confidence in their ability to: manage their diabetes (93%); make lifestyle changes (75%); and

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maintain lifestyle changes (70%). In addition, the majority (60-88%) of patients specified that, as a result of being enrolled in the EMPOWER-D program, they: took their medications more regularly; made healthy food choice more often; exercised more; paid more attention to their diets; completed laboratory tests more regularly; tested glucose at home more often; and kept up with preventative actions more routinely.

When asked to share their feeling about the EMPOWER-D program in general, 93% of patients specified that they felt this program suited their needs and lifestyle. Overall, 88% of survey participants were very satisfied (73% or 29 respondents) or somewhat satisfied (15% or 6 respondents with the EMPOWER-D program.

Physician Satisfaction Survey Summary

After the EMPOWER-D project concluded and all patient contact with study staff ceased, all primary care providers (PCP) with patients that received the EMPOWER-D intervention were invited to complete a feedback survey. One hundred and five survey invitations were sent out to physicians; 14 physicians completed the survey. The low response rate was likely due to the 3-year delay between the physician's awareness of the project and the receipt of the survey following completion of the study. The majority of physicians agreed that the EMPOWER-D program decreased the amount of time required for them to manage their diabetic patients (64% or 9 respondents); no physicians believed that the program increased that time. Moreover, 79% (or 11 respondents) of physicians found that the EMPOWER-D program was at least somewhat helpful in managing aspects of their patients' care. When asked about the EMPOWER-D clinical staff, known as nurse care managers, a majority of physicians specified that the patient-related EPIC communications (65% or 9 respondents), medication suggestions or dose titrations (65% or 9 respondents), ongoing followup communication with patient (71% or 10 respondents), and clinical messages from nurse care managers about patient issues (79% or 11 respondents) were either moderately helpful (43% or 6 respondents) or very helpful (36% or 5 respondents).

Serious Adverse Events (SAEs)

All SAEs were reported to the IRB and Data Safety and Monitoring Board (DSMB). There were no deaths in the study population. There was no significant difference in the number of serious adverse events or adverse events between the INT and UC groups, and none of the adverse events were attributed to study participation.

<u>Discussion</u>

In a comprehensive review of quality improvement strategies for type 2 diabetes, Shojania et al.[13] concluded that "most quality improvement strategies produce small to modest improvements in glycemic control." Across their analysis of studies, including randomized or quasi-randomized controlled trials and controlled before-after studies, they found the mean postintervention difference in A1C was -0.42%. Using multivariate analysis, Shojania determined that two quality improvement strategies were associated with mean reductions in A1C of at least 0.5% - team care and case management, especially when case managers could adjust medications. Our intervention included both of these components.

Employing our comprehensive intervention package, we were able to achieve a significant reduction in A1C both at six (-1.32%) and 12 (-1.14%) months following randomization. While the reduction in A1C was statistically significant from usual care at six months, and the intervention group maintained a greater reduction of A1C than usual care at 12 months, it was no longer statistically significant. Although the intervention group maintained a significant reduction in A1C, the usual care group also improved fairly significantly. The context for managing diabetes at the clinical sites of the Palo Alto Medical Foundation (PAMF), where the study was conducted, is that diabetes has been a focus for quality improvement (QI) projects for over a decade. Physicians and their patients who were participating in an ongoing diabetes quality improvement project were excluded from our study. In fact, because of the ongoing QI projects involving diabetes, PAMF has been able to control (A1C <7%) up to 70% of the diabetes patients in its patient population and have very high adherence to laboratory orders and preventive care. This is likely to have had a significant impact on diabetes management of the usual-care group over the time period of the study.

Also, for those intervention patients with a > 0.5% reduction in A1C, it is notable that patients who checked glucose readings and uploaded them regularly obtained their reduction at 6 months and sustained a reduction in A1C at 12 months.

Significance

Previous online approaches to management of diabetes that we are aware of were smaller and shorter in duration than our study. One (n=83) randomized controlled trial of Web-based collaborative care for type 2 diabetes which evaluated a program consisting of online access to the electronic health record, secure electronic communications between patients and providers, and interactive disease management tools reported a 0.7% improvement of A1C compared with usual care.[14] In their trial, baseline A1Cs were not obtained. Patients were enrolled based on the most recent A1C in the 12 months prior to randomization, and their followup A1Cs were determined by measurements occurring 9 to15 months following randomization. It is unknown how their methods may have affected their results or its comparability to our study. Jimison, et al reported four randomized trials (of less than 30 weeks) of persons with diabetes, each reporting improved outcomes on A1C and self-management (e.g., home glucose monitoring).[12]

In addition to use of a multidisciplinary care team, our intervention employed several of the components enumerated by Jimison, et al (2008)[11] regarding effective consumer health IT and the taxonomy adapted from the Cochrane Effective Practice and Organization of Care group[15], including electronic patient registry, clinician reminders, facilitated relay of clinical information to clinicians, patient education, promotion of self-management, and patient reminder systems. Our disease management program is designed to be integrated within the existing physician-patient relationship.

Dissemination Plans

We have used the knowledge and experience gained from the EMPOWER-D clinical trial to improve and expand the technology and tools used in PHCP. Some of the technology that was

created for EMPOWER-D (e.g., the Bluetooth® adaptor prototype, Palm Treo™ smartphone) is no longer commercially available. Consequently, we cannot deploy the identical technology throughout our diabetes clinical practice. However, since the start of EMPOWER-D, a new smartphone platform has been created and has met with excellent market success – the Apple iPhone™. Because of the success of the iPhone platform in our local market, and technical considerations related to the Apple platform, we have developed an interface with other remote monitoring devices (e.g., blood pressure device, scale, pedometer), which we will study in a clinical trial using PHCP to manage patients with hypertension (EMPOWER-H). We are also developing an iPhone application to provide graphical feedback to patients, which does not rely on patients accessing a Web application on a desktop computer. We believe the more reliable technology delivery platform and better, more timely feedback to the patient using mobile technology will overcome some of the technical challenges that may have detracted from some of the benefits in EMPOWER-D. Our plan remains to use the knowledge we gained through EMPOWER-D to deploy the online, team-based, patient-centered approach to managing patients with chronic diseases at PAMF.

Limitations

The study has several limitations. We purposefully focused our attention on uncontrolled diabetics who had been treated for over a year. Consequently, some of the patients who could potentially benefit from the intervention were not eligible to receive it.

A significant limitation of the study was its conduct in a large integrated group practice that has a track record of using quality improvement strategies to improve care. The magnitude of our absolute reduction in A1C (1.14%) might have been more meaningful in a different setting where continuous QI activities are not the norm.

Additional Outcome Measures Required by AHRQ

In addition to the outcome measures incorporated in the above report, AHRQ requested the following information not specifically addressed above.

- Whether patients are able to access reports of ambulatory care quality and safety for their providers.

Palo Alto Medical Foundation participates in the Integrated Healthcare Association, a statewide multi-stakeholder leadership group that promotes quality improvement, accountability and affordability of health care in California. The results of these quality reports are posted publicly on an annual basis. PAMF has been consistently recognized as a top performer based on pay-for-performance measures of clinical quality, patient experience, IT-enabled systemness, and coordinated diabetes care.

- The impact of projects in low-resourced rural and urban safety net settings where health IT diffusion is likely low.

Although the communities served by PAMF are not considered "low-resourced rural and urban safety net settings," not all participants in EMPOWER-D owned their own computer. Some of our patients accessed the Internet from computers available at public venues such as the public

library or from work. This was self reported by participants and not actually tracked by the study.

- Patients' access to and utilization of quality measurement reports of their providers.
Patients have access to aggregate information about the PAMF physician performance on quality measures as reported by the Integrated Healthcare Association Pay-for-Performance (P4P) program as discussed above. The extent of their use of the information is not known.

- The percent of ambulatory clinicians within the practices that they partner with who routinely use measurement tools to evaluate their patient's experience.
The Palo Alto Medical Foundation actively uses the Press-Ganey scores to track patient satisfaction with services, staff, and physicians.   One hundred percent of physicians who participate in patient-facing, direct patient care activities are evaluated by this method.

Manuscripts submitted for publication:

Online Disease Management of Diabetes: Engaging & Motivating Patients Online With Enhanced Resources-Diabetes (EMPOWER-D). Submitted to <u>Diabetes Care</u>, under review.

EMPOWER-D: A Personalized Health Care Program for the Online Management of Diabetes. Manuscript prepared for submission to <u>The Diabetes Educator</u>.

Reference List

1. Committee on Identifying Priority Areas for Quality Improvement. Priority Areas for National Action: Transforming Health Care Quality. Washington DC: National Academies Press; 2003.

2. Centers for Disease Control and Prevention. National Diabetes Fact Sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. 2011

3. Boyle JP, Thompson TJ, Gregg EW, Barker LE, Williamson DF. Projection of the year 2050 burden of diabetes in the US adult population: dynamic modeling of incidence, mortality, and prediabetes prevalence. Popul Health Metr 2010;8:29.

4. Cheung BM, Ong KL, Cherny SS, Sham PC, Tso AW, Lam KS. Diabetes prevalence and therapeutic target achievement in the United States, 1999 to 2006. Am J Med 2009;122(5):443-453.

5. Porter ME. A strategy for health care reform--toward a value-based system. N Engl J Med 2009;361(2):109-112.

6. Bratcher C, Bello E. Traditional or centralized models of diabetes care: The multidisciplinary diabetes team approach. Journal of Family Practice 2011;60 (11):S6-S11.

7. Tang PC, Black W, Buchanan J et al. PAMFOnline: integrating EHealth with an electronic medical record system. AMIA Annu Symp Proc 2003;649-653.

8. Tang PC, Lansky D. The missing link: bridging the patient-provider health information gap. Health Aff (Millwood) 2005;24(5):1290-1295.

9. Pocock SJ, Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. Biometrics 1975;31(1):103-115.

10. Polonsky WH, Anderson BJ, Lohrer PA et al. Assessment of diabetes-related distress. Diabetes Care 1995;18(6):754-760.

11. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001;16(9):606-613.

12. Jimison H, Woods S, Nygren P, Walker M, Norris S, Hersh W.R. Barriers and Drivers of Health Information Technology Use for the Elderly, Chronically Ill, and Underserved. 2008AHRQ Publication # 09-E004.)

13. Shojania KG, Ranji SR, McDonald KM et al. Effects of quality improvement strategies for type 2 diabetes on glycemic control: a meta-regression analysis. JAMA 2006;296(4):427-440.

14. Ralston JD, Hirsch IB, Hoath J, Mullen M, Cheadle A, Goldberg HI. Web-based collaborative care for type 2 diabetes: a pilot randomized trial. Diabetes Care 2009;32(2):234-239.

15. Shojania KG, Ranji SR, Shaw LK et al. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. 2004 AHRQ Publication No. 04-0051-2 .)