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Utilization of Telehealth Technology to Develop and Implement a Comprehensive Management Initiative for Chronic Diseases

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14. ABSTRACT

Chronic diseases affect over 90 million Americans and result in high health care costs and tremendous personal and societal burden. Diabetes is, arguably, among the most pervasive and researched chronic diseases. Research shows that much of the costs and burden of diabetes can be mitigated with appropriate education, care- and self-management. This project, called the Comprehensive Management for Chronic Disease (CMICD), focuses on innovative technology approaches to improving education about and management of diabetes. The CMICD includes: virtual education techniques for training nurses (VNE); an Internet-based medical informatics tool for the management of people with diabetes called the Comprehensive Diabetes Management Program (CDMP) and its associated telehealth eye care program that can remotely evaluate eye disease without need of dilation or a specialist to conduct a live exam; a video cell phone approach to providing patients with daily, personalized reminders and education; and a computer-assisted decision support (CADS) tool that equips primary care providers with the latest clinical guidelines and specialty expertise to support their decision making about diabetes, hypertension, and hyperlipidemia. Components of the CMICD are being developed and evaluated for accuracy and usability as part of this effort (CADS), other components are being deployed and tested in rural PA in collaboration with Mt. Aloysius College (VNE and CDMP/telehealth eye care program), and others are being deployed and tested at Walter Reed Health Care System (Cell Phone). Using a variety of study designs, this project is examining both patient outcomes and providers' changes in knowledge as appropriate. Currently the CMICD focuses on the management of diabetes; however, the management approaches within the CMICD are applicable to a variety of other chronic diseases including asthma, depression, and arthritis. This Annual Report presents progress and challenges to date as well as some findings.

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Introduction

Diabetes mellitus (DM) affects approximately 24 million people in the United States (Centers for Disease Control, 2005) and is associated with devastating complications in both personal and financial terms. Diabetes is the leading cause of blindness, non-traumatic amputations, and renal failure in adults and reduces life expectancy by 5-10 years. The direct ($153 billion) and indirect ($65 billion) costs of DM care have dramatically increased along with the epidemic increase in the number of those with DM over the past 10 years (Centers for Disease Control and Prevention, 2008; PharmaLive.com, accessed 14January2010). The vast majority of these costs are related to hospitalizations resulting from the chronic complications of diabetes, with only about 15% of the costs attributable to professional visits and pharmaceuticals. Much of the costs and burden of diabetes can be mitigated with appropriate education, care, and self-management. This project, a collaboration among Walter Reed Army Medical Center (WRAMC), Mount Aloysius College, and the Henry M. Jackson Foundation, is deploying and testing an innovative, technologically sophisticated program for managing and improving outcomes of diabetes. The program is called the Comprehensive Management Initiative for Chronic Disease (CMICD) and includes the following: a) virtual education techniques for training nurses (VNE); b) a video cell phone approach to providing patients with daily, personalized reminders and education; c) an Internet-based medical informatics tool for the management of people with diabetes called the Comprehensive Diabetes Management Program (CDMP) and its associated telehealth eye care program that can remotely evaluate eye disease without need of dilation or a specialist to conduct a live exam; and d) a computer-assisted decision support (CADS) tool that equips primary care providers with the latest clinical guidelines and specialty expertise to support their decision making about diabetes, hypertension, and hyperlipidemia. Components of the CMICD are being developed and evaluated for accuracy and usability as part of this effort (CADS), other components are being deployed and tested in rural PA in collaboration with Mt. Aloysius College (VNE and CDMP/telehealth eye care program), and others are being deployed and tested at Walter Reed Health Care System (Cell Phone). Using a variety of study designs, this project is examining both patient outcomes and providers' changes in knowledge as appropriate. Although the CMICD focuses on the management of diabetes, the management approaches within the CMICD are applicable to a variety of other chronic diseases including asthma, depression, and arthritis. Currently the overall project and its components are ongoing. This report describes our progress to date based on the original Statement of Work and our plans for the following year.

Body

a. Task/objective regarding Virtual Education Techniques -- to determine whether the use of virtual education techniques can improve diabetes knowledge for practicing registered nurses as well as student nurses

The increased incidence and prevalence of diabetes in rural areas of west-central Pennsylvania, coupled with the scarcity of certified diabetes educators in this geographic location, threatens to become a major public health concern. One response to this growing crisis would be to provide continuing, high quality diabetes education for nurses who care for patients with diabetes in a variety of in-patient and out-patient settings. Such education is often less accessible to nurses who live and practice in rural areas, where distance and time present formidable barriers to educational access. Virtual diabetes education techniques that combine best educational practices with telehealth technology offer a promising solution to this problem.

Toward this task/objective, we have completed many steps:

1) **We drafted a study protocol to evaluate the effectiveness of and satisfaction with virtual diabetes nursing education techniques compared to the effectiveness of and satisfaction with traditional, face-to-face, classroom-based diabetes nursing education. The protocol was approved by the local and federal IRBs.** The study design is that of a quasi-experimental design (i.e., nonrandom assignment) with two groups. Specifically, traditional diabetes education for nurses taught by certified diabetes

educators and clinicians and offered on-site at the Walter Reed Army Medical Center (WRAMC) will be made available in a web-based format to registered nurses in a rural area of west-central Pennsylvania (PA). Certain lectures will also be provided via video-teleconference to facilitate communication between the students in rural PA with the instructors in Washington, DC, and to integrate the PA students into the course. Effectiveness will be measured as change (improvement) in diabetes knowledge and nursing skill as measured by pre- and post-class questionnaires. Satisfaction with the education delivery methods will be measured using validated questionnaires. One hundred and two participants will be recruited, with half receiving the in-person training and half the web-based version. Statistical analyses are intended to show whether there are within and between group differences in learning outcomes and satisfaction.

2) **Additionally, we accomplished several technology-related tasks that are necessary for the completion of the objectives.** First, we identified a location (not at WRAMC, for a variety of reasons) for a synchronous video-teleconference between PA and DC to take place, which was important for the first Nurses' Workshop. Second, after much negotiation with several prospects, we came to agreement with a vendor in central PA who uploaded all course content to a secure web site available only to the PA students. The course content was divided into 'modules' (by lecture) and was synchronized with the "live" lectures delivered by the instructors. After each module, the web site interactively "quizzes" the students on the material presented. Third, the study completed the development of all the course content, quizzes, and pre-/post-knowledge tests for the web site and study measures. Lastly, the study has identified a vendor to videotape a "live" examination of a patient with diabetes by a Nurse Practitioner of the Diabetes Institute at WRAMC.

3) **We have held three Nurses Workshops to date. We have enrolled 24 at the WRAMC site and 32 for the rural PA site.**

4) **We have interim findings from the first 31 study participants (19 at WRAMC and the rural PA site). The findings indicate that the students:**

   i) Preferred face-to-face interaction with instructors and other students. Difference between the groups was significant: $t=2.70$, $df = 34$, $p< .01$;

   ii) In the WRAMC group felt that they knew the instructor and other students better than did the rural PA group. Not surprisingly, the online students had little to no knowledge of or interaction with other nurses taking the online course. The difference between the groups was large and highly significant: $t=7.75$, $df=34$, $p<0001$;

   iii) Both groups felt that material presented met their professional needs. There was no difference between the 2 groups on this measure. Means were very close and highly positive;

   iv) Both groups were highly satisfied with the content of the course and were likely to take a similar course in the future (the groups did not differ);

   v) Both groups performed significantly better on the knowledge (pre and post-test) scores after taking the course [$F(1, 34)$ 48.24, $p < .001$]. There was no significant difference between the in-class and on-line scores and both groups increased about equally (i.e., no significant interaction).

Our tasks in the coming year involve completing another round of analyses and conducting focus groups. Depending on the results of the analyses, we may cease enrollment. The reason for that would be that further enrollment would not change the conclusions we might draw from this study.

b. Task/objective regarding Video Cell Phone Reminders – to determine if a video cell phone reminder system will improve compliance and glycemic control in patients with diabetes mellitus

Control of blood sugar has been shown in multiple studies to reduce the incidence of diabetes complications (Diabetes Control and Complications Trial Research Group, 1993; United Kingdom Prevention of Diabetes Study, 1998). Many people with diabetes struggle to achieve and maintain good glycemic control despite numerous new medications and technologies. There are numerous challenges to accomplishing appropriate control and various approaches to doing so.

The use of self blood glucose monitoring and techniques to improve medication compliance are among the more "non-invasive" methods that have been associated with improvement in diabetes management. Self blood glucose monitoring and medication adherence are each associated with improved glycemic control and reduction in adverse outcomes in both type 1 and in type 2 diabetes. For example, each additional blood glucose measurement results in a decrease in A1c of 0.32% (Schutt et al., 2006). Also, there is a lower rate of fatal and non-fatal cardiovascular events in those who self-monitor their blood glucose (Martin et al., 2006). With respect to medication adherence, once study found that for every 10% increment in drug adherence on a continuous scale resulted in a 0.6% improvement in A1c (Schectman et al, 2002). However, another study found that 27% of patients on 1 or more meds were non-adherent with their drug regimen, resulting in higher A1c's (Krapek et al., 2004). Despite the evidence in favor of these relatively non-invasive methods for achieving diabetes control, patient adherence to self-monitoring and medications is not consistent with providers' recommendations; e.g., 23% of patients with type 1 diabetes are non-adherent (Cramer and Pugh, 2005).

To address this, we conducted a study examining the clinical efficacy of video-based, diabetes/tips reminders, delivered daily via cell phone, on A1c, medication adherence, self-monitoring of blood glucose, and various psychosocial outcomes.

Toward this goal/objective, we have completed almost all of the necessary steps:

1) **The study obtained local and federal IRB approval**

2) **Moreover, 65 participants have enrolled in and completed the study.**

   We have conducted analyses of the data for these 65 subjects and are preparing a manuscript for submission to a journal. Below we describe our analytic approach and our findings.

Methods:

Study participants were recruited from the Diabetes Institute in the Walter Reed Health Care System in the greater Washington, DC area. Potential participants were identified by their providers and screened for eligibility by the study coordinator. Inclusion criteria were age 18 or greater, A1c greater than 8%, ability to use a cell phone and glucose meter, ability to understand English, on oral therapy and/or insulin, and a patient of the Diabetes Institute for 6 months or longer. Potential participants were excluded if they were a) pregnant, lactating, or planning to become pregnant, and/or b) using glucocorticoids, amphetamines, anabolic, or weight-reducing agents.

The study enrolled 65 participants. This sample size is sufficient to detect a decline in A1C of 1.0% (with a standard deviation of 0.90) in the treatment group of 0.50% (with a standard deviation of 0.40) in the usual care group, assuming power is 0.80 and alpha is 0.05. Note that the study had planned for smaller within-group declines in A1C and smaller between-group differences, so the sample size estimate was larger, but interim analyses of A1C change and funding constraints pointed to stopping recruitment at 65.

The study was a prospective, one-year randomized trial, with the active intervention portion of the trial lasting 6 months. All participants were given a broadband cell phone and cell phone service. Participants

were then randomized into either a "cell phone" group ('usual care') or a "cell phone plus reminder" group ('intervention'). Participants randomized to the intervention received daily, 30-60 second videos on their cell phones, reminding them to check their blood sugar, take their medications, an educational diabetes "tip of the day," etc. The videos were of the participants' own diabetes Nurse Practitioner. Participants could view the daily video multiple times within the day that it was sent; each video was sent twice over the course of the 6 months.

The primary endpoint was glycemic control as measured by A1C and the secondary endpoints were mean SMBG levels, the proportion of hyperglycemic events, and improvement the perceived level of diabetes-related stress. The study collected A1C data at baseline, and then every three months thereafter. Self-monitoring of blood glucose (SMBG) data were collected during quarterly provider visits; however, study participants were not asked by study staff to change their self-monitoring patterns or to record self-monitoring data in a systematic way. Often these data were downloaded from the study participants' glucometers, although occasionally the data were handwritten. Using the self-monitoring data, we created a binary measure indicating whether the subjects provided SMBG data or not, the proportion of SMBG measurements that were above 180 mg/dL, and the average of the each participants' measurements as of each quarterly visit. To measure diabetes distress, the study administered the Problem Areas in Diabetes (PAID) questionnaire, at baseline, 6 months, and at the end of the study**.** The PAID comprises 20 items summed to provide a total score of diabetes distress. The scale asks about feelings of guilt, anxiety, worry, loneliness, and burn-out around diabetes, feelings about diabetes care providers, and level of comfort with social situations, among other things. Each item is coded to indicate the severity of a problem (0 = not a problem to 4 = serious problem). We summed the 20 items and multiplied by 1.25 to yield a final score between 0 and 100.

Additionally, the study obtained demographic information regarding age, gender, race/ethnicity, duration of diabetes, type of diabetes, height, weight, vital signs, labs, and medications used to manage diabetes at baseline. We collected this information to insure that the two groups were comparable and, if they were not, to include the information in our statistical analyses so as to observe the net effects of treatment group after considering confounders.

Among subjects in the treatment group, we characterized viewership patterns by counting the number of videos each participant viewed per month and identifying common patterns of viewership over time. The most common patterns observed were: 1) did not view videos at all or did so only for the first 1-2 months (about one-third of the participants); 2) viewed the videos throughout the intervention period but did so inconsistently, sometimes skipping whole months of videos (about one-third of the participants); and 3) viewed 10 or more of the videos for the entire intervention period (about one-third of the participants). The participants who did not view the videos at all or viewed them inconsistently had similar A1C patterns over time, so we combined these two groups to simplify interpretation of the results.

The analyses tested for group differences in baseline characteristics using t-tests for continuous variables and chi-square tests for categorical variables. Next, the analyses estimated multilevel models to characterize within-individual and interindividual change over time in A1C and PAID scores. In these models, we included group (i.e., treatment or usual care; no-to-low /inconsistent or consistent viewership) as a fixed effect and repeated measures analysis to specify covariance structures for repeated measurements on the study participants over time. Any background, baseline measures that differed between the two groups were included in these analyses. Lastly, the analyses used chi-square tests to test for group differences in the provision of SMBG data and the proportion of hyperglycemia, and used t-tests to compare the group's average SMBG levels at each quarter. All statistical analyses were performed using SAS 9.1 (SAS Institute, Cary, NC).

Results:

One participant had an A1C at baseline that was greater than 15%, which represented an outlying value. This participant did not return for follow-up lab tests, so the remaining analyses exclude his/her data. Inclusion of this participant's data would have yielded results that were not representative of the study sample.

Table 1 presents the baseline characteristics of the remaining 64 study participants by study group. The average age of the study participants was between 55 (tips/reminders group) and 60 years (usual care group). In both groups, the educational attainment of study participants was some college or more, the predominant race/ethnicity reported was African American, most study participants had type 2 diabetes, and on average the study participants were obese. The average number of years since the diagnosis of diabetes was 13.8 (tips/reminders group) and 12.7 years (usual care group). A *t*-test comparing the average age of the two groups suggests that the difference was not by chance ($p = 0.06$). No other group differences were statistically significant or trends.

Table 1. Baseline Characteristics of the Study Participants, Altogether and By Group (n = 64)

Baseline Characteristic	**Total Sample**	**Tips/Reminders Group**	**Usual Care Group**	***P*-Value**
Age (mean, SD)	57.9 (10.7)	55.3 (10.1)	60.4 (10.9)	0.06
Male/Female (n)	35/29	15/16	20/13	0.33
Education (n)				
Less than HS Grad	4	1	3	0.23
Completed HS	8	4	4	
Some College	28	17	11	
College Grad or Higher	23	8	15	
Ethnicity (n)				
Black	37	19	18	0.78
Asian	3	2	1	
Hispanic	4	2	2	
White	20	8	12	
Type2/Type 1 (n)	59/5	27/4	32/1	0.14
Years since diabetes diagnosis (mean, SD)	13.3 (8.5)	13.8 (8.7)	12.7 (8.5)	0.64

Systolic BP (mean, SD)	135.6 (18.9)	132.2 (20.5)	138.9 (16.9)	0.16
Diastolic BP	78.3 (10.9)	76.5 (9.9)	80.0 (11.7)	0.20
Body Mass Index (mean, SD)	34.0 (7.2)	33.1 (5.9)	34.9 (8.2)	0.29
Medications – Taking (n):				
Exanatide (Byetta®)	4	2	2	0.95
Sitagliptin (Januvia®)	1	1	0	0.30
Metformin	34	18	16	0.44
Sulfonylurea	25	11	14	0.57
Thiazolidinedione (TZD)	8	3	5	0.51
Basal Insulin +/- other medication	28	15	13	0.54
Prandial Insulin +/- Basal Insulin	45	22	23	0.91

Notes: One subject excluded from analyses because s/he had an outlying A1c value at baseline and did not return for follow-up measurements. This meant the results were not representative of the population when s/he was included. Not all columns total 64 because of missing data resulting from non-response. SD refers to "standard deviation." P-Values are for the statistical comparisons of the two treatment groups.

Figure 1 shows the A1C patterns over time, by study group and including age. The estimated baseline A1C for participants in the tips/reminders group and the usual care group was 9.5% and 9.0% ($p < 0.0001$), respectively. Over time, estimated baseline A1C declined linearly at a rate of 0.37% ($p < 0.0001$) per quarter for the tips/reminders group and 0.20% ($p = 0.004$) for the usual care group, resulting in a lower A1C on average at the end of the study for the tips/reminders group.

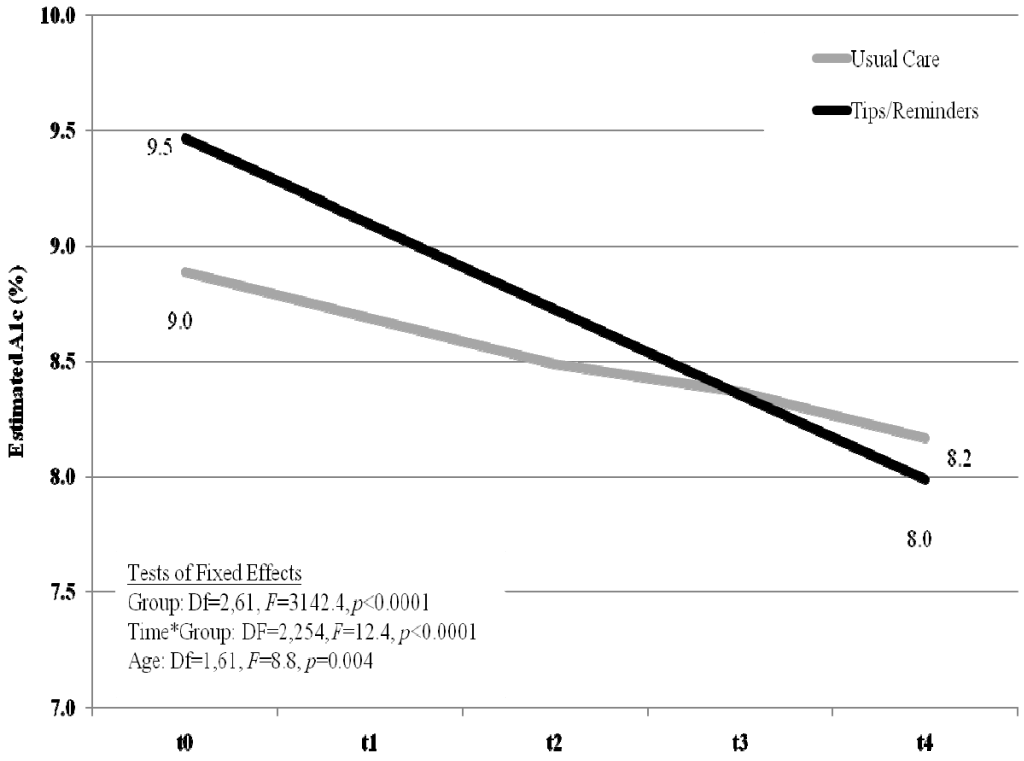

Figure 1. A1C Values Over Time by Treatment Group, Estimated from Multilevel Models for Longitudinal Data (n = 64)

A1C patterns differed across viewership groups and usual care (Figure 2). The estimated baseline A1C for the group that consistently viewed the videos was higher than that of the other groups [9.3% ($p < 0.001$) vs. 8.5% ($p < 0.001$) for the usual care group and 8.8% ($p < 0.001$) for the participants who did not watch the views or did so inconsistently]. The rate of decline in A1C by quarter was 0.48% ($p = 0.002$) for the group that watched the videos consistently vs. 0.20% ($p = 0.017$) for the usual care group and 0.33% ($p = 0.002$) for the group that did not watch the videos or did so inconsistently.

With respect adherence to self-care as measured by SMBG, the two treatment groups did not differ in terms of whether they provided (yes/no) SMBG logs or glucometers at study visits. Likewise, the likelihood of providing SMBG logs or glucomters did not differ by viewership group. The proportion 'high' (i.e., above 180 mg/dL) and 'low' (i.e., less than 70 mgldL) also did not differ by treatment group or viewership group. The mean SMBG values for each time point – which are shown in parentheses above the whiskers of each time point in Figure 3 -- appeared to be lower over time for the group that consistently viewed the videos compared with both the usual care group and the treatment group that did not view the videos or did so inconsistently; but the means did not differ significantly according to Analyses of Variance.

However, according to the ranges, the variability of the SMBG values differed by viewership group (Figure 3) with the usual care group having the biggest range in average SMBG values at each time point.

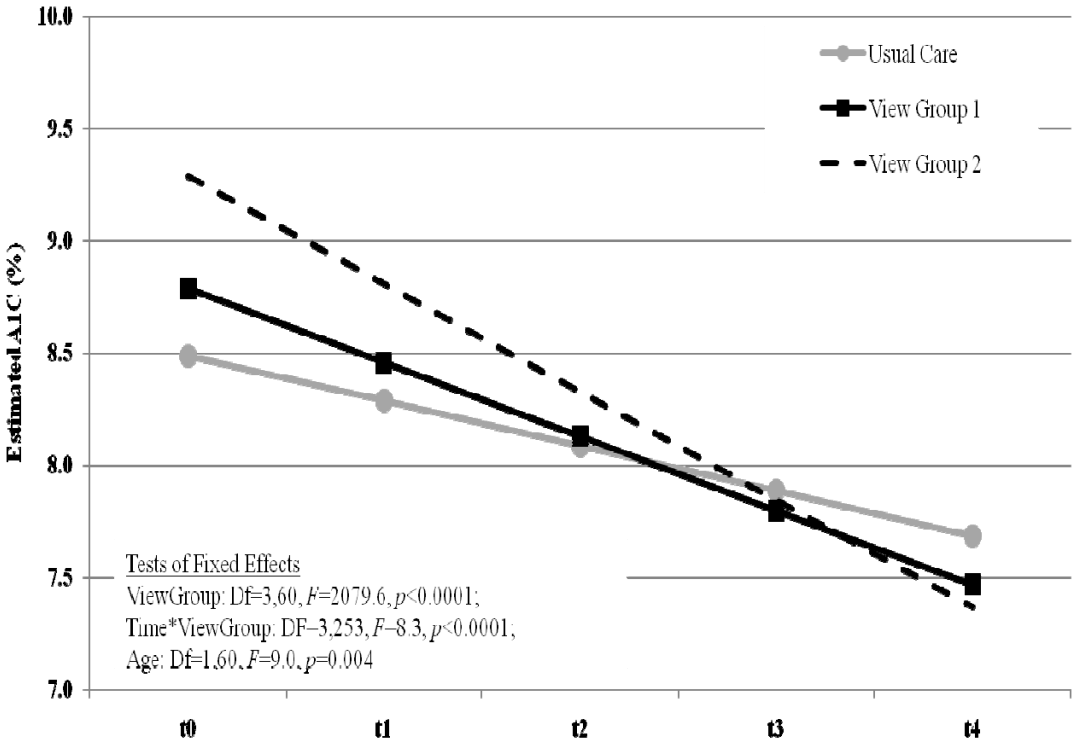

Figure 2. A1C Values Over Time by Viewership Group and Usual Care, Estimated from Multilevel Models for Longitudinal Data (n = 64)

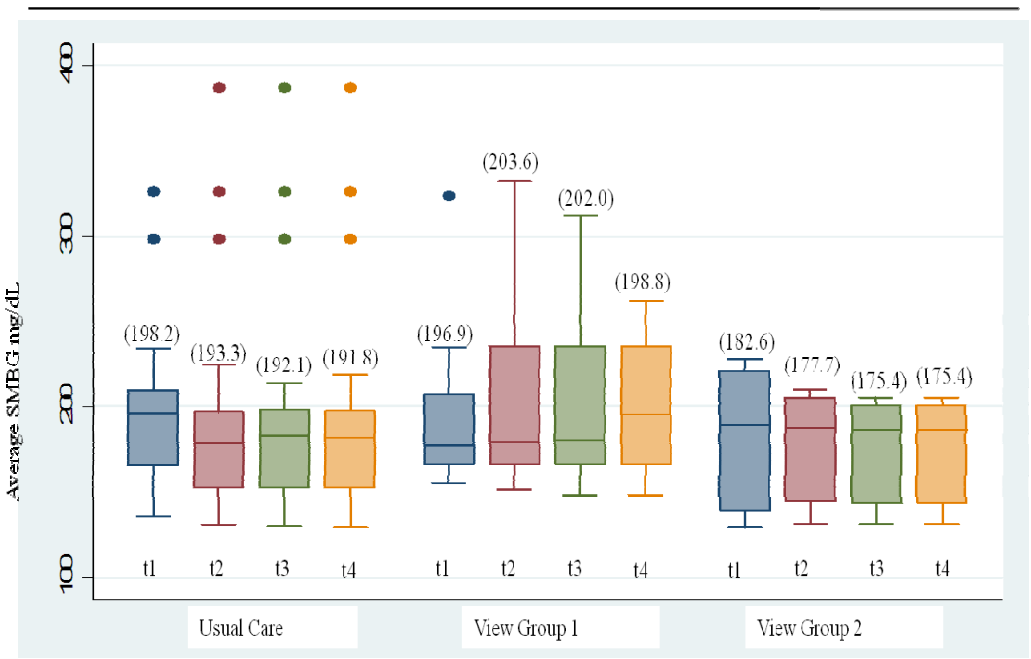

Figure 3. Medians, Ranges, and Means of the Average Self-Monitored Blood Glucose (SMBG) Values Over Time by Viewership Group and Usual Care (n = 64)

With respect to next steps for the Cell Phone study, we have drafted a manuscript for publication. The remaining step, before we can submit the manuscript, is to address the question of whether study participants differed in terms of adherence to taking prescribed medications. Differences in adherence might account for the observed differences in A1c.

Also, we are considering making the comprehensive library of videos that we created for this project freely available at the Diabetes Institute's web site, for all of our patients who might be interested,

c. Task/objective regarding the Deployment of a Telehealth Eye Care Program in rural PA – to deploy this program in clinics in the 12th Congressional District of PA with links to a central reading station at WRAMC

Diabetic eye disease is the leading cause of blindness among working-age adults, yet it is largely preventable with timely diagnosis and treatment (Diabetic Retinopathy Study Research Group, 1981; Early Treatment Diabetic Retinopathy Research Group, 1991). Diabetes-related vision loss is often caused by a combination of poor access to and compliance with periodic eye examinations that target early detection of sight-threatening eye disease. Even in settings with little or no financial barriers to health care, compliance with periodic eye examinations is suboptimal. For example, annual compliance with eye examinations among diabetic patients is 53%, 67.7%, and 52.2% in the Indian Health Service, Department of Veterans Affairs, and the Department of Defense health care systems (Indian Health Service, 2000; Department of Veterans Affairs, 2000; Department of Defense, 2000). We suspect these rates are worse in geographical regions, such as rural PA, where access to care is more difficult.

To address this problem, we have planned to bring a telehealth eye care program to rural PA. The program was originally developed at the Beetham Eye Institute. This program and those modeled after it are well-described and validated (Aiello et al., 1998; Cavallerano AA et al., 2003; Cavallerano JD et al, 2005; Bursell et al., 2001; Chow et al., 2006). For diagnosis of diabetic retinopathy and diabetic macular edema, the telehealth eye care assessments agree substantially with mydriatic seven-standard field Early Treatment Diabetic Retinopathy Study (ETDRS) protocol photography (Bursell et al., 2001) and with dilated clinical examinations by retina specialists (Cavallerano JD et al., 2005). For diagnosis of nondiabetic eye disease among people with DM, the telehealth eye care assessments agree substantially with dilated clinical examinations by retina specialists (Chow et al., 2006). The Principal Investigator of this grant has validated the telehealth eye care program in both a single clinic and multi-clinic setting, the latter utilizing a hub-and-spoke design with cameras deployed in satellite clinics and a central reading facility at a tertiary care facility; Ahmed and colleagues have shown the telehealth eye care program to be nearly 100% sensitive and specific in the two-thirds of images that are technically capable of being graded (Ahmed et al., 2006). The telehealth diabetes eye care program has also been shown to have better diagnostic and clinical outcomes at lower costs compared to conventional clinic-based eye examinations when used to detect sight-threatening proliferative diabetic retinopathy in the Indian Health Service, the Department of Defense, and the Department of Veterans Affairs (Whited et al., 2005). In addition to being clinically valid and cost-effective, the telehealth eye care program increased patient adherence with recommended standards of care for periodic eye examinations and follow-up treatment (Davis et al., 2003; Conlin et al., 2006; Wilson et al., 2005) and was found to be associated with decline in A1c and lipid levels over time (compared with standard care not involving the telehealth eye care program) (Fonda et al., 2007).

Toward the accomplishment of our technical objective of deploying the telehealth eye care program and testing its efficacy, we have**:**

1) **Sought to enlist clinics in PA to participate in a randomized controlled trial of the program.** We attended 4 meetings, one of which was with the Medical Director of the largest health care provider in the area (Conemaugh Health System). Although initially expressing interest, physicians

in that area have refused to participate. They did not agree with substituting the telehealth program for an annual dilated exam (which would be a requirement of a randomized controlled trial) and they were concerned that supporting such a program would adversely affect their revenue by taking patients away. Their refusal forced us to rethink the original research plan.

2) **(Since physicians in PA were not willing to conduct a randomized controlled trial of the telehealth eye care program) we have developed a new deployment and evaluation plan.** In this plan we will have a pre-/post-test of the deployment as before, but the deployment involves participating in health fairs and weeklong screenings throughout that targeted geographical area, rather than integrating into a clinic. All people with diabetes who have no prior history of diabetic retinopathy will be eligible, and we will screen them and provide education in the public health-oriented format of the health fair. We will follow study participants over time. This approach is novel and has a public health focus.

3) **We submitted a revised Statement of Work which was approved.**

4) **Identified 2 local sites willing to participate in weeklong "fairs" or screenings, as well as a local collaborator to assist us. We have also identified an Ophthalmology practice in the area where we will, if necessary, be able to refer study/screening participants who are found to have diabetic retinopathy during the screening.** This was a challenge because it is still the case that most telehealth eye care programs take place in fixed locations, namely clinics.

5) **Received IRB approval at the local level.** We must now respond to the federal review.

Our goals in the coming year are to obtain federal approval and conduct the study.

d. Task/objective regarding the Use of the Comprehensive Diabetes Management Program (CDMP) by Primary Care Providers – to supply providers in rural PA with CDMP, an interactive, modular, web-based care- and self-management tool for physician, care managers and patients

The CDMP is an interactive, modular, web-based tool for physicians, care managers, and patients, designed to a) provide a high level of continuous care and communication between patients, care managers, and physicians, b) draw on the latest clinical guidelines and guide care managers and physicians in following them, c) focus on patients' clinical and behavioral problem areas, and d) increase the role of the diabetes patient in the care planning process and management. Among the CDMP's modules are the Behavior Assessment Tool (BAT), which is a questionnaire designed to assess patients' barriers to effective diabetes care, and two Nutrition Assessment Tools (NAT-A and NAT-B), which are intended to assess why people eat certain ways. The CDMP also has an overall risk stratification algorithm, which uses a variety of data drawn from the patient's record (such as lab values, blood pressure readings, smoking status, whether or not the patient had a particular exam, etc.) to indicate how the patient compares to established goals in the areas of glycemic control, nephropathy, peripheral vascular disease, peripheral neuropathy, and retinopathy. The CDMP was developed after the aforementioned telehealth eye care program, because it is well-known that prevention and appropriate management of diabetic retinopathy requires good care- and self-management of diabetes overall. The telehealth eye care program is integrated into the CDMP.

As with the telehealth eye care program, the original study was proposing an evaluation of the quality of diabetes care pre- and post-implementation of the CDMP. The challenges encountered for the above apply to this project as well. Further, the change in scope approved in the revised Statement of Work applies here as well.

To review, we identified 2 local sites willing to participate in weeklong "fairs" or screenings, as well as a local collaborator to assist us with this project. As part of the screenings, we will administer the BAT and the risk stratification algorithm; the former will be applied to the educational component of the intervention and the latter will be applied to both the outcome measures and to the care plan generated from reading the teleretinal images.

e. Task/objective regarding the Use of a Computer-Assisted Decision Support (CADS) System to improve glycemic control -- to deploy CADS to primary care providers in a pilot study as a proof-of-concept study

Due to the complexity of diabetes, its co-morbidities such as hypertension and hyperlipidemia, and the seriousness of its complications, people with diabetes are usually best monitored by highly skilled health care professionals who are equipped with the latest information to help ensure early detection and appropriate treatment and to provide diabetes education to patients. But due to a dearth of endocrinologists in both military and civilian health care settings, primary care providers (PCPs) (including family practitioners, nurse generalists and physicians' assistants) provide care to the vast majority of patients with diabetes who are not necessarily equipped with the latest information. And in a healthcare environment where a shortage of Certified Diabetes Educators exists, especially in rural areas, the burden of diabetes education often falls on staff registered nurses in hospitals, physician offices, and other healthcare facilities who may lack the expertise and/or time to provide this service. It is imperative, therefore, to give these providers the advanced technology and health information management tools to support effective care management.

To transfer this knowledge to PCPs, the Principal Investigator developed a series of rules-based algorithms to provide decision support to primary care providers for the management of their patients with diabetes. We call it a Computer-Assisted Decision Support (CADS) System. The software allows for: download of patient self-monitored blood glucose data from memory meters to a central database; display of the data in tabular and graphical form; generation of descriptive statistics; assessment of overall level of control; and evaluation of hypoglycemia and hyperglycemia. A numerical score synthesizing all of the elements of good control is computed and presented. The software identifies a series of potential problems and prioritizes them (e.g. overnight hypoglycemia, hypoglycemia at other times of day, hyperglycemia, excessive postprandial excursions, etc.). The programs then identify the most appropriate change(s) needed in therapy involving oral or injectable regimens for type 2 diabetes, alone or in various combinations. The program indicates which dose or doses of medications should be increased or decreased, when there has been 'failure' of a regimen to provide an adequate level of control consistent with goals for A1c and glycemic levels, and also provides recommendations for moving to another regimen.

After the first version of the CADS System was developed, we determined that we should integrate it with the CDMP so as to facilitate remote patient upload of their self-monitored blood glucose data and to provide the CADS System with as much background information about each patient as possible.

At the beginning of the funding period for this grant, the original software developer, Health Sentry, did not release the required software code to us as scheduled, seriously delaying the integration of CADS with the aforementioned CDMP. The need to integrate with CDMP means we need additional time and a Revised Statement of Work. **We submitted a Revised Statement of Work and it was approved. The integration has now been accomplished.**

In a user evaluation of the CADS System by a Nurse Practitioner in our clinic, we found that the system was not yet ready for circulation to PCPs. **In response, we developed the interface more fully, we devised an improved process for collecting the patients' self-monitored blood glucose data, and we created new, more user-friendly graphs of the self-monitored blood glucose data. Also, new medications for diabetes have been added to the market since the drafting of the original rules and algorithms for the CADS**

System, so we expanded the application to include those. We additionally developed new use cases, which we discovered as part of the user feedback process. The new use cases ensure that the CADS System is more accurate and complete. **Lastly, we wrote a protocol for a full testing of the application (to be performed under separate funding) and developed a Technical Assessment Questionnaire to be administered to providers using the application.**

Per the Revised Statement of Work, the outstanding deliverable is now a vetted (with respect to usability and accuracy) CADS System. No further work is due on the CADS System as part of this grant.

Key Research Accomplishments

Virtual Education Techniques:

- Completed construction of computer and video-teleconferencing lab at Mount Aloysius
- Scheduled the workshop events
- Completed protocol draft and submitted to IRB
- Completed workshop agenda at Walter Reed
- Developed interactive web site for all of the course content and quizzes
- Conducted 3 workshops and enrolled study participants
- Conducted preliminary analyses and presented results in this report

Video Cell Phone Tips/Reminders:

- Created an extensive library of videos
- Drafted protocol, submitted it to the IRB, and received approval
- Recruited 65 subjects and completed the protocol with them
- Conducted analyses the outcomes A1c and self-monitoring of blood glucose
- Drafted a manuscript for submission to a journal, and this will be complete after we analyze the data on adherence to prescribed diabetes medications

Telehealth Eye Care Program and Comprehensive Diabetes Management Program:

- Met with health care providers and Medical Directors to enlist clinics to participate – which led to rethinking the methodology
- Contracted to buy the equipment needed
- Identified local champions
- Identified and enlisted local sites for a public health-type "fair" or screening
- Established the new methodology by which we will conduct the study
- Drafted a protocol
- The protocol was approved by the local IRB and now we are preparing a response to the federal IRB

Computer-Assisted Decision Support System:

- Developed the interface and how we are going to collect the data so that the application can perform its tasks
- Through user feedback process, discovered/developed additional use cases
- Developed a Technical Assessment Questionnaire to be administered to providers observing the application
- Wrote a protocol for a full test under new funding
- Created new and improved graphs of the self-monitored blood sugar data
- Completed integration of the system with CDMP

Reportable Outcomes

The following are presentations we have given to date and include some information from these projects:

- Vigersky R, Bell A, Fonda S, Sami S, Walker S, Schmidt V. Using cell phone reminders in diabetes mellitus. Abstract. *Telemedicine and e-Health* 2009; 15: S31.
- Fonda SJ. A cell phone intervention for improving adherence to diabetes therapy. Presented at the US Army Telemedicine Partnership Series 2010. mHealth: The use of cell phones for Healthcare Applications. Annual Meeting of the American Telemedicine Association, May 2010.
- Fonda SJ. "e-, i-, or m-health? Blurring Boundaries between Provider and Patient-Centered Management". Annual Meeting of the Diabetes Technology Society, November 13, 2010.

The following are projects that we have applied for funds to support. Aspects of these projects have grown out of what we have learned conducting this project. In brief, the projects will:

- Develop and study a Personal Health Record Application (PHR-A) that captures information about daily living important for diabetes & provides decision support with actionable advice for diabetes self-care
- Develop a self administered stereo non mydriatic automated retinal camera (SNARC) containing automated retinal lesion (ARL) detection using adaptive optics
- Study the use of a Computer-Assisted Decision Support (CADS) system to improve outcomes in patients with Type 2 Diabetes who are treated by Primary Care Providers.

Conclusion

The CMICD is an ongoing, multi-project effort and as yet we do not have final research and development results to report for all of the projects; several are close, however, including the Video Cell Phone Study, the Virtual Nursing Education Study, and the Computer Assisted Decision Support System development effort.

We believe that the projects herein have the potential to address and/or prevent the serious complications of diabetes, even in geographical regions or socioeconomic settings where access to diabetes education and/or care are limited. One such project can reduce or prevent complications through the use of diabetes tips and reminders sent via a relatively low-cost, ubiquitous and familiar tool, the cell phone. Another project can do so through the combination of telemedicine technologies and public health-based education to provide a quick, convenient, and low-cost evaluation for diabetic retinopathy. The evaluation for diabetic retinopathy can then lead to a care management plan based in best practices guidelines, using our medical informatics tool, the CDMP. Yet another project can mitigate diabetes complications with the development and distribution of diabetes expertise – as computer-assisted decision support – to providers who are generalists and/or do not have the time to stay apprised of the many and varied drug regimens for diabetes management. Finally, with the CMICD, nurses in rural areas who care for patients with diabetes but do not have access to or time-flexibility for diabetes-specific continuing education can now receive this education through the Internet, at their own pace and while continuing to work. Although the content of the tips, decision support, education, and clinical guidelines is all about diabetes, the approaches here can easily be applied to other chronic diseases.

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Appendices

None