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PRINCIPAL INVESTIGATOR: Robert A. Vigersky

CONTRACTING ORGANIZATION: T.R.U.E Research Foundation
San Antonio, TX 78217

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Robert A. Vigersky

E-Mail: vigersky@na.amedd.army.mil

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14. ABSTRACT
The major goals of this continuing project are the establishment of a telemedicine system for comprehensive diabetes management andassessment of diabetic retinopathy that provides increased access for diabetic patients to appropriate care, that centralizes the patients in the cprocess, that empowers the patient to better manage their disease, that can be performed in a cost effective manner, and that maintains the hstandard of care required for the appropriate management of diabetic patients. The aim of this program of research was to perform the appropriate clinical validation, cost efficiency, and risk benefit studies associated with the use of the recently developed Comprehensive Diabetes Management Program (CDMP) and the Joslin Vision Network (JVN) Eye Health Care Program that is now a module of the CDMP. The need for diabetes disease management is driven by the knowledge that diabetes is not currently curable, but it is treatable, and its complications are preventable. The primary goal of treatment is to manage diabetes to live a healthy lifeIn general, the traditional physician-centered, episodic, acute-care model is not designed to care for large numbers of diabetic patients (more than 2,200 new cases diagnosed every day in the US) and in order to meet this challenge the health care delivery system will need to be re-engineered. Tcan become a reality with the use of the CDMP developed under this collaborative effort.

15. SUBJECT TERMS
Joslin Vision Network, telemedicine, diabetes mellitus, diabetic retinopathy, comprehensive diabetes management, diabetes case management, diabetes behavioral assessment tool

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Introduction

Diabetes Mellitus (DM) is a prevalent costly condition that causes significant morbidity and mortality. In the United States nearly 21 million people or 7% of the total population have diabetes and of whom at least 6 million are undiagnosed. An additional 41 million people are estimated to have pre-diabetes. Diabetes is the sixth leading cause of death in the United States. Consistent with devastating personal effects of diabetes, the costs to the health care system were estimated at $132 billion in 2002 ($92 billion in direct medical costs and $40.8 billion, including 88 million disability days and 176,000 cases of diabetes related disability, in indirect costs) compared to $98 billion in 1997. The per person expenditures for managed care organization members with diabetes is 2.4 times higher than those without diabetes. There is abundant evidence and documentation that diabetes is a major component of all health care expenditures in the United States with most of this cost associated with long term complications of diabetes specifically, retinopathy, nerve damage (neuropathy), heart disease, stroke, kidney failure, and peripheral vascular disease resulting in amputations.

Traditional health care delivery involves individual providers reacting to patient-initiated complaints and visits. Care is often fragmented, disorganized, duplicative, and focused on managing established disease and complications. Management of the disease is provider directed and focuses on pharmacologic and technologic interventions with little attention to patient self-management behaviors and provider-patient interactions (6). Evidence shows that improving care for diabetic patients results in cost savings for health care organizations and recent economic analysis studies have shown that diabetes eye care and preconception care were found to be cost saving as was preventing neuropathy and improving glycemic control.

Despite advances in treating these complications, efforts aimed at prevention are the best approach to reduce morbidity and mortality. In the last decade, innovative interventions for health care delivery have emerged that show promise for improving care, outcomes and costs for individuals and populations with diabetes. Disease and case management are two interventions that continue to demonstrate considerable potential and promise. In the arena of prevention, objectives 5-11 through 5-15 of the ***Healthy People 2010*** for the United States directly relate to improving screening for complications involving the retina, the kidney, the extremities, the oral cavity and the monitoring of glycemic control.

Two problems to overcome in order to reduce or prevent diabetic complications are (1) providing access of all diabetic patients to proven diagnostic and treatment strategies which reduce the risk of vision loss and (2) identifying effective methods to improve the metabolic control of patients with diabetes to reduce the risk of chronic complications. The challenge to overcome these problems is formidable. For example, intensive research over the last 30 years has developed methods that virtually eliminate diabetic retinopathy as a cause of severe vision loss. Nevertheless, diabetes remains the leading cause of new blindness in working-aged adults in the United States. The reason for this incongruity is many patients do not receive quality eye care because of geographical barriers, insufficient health insurance or financial resources, or patient or health care provider ignorance.

In a review article aimed at examining the effectiveness of disease management and case or care management for people with diabetes, the authors found that disease and care management was effective as interventions when delivered concurrently and also when delivered in conjunction with educational

interventions, decision support and reminders on performance issues, such as, timely retinal evaluation. These authors went on to indicate that one of the most pressing needs is to better define effective interventions as disease management has multiple component interventions. It may be that for the optimal use of resources only the interventions that contribute the most to positive outcomes need to be implemented. These interventions have yet to be defined. Additional research will need to be done, however, to identify the optimal intensity and frequency of these interventions as well as a consideration of whether professionals other than nurses (social workers, health aids or pharmacists) can function as care mangers. Other research areas of importance were identified as: consideration of integration of disease management into existing health care systems, the effect of disease and care management on long-term health and quality of life outcomes, such as, cardiovascular disease events, visual impairment, amputations, renal failure and mortality, and the effect of care management on blood pressure, weight, lipid levels and provider screening rates for retinopathy, peripheral neuropathy and microalbuminuria. Finally this review was unable to identify any appropriately rigorous studies aimed at evaluating the cost effectiveness of the care management intervention.

Overview

This annual report for the ongoing JVN Telehealth program at WRAMC provides an overview and status report of the studies designed to address the research questions posed above. This telehealth initiative is a unique opportunity to leverage the technological developments achieved over the past 5 years in the development of the JVN eye care and disease management programs to provide evaluations of the multiple diabetes disease management interventions from a single unified platform, the JVN Comprehensive Diabetes Management Program. The implementation of the JVN programs is extraordinarily timely in light of a recent publication in the Journal of the American Medical Association promoting the use of organized care management processes to improve the health care quality for patients with chronic diseases. The authors conclude that, although the use of care management processes vary greatly among physician organizations, the usage is low on average. They call on government and private purchasers of health care to increase the usage of care management processes through provision of external incentives for improvement of health care quality and to promote and assist physician organization to increase or improve their information technology capabilities. This continuation proposal is positioned to allow participants to play a lead role in developing evidence from rigorous multi-center studies to further support these recommendations.

The research proposals described below will leverage the successful deployment of the Joslin Vision Network (JVN) Eye Health Care program and the integration of the Comprehensive Diabetes Management Program (CDMP) to provide continuum of care for diabetic patients. The CDMP application has been developed under this collaboration and represents participation and input from leading experts in diabetes care from the Joslin Diabetes Center, Department of Defense, and the Veterans Health Administration.

Various studies have been deemed critical in order to provide the medical evidence to support preliminary data and expectations that this program will provide significant reductions in health care dollar expenses while maintaining a high quality of care as assessed through a reduction in complications such as blindness from diabetes. The expectation is that the use of this program will also increase the access of patients to appropriate care and provide a very powerful tool that will empower the patient to improve their own management of their diabetes.

The studies proposed in this continuing proposal are prospective in nature and involve multiple participating centers. There are 8 different research projects associated with the Joslin/University of Hawaii ***research program*** (as distinct from the research related to the development of new CDMP functionality) taking place across 4 sites. As shown in the table below, four of these research projects are taking place at Walter Reed. The study designs across the four Walter Reed projects vary from each other. Two are observational studies (those designed to assess the test-retest reliability of the BAT), one is a randomized clinical trial that will provide prospective data for insertion into decision models (the JVN cost efficiency study), and one is pre-/post- usability test of the implementation of the CDMP in the Diabetes Institute at Walter Reed (CDMP usability/workflow study). The specifics of the study designs are described in the attached Statements of Work.

User evaluations of the Study Manager Module are not a scientific aim and therefore do not have a study associated with them. Rather, Walter Reed has been using the Study Manager Module more than any other site, for the projects enumerated here as well as others, and we have been refining it as we gain experience with this tool.

Research Studies by Site

Project	Site				Status
	Joslin	**Hawaii**	**WRAMC**	**VA**	
Prospective cost efficiency study performed using the Telehealth Eye Care Module			√		Recruitment ongoing
Prospective risk benefit study using the Telehealth Eye Care Module				√	Recruitment ongoing
Human Factors study of the CDMP: Usability Lab	√				Complete; Manuscript published
CDMP usability and impact on clinical workflow study			√		Data collection and initial analyses completed
Prospective clinical outcomes efficacy and cost efficiency study using the CDMP (aka Internet-based Diabetes Education and Case Management)				√	Data collection complete and the last subject has completed the protocol; analyses ongoing
An Assessment of the Test-Retest Reliability of the CDMP BAT	√	√	√		Data collection complete at Joslin, VA and WRAMC; recruitment ongoing in HI, analyses of Joslin and WRAMC data being conducted together at WRAMCI
An Assessment of the Validity of the CDMP BAT	√	√	√		Recruitment ongoing at WRAMC; pending in HI
Additional Human Factors Study for the CDMP Application: Expert Review of	NA	NA	NA	NA	Completed; suggested changes to CDMP incorporated

the CDMP					

Notes: NA means not applicable. The Expert Review of the CDMP did not require recruiting subjects and was done by employees of the American Institutes for Research at their offices.

Statement of Work and Key Research Accomplishments

The different studies and progress since FY06 are enumerated below:

1. Prospective multi center cost efficiency study performed using the JVN Telehealth Eye care module

DESCRIPTION:

The primary questions are: What are the costs associated with diabetic retinopathy evaluations performed by an Ophthalmologist with a dilated eye examination and the JVN system using digital video imaging through an undilated pupil? What is the cost-effectiveness of ophthalmoscopy performed by eye care professionals compared to the Joslin Vision Network?

Specifically, the purpose of this study is to compare the costs and cost-effectiveness of the Telehealth Eye Care module with conventional clinic-based eye examinations among a diabetic cohort receiving annual eye examinations. The Eye Care Module is a digital teleophthalmology system developed by the Beetham Eye Institute at the Joslin Diabetes Center in cooperation with the Departments of Defense and Veterans Affairs. The research design for this study is a randomized clinical trial that will provide prospective data for insertion into decision models. In turn, the decision models will generate the data to evaluate the cost-effectiveness of the Eye Care Module versus conventional clinic-based eye examinations. Consenting patients (n = 243) at sites of the Walter Reed Army Health Care System (WRHCS) with type 1 or type 2 diabetes mellitus and scheduled for eye examinations on an annual basis will be enrolled in the study and randomized to conventional clinic-based eye examinations or eye examinations performed by the Telehealth Eye Care Module (plus an assessment of visual acuity). Subjects will be followed for one year. The study will track all costs that accrue over that year in the provision of care for both modalities, including labor, equipment, travel for the study subjects, and lost wages/productivity for study subjects, among others. Cost-effectiveness will be measured based on study subjects' compliance with the clinical eye examination and follow-up recommendations and diagnostic and treatment outcomes. We will ***a priori*** generate cost-effectiveness data based on diagnoses of diabetic retinopathy and macular edema. In a cost consequence analysis, we will consider other diagnostic outcomes and outcomes in aggregate. Additionally, we will impute cases of expected vision loss and, therefore, project differences in the number of cases of vision loss averted between modalities.

PROGRESS:

Rigorous study design completed. The study protocol has been written and approved by the Walter Reed Army Medical Center (WRAMC) Human Use Committee (HUC)/IRB. Four JVN retinal imaging workstations are located at WRAMC, KACC, DeWitt, and the Fairfax Family Health Center. Two retinal reading stations are located in the WRAMC Department of Ophthalmology and the KACC Department of Optometry. Recruitment began in September, 2006. An addendum to increase the target enrollment from 243 to 393 was approved by WRAMC HUC in January, 2008. The addendum was submitted due to the rate of ungradable images taken in the JVN study arm which, at the beginning of the study, was substantially higher than the expected rate of 10-15%, thus necessitating an increase in enrollment in order to achieve statistical power.

There were several reasons for the comparatively high ungradable rate early in this study. First, there were unanticipated technical challenges involving the reader workstations, the WRAMC server, WRAMC firewalls, software and hardware changes, changes in readers and imagers, thus requiring additional training, and changes in technical support staff at the Joslin Diabetes Center (JDC) in Boston, MA.

Second, upgraded JVN software necessitated imaging techniques that were not taught in the JDC certification classes for 3 of the 6 retinal imagers. To reduce the number of ungradable images, an imaging refresher course was provided by JDC at WRAMC on August 24, 2007. The quality of the images that have been taken since that time has improved and the majority of images are gradable. Recruitment is currently ongoing at four sites and we have enrolled approximately 250 subjects.

Third, the original study on which this particular protocol is based was recognized as the best paper publication in the journal of ***Telemedicine and e-Health*** for 2006 (Whited JD, Datta SK, Aiello LM, Aiello LP, Cavallerano JD, Conlin PR, Horton MB, Vigersky RA, Poropatich RK, Challa P, Darkins AW, Bursell SE: A modeled economic analysis of a digital teleophthalmology system as used by three federal healthcare agencies for detecting proliferative diabetic retinopathy. ***Telemedicine and e-Health.*** 2005;11: 641-651).

MILESTONES AND DELIVERABLES:

Completion of data collection and completion of initial data analyses for presentation at an annual meeting (TBD). Ultimately we hope to publish our findings and deploy the JVN telehealth eye care module throughout military treatment facilities (MTFs) and civilian clinics in the United States and abroad, thus providing an effective and economic means of screening retinal eye disease in medically underserved areas.

2. The Usability and Workflow Impact on Diabetes Care Specialists of the Comprehensive Diabetes Management Program (CDMP).

DESCRIPTION:

This project examined the usability and impact on clinical workflow of the Comprehensive Diabetes Management Program (CDMP). The CDMP is an, interactive, web-based tool for physicians, care managers and people with diabetes. The project examined the CDMP's usability and impact on clinical workflow by comparing them to those of the existing, baseline health information system in the Walter Reed Army Health Care System (WRHCS). Specifically, we examined the Diabetes Health***e***Card data (which documents the process and quality measures of the Diabetes Quality Improvement Program (DQIP)) of selected diabetes health care providers and administered several different questionnaires regarding the usability of the diabetes care system before and after adoption of the CDMP. We also conducted structured focus group discussions with the providers lead by a trained, experienced facilitator. Health care providers selected for this study were the Nurse Practitioners (NPs) of the Diabetes Institute of the Walter Reed Health Care System (not just Walter Reed Army Medical Center). All of the recruiting, data collection, and data analyses were done through a contract with the American Institutes for Research so as to minimize coercion of the study participants and maintain objectivity.

PROGRESS:

The study protocol was reviewed and approved by the Walter Reed Army Medical Center (WRAMC) Human Use Committee (HUC)/IRB in October, 2004. The

USAMRMC Human Subjects Research Review Board (HSRRB) deferred their second tier review to the Clinical Investigations Regulatory Office (CIRO). The study protocol was reviewed approved by CIRO on 16 November 2004. The nurse practitioners in the Diabetes Institute were trained on the CDMP and consented for their participation in this study in 2005. The CDMP was further refined and technical problems primarily related to software changes and WRAMC, DeWitt, and Meade firewalls that complicated access were resolved in 2005.

The original intent of the study was to compare the usability and impact on clinical workflow of the CDMP with the baseline HIT program entitled ICDB that was in use when the CDMP was developed. However, the removal of ICDB and the implementation of AHLTA as the DoD-wide electronic medical record (EMR) further delayed the implementation of this study. The start date for the CDMP usability study was therefore delayed until July, 2006. Data collection, including a structured focus group discussion with the providers lead by a trained, experienced facilitator, was completed by March 2007.

Three reports from this study -- corresponding with the three main types of data collected -- were completed and circulated by the American Institutes for Research in June 2007.

MILESTONES AND DELIVERABLES:

As this is just one component of a multi-factored and ongoing project, the findings are being used to further refine and develop CDMP as a tool to enhance case managers and primary care providers' management of patients with diabetes.

3 and 4. Clinical Validation of the Behavior Assessment Tool (BAT) developed for the CDMP application (including test-retest reliability and validity).

The Behavioral Assessment Tool (BAT) was developed as a stand-alone module within the CDMP. It is a screening questionnaire containing questions about psycho-social factors, nutrition, physical activity, alcohol and tobacco use, medications, general health, self-monitoring of blood glucose and economic factors. There are two studies associated with testing its reliability and validity -- An Assessment of the Test-Retest Reliability of the CDMP BAT and An Assessment of the Validity of the CDMP BAT.

DESCRIPTION:

The reliability assessment is a multi-site observational study with two measurements per study subject taking place 2 to 4 weeks apart. The sites are: the VA Boston Healthcare System (n = 42), Joslin Diabetes Center (n = 43 – with the additional subject being approved by the IRBs), Walter Reed Army Medical Center (n = 42), and community health centers in Hawaii (n = 42). The study protocol involves recruiting English-speaking individuals who are 20+ years of age and have type 1 or 2 diabetes. Eligible and interested participants are administered the following: a) an Informed Consent; b) a test to assess executive/cognitive function; c) questions about their social-demographics; and d) the BAT. Two to four weeks later, participants are asked to complete the same procedures (excluding the Informed Consent and questions about social-demographics). In addition, the study reviews participants' medical records to obtain their most recent A1c measure, Body Mass Index (BMI), and blood pressure. This information might be examined to help explain any low correlations between BAT responses over time.

PROGRESS: The VA, Joslin, and Walter Reed have completed all data collection. We presented a poster of the results for the Joslin site at the CDC Diabetes

Translation Conference (Garren, J, Fonda, SJ, Bursell, SE, Conlin, PR, Vigersky RA, Birkmire-Peters D). Test-Retest Reliability of a New Screening Questionnaire for People with Diabetes. Poster presented at the CDC Diabetes Translation Conference, Atlanta, April - May 2007). Analyses are ongoing for the VA, Joslin, and Walter Reed sites. Because the investigators are no longer at Joslin, the Joslin data were transferred to Walter Reed with Stephanie Fonda, for analyses and reporting. The transfer was approved by Joslin and Walter Reed and we are awaiting approval from the DoD.

MILESTONES AND DELIVERABLES:

DESCRIPTION:

The validity assessment is also a multi-site observational study. This study will examine two types of validity – concurrent and predictive. We will measure concurrent validity by examining how study subjects' responses to its questions correlate with a) their responses to similar questions in other questionnaires administered at the same time, b) recent self-report physical activity and food "logs", c) a cotinine test (to assess smoking status), and d) concurrent health-related factors obtained from their medical records, including current or recent hemoglobin A1c (A1c), current or recent Body Mass Index (BMI), current prescribed medications, and current health conditions. We will measure predictive validity by assessing how study subjects' responses to BAT questions correlate with their future health-related factors, namely health-related factors at six months and twelve months after the BAT administration completed at the beginning of the study as part of Objective 1. The health-related factors we will examine include: new A1c; new BMI; adherence to recommended foot and eye exams in the intervening period; number of hospitalizations, number of hospital days, and number of emergency room visits in the intervening period; new medications; frequency of provider use and type of provider use in the intervening period; and new health conditions. We are recruiting 75 subjects from Joslin, 75 from Walter Reed, and 75 from the community health centers in Hawaii for this assessment.

PROGRESS: Data collection for this study is complete at Joslin. Again, since the investigators are no longer at Joslin, the data were transferred with Stephanie Fonda to Walter Reed for analyses and reporting. This transfer was approved by Joslin and Walter Reed and is under review by the DoD. Moreover, data collection is nearly complete at Walter Reed (n = 64 have completed visit 1 and n = 50 have completed both visits).

MILESTONE AND DELIVERABLES:

5. Deployment of JVN Telehealth CDMP application into the Department of Defense HealtheForces. Robert Vigersky MD, and Sven-Erik Bursell PhD

PROGRESS: Deployment of CDMP into HealtheForces at Walter Reed Army Medical Center (WRAMC) was completed in May 2005. Diabetes Institute staff at WRAMC received CDMP training in June 2005. The Diabetes Institute staff is currently developing the process and procedures for use of the CDMP in their clinic and the Usability/Workflow Study has been completed and findings are being used to further refine CDMP as a case management tool (see #2 above). Recent requirements regarding interfacing to CHCSII are currently being investigated. A three-stage plan for integration which was initiated after discussions with representatives of the Office of the Surgeon General of the Army is being modified to be consistent with the Common Development

Environment (CDE) being developed by TATRC as a platform for the integration of clinical programs such as CDMP into AHLTA.

Project Deviations

The SOWs in previous fiscal years identified CDMP and related telehealth studies that were being conducted at consortium members' facilities. This SOW specifically provides an overview of the studies and their progress being conducted at WRAMC. Description of the accomplishments and problems encountered to data are identified under the section for each study.

Implementation of Study Manager

Study Manager is currently being used to manage and monitor the progress of three studies being conducted under the direction of COL Vigersky. The primary objective of each study is: 1) Measure the impact of a real-time continuous glucose monitoring (CGM) device on patients with Type 2 diabetes; 2) Determine the impact of a video cell phone reminder system on glycemic control in patients with diabetes mellitus: and 3) Obtain blood for genetic analysis from patients with diabetes mellitus complicated by nephropathy, autonomic neuropathy, or retinopathy and from their parents and/or siblings in order to determine if any or all of these complications are linked to one or more of the proposed candidate genes.

Each study is being managed by one project officer. It is expected that study manager will be implemented with the initiation of a minimum of two additional studies this year. The diversity of the studies as well as the diversity of personnel managing the studies provides an informal, but comprehensive platform from which to measure the usability and impact of study manager on workflow (efficiency) and effectiveness of data collection.

Deployment of JVN Telehealth CDMP application into the Department of Defense HealtheForces. Robert Vigersky MD, and Sven-Erik Bursell PhD

Deployment of CDMP into HealtheForces at Walter Reed Army Medical Center (WRAMC) was completed in May 2005. The Diabetes Institute staff is currently developing the process and procedures for use of the CDMP in their clinic and the Usability/Workflow Study has been completed and findings are being used to further refine CDMP as a case management tool (see #2 above). Recent requirements, however, regarding the elimination of HealtheForces and, consequently interfacing to AHLTA (CHCSII) are currently being investigated. A three-stage plan for integration which was initiated after discussions with representatives of the Office of the Surgeon General of the Army is being modified to be consistent with the Common Development Environment (CDE) being developed by TATRC as a platform for the integration of clinical programs such as CDMP into AHLTA.

A protocol entitled, "Integration and Assessment of a Diabetes Assessment Took Kit in AHLTA", has been approved by the WRAMC Department of Clinical Investigations and is pending approval by CIRO. The protocol reflects the modifications required the CDE. The implementation of this study will serve as one of the first prototypes for the integration of clinical programs into AHLTA.

Since the investigators are no longer at Joslin, the title of this report has been changed to reflect the addition of the University of Hawaii.

Conclusion

Diabetes mellitus is a significant cause of morbidity and mortality in the United States, and the leading cause of new blindness, chronic kidney disease, and non-traumatic amputation in the working-aged American population. Strategies are in place that, based on solid clinical and scientific evidence, can significantly reduce complications of diabetes through timely treatments and appropriate management. Unfortunately, less than 50% of patients with diabetes obtain appropriate medical care. Additionally, there are nearly 8 million Americans with diabetes who are unaware of their condition.

The Joslin Vision Network is a telemedicine initiative that has the potential to bring the highest quality care to all patients with diabetes. The JVN Telehealth program is a web-based interactive telemedicine application that can systematize the organization of disease and care management, that centralizes the patient in the care process, that can impact the ability of diabetic patients to more effectively mange their diabetes, improve their metabolic control, reduce the level of emotional stress associated with managing diabetes, and reduce the incidence of complications through implementation of the CDMP program.

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Appendix A

The CDMP is a web-based diabetes case management tool developed by a consortium of researchers, physicians, and educators specializing in diabetes and its management. The consortium is drawn from the Joslin Diabetes Center, the Department of Defense [Walter Reed Army Medical Center (WRAMC) and Tripler Army Medical Center (TAMC)], Veterans Health Affairs (Boston Veterans Hospital), and the Indian Health Service (IHS). The overall goal behind the development of the CDMP is to provide an interactive, web-based clinical tool for care managers that improves diabetes care. The CDMP is intended to: provide an automatic system to foster a high level of continuous care and communication among patients, care managers, and physicians; insure that the latest clinical guidelines are used in the care; and focus on *both* clinical and behavioral patient problem areas, rather than just clinical areas, as is usually the case in diabetes care.

The standard clinical care for a patient with diabetes typically follows a pattern similar to that outlined below:

1) Patient assessment by review of medical records and lab reports, taking a medical history, and performing a physical examination;
2) Assessment of the physical, psychological, and learning status of the patient (via formal or informal interviewing techniques and/or exams);
3) Preparation and maintenance of a treatment plan for the patient, with an emphasis on patient self-management;
4) Referral of patient needing immediate medical care for non-diabetic problems to his/her primary care provider (PCP) or identification of a PCP for any patient who does not have one;
5) Referral of the patient to consultants (e.g. ophthalmology, cardiology, and nephrology) as needed;
6) Referral of the patient to diabetes education services, including classes, booklets, and other media;
7) Ongoing follow-up and feedback to the patient and treatment providers.

By contrast, the CDMP was designed to contribute to the standard clinical process by:

1) Generating three levels of alerts for the care manager or provider, all of which are based on a risk assessment algorithm and American Diabetes Association (ADA) and Diabetes Institute (DI) diabetes management guidelines (see below) in advance of the clinic visit;
2) Providing clinical assessment, notification, and communication tools;
3) Tracking availability and patient use of educational resources that are site and user specific;
4) Summarizing patient knowledge and the impact of educational interventions;
5) Providing dynamic care planning which is done with the patient and targets physical wellness, lifestyle self-management, and psychosocial health (including possible patient barriers in these areas);
6) Connecting with the health organization's health information system or available electronic data (with provisions for client and medical records privacy).

The CDMP is based on current ADA clinical practice guidelines (CPGs) and those of the Diabetes Institute of the WRHCS. They focus on diabetes clinical management, lifestyle modification and psychosocial health. In the CDMP case management model, the care manager is the key coordinator between patients and

the healthcare team that includes MDs, NPs, educators, sub-specialists, nutritionists, and behavioral clinicians.

The CDMP is designed to be superimposed functionally and integrated into the Health*e*Forces Integrated Clinical Data Base (ICDB) until it is de-commissioned and then into CHCS II. There is a CDMP server housed in the Department of Information Management, WRAMC.

CDMP generates "alerts" when a patient has experienced a particular health event or when the results from a patient's test exceed a pre-determined clinical threshold. Alerts are presented to the care manager/provider on his/her home page when next s/he logs into ICDB. The alerts are "red" (high risk), "yellow" (medium risk), and "green" (low risk) icons and are based on the CPGs. Selecting the alert icon activates search options specific to the patient; e.g., demographic data, medication list, laboratory results, the event or result that generated the alert, available options for the care plan, and follow-up actions. These are displayed with a pull-down menu from which the care manager/provider can select various actions to be taken in response to the alert.

The CDMP also provides an overall clinical risk stratification of each patient. The stratification indicates whether and how the patient is above or below established goals in the areas of glycemic control, nephropathy, peripheral vascular disease, peripheral neuropathy, and retinopathy. Together with the care manager's/provider's knowledge of his/her patient, the risk stratification allows the care manager/provider to devise an individualized care plan that includes recommendations regarding the patient's goals, lifestyle, monitoring needs, and areas requiring further education. The risk stratification indicates whether patients are "high risk", "moderate risk", or "low risk" based on the Joslin Diabetes Center Clinical Guidelines for Adults with Diabetes.

CDMP has a section on patient education. This section lists the educational tools available at a particular site (e.g., videos, books, classes) and provides an evaluation of how advanced each tool is. The care manager and/or the diabetes educator can then assign educational tools, track each patient's use of the tools, and thus obtain a summary of a patient's knowledge and the impact of the educational intervention.

The CDMP contains other features intended to assist the care manager/provider in the organization of his/her caseload. For example, the CDMP home page shows the care manager's/provider's daily reminders. The reminders show the patient's name, the type of reminder needed (e.g., clinical assessment, modification of the care plan, etc.), and pertinent details regarding the reminder such as type of action needed. The CDMP home page also shows each day's upcoming appointments. Further, there is a scheduler within the CDMP that helps care managers to schedule routine appointments. Finally, the CDMP provides the care manager/provider easy access to complete, and/or up-to-date paperless records of each patient in his/her caseload. For each patient, these records include a history of his/her behavioral assessment, a photograph, demographics and vital signs, medication usage, record of laboratory results, health care procedures the patient has had, diagnoses, patient admission history, education history, and the results (if performed) of the non-dilated retinal examination using the Joslin Vision Network digital, stereo non-mydriatic cameras. The Joslin Vision Network is already located in 4 sites in the Walter Reed Health Care System (WRAMC, Kimbrough Ambulatory Care Center, Dewitt Army Community Hospital, and Fairfax Family Health Clinic), so this

information will be included in the CDMP at the Diabetes Institute when it is deployed.

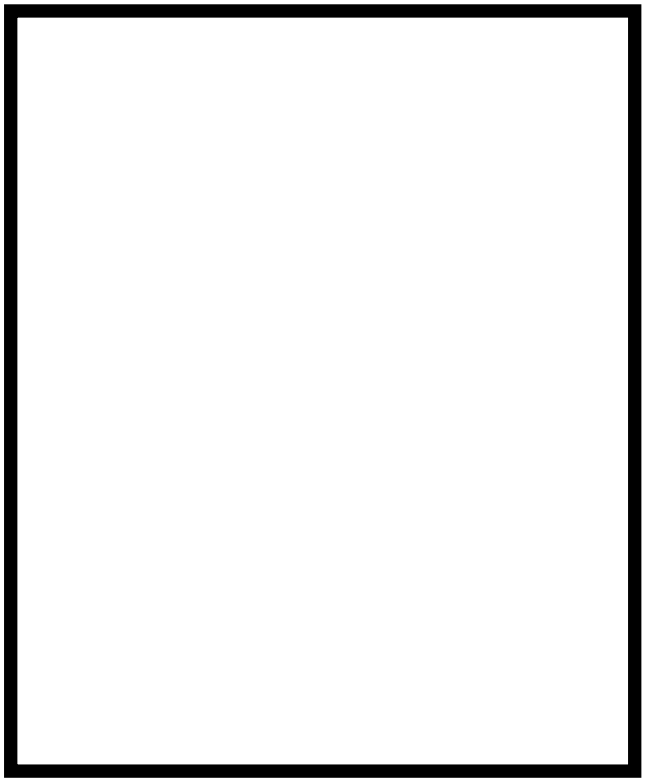
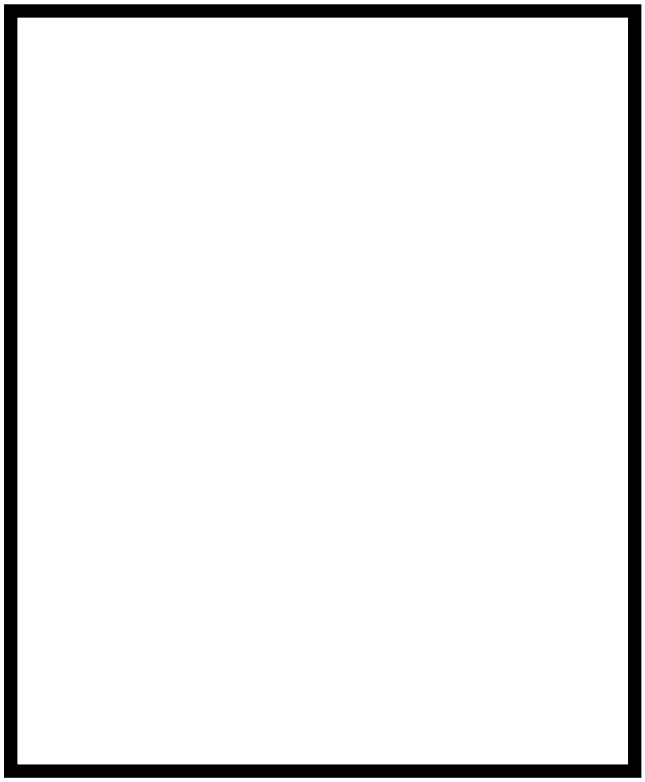
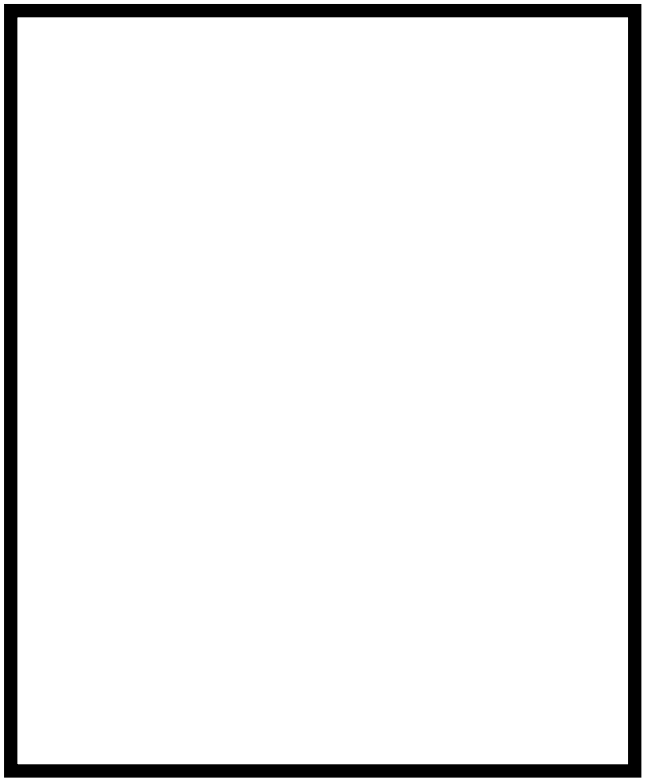
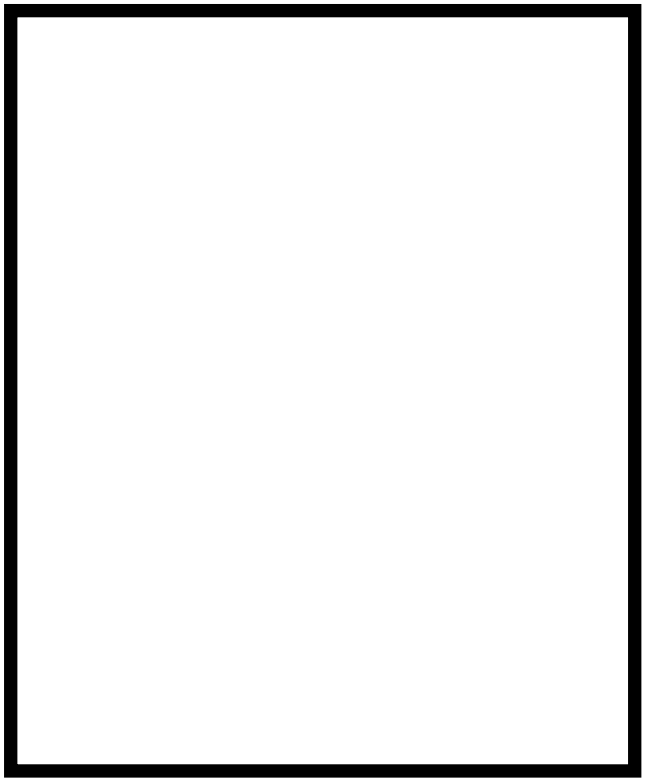
Appendix B

SECTION A. CLOCK DRAWING EXERCISE

Please read and do the following carefully:

- *In the blue box on the next page:*
- *Draw a picture of a clock*
- *Put in all the numbers*
- *Set the time to ten after eleven*

Hand this sheet back and go to the next page

SECTION B. BACKGROUND INFORMATION

1. ***What is your date of birth?***

		/			/				
M	*M*		*D*	*D*		*Y*	*Y*	*Y*	*Y*

2. ***Are you male or female?***

O Male

O Female

3. ***Do you consider yourself to be Spanish, Hispanic, or Latino (Latina)?***

O Yes

O No

4. ***What race do you consider yourself to be? Select one or more of the following:***

	Yes	***No***
a. American Indian or Alaska Native	*O*	*O*
b. Asian	*O*	*O*
c. Black or African American	*O*	*O*
d. Native Hawaiian or other Pacific Islander	*O*	*O*
e. White or Caucasian	*O*	*O*
f. OTHER	*O*	*O*
f1. SPECIFY		

5. ***What is the highest grade or level of school you have completed or the highest degree you have received?***

- *O* *Less than high school*
- *O* *High school diploma (including GED)*
- *O* *Some college*
- *O* *College degree (including Associate's or Bachelor's Degree)*
- *O* *Some graduate school*

O *Graduate or professional degree (including MA; MS; Master's, MBA, Law and MD, PhD)*

6. ***How many people, including yourself, are supported on your household's income?*** | | | *# PEOPLE*

7. ***Including income from wages, salaries, Social Security or retirement benefits, help from relatives, veteran's benefits, real estate, investments, and other sources, about how much was your total <u>household income</u> in the last 12 months?***

O *Less than $5,000*

O $5,000 - $9,999

O $10,000 - $19,999

O $20,000 - $29,999

O $30,000 - $39,999

O $40,000 - $49,999

O $50,000 - $59,999

O $60,000 - $69,999

O $70,000 - $79,999

O $80,000 - $89,999

O $90,000 - $99,999

O $100,000 or more

O Don't know

8. ***Are you currently covered by public (e.g., Medicare, Medicaid) or private (e.g., through your or your spouses' job, etc.) health insurance?***

O *Yes*

O *No*

SECTION C. BEHAVIORAL ASSESSMENT TOOL

Bat Study Questionnaire	*STUDY PARTICIPANT ID*							
	DATE							
			/			/		
	M	*M*		*D*	*D*		*Y*	*Y*

1. *Is English your native language?*

   O No
   O Yes

   Go to next question
   Skip to question # 3

2. *When you learn something new, does it help to hear it in your native language?*

   O *Yes*
   O *No*
   O *Don't know or not sure*

3. *Would you like someone who speaks your native language to help you complete this survey?*

   O *Yes*
   O *No*
   O *Don't know or not sure*

4. *Do you have problems reading and understanding written materials?*

   O *Yes*
   O *No*
   O *Don't know or not sure*

   Go to next question
   Skip to question #6

5. *Would you like someone to read the survey questions to you?*

   O *Yes*
   O *No*
   O *Don't know or not sure*

Diabetes History

6. *When were you first told you have diabetes?*

- O *I was just diagnosed within the last 12 months*
- O *1 - 5 years ago*
- O *6 - 10 years ago*
- O *More than 10 years ago*
- O *Don't know or not sure*

Nutrition

7. *On a typical day, how many servings of fruits and vegetables do you eat?*

- O *None*
- O *1 - 5 servings*
- O *6 – 10 servings*
- O *More than 10 servings*
- O *Don't know or not sure*

8. *During the past 7 days, how often did you eat 3 meals a day (that is, you did not skip a meal)?*

- O *0 days*
- O *1 - 5 days a week*
- O *6 - 7 days a week*
- O *Don't know or not sure*

9. *How many times in the past 7 days have you eaten food prepared in a restaurant or cafeteria?*

- O *0 times*
- O *1 - 2 times*
- O *3 - 5 times*
- O *6 or more times*
- O *Don't know or not sure*

Physical Activity

10. *How would you describe your physical activity level?*

- O *Sedentary or lightly active (Mostly sitting or lying down, e.g., TV, reading; Sitting or standing most of the day, e.g., desk work, teaching, white collar work, light housework)*
- O *Moderately active (Standing or walking, moving most of the day, e.g., heavy housework, brisk walking, gardening)*
- O *Very active (Moving strenuously, e.g., aerobics, biking, hiking, running, climbing stairs, mowing lawn, manual labor)*
- O *Don't know or not sure*

11. *In the last 7 days, how many times were you moderately to very physically active for 30 minutes or more?*

- O *0 times*
- O *1 - 3 times*
- O *4 - 6 times*
- O *More than 6 times*
- O *Don't know or not sure*

Checking Blood Sugars

12. How often do you check your blood sugar?

- O *Never*
- O *Less than once a week*
- O *1 - 5 days a week*
- O *About once a day*
- O *Twice a day or more*
- O *Don't know or not sure*

Medications

13. In the last 7 days, how often did you miss taking your diabetes pills or insulin?

- O *One time a week*
- O *2 - 4 times a week*
- O *Most days*
- O *Everyday*

Mood

14. During the past month have you often been bothered by feeling down, depressed, or hopeless?

- *O* *Yes*
- *O* *No*
- *O* *Don't know or not sure*

15. *During the past month have you often had little interest or pleasure in doing things?*

- O *Yes*
- O *No*
- O *Don't know or not sure*

Alcohol

16. *Do you drink alcohol?*

- O *Yes*
- O *No*

Go to next question
Skip to question #18

17. *Are you concerned about your drinking?*

- O *Yes*
- O *No*

Smoking

18. *Do you smoke cigarettes, cigars, a pipe, or chew tobacco?*

- O *Yes*
- O *No*
- O *No, but I quit within the last 6 months*

Your health

19. *In general, would you say your health is:*

- O *Excellent*
- O *Very Good*
- O *Good*
- O *Fair*
- O *Poor*

20. *Have you been examined by an eye doctor in the last 12 months?*

- O *Yes*
- O *No*
- O *Don't know or not sure*

21. *How often do you check your feet for sores, cuts, or bruises?*

- O *Never*
- O *Once a month*
- O *Every couple of weeks*
- O *At least once a week*
- O *Every day*
- O *Don't know or not sure*

22. *Have your feet been examined by a doctor in the last 12 months?*

- O *Yes*
- O *No*
- O *Don't know or not sure*

23. *Do you use other healing methods or remedies in addition to those prescribed for you?*

- O *Yes*
- O *No*
- O *Don't know or not sure*

Support from Family and Friends

24. *Do you have family and friends you can ask for help?*

- O *Yes* — ***Go to next question***
- O *No* — ***Skip to question #26***
- O Don't know or not sure — ***Skip to question #26***

25. *Do your family and friends live in your house or nearby?*

- O *Yes*
- O *No*
- O *Don't know or not sure*

26. *Do you agree with the following statement? My family and friends support me by encouraging me to do things to improve my health.*

- O *Strongly agree*
- O Agree
- O *Neither agree nor disagree*
- O *Disagree*
- O *Strongly disagree*

Coming to the clinic

27. *Do you have problems getting to the clinic?*

- O *Yes*
- O *No*

28. *How long does it usually take you to get to the clinic?*

- O *Less than 30 minutes*
- O *30 minutes to an hour*
- O *More than an hour*
- O *Don't know or not sure*

29. *How do you usually get to the clinic?*

- O *My family or a friend drives me*
- O *I drive myself*
- O *I ride a van or bus or train*
- O *I walk or ride a bicycle*
- O *Other*

Education

30. *How do you like to learn about new things?*

		Yes	***No***
a.	*Watching slides or videos*	*O*	*O*
b.	*Reading*	*O*	*O*

c.	*Others showing me how*	*O*	*O*
d.	*Discussions*	*O*	*O*
e.	*Listening to others*	*O*	*O*
f.	*Using computers*	*O*	*O*
g.	*In a class*	*O*	*O*
h.	*Other ways*	*O*	*O*

31. *How much have you learned about diabetes from reading materials, visits with nurses, or attending classes?*

- *O* *A lot*
- *O* *Some*
- *O* *None*
- *O* *Don't know or not sure*

32. *Would you like to learn more about taking care of your diabetes?*

- *O* *Yes*
- *O* *No*
- *O* *Don't know or not sure*

More About You

33. *Which **BEST** describes you? (Choose only one answer.)*

- *O* *Employed full-time*
- *O* *Employed part-time*
- *O* *Disabled*
- *O* *Retired*
- *O* *Student*
- *O* *Looking for work*
- *O* Other

34. *Do you have any vision problems?*

- *O* *Yes*
- *O* *No*
- *O* *Don't know or not sure*

35. *Do you have any hearing problems?*

- *O* *Yes*

O *No*

O *Don't know or not sure*

36. *Do you have any problems walking?*

O *Yes*

O *No*

O *Don't know or not sure*

37. *Do you have problems remembering things?*

O *Yes*

O *No*

O *Don't know or not sure*

38. *Do you have any money issues that affect your ability to take care of any of the following items?*

		Yes	***No***
a.	*Medication*	*O*	*O*
b.	*Food*	*O*	*O*
c.	*Transportation*	*O*	*O*
d.	*Self-monitoring supplies*	*O*	*O*

39. *Do you have any concerns about your diabetes that we have not covered today? If you check yes, someone from the staff will talk to you about them. (NOTE: QUESTION WILL NOT BE ASKED FOR THIS STUDY)*

O *Yes*

O *No*

O Don't know or not sure

SECTION D. FINAL QUESTION

1. *Did you complete these questions with help from another person?*

   O *Yes*

   O *No*

   O *Don't know or not sure*