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Award Number: W81XWH-05-2-0018

TITLE: Diabetes Care and Treatment

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14. ABSTRACT The major goals of this continuing project are the establishment of a telemedicine system for comprehensive diabetes management and the assessment of diabetic retinopathy that provides increased access for diabetic patients to appropriate care, that centralizes the patients in the care process, that empowers the patient to better manage their disease, that can be performed in a cost effective manner, and that maintains the high standard of care required for the appropriate management of diabetic patients. The aim of this program of research will be 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. These research studies and the implementation of CDMP were originally planned at Tripler Army Medical Center (TAMC) in Honolulu, HI. Because the decision was made at TAMC to accelerate the adoption of a new electronic medical record (AHLTA), implementation of the CDMP was delayed indefinitely. Consequently, alternative sites were chosen for these research studies and the implementation of the CDMP: Waianae Coast Community Health Center, Waianae, HI; The Physicians Center at Mililani, Mililani, HI; and the Molokai General Hospital, Kaunakakai, HI. Retinal imaging with a JVN system was implemented into an additional site, Koolauloa Community Health Center.					
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Introduction:

The major goals of this continuing project are the establishment of a telemedicine system for comprehensive diabetes management and the assessment of diabetic retinopathy that provides increased access for diabetic patients to appropriate care, that centralizes the patients in the care process, that empowers the patient to better manage their disease, that can be performed in a cost effective manner, and that maintains the high standard of care required for the appropriate management of diabetic patients. The aim of this program of research will be 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 Hawaiian sites chosen for these research studies and the implementation of the CDMP are: Waianae Coast Community Health Center, Waianae, HI; The Physicians Center at Mililani, Mililani, HI; and the Molokai General Hospital, Kaunakakai, HI. The JVN retinal imaging system was also implemented into the Koolauloa Community Health Center during this period.

Body:

This research program will leverage the recently developed Comprehensive Diabetes Management Program (CDMP) and the Joslin Vision Network (JVN) Eye Health Care Program that is now a module within the CDMP to provide continuum of care for diabetic patients. The CDMP application has been developed with participation and input from leading experts in diabetes care from the Joslin Diabetes Center,

Department of Defense, the Veterans Health Administration, and the University of Hawaii.

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.

Research Sites

Originally these research studies and the implementation of the CDMP were planned at Tripler Army Medical Center (TAMC) in Honolulu, HI and at Hawaii VA Community Based Outpatient Clinics (CBOCs) located in: Hilo, Hawaii County; Kahalui, Maui County; and Lihue, Kauai County. The decision was made at TAMC, however, to accelerate the adoption of a new electronic medical record (AHLTA or CHCSII), thereby, delaying the implementation of the CDMP indefinitely. During ensuing discussions with the government, it was proposed that the implementation of the CDMP and planned research studies be relocated to community health centers and clinics within the state of Hawaii. Site visits were conducted and evaluated for the proposed implementation of the CDMP and JVN imaging system and the proposed research studies. The sites selected for the project were: The Waianae Coast Community Health Center, The Physicians Center at Mililani, and the Molakai General Hospital. A

proposal modification and re-directed budget were submitted and approved by the government.

In addition the Koolauloa Community Health Center was awarded a grant from AlohaCare to implement a retinal imaging program into their center. After discussions with personnel from this project, they chose the JVN imaging system and agreed to become a fourth site for our studies.

The change in research sites required the relocation of equipment from the Ophthalmology Service at Tripler Army Medical Center, and the Community Based Outpatient Clinics in Kahalui, Maui County and Lihue, Kauai County into the new sites. Deployment of the CDMP and the JVN retinal imaging system into The Waianae Coast Community Health Center, The Physicians Center at Mililani, and the Molokai General Hospital was completed in April 2006. Training of imagers from Waianae Coast Comprehensive Health Center and Molokai General Hospital for the JVN Eye Health Care Program was completed from February. 27, 2006 to March 2, 2006. JVN imager review and refresher training was conducted for imagers at Waianae Coast Comprehensive Health Center and Molokai General Hospital from July 19-21, 2006. An additional imager from Koolauloa Community Health Center was trained from June 12 – 14, 2007. The number of patients imaged is displayed in Appendix H.

Development of the CDMP Behavioral Assessment Tool (BAT)

Diabetes mellitus is a significant cause of morbidity and mortality in the United States.¹ Clinical and scientific evidence has led to the development of strategies that can reduce the complications of diabetes through timely treatments and appropriate management. Reduction or prevention of costly diabetes-related complications requires

blood glucose levels be kept as close as possible to the normal range.^{2,3} This is achieved through daily patient adherence to a healthy diet, including control of carbohydrate intake, regular exercise, appropriate use of diabetes medications (insulin and oral agents), and regular blood glucose monitoring to guide daily management decisions. In addition, hypoglycemia management and prevention, foot care, clinic visits, diabetes education, and various necessary medical screenings must all be incorporated into daily life.

Health care professionals usually attempt to assess a diabetic patient's current behaviors during routine clinic visits. These assessments, however, are problematic for several reasons, including practical time constraints in busy clinical practices, lack of professional training, institutional support, reimbursement practices, and a paucity of user-friendly behavioral assessment tools. Thus, there is need for efficient and effective methods to measure diabetic patients' current behaviors.

In response to this need, the Behavioral Assessment Tool (BAT) was developed as a stand-alone module within the Comprehensive Diabetes Management Program (See Appendix G). The BAT was developed by a panel of health care experts in diabetes representing the Joslin Diabetes Center, the Department of the Army or the Medical Research and Materiel Command (MRMC), the Veteran's Administration, the University of Hawaii, and the Indian Health Service. The instrument consists of 39 multiple-choice questions about an individual's behavior. There are 13 sub-sections as follows: Diabetes History, Nutrition, Physical Activity, Checking Blood Sugars, Medications, Mood, Alcohol, Tobacco Use, Your Health, Support from Family and Friends, Coming to the Clinic, Education, and More about You. These sub-sections

encompass behaviors with respect to three major behavioral categories: physical wellness (i.e., medications and general health), lifestyle and self-management (i.e., nutrition, physical activity, tobacco and alcohol use, and checking blood glucose levels), and psycho-social (i.e., mood, support network, and access to clinic). The panel deemed tobacco use to be critically important, and responses to tobacco use questions are reported separately, rather than in the category lifestyle and self-management. Additionally, the instrument collects some personal information (i.e., learning preferences and work status). The instrument was designed to require approximately 15 minutes to complete and to be usable for repeated applications.

Most of the BAT questions are structured to indicate low, intermediate and high risk of diabetes complications. Weights have been assigned to responses and summarized scores can be presented to the healthcare provider for each of the three behavioral categories (i.e., physical wellness, lifestyle and self-management, and psycho-social). A risk stratification scheme was developed in which ranges of scores in each of the three behavioral categories correspond to high, intermediate, and low risk. The range of scores for risk assessment was determined by a consensus of the panel that developed the instrument. The software program generates “alerts” based on a patient’s risk level and notifies the health care provider of the patient’s status. These alerts can be used to target areas for behavioral and/or educational interventions.

CDMP Behavioral Assessment Tool (BAT) Research Studies

Given that the BAT is a new instrument with much promise as a care management tool, it is necessary to test its measurement properties, including test-retest reliability and validity. The two studies listed below are prospective in nature and involve multiple

participating centers, including The Waianae Coast Community Health Center, The Physicians Center at Mililani, and the Molakai General Hospital. These proposed prospective studies will require 2 to 3 years for successful completion. Both studies have the overall goal of suggesting approaches to modify the BAT in response to what is learned from the data collection and analyses.

A. An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program's (CDMP) Behavioral Assessment Tool: This research study focuses on assessing the test-retest reliability of the Behavioral Assessment Tool (BAT). The specific objectives of this study are:

- (1) To determine the test-retest reliability of the BAT.
- (2) To examine whether the BAT's test-retest reliability is invariant across social-demographic groups.
- (3) To aggregate BAT data from all of the sites participating in the study (including Joslin) and examine whether test-retest reliability is invariant across sites.

B. An Assessment of the Validity of the Comprehensive Diabetes Management Program (CDMP) Behavioral Assessment Tool: This focuses on two types of criterion validity; concurrent validity and predictive validity. Concurrent validity is the correlation between a measure and an external criterion at the same point in time. Predictive validity¹ is the correlation between a measure and an external future criterion.^{4,5} The specific objectives are:

¹ To illustrate predictive validity: Scholastic Aptitude Test (SAT) scores have a high predictive validity with College Grade Point Average (CGPA) (with a correlation of about .40). That is, the scores on a test routinely administered to high school students (SAT) "predicts" one measure of

- (1) To establish the concurrent validity of the BAT by examining how study subjects' responses to its questions correlate with the following: 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.
- (2) To establish the predictive validity of the BAT by assessing how study subjects' responses to BAT questions (and subjects' risk stratification scores) 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.
- (3) To aggregate BAT data from all of the sites participating in the study (including Joslin) and examine whether these types of validity are invariant across sites.

academic achievement in college (CGPA). Thus SAT scores are often used to justify college admission decisions.

Key Research Accomplishments:

- JVN imaging of diabetic patients became standard of care in the Ophthalmology Service at Tripler Army Medical Center
- The number of patients who received JVN imaging in Hawaii was 3203
- Research studies completed
 - o Reading Center Certification
 - o DOIT: Patient Education
 - o JVN Imaging compared to dilated eye examination
- Recruitment of four new clinical sites for CDMP and JVN implementation and proposed research studies: The Waianae Coast Community Health Center, The Physicians Center at Mililani, Molakai General Hospital, and Koolauloa Community Health Center.
- The CDMP Behavioral Assessment Tool was developed as a joint effort with representatives of the Joslin Diabetes Center, the New England VA, Walter Reed Army Medical Center, and the University of Hawaii
- A research protocol entitled “An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program’s (CDMP) Behavioral Assessment Tool” has received final approval from the Institutional Review Boards of the Joslin Diabetes Center, the Boston VA, the Walter Reed Army Medical Center, the University of Hawaii, and the MRMC ORP Human Subjects Research Review Board.
- A research protocol entitled “An Assessment of the Validity of the Comprehensive Diabetes Management Program (CDMP) Behavioral Assessment Tool” has

received final approval from the Institutional Review Boards of the Joslin Diabetes Center, the Boston VA, Walter Reed Army Medical Center, and the MPMC ORP Human Subjects Research Review Board. Additionally, the protocol has been drafted for submission to the University of Hawaii Committee on Human Studies.

- Invited presentations on the Comprehensive Diabetes Management Program were given to
 - o The University of Hawaii Bioinformatics class (ICS 614)
 - o The Chronic Kidney Disease Alliance of the National Kidney Foundation of Hawaii
 - o COL Karl Friedl, Director, Telemedicine and Advanced Technology Research Center, US Army Medical and Materiel Command

Reportable Outcomes:

Papers and Presentations:

Garren, J., Fonda, S., Bursell, S., Conlin, P., Vigersky, R., & Birkmire-Peters, D. (2007, April - May). Test-Retest Reliability of a New Screening Questionnaire for People with Diabetes. Poster presented to the 2007 CDC Diabetes Translation Conference, Atlanta, GA. (See Appendix J)

Bursell S-E, Birkmire-Peters D, Conlin PR, Fonda SJ, Kedziora RJ, Paulsen C, Perkins J, Rodbard D, Vigersky R. (2006, May). Human Factors Analysis: Joslin Vision Network Comprehensive Diabetes Management Program. Poster presented at the 11th Annual Meeting of the American Telemedicine Association, San Diego, CA. **(Award for Best Poster)**

Birkmire-Peters, D.P. (2006, May). Use of Human Factors Principles in Telemedicine Research. Paper presented in The People Make the Difference: Human Factors in Telemedicine Panel at the 11th Annual Meeting of the American Telemedicine Association, San Diego, CA.

Coll, K.J., Birkmire-Peters, D.P., Pelletier, M.V., Cavallerano, J., Bursell, S., Winkle, R.K. & Aiello, L.M. (2005, April). Joslin Vision Network: Eye Care Visits Following JVN Imaging. Poster presented at the 10th Annual Meeting of the American Telemedicine Association, Denver, CO.

Birkmire-Peters, D.P., Coll, K.J., Dunlap, W.A., Bursell, S.-E., Cavallerano, J.D., & Aiello, L.M. (2004, May). Comparison of Dilated Eye Examinations to JVN Imaging at TAMC. Paper presented at the 9th Annual Meeting of the American Telemedicine Association, Tampa, FL.

Coll, K.J., Birkmire-Peters, D.P., Pelletier, M.V., Cavallerano, J., Bursell, S., Dunlap, W., Winkle, R.K. & Aiello, L.M. (2004, May). Joslin Vision Network: Evidence Supporting Need for Comprehensive Disease Management. Poster presented at the 9th Annual Meeting of the American Telemedicine Association, Tampa, FL.

Coll, K.J., Birkmire-Peters, D.P., Pelletier, M.V., Cavallerano, J., Bursell, S., Dunlap, W., Winkle, R.K. & Aiello, L.M. (2004, May). Joslin Vision Network: Evidence Supporting Need for Comprehensive Disease Management in Asians and Pacific Islanders. Poster presented at the 14th Asia Pacific Military Conference, Brisbane, Australia.

Coll, K.J.; Birkmire-Peters, D.P., Katalinic, P., Ann Tolson, BA, Cavallerano, A.; Cavallerano, J., Bursell, S., Dunlap, W.; & Aiello, L.M. (2003, May). Joslin Vision Network: Impact on Clinical Operations at Tripler Army Medical Center. Poster presented at the 8th Annual Meeting of the American Telemedicine Association, Orlando, FL.

Sakuda, J.M., Swain, G., Yanellas, T., Saiki, S.M., Birkmire-Peters, D.P. & Kim, G. (2003, May). Tele-Health Applications in the VA Health Care System in Hawaii. Poster presented at the 8th Annual Meeting of the American Telemedicine Association, Orlando, FL.

Coll, K.J.; Birkmire-Peters, D.P.; Katalinic, P.; Ann Tolson, BA³; Cavallerano, A.; Cavallerano, J.; Bursell, S.; Dunlap, W.; & Aiello, L.M. (2002, June). Joslin Vision Network Increases Access for Diabetic Eye Care at Tripler Army Medical Center. Poster presented at the 7th Annual Meeting of the American Telemedicine Association, Los Angeles, CA.

Birkmire-Peters, D.P., Coll, K.J., Dunlap, W. & Sukada, J. (2001, June). Joslin Vision Network Initiatives: Tripler Army Medical Center and Honolulu Veteran's Administration. Paper presented at the 6th Annual Meeting of the American Telemedicine Association, Ft. Lauderdale, Florida.

Bursell, S.-E., Cavallerano, J., Cavallerano, A., Clermont, A.C., Birkmire-Peters, D., Aiello, L. & the Joslin Vision Network Research Team. (2000). Joslin Vision

Network Image Validation: Non-mydriatic, digital video retinal images compared to standard 35-mm photography for diabetic retinopathy diagnosis. Ophthalmology, 108 (3), 572-585.

Conclusions:

The implementation of the Comprehensive Diabetes Management Program, including the Joslin Vision Network (JVN) Eye Health Care Program that is now a module within the CDMP, should result in increased clinical effectiveness and economic efficiency through the use of disease management and care management for people with diabetes. Additionally, the use of the CDMP has the potential to markedly decrease vision loss secondary to diabetes, improve management of diabetes with a resultant decrease in mortality and morbidity, reduce patient associated emotional stress in dealing with their own diabetes, increase patient and provider satisfaction, and increase the cost-savings in the management of a chronic disease. The use of telemedicine here will enable the care management follow-up and coordination to take place easily over wide geographic areas.

The relocation of the planned CDMP implementation into the community health centers in Hawaii can potentially increase the generalizability of the results of the overall research program to a larger number of settings and to wider populations. First, the CDMP will be used and evaluated in primary care settings, as opposed to specialty clinics. Second, the populations served at these health centers are ethnically diverse and not represented in large part at other sites.

References:

¹Centers for Disease Control and Prevention. National diabetes fact sheet: National estimates on diabetes. Atlanta, GA: US Department of Health and Human Services, CDC, 2002.

²Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine* 1993, 329: 977-86.

³United Kingdom Prevention of Diabetes Study, Prospective Diabetes Study Group. Intensive blood glucose control with sulfonylureas or insulin compared with conventional treatment and risk of complications with type 2 diabetes. *Lancet* 1998, 352: 837-53.

⁴Carmines, Edward G. and Zeller, Richard A. 1979. "Reliability and Validity Assessment." Newbury Park, CA: Sage Publications, Inc.

⁵Crocker L, Algina J. Introduction to classical and modern test theory. New York:Holt, Rinehart & Winston, 1986; 224.

Appendix A

First Quarter (Year 2) Activities

January 1, 2006 to March 31, 2006

Quarterly Report Format

1. Award No: W81XWH-05-2-0018
2. Report Date: 4/14/2006
3. Reporting period: 1/01/2006 – 3/31/2006 (Q1 Year 2)
4. Principal Investigator: Deborah Birkmire-Peters, PhD
5. Telephone No.: 808-692-1090
6. Award Organization: University of Hawaii
7. Project Title: Diabetes Care and Treatment
8. Current staff, role and percent effort of each on project.

STAFF MEMBER	ROLE	% EFFORT
Deborah Birkmire-Peters, PhD	PI	50%
Dale Vincent, MD	Co-I	25%
Joseph Humphry, MD	Co-I	10%
Kristin Okahashi, BA	Administrative Assistant	25%
Kari-Jo Parisi	Imager/Reader	Intermittent

9. Contract expenditures to date (as applicable):

COST ELEMENTS	THIS QUARTER	CUMULATIVE
Personnel	\$ 29,742.06	\$ 88,619.33
Fringe Benefits	\$ 5,339.03	\$ 16,666.99
Supplies	\$ 1,652.33	\$ 3,061.16
Equipment	\$ 2,493.73	\$ 2,592.73
Travel	\$ 9,740.54	\$ 40,573.77
Other Direct Costs		\$ 4,270.57
Subtotal	\$ 48,967.69	\$155,784.55
Indirect Costs	\$ 10,087.35	\$132,091.63
Fee		
Total	\$ 59,055.04	\$187,876.18

10. Comments on administrative and logistical matters.

A. Final report covering period from January 1, 2005 to December 31, 2005 was completed and submitted.

B. Subcontracts for Waianae Coast Comprehensive Health Center (WCCHC), the Physician Center at Mililani (PCM), Molokai General Hospital (MGH), and Estenda Solutions, Inc. were prepared and submitted to the John A. Burns School of Medicine Fiscal Office for review. Dr. Birkmire-Peters met with Avis Lam, the Telehealth Research Institute fiscal officer, to discuss those contracts on February 2, 2006.

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this contract. Explain deviations where this isn't possible. Include data where possible.

A. Drs. Birkmire-Peters, Vincent, and Humphry attended the 2005 CDMP Winter Summit in Santa Cruz, CA from January 11-12, 2005. Dr. Vincent gave a presentation on group medical visits and discussed the use of the CDMP to facilitate those visits.

B. Dr. Birkmire-Peters attended the Distance Medicine Product Line Review in Frederick, MD on January 17, 2006. She presented the status of the project at the three community health centers (Waianae Coast Comprehensive Health Center (WCCHC), the Physician Center at Mililani (PCM), and Molokai General Hospital) in Hawaii and the status of the protocol entitled "An Assessment of the Validity of the Comprehensive Diabetes Management Program (CDMP) Behavioral Assessment Tool."

C. Drs. Birkmire-Peters and Humphry held planning meetings to discuss the Comprehensive Diabetes Management Program (CDMP) and implementation of the CDMP and JVN imaging systems into the three community health centers in Hawaii (January 5, February 2, March 9, 23, and 30, 2006). Dr. Humphry called the two primary medical laboratories in the state, Clinical Laboratories of Hawaii (CLH) and Diagnostic Laboratory Services (DLS), to initiate discussions regarding the electronic download of laboratory reports into the CDMP.

D. Drew Lewis and Rick Walsh, Estenda Solutions, Inc., and Michael Dech, Joslin Diabetes Center, installed the JVN imaging systems into the clinics at Waianae Coast Comprehensive Health Center, the Physicians Center at Mililani, and Molokai General Hospital from February 13 – 17, 2006.

E. Dr. Birkmire-Peters and Humphry participated in demonstration of the CDMP to the Hawaii Affiliate of the National Kidney Foundation on 13 Jan 2006. The NKF is interested in adopting a modified version of the CDMP for a project for the early identification patients at risk for chronic kidney disease for enrollment into specialized clinics.

F. Kari-Jo Parisi met with Rick Walsh, Estenda Solutions, Inc., to discuss the set-up of her remote reading station. Additionally, they prepared the equipment to be shipped to San Jose, CA. Mr. Walsh later set up the IP address for Ms. Parisi's workstation.

- G. Dr. Birkmire-Peters and Ms. Parisi held a VTC with Radmila Esteron, JVN imager, and Desiree Puhi, Director of Outpatient Services, Molokai General Hospital, to discuss the upcoming imager training and aspects of the project with respect to the JVN imaging (February 22, 2006).
 - H. Dr. Birkmire-Peters and Ms. Parisi met to finalize details of the remote reading station on Feb. 24, 2006.
 - I. Darlene Kaahaaina, Waianae Coast Comprehensive Health Center, Radmila Esteron, Molokai General Hospital, and Rick Walsh, Estenda Solutions, completed JVN Imager Training from March 1 – 3, 2006.
 - J. Dr. Birkmire-Peters attended meetings at the Joslin Diabetes Center from March 1 - 3, 2005. She met with Dr. Sven Bursell to discuss issues with respect to the project in Hawaii. Additionally, she met with Dr. Stephanie Fonda to discuss the planned reliability and validity studies for the Behavioral Assessment Tool (BAT) of the CDMP. She also attended the introductory imager training sessions presented by Dr. Jerry Cavallerano and Kristin Hock.
 - K. Frederick Walsh, who is funded under the subcontract to Estenda Solutions, completed the JVN imager training from March 1 – 3, 2006.
 - L. Dr. Birkmire-Peters and Darlene Kaahaaina met with Dr. Ravi Reddy and Gail Kaneshige, the Physicians Center at Mililani (PCM), to discuss implementation of the JVN imaging at PCM on March 28, 2006.
 - M. Rick Walsh, Estenda Solutions, began the work on the VPN for Molokai General Hospital. Additionally, he contacted the Information Systems Department for Queen's Hospital to initiate discussions regarding the VPN for Molokai General Hospital. He also initiated discussions with Clinical Laboratories of Hawaii regarding the download of lab data into the CDMP for the sites in Hawaii. He also arranged for the repair of the retinal imaging camera in Molokai.
12. Use additional page(s) to present a brief statement of plans or milestones for the next quarter.
- A. Finalize subcontracts to Waianae Coast Comprehensive Health Center, The Physician Center at Mililani, and Molokai General Hospital.
 - B. Submit subcontract for Estenda Solutions, Inc. for processing.
 - C. Draft protocol entitled "An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program's (CDMP) Behavioral Assessment Tool" for The Physician Center at Mililani.

CDMP Winter Summit
January 10-11, 2006, Santa Cruz, CA

Day 1- Tuesday, January 10

8:30-9 Breakfast networking and introductions

9-9:30 PPT: A look at latest release of CDMP, Patient Portal, Survey Tools, Q&A

Break – 15 minutes

9:45-11:45 JVN Eye Care – Integration with CDMP and AHLTA (CHCS2)
Sven Bursell and JVN Team

Lunch – 1 hour

1-3 Mary Goldstein – BP decision support system, Stanford Medical School

Break – 15 minutes

3:15 to 5:30 Chronic Care Network – Demonstration, presentation and discussion

6PM on Wine tasting, light fare with Wells Shoemaker, at Chaminade:
<http://www.salamandrewine.com/index.shtml>

Day 2 – Wednesday, January 11

7-10 Research Group meeting

8:30-9 Breakfast and networking for the rest of us

9-10 CDMP – New directions: InforMedix, iMetrikus

Break – 15 minutes

10:15 –12:15 Kate Lorig – Programs of the Stanford Patient Education Research Center

Lunch – 45 minutes

1-2 Dale Vincent – Group visits using CDMP

2-3 Jamie Rosenzweig – Quality Assurance and Quality improvement

Break – 15 minutes

3:15-4:45 Working groups – Concentrating on a particular topic* - nutrition, mental health care delivery, CADs and/or a CDMP demo for those who wish to see it

4:45-5 Notes and Adjournment - Next meeting, **July 11-12, 2006**, in Boston

*Generally a topic that is either an ongoing working group or something that arises at the Summit

Appendix B

Second Quarter (Year 2) Activities

April 1, 2006 to June 30, 2006

Quarterly Report Format

1. Award No: W81XWH-05-2-0018
2. Report Date: 7/31/2006
3. Reporting period: 4/01/2006 – 6/30/2006 (Q2 Year 2)
4. Principal Investigator: Deborah Birkmire-Peters, PhD
5. Telephone No.: 808-692-1090
6. Award Organization: University of Hawaii
7. Project Title: Diabetes Care and Treatment
8. Current staff, role and percent effort of each on project.

STAFF MEMBER	ROLE	% EFFORT
Deborah Birkmire-Peters, PhD	PI	50%
Dale Vincent, MD	Co-I	25%
Joseph Humphry, MD	Co-I	10%
Kristin Okahashi, BA	Administrative Assistant	25%
Kari-Jo Parisi	Imager/Reader	Intermittent

9. Contract expenditures to date (as applicable):

COST ELEMENTS	THIS QUARTER	CUMULATIVE
Personnel	\$ 30,285.00	\$ 118,904.33
Fringe Benefits	\$ 5,596.95	\$ 22,263.94
Supplies	\$ 3,314.72	\$ 6,375.88
Equipment	\$ 0.00	\$ 2,592.73
Travel	\$ 8,390.36	\$ 48,964.13
Other Direct Costs	\$ 647.80	\$ 4,918.37
Subtotal	\$ 48,234.83	\$ 204,019.38
Indirect Costs	\$ 9,936.38	\$ 42,028.01
Fee		
Total	\$ 58,171.21	\$246,047.39

10. Comments on administrative and logistical matters.

A. The subcontract for the CDMP project at the Waianae Coast Comprehensive Health Center (WCCHC) was signed and a purchase order issued on 13 April 2006. The subcontract covers the JVN retinal imager for both WCCHC and the Physician Center at Mililani (PCM). Additional funds were allocated to cover IT support at WCCHC.

B. The subcontract for the CDMP project at Molokai General Hospital (MGH) was signed and a purchase order issued on 20 April 2006. The subcontract covers the JVN retinal imager MGH. Additional funds were allocated to cover IT and project support at MGH.

C. The subcontract for the CDMP project at the Physician Center at Mililani (PCM) was submitted to the Research Corporation of the University of Hawaii. It was returned, because all the signing authorities for PCM hold appointments with the University of Hawaii and cannot sign a contract with another UH entity. Alternative funding mechanisms are being explored.

D. As a result of the reorganization of the Fiscal Office in the UH School of Medicine, the project has been assigned a new fiscal officer.

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this contract. Explain deviations where this isn't possible. Include data where possible.

- A. Dr. Birkmire-Peters worked with Dr. Stephanie Fonda to finalize the protocol entitled "An Assessment of the Validity of the Comprehensive Diabetes Management Program (CDMP) Behavioral Assessment Tool." It was submitted to the Joslin Committee on Human Studies and the ORP Human Subjects Research Review Board for review.
- B. Drs. Birkmire-Peters and Humphry held status meetings to discuss the Comprehensive Diabetes Management Program (CDMP) and implementation of the CDMP and JVN imaging systems into the three community health centers in Hawaii (6 April, 20 April, 27 April, 18 May, 15 June, 22 June, and 29 June). Rick Walsh attended the meetings in May and June.
- C. Dr. Humphry arranged to have the CDMP demonstrated to Dr. Heslinga, the IT Director for the Hawaii Independent Physicians Association (IPA).
- D. Dr. Birkmire-Peters attended the official open house for the new clinic at the Waianae Coast Comprehensive Health Center.
- E. Dr. Birkmire-Peters met with Dr. Vincent on 28 April 2006 to review budgets for a proposal to use the CDMP for group medical visits.
- F. Dr. Birkmire-Peters met with Dr. Timothy Duerler, UH Family Practice Resident, the Physician Center at Mililani (PCM), to discuss revision of the protocol entitled "An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program's (CDMP) Behavioral Assessment Tool" to be conducted at PCM. The protocol will be submitted to the University of Hawaii Committee on

Human Studies and the ORP Human Subjects Research Review Board for review and approval.

- G. Dr. Birkmire-Peters attended the conference entitled "He Huliau – A Turning Point: Eliminating Health Disparities in Native Hawaiians and Pacific Peoples: Cardiovascular Disease" in Ko Olina, Hawaii from May 4-6.
- H. Drs. Birkmire-Peters, Dale Vincent and Joseph Humphry attended the Annual Meeting of the American Telemedicine Association in San Diego, CA. Dr. Birkmire-Peters made a presentation on performance measures in the panel entitled "The People Make the Difference: Human Factors in Telemedicine." She co-authored a poster presentation entitled "Human Factors Analysis: Joslin Vision Network Comprehensive Diabetes Management Program." The poster was awarded a Blue Ribbon for the presentation. She also chaired a session entitled "Human Factor Considerations in Other Countries" and attended meetings of the Human Factors SIG and the Joslin/DoD/VA Cooperative.
- I. Dr. Birkmire-Peters participated in a conference call with Dr. Stephanie Fonda and Jeonifer Garren, Joslin Diabetes Center, to discuss issues with respect to the CDMP Behavioral Assessment Tool protocols assessing reliability and validity.
- J. Drs. Dale Vincent and Birkmire-Peters participated in a meeting with Dr. Kim Binstead, Associate Professor, Dept. of Information and Computer Sciences, University of Hawaii, Kathleen Kihmm, Telehealth Research Institute, UH, and Drew Lewis, President, Estenda Solutions, to discuss the use of text messaging for diabetes management for adolescents. It was decided that the idea would be developed into a proposal.
- K. Dr. Birkmire-Peters attended a demonstration of the Comprehensive Diabetes Management Program on May 25, 2006 given by Drew Lewis to the Hawaii Affiliate of the National Kidney Foundation. The NKF is interested in adopting a modified version of the CDMP for a project for the early identification patients at risk for chronic kidney disease for enrollment into specialized clinics.
- L. Dr. Birkmire-Peters met with Dr. Robert Vigersky, Director, Diabetes Institute, Walter Reed Army Medical Center, to discuss issues with regard to the protocol entitled "An Assessment of the Validity of the Comprehensive Diabetes Management Program (CDMP) Behavioral Assessment Tool." Dr. Birkmire-Peters sent the final protocol and associated documents to Dr. Vigersky for review and submission to the WRAMC Department of Clinical Investigation.
- M. Dr. Birkmire-Peters met with Drew Lewis on June 2, 1006 to finalize the subcontract with Estenda Solutions, Inc.
- N. Dr. Birkmire-Peters attended the statistics courses offered by SPSS on Advanced Techniques: Regression and Advanced Techniques: ANOVA from June 5-9, 2006.
- O. Rick Walsh, Estenda Solutions, Inc, was assigned to Hawaii to provide support to the CDMP projects in the state. He re-located to Hawaii in May 2006.
- P. In response to a request from the Queens Medical Center IT Department, Mr. Walsh researched the JVN's DICOM protocol and consulted with the Joslin Diabetes Center technical staff. He described the protocol to Steve Gose and Will

Twiggs of the Queens Medical Center. As a result they granted permission for bi-directional communication between Molokai General Hospital (part of the Queens Medical Center) and the JVN server located at the University of Hawaii.

- Q. As a result of these discussions, Mr. Walsh changed the UH local network JVN configuration to accommodate the Queens network structure.
- R. Mr. Walsh made a site visit to Molokai General Hospital (MGH) to demonstrate the CDMP to the clinic staff and do individual and small group training on the CDMP. Because the MGH IT staff reported that their workstation was not operating properly, the workstation from The Physician Center at Mililani (PCM) was shipped to MGH. The Frame Grabber Card was broken in transit and had to be replaced.
- S. Mr. Walsh made 4 trips to The Physician Center at Mililani (PCM) to repair a synchronization problem with the JVN workstation. The problem was repaired.
- T. Mr. Walsh met with the PCM IT staff to discuss the interface of CDMP with Open Vista.
- U. Mr. Walsh met with the Waianae Coast Comprehensive Health Center (WCCHC) IT staff and was granted limited access to the WCCHC NextGen database for development of the interface with CDMP.
- V. Mr. Walsh met with representatives of Clinical Laboratories of Hawaii (CLH) to discuss the electronic download of their laboratory results into the CDMP. He also has a telephone conference with representatives of Diagnostic Laboratory Services (DLS) to discuss the electronic download of their laboratory results into the CDMP. CLH and DLS are the two largest laboratory providers in the state. Mr. Walsh wrote the code to allow imports of laboratory data into the CDMP.

12. Use additional page(s) to present a brief statement of plans or milestones for the next quarter.

A. Submit the protocol entitled "An Assessment of the Validity of the Comprehensive Diabetes Management Program (CDMP) Behavioral Assessment Tool" to the Walter Reed Army Medical Center Department of Clinical Investigations for review.

B. Submit the Physicians Center at Mililani protocol entitled "An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program's (CDMP) Behavioral Assessment Tool" to the University of Hawaii Committee on Human Studies and the ORP Human Subjects Research Review Board for review.

C. Finalize the subcontract for Estenda Solutions, Inc.

D. Complete hiring actions for staff at the Physician Center at Mililani.

Appendix C

Third Quarter (Year 2) Activities

July 1, 2006 to September 30, 2006

Quarterly Report Format

1. Award No: W81XWH-05-2-0018
2. Report Date: 10/31/2006
3. Reporting period: 7/01/2006 – 9/30/2006 (Q3 Year 2)
4. Principal Investigator: Deborah Birkmire-Peters, PhD
5. Telephone No.: 808-692-1090
6. Award Organization: University of Hawaii
7. Project Title: Diabetes Care and Treatment
8. Current staff, role and percent effort of each on project.

STAFF MEMBER	ROLE	% EFFORT
Deborah Birkmire-Peters, PhD	PI	47.5%
Dale Vincent, MD	Co-I	25%
Joseph Humphry, MD	Co-I	10%
Kristin Okahashi, BA	Administrative Assistant	25%
Kari-Jo Parisi	Imager/Reader	Intermittent
Gail Kaneshige	Project Manager PCM	Intermittent
Desiree Navarro	Data Entry PCM	Intermittent

9. Contract expenditures to date (as applicable):

COST ELEMENTS	THIS QUARTER	CUMULATIVE
Personnel	\$ 33,262.00	\$ 152,166.33
Fringe Benefits	\$ 5,286.89	\$ 27,550.83
Supplies	\$ 956.90	\$ 7,332.78
Equipment	\$ 129.90	\$ 2,722.63
Travel	\$ 7,794.77	\$ 56,758.90
Other Direct Costs	\$ 25,731.44	\$ 30,649.81
Subtotal	\$ 73,161.90	\$277,181.28
Indirect Costs	\$ 5,044.59	\$ 57,072.60
Fee		
Total	\$ 88,206.49	\$334,253.88

10. Comments on administrative and logistical matters.

A. Supplies and furniture were purchased for the JVN examination rooms at Waianae Coast Comprehensive Health Center and Molokai General Hospital.

B. The subcontract for the CDMP project between Estenda Solutions, Inc. and the Research Corporation of Hawaii was signed and a purchase order issued on September 6, 2006. The subcontract covers the Implementation and maintenance of the CDMP at the sites in Hawaii.

C. Gail Kaneshige and Desiree Navarro were hired as intermittent employees to serve as project manager and data entry clerk, respectively, for the CDMP project at the Physician Center at Mililani.

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this contract. Explain deviations where this isn't possible. Include data where possible.

A. Drs. Birkmire-Peters, Vincent, and Humphry attended the CDMP Summer Summit from July 11-12, 2006 held at the Joslin Diabetes Center in Boston, MA. Dr. Vincent gave a presentation on the use of mobile phones for the management of diabetes. Dr. Humphry gave a status report on the medications module in the CDMP. See attached agenda for details.

B. Drs. Birkmire-Peters and Humphry and Rick Walsh, Estenda Solutions, held status meetings to discuss the Comprehensive Diabetes Management Program (CDMP) and implementation of the CDMP and JVN imaging systems into the three community health centers in Hawaii (July 6, July 20, Sept. 14, Sept. 21, and Sept. 28).

C. Dr. Birkmire-Peters gave a presentation on the Comprehensive Disease Management Program (CDMP) to the National Kidney Foundation (Hawaii Affiliate) Alliance meeting. The NKF is interested in adopting a modified version of the CDMP for a project for the early identification patients at risk for chronic kidney disease for enrollment into specialized clinics.

D. Dr. Birkmire-Peters met with Dr. Timothy Duerler, UH Family Practice Resident, the Physician Center at Mililani (PCM), on July 17, 2006 to finalize the protocol entitled "An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program's (CDMP) Behavioral Assessment Tool" to be conducted at PCM. The protocol was submitted on September 1, 2006 to the University of Hawaii Committee on Human Studies (CHS) and to the ORP Human Subjects Research Review Board for review and approval. The project was approved by the UH CHS on September 21, 2006.

E. Kari-Jo Parisi conducted JVN imager review and refresher training from July 19-21, 2006. She met with Darlene Kaahaaina at Waianae Coast Comprehensive Health Center and Radmila Esteron at Molokai General Hospital. Ms. Parisi reviewed their imaging techniques and made recommendations for image acquisition. In addition, she recommended several changes in the arrangements of the image acquisition rooms.

F. Dr. Birkmire-Peters met with Sheila Beckham, Waianae Coast Comprehensive Health Center, on July 21, 2006 to discuss the status of the CDMP project at her facility.

G. The protocol entitled “An Assessment of the Validity of the Comprehensive Diabetes Management Program (CDMP) Behavioral Assessment Tool” was submitted to the Walter Reed Army Medical Center Department of Clinical Investigation for review and approval on July 18, 2006.

H. Dr. Dale Vincent wrote a proposal entitled “SMART Visits: Shared Medical Appointments Re-Tooled” to assess the feasibility of group medical visits, to develop a clinical prototype of group medical visits, and to perform a clinical trial. Dr. Birkmire-Peters reviewed the proposal and developed the budget for the proposal. The proposal was submitted to TATRC for review and possible funding.

I. Drs. Vincent and Birkmire-Peters participated in a conference call with Dr. Stephen Waller and members of his staff at Wilford Hall Medical Center to discuss possible collaboration on a proposed project on group medical visits.

J. Dr. Birkmire-Peters attended meetings with the Hawaii Affiliate of the National Kidney Foundation on August 10, 2006 and August 24, 2006 to discuss the use of the CDMP in the Chronic Kidney Disease Clinics pilot project. During the meeting on August 24th, Rick Walsh, Estenda Solutions, gave a demonstration of the CDMP to Dr. Lee, a nephrologist with Kaiser Permanente Hawaii, and his staff.

K. Dr. Birkmire-Peters scheduled a meeting with Dr. Robert Vigersky, Director, Diabetes Institute, Walter Reed Army Medical Center, and John Winston, TATRC, to discuss possible joint projects.

K. Rick Walsh, Estenda Solutions, set up a VPN connection with Paula Katalinic, OD, in Australia. Dr. Katalinic will serve as a back-up JVN reader for the Hawaii JVN sites.

L. Rick Walsh troubleshoot networking, hardware, and software issues at both the Physician Center at Mililani and Molokai General Hospital.

M. Rick Walsh continued coding for the laboratory integration between laboratories (Clinical Laboratories of Hawaii and Diagnostic Laboratory Services) and CDMP.

12. Use additional page(s) to present a brief statement of plans or milestones for the next quarter.

A. Meet with Dr. Vigersky, Director, Diabetes Institute, Walter Reed Army Medical Center, and John Winston, TATRC.

B. Attend the “Connecting Americans to Their Health Care: Empowered Consumers, Personal Health Records, and Emerging Technologies” Conference.”

C. Obtain final approval for the protocol entitled “An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program’s (CDMP) Behavioral Assessment Tool” to be conducted at PCM from the ORP Human Subjects Research Review Board.

Agenda for CDMP Summer Summit, July 11-12, Joslin Diabetes Center

Day one – Tuesday, July 11

8:45-9:00 Breakfast and Networking

9:15-9:30 Introductions all around

9:30-10:00 Welcoming new members from Wilford Hall and asking them to talk about their practices and medical center and how they plan to use JVN/CDMP

10:00-10:15 Bio Moment

10:15-11:15 Demo of new JVN/CDMP application

11:15-Noon CADS – Decision support for insulin dosing

Lunch Break

1:00-4:30 Research Group Breakout

1:00-1:30 CDMP Demos – Q and A

1:30-4:30 Working Groups:

1:30-2:00 Medications: Presentation, DM or DM and other meds? Examples from organizations and recommendations for CDMP

2:00-2:30 Mental Health – Framing the issues

2:30-4:30 Nutrition: Speaker, Dr. Susan Oliverio - Interactive Nutrition and nutrition for self-management

- o Nutrition decision support tools
- o Obesity
- o Discussion

4:30-5:00 Recap, announcements, break for the day, plans for group dinner this evening

Day two – Wednesday, July 12

9:00-10:30 Reports:

9:00-9:30 VA - using CDMP and DME in the real world

9:30-10:00 Digital camera and food study – Stephanie Fonda, Judy Phillips

10:00-10:30 Pilot use of iMetrikus' MetrikLink with patients

10:45-11:30 Dale Vincent and mobile phone DM management

Lunch Break

1:00-1:30 AIR CDMP usability report

1:30-2:30 Garry Welch – BayState Medical Center – Hispanic initiative and CHCs

2:30-2:45 Bio moment

2:45-4:30 Demo and discussion of the use of ultrasound to heal wounds –
Celleration joins us to talk about this innovation

4:30-4:45 CDMP - The next six months – Winter Summit, January 8-9th, Boston

Adjourn

Appendix D

Fourth Quarter (Year 2) Activities

October 1, 2006 to December 31, 2006

Quarterly Report Format

1. Award No: W81XWH-05-2-0018
2. Report Date: 1/31/2007
3. Reporting period: 10/01/2006 – 12/31/2006 (Q4 Year 2)
4. Principal Investigator: Deborah Birkmire-Peters, PhD
5. Telephone No.: 808-692-1090
6. Award Organization: University of Hawaii
7. Project Title: Diabetes Care and Treatment
8. Current staff, role and percent effort of each on project.

STAFF MEMBER	ROLE	% EFFORT
Deborah Birkmire-Peters, PhD	PI	50%
Dale Vincent, MD	Co-I	25%
Joseph Humphry, MD	Co-I	10%
Kristin Okahashi, BA	Administrative Assistant	25%
Kari-Jo Parisi	Imager/Reader	Intermittent
Gail Kaneshige	Project Manager PCM	Intermittent
Desiree Navarro	Data Entry PCM	Intermittent

9. Contract expenditures to date (as applicable):

COST ELEMENTS	THIS QUARTER	CUMULATIVE
Personnel	\$ 40,157.43	\$ 192,323.76
Fringe Benefits	\$ 5,540.09	\$ 33,090.92
Supplies	\$ 109.97	\$ 7,442.75
Equipment	\$ 0.00	\$ 2,722.63
Travel	\$ 3,876.86	\$ 60,635.76
Other Direct Costs	\$ 42,609.71	\$ 73,259.52
Subtotal	\$ 92,294.06	\$369,475.34
Indirect Costs	\$ 16,564.92	\$ 73,637.52
Fee		
Total	\$ 108,859.00	\$ 443,112.86

10. Comments on administrative and logistical matters.

A. Dr. Birkmire-Peters met with Drew Lewis, President, Estenda Solutions, Inc. to discuss contractual issues.

B. Dr. Birkmire-Peters provided the status of the "Diabetes Care and Treatment: A Joslin Telemedicine Initiative" project in Hawaii to Dr. Sven Bursell for inclusion in the annual report for the prime contract in October 2006.

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this contract. Explain deviations where this isn't possible. Include data where possible.

A. Dr. Birkmire-Peters met with Dr. Robert Vigersky, Director, Diabetes Institute, Walter Reed Army Medical Center, Susan Walker, Diabetes Institute, WRAMC, John Winston, TATRC, and Steven O'Neill, TATRC, on October 10, 2006 to discuss potential collaborative research projects. One possible project was the use of a kiosk for patient check-in. The proposed concept was that the patient would use an electronically coded card to check-in upon arrival at a clinic. The kiosk would be linked to the patient's record which would be reviewed for missed labs, appointments, and other alerts.

B. Drs. Birkmire-Peters and Joseph Humphry participated in conference calls on Oct. 5, Oct. 17, and Nov. 8, with Dr. Sven Bursell, Joslin Diabetes Center, Boston, MA, and Jack Corley, Advanced Technology Institute (ATI), N. Charleston, SC, to discuss possible collaborative research projects. Dr. Norman Okamura, Telecommunication Information Policy Group (TIPG), University of Hawaii, participated in one of the conference calls.

C. Drs. Birkmire-Peters and Humphry and Rick Walsh, Estenda Solutions, held status meetings to discuss the Comprehensive Diabetes Management Program (CDMP) and implementation of the CDMP and JVN imaging systems into the three community health centers in Hawaii (Oct. 19 and Oct. 26)

D. Dr. Birkmire-Peters was invited to present a lecture on October 31, 2006 to the University of Hawaii graduate level Bioinformatics class (ICS 614) on the Comprehensive Diabetes Management Program project. The lecture included a history of the project, its implementation in Hawaii, and a demonstration of the CDMP.

E. Drs. Birkmire-Peters, Lawrence Burgess, Dale Vincent, and Benjamin Berg met with Charles Doarn, Associate Professor of Surgery and Biomedical Engineering and Executive Director, Center for Surgical Innovation, University of Cincinnati. Mr. Doarn gave a presentation on the Center for Surgical Innovation. The ensuing discussion included business models for setting up a sustainable medical simulation center.

F. As a result of the review by the ORP Human Subjects Research Review Board, Dr. Birkmire-Peters provided requested revisions to the protocol entitled "An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program's (CDMP) Behavioral Assessment Tool" to be conducted at PCM.

G. Dr. Birkmire-Peters attended the "Connecting Americans to Their Health Care: Empowered Consumers, Personal Health Records, and Emerging Technologies" Conference" held in Washington, DC December 7-8, 2006. The focus of the conference was the development of personal health applications.

H. Dr. Humphry attended the Blue Cross/Blue Shield Health Information Technology National Conference in November 2006. The conference presented the current status of health information technology for disease management and information systems from the perspective of the health plans.

I. Dr. Humphry met with staff from the Waianae Coast Comprehensive Health Center, including Dr. Rick Custodio, Medical Director, Sheila Beckham, Chair, Research Committee, Mary Oneha, Administrator for IT, and IT staff. Issues addressed included privacy, security, and HIPAA. As a result of the discussions, HIPAA requirements for a Business Association Agreement (BAA) were clarified, including how the BAA provided protection for both entities. Technical aspects of security and privacy related to the implementation of the CDMP at WCCHC were reviewed.

J. Dr. Humphry and Rick Walsh, Estenda Solutions, made a site visit to Molokai General Hospital on November 30, 2006. They provided training for the staff and introduced the CDMP to the Molokai Community Health Center physicians.

K. Rick Walsh, Estenda Solutions, developed the laboratory value aggregator software. It transmits and stores laboratory data into the CDMP and supports multiple HL7 implementations.

L. Mr. Walsh obtained the laboratory data feeds from Clinical Laboratories of Hawaii.

M. Mr. Walsh provided support for the project by providing activity reports and repairing network and hardware problems.

12. Use additional page(s) to present a brief statement of plans or milestones for the next quarter.

A. Dr. Birkmire-Peters will make a site visit to Walter Reed Army Medical Center to observe data collection for the protocol entitled "An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program's (CDMP) Behavioral Assessment Tool" to be conducted at PCM and to attend research planning meetings.

B. Dr. Birkmire-Peters will attend the "Nephrology for the Non-Nephrologist" course.

C. Dr. Birkmire-Peters will attend the "Designing Effective Survey Instruments and Increasing Returns Workshop."

D. Dr. Humphry will give a presentation on the CDMP project to the Hawaii Diabetes Prevention and Control Program Network Meeting.

E. Mr. Walsh will write the interface to integrate the Open VistA application implemented at the Physician Center at Mililani to the CDMP.

Appendix E

Fifth Quarter (Year 2) Activities

January 1, 2007 to March 31, 2007

Quarterly Report Format

1. Award No: W81XWH-05-2-0018
2. Report Date: 4/30/2007
3. Reporting period: 1/01/2007– 3/31/2007 (Q5 Year 2)
4. Principal Investigator: Deborah Birkmire-Peters, PhD
5. Telephone No.: 808-692-1090
6. Award Organization: University of Hawaii
7. Project Title: Diabetes Care and Treatment
8. Current staff, role and percent effort of each on project.

STAFF MEMBER	ROLE	% EFFORT
Deborah Birkmire-Peters, PhD	PI	47.5%
Dale Vincent, MD	Co-I	25%
Joseph Humphry, MD	Co-I	10%
Kristin Okahashi, BA	Administrative Assistant	25%
Kari-Jo Parisi	Imager/Reader	20%
Gail Kaneshige	Project Manager PCM	Intermittent
Desiree Navarro	Data Entry PCM	Intermittent

9. Contract expenditures to date (as applicable):

COST ELEMENTS	THIS QUARTER	CUMULATIVE
Personnel	\$ 36,152.67	\$ 228,476.43
Fringe Benefits	\$ 7,317.06	\$ 40,407.98
Supplies	\$ 12.25	\$ 7,455.00
Equipment	\$ 0.00	\$ 2,722.63
Travel	\$ 7,013.17	\$ 67,648.93
Other Direct Costs	\$ 27,080.23	\$ 100,339.75
Subtotal	\$ 77,575.38	\$ 447,050.72
Indirect Costs	\$ 11,348.71	\$ 84,986.23
Fee		
Total	\$ 88,924.09	\$ 532,036.95

10. Comments on administrative and logistical matters.

A. Kari-Jo Parisi was converted from an intermittent hire to a part-time employee at .20 FTE.

B. Dr. Birkmire-Peters submitted the contract continuation proposal modification to the USAMMRC Telemedicine and Technology Research Center for Year 3 funding on March 23, 2007.

C. Dr. Birkmire-Peters submitted project extensions to the Research Corporation of the University of Hawaii for subcontracts to: the Waianae Coast Comprehensive Health Center, Molokai General Hospital, and Estenda Solutions, Inc. The period of performance was extended on each subcontract until April 30, 2007.

D. Dr. Birkmire-Peters met with Gail Kaneshige and Desiree Navarro on Jan. 31, 2007 to discuss the progress and their roles on the project at the Physicians Center at Mililani.

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this contract. Explain deviations where this isn't possible. Include data where possible.

A. The revised protocol entitled "An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program's (CDMP) Behavioral Assessment Tool" to be conducted at PCM was submitted to the University of Hawaii Committee on Human Studies (CHS) and approved on March 2, 2007. The approval letter from the UH CHS was forwarded to the ORP Human Subjects Research Review Board for final approval.

B. Drs. Birkmire-Peters and Humphry and Rick Walsh, Estenda Solutions, held status meetings to discuss the Comprehensive Diabetes Management Program (CDMP) and implementation of the CDMP and JVN imaging systems into the three community health centers in Hawaii (Jan. 4, Jan. 18, Feb. 1, Mar. 8 and Mar. 22.)

C. Drs. Birkmire-Peters and Humphry met on Jan. 30, 2007 with Drs. Ravi Reddy, Clinic Director, Physicians Center of Mililani (PCM), Gregory Maskarinec, Associate Professor, Department of Family Medicine and Community Health, and Timothy Duerler, Resident, Department of Family Medicine and Community Health, to discuss the status of the CDMP project at the PCM. Drs. Birkmire-Peters and Humphry also met with Dr. Reddy on Feb 6, 2007 to follow-up on issues raised in the previous meeting and to discuss a change in roles and responsibilities on the project at PCM. It was decided that a project manager was not needed at PCM. Additionally, changes in the input of data into the CDMP were discussed.

D. Dr. Birkmire-Peters attended a meeting of the Hawaii Affiliate of the National Kidney Foundation Alliance meeting on Feb. 8, 2007.

E. Rick Walsh and Dr. Birkmire-Peters gave a presentation and demonstration of the CDMP to staff from Kaiser Permanente Hawaii Nephrology Division.

F. Dr. Birkmire-Peters gave a briefing to COL Karl Friedl, PhD, Director, TATRC, on the Diabetes Care and Treatment Project in Hawaii on Feb. 14, 2007.

G. Dr. Birkmire-Peters made a site visit to the Diabetes Institute at Walter Reed Army Medical Center from Feb. 16 – 23, 2007. During the visit, she observed both the first and second data collection sessions for the Test-Retest Reliability Study. She

attended the Diabetes Institute Research Planning meeting during which the project to integrate the CDMP into AHLTA was initiated. She also met with Dr. Stephanie Fonda to discuss the status of the CDMP Behavioral Assessment Tool research studies.

H. Dr. Birkmire-Peters and Rick Walsh, Estenda Solutions, made a site visit to the Physician Center at Mililani (PCM) on March 1 to discuss the download of information in the PCM electronic medical record (Open VistA) into the CDMP. Mr. Walsh and Dr. Humphry worked with the staff from the Telecommunications Information Policy Group at the University of Hawaii which oversees the Open VistA project at PCM to facilitate the data extraction from VistA to enter into the CDMP to reduce duplicate entry.

I. Drs. Birkmire-Peters and Joseph Humphry participated in conference calls on Mar. 2 and 6, 2007, with Dr. Sven Bursell, Joslin Diabetes Center, Boston, MA, Jack Corley, Advanced Technology Institute (ATI), N. Charleston, SC, and Dr. Norman Okamura, Telecommunication Information Policy Group (TIPG), University of Hawaii to discuss possible collaborative research projects.

J. Drs. Birkmire-Peters and Humphry met with Naty Hopewell from Koolauloa Community Health Center to discuss the JVN retinal imaging system. Ms. Hopewell has obtained a small grant from Aloha Care to purchase a retinal imaging camera for use in her clinic. She decided to acquire the JVN system for use in her project. Dr. Peters agreed to work with her in implementing the system into her clinic.

K. Dr. Birkmire-Peters attended the "Nephrology for the Non-Nephrologist Conference" on March 29, 2007.

L. Dr. Birkmire-Peters attended the "Designing Effective Survey Instruments and Increasing Returns Workshop" held by the University of Hawaii on March 30, 2007.

M. Dr. Birkmire-Peters completed the CITI Course in The Protection of Human Research Subjects on Feb. 9, 2007.

N. Letters were sent to eye care specialists in Hawaii describing the JVN retinal imaging project at Waianae Coast Comprehensive Health Center, the Physicians Center at Mililani, and Molokai General Hospital. Several ophthalmologist in the community responded that they were interested in working with the project.

O. Dr. Humphry gave a presentation on the Diabetes Care and Treatment Project in Hawaii to the Hawaii Diabetes Prevention and Control Program Network Meeting on Mar. 16, 2007. His presentation focused on the JVN retinal imaging system and improvement in the rates of retinal eye examinations for diabetic patients.

P. Rick Walsh added complete logging and error handling to the laboratory value aggregator software and data back-ups for all incoming data. The software allows for the electronic transmission of laboratory values and automatic population of the CDMP.

Q. Rick Walsh implemented the JVN 4 reader and reporting software for the Hawaii sites. JVN 4 integrates the JVN diagnostic display and the CDMP and allows for greater flexibility for reporting of images. He established a IPsec and DICOM link between the JVN server at the University of Hawaii and the Estenda servers.

R. Rick Walsh performed routine maintenance to include repair of the camera lens at the Physician Center at Mililani, repair of network errors that resulted in communication failures, and repair of other acquisition/reader workstation issues.

12. Use additional page(s) to present a brief statement of plans or milestones for the next quarter.

A. Drs. Birkmire-Peters, Vincent, and Humphry will attend the annual meeting of the American Telemedicine Association Meeting in Nashville, TN.

B. Drs. Vincent and Birkmire-Peters will meet with Sunil Hazaray and Lisa Roberts of Viterion to discuss the CDMP and potential areas of collaboration.

C. Drs. Birkmire-Peters and Vincent will work with representatives from TATRC to develop an agenda for a conference on diabetes to be held in Hawaii in December. The conference will address issues raised as a result of the current research program.

Appendix F

Sixth Quarter (Year 2) Activities

April 1, 2007 to June 30, 2007

Quarterly Report Format

1. Award No: W81XWH-05-2-0018
2. Report Date:
3. Reporting period: April 1 – June 30, 2007
4. Principal Investigator:
5. Telephone No.:
6. Award Organization: University of Hawaii
7. Project Title: Diabetes Care and Treatment
8. Current staff, role and percent effort of each on project.

STAFF MEMBER	ROLE	% EFFORT
Deborah Birkmire-Peters, PhD	PI	42.5%
Dale Vincent, MD	Co-I	20%
Joseph Humphry, MD	Co-I	10%
Kristin Okahashi, BA	Administrative Assistant	25%
Kari-Jo Parisi	Imager/Reader	20%
Lori DeBernardis	Program Research Administrator	100%
Brooke Burgess	Research Assistant	10%

9. Contract expenditures to date (as applicable):

COST ELEMENTS	THIS QUARTER	CUMULATIVE
Personnel	34,267.64	262,744.07
Fringe Benefits	7,059.60	47,467.58
Supplies	14.53	7,469.53
Equipment	0	2,722.63
Travel	2,132.51	69,781.44
Other Direct Costs	29,918.75	130,258.5
Subtotal	73,393.03	520,443.75
Indirect Costs	9,878.15	94,864.38
Fee	0	0
Total	83,271.18	615,308.13

10. Comments on administrative and logistical matters.

- A. Brooke Burgess was hired as a research assistant to recruit subjects and collect data for the CDMP Behavioral Assessment Tool Test-Retest and Validity studies.
- B. A proposal to modify the existing University of Hawaii Diabetes Care and Treatment contract to fund a kick-off workshop for the new Institute for Emerging Healthcare Technologies was written and submitted to the Telemedicine and Technology Research Center (TATRC) for funding.
- C. A budget was drafted for funding for Year 4 of the University of Hawaii Diabetes Care and Treatment contract.

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this contract. Explain deviations where this isn't possible. Include data where possible.

- A. Drs. Birkmire-Peters and Vincent participated in conference calls with other members of the planning committee for the kick-off meeting for the new institute to investigate emerging healthcare technologies in Hawaii and the Pacific Rim. Draft white papers and agendas were discussed in each of the calls. (2 April, 11 April, 2 May, 9 May, and 27 June)
- B. Drs. Birkmire-Peters and Humphry and Rick Walsh, Estenda Solutions, met to discuss the implementation of the Comprehensive Disease Management Program (CDMP) and JVN imaging systems into the three community health centers in Hawaii. (5 April, 19 April, 26 April and 10 May)
- C. Drs. Birkmire-Peters and Vincent met with Dr. Saiki, Director, Pacific Telehealth and Technology Hui, on 5 April to discuss the formation of an institute in Hawaii to study chronic disease management and the role of technology in it. The proposed meeting to kick-off the formation of this new institute was also discussed. Drs. Birkmire-Peters and Vincent held a follow-on meeting regarding the new institute on 12 April.
- D. Drs. Birkmire-Peters and Humphry attended the GFR Alliance Meeting of the National Kidney Foundation of Hawaii on 25 April. The status of the Chronic Kidney Disease (CKD) Clinics was updated. The CKD Clinics are a pilot program for the identification of early chronic kidney disease patients by primary care providers in the state. Once identified, patients are recruited for enrollment in a CKD where they are monitored and receive education regarding their disease. The goal of the clinics is to delay or halt progression of the disease. The CDMP has been modified and is being used by care providers in the clinics to manage their patients and to report outcomes.
- E. Drs. Birkmire-Peters and Vincent met with Dr. Phil Bossert, Chairman and CEO, China Hawaii Investment Corporation, on 8 May to discuss the implementation and sustainability of the proposed institute for emerging healthcare technologies.

- F. Drs. Birkmire-Peters, Vincent, and Humphry attended the 12th Annual Meeting of the American Telemedicine Association Meeting in Nashville, TN from 12 – 16 May.
- G. While at ATA Drs. Birkmire-Peters and Burgess attended a meeting with COL Friedl, COL Poropatich, Robert Read, Dr. Sven-Erik Bursell, and Lori DeBernardis to discuss the agenda for the proposed kick-off meeting for the Institute for Emerging Healthcare Technologies. (14 May)
- H. Drs. Vincent and Birkmire-Peters met with Dr. Sunil Hazaray, President and CEO of Viterion Telehealthcare and Dr. Lisa Roberts, Business Manager, Health Innovations & Grants, Viterion TeleHealthcare, met on 14 May to discuss areas of mutual interest and potential collaboration.
- I. Drs. Birkmire-Peters and Vincent met with Harold Matsumoto, Program Director, High Technology Development Venture, to discuss the implementation and sustainability of the proposed institute for emerging healthcare technologies in Hawaii. (4 June)
- J. Dr. Birkmire-Peters met with Drs. Sven-Erik Bursell and Stephanie Fonda to discuss the transition of the DOD Cooperative Agreement “Diabetes Care and Treatment Program: A Joslin Telemedicine Initiative” from the Joslin Diabetes Center to the University of Hawaii. (10 – 14 June)
- K. Dr. Birkmire-Peters provided input for the Hawaii site to be presented at the TATRC Product Line Review on Chronic Disease Management. Details are provided in the attached slide.
- L. Drs. Birkmire-Peters and Humphry worked with Ms. Naty Hopewell, Koolauloa Community Health Center to acquire the JVN retinal imaging camera with a grant from Aloha Care. Fisi'i Drummondo was selected as the imager for Koolauloa CHC and was trained at the Joslin Diabetes Center from 12-14 June.
- M. Dr. Birkmire-Peters co-authored a poster presentation entitled “Test-Retest Reliability of a New Screening Questionnaire for People with Diabetes” presented to the 2007 CDC Diabetes Conference held in Atlanta, GA. (30 April – 3 May) See attached.
- N. Brooke Burgess, research assistant, met with staff at the Physician’s Center at Mililani to discuss recruitment of patients to participate in the CDMP Behavioral Assessment Tool (BAT) Test-Retest Reliability study.
- O. Dr. Humphry attended the monthly meeting of the Pacific Island Chapter of the American Telemedicine Association. (8 May)
- P. Dr. Humphry attended the Board Meeting of the Northwest Telehealth Resource Center held during the American Telemedicine Association Annual Meeting. (14 May)
- Q. Dr. Humphry participated in a teleconference with the National Diabetes Education Provider Workgroup (NIH/CDC). (15 June)
- R. Dr. Humphry attended the American Diabetes Association Conference in Chicago, IL. (23 -27 Jun)

- S. The following table presents the number of JVN retinal images acquired and read from the three sites in Hawaii:

	April	May	June	Totals
Waianae Coast Comprehensive Health Center	23	25	2	50
The Physicians Center at Mililani	1	6	3	10
Molokai General Hospital	0	1	0	1
	24	32	5	61

- T. Rick Walsh, Estenda Solutions, Inc., configured the connection between the JVN server and the Estenda CDM/ JVN4 server and connected it via a VPN (IPSEC). (17 April – 10 May)
- U. Rick Walsh, Estenda Solutions, Inc., met with John Williams of the Waianae Coast Comprehensive Health Center to initiate the integration of the CDM/ JVN4 into the clinic with their electronic health record (NextGen). (6 June)
- V. Rick Walsh troubleshoot a number of software problems at the clinics, i.e., retinal imaging studies failing to transfer.
12. Use additional page(s) to present a brief statement of plans or milestones for the next quarter.
- A. Drs. Birkmire-Peters and Vincent will work with representatives from TATRC and the Pacific Telemedicine and Technology Hui to develop an agenda for a conference on diabetes to be held in Hawaii in December. The conference will address issues raised as a result of the current research program.
- B. Dr. Birkmire-Peters will attend a CDM/ JVN4 Research Working Group meeting in Boston planned for August 2007
- C. Brooke Burgess will collect data at the Physicians Center at Mililani for the BAT Test-Retest Reliability Study.
- D. Kari-Jo Parisi will meet with Dr. Lloyd M. Aiello and other personnel at the Joslin Diabetes Center for advanced JVN imager/reader training.

Appendix G

Project Personnel

Project Personnel

Staff Member	Role	% Effort
Deborah Birkmire-Peters, PhD	PI	50%
Dale Vincent, MD	Co-I	25%
Joseph Humphry, MD	Co-I	10%
Kari-Jo Parisi, RN	Imager/Reader	20%
Lori DeBernardis	Program Research Administrator	100%
Brooke Burgess	Research Assistant	10%

Appendix H

JVN Imaging Studies Completed

JVN Imaging Studies Completed by Site 2006

SITE-2006	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
WAIANAE	0	0	0	0	19	35	25	40	23	22	13	12	189
MILILANI	0	0	0	2	9	3	1	0	0	2	11	4	32
MOLOKAI	0	0	0	1	4	0	1	0	0	1	0	0	7
TOTAL	0	0	0	3	32	38	27	40	23	25	24	16	228

JVN Imaging Studies Completed by Site 2007

SITE-2007	JAN	FEB	MAR	APR	MAY	JUN	TOTAL
WAIANAE	14	6	21	23	25	2	91
MILILANI	5	3	7	1	6	3	25
MOLOKAI	3	2	1	0	1	0	7
TOTAL	22	11	29	24	32	5	123

Appendix I

Presentation to the Distance Medicine Product Line Review



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Diabetes Care and Treatment Program: A Joslin Telemedicine Initiative

Deborah Birkmire-Peters, PhD

Telehealth Research Institute

University of Hawaii



Project Information

Lab/Company/Group: University of Hawaii
Principal Investigator: Deborah Birkmire-Peters, PhD

Government COR: Colonel Ronald Poropatich

Government Project Officer: Mr. Robert Read

Contract Instrument: W81XWH-05-2-0018

Period of Performance: 1 Jan 2005 – 31 Jan 2007

Contract Specialist: Chris Helman

Date Initiated: 1 Jan 2005

EDMS Number: 2677

MIPR Number: NA

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Tripler Army Medical Center

- **Project initiated in 1999**
- **JVN retinal imaging of diabetic patients in Ophthalmology Service**
- **Reading Center established**
- **Patient education project**

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Tripler Army Medical Center



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JVN Imaging: Number of Patients			
	TAMC	HILO	KAHULUI
1999	11		
2000	482		
2001	560		
2002	652	102	91
2003	687	102	90
2004	356	43	27
TOTAL	2748	247	208



Tripler Army Medical Center

Successes to Date:

- JVN imaging of diabetic patients standard of care
- Number of patients receiving JVN imaging: 3203
- Research studies completed
 - Reading Center Certification
 - JVN Imaging vs. Dilated Eye Exam
 - DOIT: Patient Education

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Transition

- Accelerated adoption of AHLTA (CHCS II) at TAMC delayed implementation of CDMP indefinitely
- Project transitioned into Hawaii community health centers

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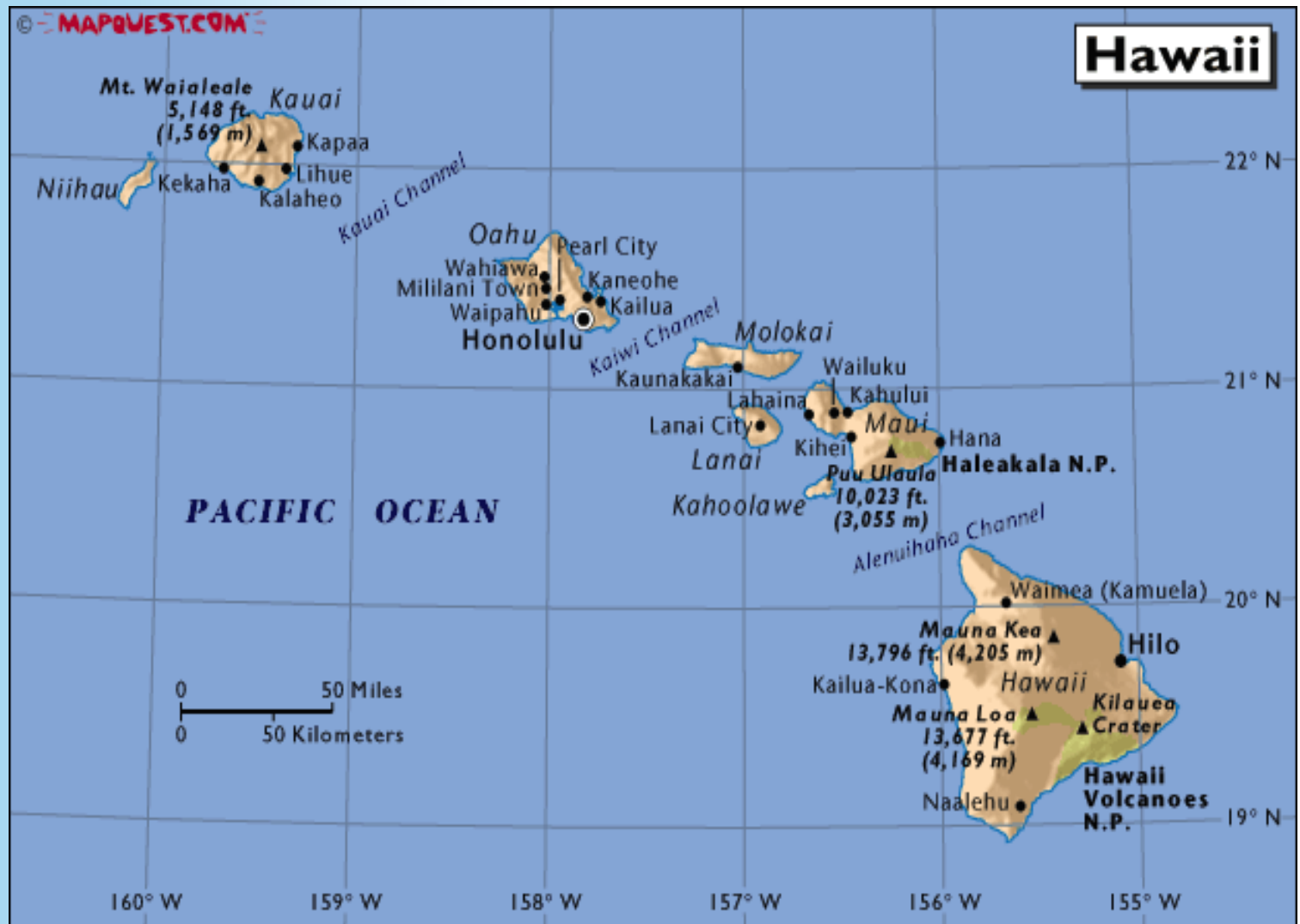
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Waianae Coast Comprehensive Health Center (WCCHC)

- **Four communities**

- Nanakuli
- Maili
- Waianae
- Makaha

- **10 miles of coastline and 5 miles inland**



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Waianae Coast Comprehensive Health Center (WCCHC)

■ Population: 42,259*

- 41% Multiracial
- 29% Native Hawaiian or other Pacific Islander
- 17% Asian
- 11% Caucasian

■ Largest population of Native Hawaiians in state

***2000 Census**



Waianae Coast Comprehensive Health Center (WCCHC)

Most economically disadvantaged on island of Oahu:

- Highest percentage of population on Oahu below 200% of federal poverty level
- Highest percentage of households receiving financial aid (23.1% in Waianae vs 4.9% in state)
- Highest percentage of households using food stamps (45.3% vs 12.9%)

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Waianae Coast Comprehensive Health Center (WCCHC)

- **Five clinics on Waianae Coast and in Kapolei and Waipahu**
- **Services:**
 - Primary care
 - Emergent care (24 hours)
 - Some specialty care
 - Laboratory (24 hours)
 - Radiology (24 hours)
 - Dental
 - Pharmacy
 - Preventative health/health education
 - Medical nutrition therapy/WIC
 - Case management and homeless outreach
 - Chronic disease management
 - Native Hawaiian healing
 - Integrative/alternative medicine
 - Lifestyle enhancement
 - Adult day care
 - Behavioral health

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Waianae Coast Comprehensive Health Center (WCCHC)

- Total number of individuals seen for services in 2003 was 23,943
- Total number of encounters in 2003 was 125,642
- Clinic population:
 - 77% Asian Pacific Islanders (51% of which were Native Hawaiians)
 - 65% were below 100% federal poverty level
 - 1500 individuals diagnosed with diabetes seen in 2003 (6.29% of total number seen at WCCHC)

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Waianae Coast Comprehensive Health Center (WCCHC)





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Waianae Coast Comprehensive Health Center (WCCHC)





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Waianae Coast Comprehensive Health Center (WCCHC)





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Waianae Coast Comprehensive Health Center (WCCHC)





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Waianae Coast Comprehensive Health Center (WCCCHC)





Waianae Coast Comprehensive Health Center (WCCHC)

- **Electronic medical record (NextGen)**
- **Research projects:**
 - **Waianae Cancer Research Project**
 - **Hawaii Diet Study**
 - **Intimate Partner Violent Pilot Study**

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The Physicians Center at Mililani

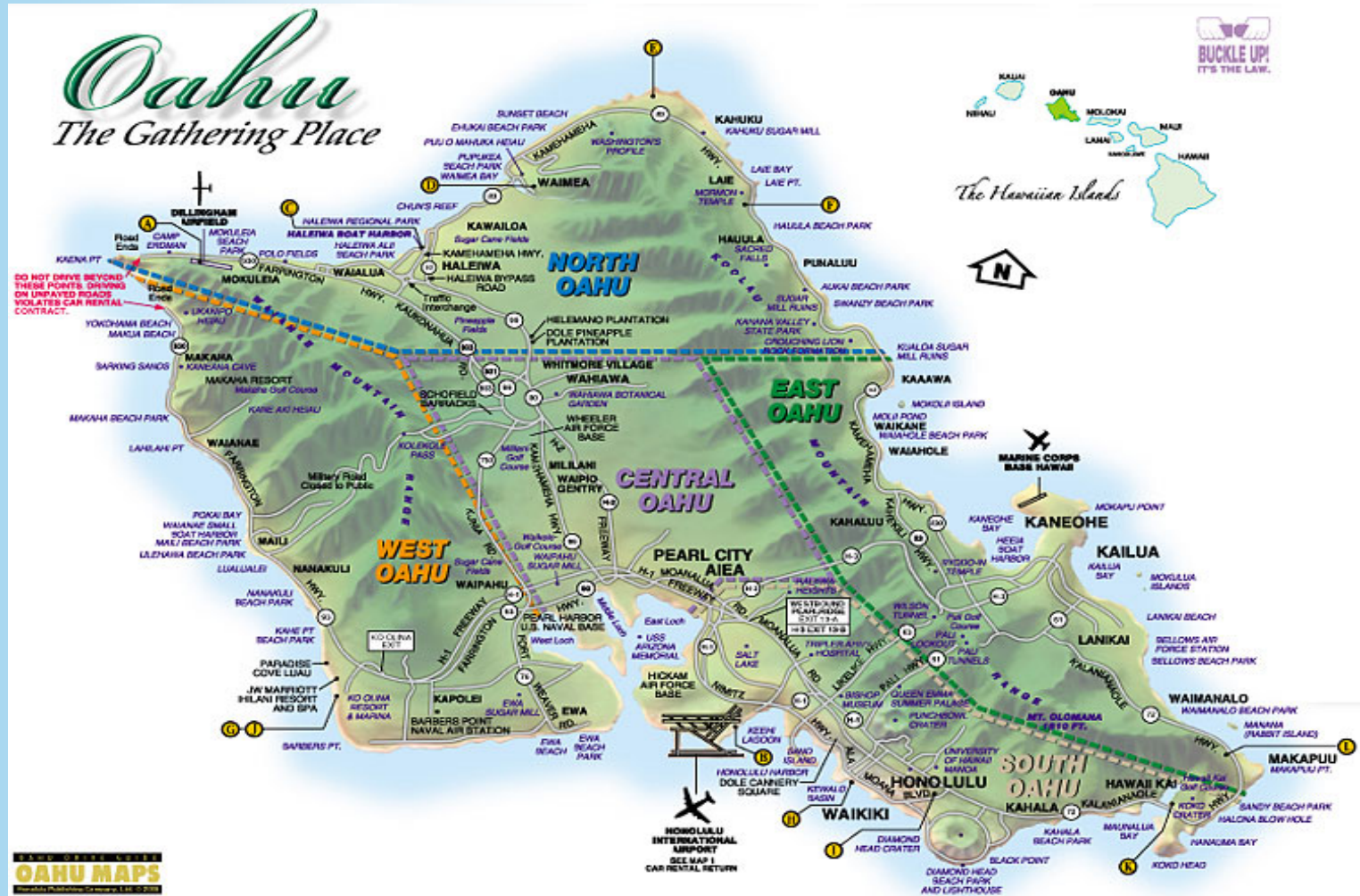
Located in central Oahu



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The Physicians Center at Mililani





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The Physicians Center at Mililani

- Outpatient clinic for residents and faculty of the University of Hawaii Family Practice Residency Program
- Mission to provide optimal health care to underserved communities in Hawaii and the Pacific Basin
- Large number of indigent patients on state-funded health insurance or with no insurance



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The Physicians Center at Mililani

■ Population:

- 1% African American
- 18% Caucasian
- 30% Asian
- 9% Native Hawaiian
- 6% Pacific Islander
- 31% Filipino
- 5% Other

■ Approximately 300 patients diagnosed with diabetes

■ No electronic medical record

■ Slated to be Beta site for VISTA



Molokai General Hospital

- Located on the island of Molokai which is the most rural and underdeveloped of the major islands in the Hawaiian chain
- Total population under 7500

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Molokai General Hospital



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Molokai General Hospital

Population largely economically disadvantaged:

- 47.6% of the population more than 200% under the federal poverty level (1998)
- The civilian unemployment rate was 11.3% in 2003
- 24.5% of the population using food stamps (2003)

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Molokai General Hospital



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Molokai General Hospital



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Molokai General Hospital



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Molokai General Hospital



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Molokai General Hospital

- 11 bed facility
- Rural Health Clinic co-located with Molokai General Hospital
- Healthcare providers wear multiple hats
- No resident specialists
- Eye care specialty care available on itinerant basis
- No electronic medical record



Research Plan

Studies to be completed at each of the following: Waianae Coast Comprehensive Health Center, The Physician Center at Mililani, and Molokai General Hospital:

- 1. An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program's Behavioral Assessment Tool (BAT)**
- 2. An Assessment of the Validity of the Comprehensive Diabetes Management Program's Behavioral Assessment Tool (BAT)**
- 3. JVN Imaging studies (TBD)**

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Status

- Site visits to Waianae Coast Comprehensive Health Center, The Physician Center at Mililani, and Molokai General Hospital (Drs. Sven Bursell, Stephanie Fonda, Joseph Humphry and Deborah Birkmire-Peters, and Drew Lewis) in June and November 2005.
- Meetings with Medical Directors, Research Directors, IT staffs, and clinic staffs
- Three clinic staff members identified for imager training
- Potential research studies identified
- University of Hawaii contract mod approved

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Military Relevance

Cost of treating diabetes significant to the military healthcare system:

- Prevalence of all veteran's receiving care is 15 – 20% in general medicine, primary care, or women's health clinic.*
- In FY94 12% of veteran's received diabetes specific medications as an outpatient accounting for 24% of all pharmacy costs.*
- 0.9% veterans with diabetes sequentially examined in an Optometry Service multi-site filed study had severe visual loss.*
- 5.6% of admissions of veterans with diabetes were associated with the metabolic complications of the disease.*

*Veterans Diabetes Mellitus Working Group

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Research/Development Timeline



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	2006												2007					
Project Activity	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
1. JVN/CDMP Installation																		
Hardware Installation																		
Software Installation																		
Imager Training																		
CDMP Training																		
2. BAT Reliability Study																		
Protocol Development																		
IRB Review																		
Data Collection																		
Data Analyses																		
Report Generation																		



Research/Development Timeline

	2006												2007					
Project Activity	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
3. BAT Validity Study																		
Protocol Development																		
IRB Review																		
Data Collection																		
Data Analyses																		
Report Generation																		

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Challenges

■ Technical:

- Lack of electronic medical record (PCM & MGH)
- Lack of IT infrastructure support (PCM & MGH)

■ Institutional:

- Relative lack of experience with IT solutions (MGH)
- Ethnic populations and cultural sensitivities
- Institutions vary widely with respect to staff, patients, and resources
- Multiple Institutional Review Boards

■ Personnel:

- Training, motivating, retaining three new JVN imagers



Quality Assurance/Regulatory Issues

Animal Use – Not Applicable

Human Use – Pending submission

FDA – Not Applicable

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Contract Funding

FY	Commitment	Obligation
02	\$385,000	\$385,000
03	309,000	309,000
04	341,836	341,836
05	345,712	345,712
Total 99-05	\$ 1,411,750	\$ 1,411,750

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Project Funding - Execution

<u>Current Budget</u>	<u>Expended Funds</u>	<u>%</u>
\$ 345,712	\$ 0	0%
(1/06 – 12/06)		

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Project Coordination



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- **Joslin Diabetes Center**
- **Walter Reed Army Medical Center**
- **Veteran's Administration – VISN 1**
- **Indian Health Service**
- **Duke University**

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Publications

- Coll, K.J., Birkmire-Peters, D.P., Pelletier, M.V., Cavallerano, J., Bursell, S., Winkle, R.K. & Aiello, L.M. (2005, April). Joslin Vision Network: Eye Care Visits Following JVN Imaging. Poster presented at the 10th Annual Meeting of the American Telemedicine Association, Denver, CO.
- Birkmire-Peters, D.P., Coll, K.J., Dunlap, W.A., Bursell, S.-E., Cavallerano, J.D., & Aiello, L.M. (2004, May). Comparison of Dilated Eye Examinations to JVN Imaging at TAMC. Poster presented at the 9th Annual Meeting of the American Telemedicine Association, Tampa, FL.
- Coll, K.J., Birkmire-Peters, D.P., Pelletier, M.V., Cavallerano, J., Bursell, S., Dunlap, W., Winkle, R.K. & Aiello, L.M. (2004, May). Joslin Vision Network: Evidence Supporting Need for Comprehensive Disease Management. Poster presented at the 9th Annual Meeting of the American Telemedicine Association, Tampa, FL.



Publications

- Coll, K.J., Birkmire-Peters, D.P., Pelletier, M.V., Cavallerano, J., Bursell, S., Dunlap, W., Winkle, R.K. & Aiello, L.M. (2004, May). Joslin Vision Network: Evidence Supporting Need for Comprehensive Disease Management in Asians and Pacific Islanders. Poster presented at the 14th Asia Pacific Military Conference, Brisbane, Australia.
- Coll, K.J.; Birkmire-Peters, D.P., Katalinic, P., Ann Tolson, BA, Cavallerano, A.; Cavallerano, J., Bursell, S., Dunlap, W; & Aiello, L.M. (2003, May). Joslin Vision Network: Impact on Clinical Operations at Tripler Army Medical Center. Poster presented at the 8th Annual Meeting of the American Telemedicine Association, Orlando, FL.
- Sakuda, J.M., Swain, G., Yanellas, T., Saiki, S.M., Birkmire-Peters, D.P. & Kim, G. (2003, May). Tele-Health Applications in the VA Health Care System in Hawaii. Poster presented at the 8th Annual Meeting of the American Telemedicine Association, Orlando, FL.

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Publications

- Coll, K.J.; Birkmire-Peters, D.P.; Katalinic, P.; Ann Tolson, BA; Cavallerano, A.; Cavallerano, J.; Bursell, S.; Dunlap, W; & Aiello, L.M. (2002, June). Joslin Vision Network Increases Access for Diabetic Eye Care at Tripler Army Medical Center. Poster presented at the 7th Annual Meeting of the American Telemedicine Association, Los Angeles, CA.
- Birkmire-Peters, D.P., Coll, K.J., Dunlap, W. & Sukada, J. (2001, June). Joslin Vision Network Initiatives: Tripler Army Medical Center and Honolulu Veteran's Administration. Paper presented at the 6th Annual Meeting of the American Telemedicine Association, Ft. Lauderdale, Florida.
- Bursell, S.-E., Cavallerano, J., Cavallerano, A., Clermont, A.C., Birkmire-Peters, D., Aiello, L. & the Joslin Vision Network Research Team. (2000). Joslin Vision Network Image Validation: Non-mydriatic, digital video retinal images compared to standard 35-mm photography for diabetic retinopathy diagnosis. Ophthalmology, 108 (3), 572-585.

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Take Home Message

- Diabetes and diabetic complications are an increasing burden on the military healthcare system.
- The CDMP has the potential to greatly decrease those costs by providing decision support for diabetes management to the patient and all members of the care management team.
- Widespread adoption of healthcare information technologies, such as the CDMP, require the empirical demonstration of their safety, efficacy and cost effectiveness. The proposed CDMP studies are critical to obtaining that data.

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An Assessment of the Validity of the Comprehensive Diabetes Management Program (CDMP) Behavioral Assessment Tool

Principal Investigators:

- Stephanie Fonda, PhD, Joslin
- Deborah Birkmire-Peters, PhD, University of Hawaii
- COL Robert Vigersky, MD, Walter Reed Army Medical Center
- Paul Conlin, MD, VA

Co-Investigators:

- James Rosenzweig, MD & Sven Erik Bursell, PhD, Joslin



Background

The Behavioral Assessment Tool (BAT) was developed:

- **Stand-alone module in CDMP**
- **Approximately 15 minutes to complete**
- **Repeated applications**
- **“Snapshot” of patient’s behaviors**
- **Provides behavioral alerts to clinician**
- **39 multiple-choice questions.**

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Objectives

To establish concurrent validity by assessing correlation of subject responses to:

- Responses to similar questions administered at same time
- Self-report of physical activity and food log
- Anthropometrics
- Medical record data

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Objectives

- **To establish predictive validity by assessing correlation of responses to BAT to future health-related factors**
 - A1c
 - BMI
 - Eye and foot examinations
 - Number of hospitalizations
 - Number of hospital days
 - Number of emergency room visits
 - Frequency and type of provider use
 - New medications

- **To aggregate BAT data from all participating sites**

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Plan

- **Multi-site observational study with repeated measurements**
- **One data collection visit**
- **Subjects will be recruited using letters (Joslin) or from clinic (VA, etc.) (n = 58 per site)**
- **Main inclusion criteria are:**
 - **Must have type 1 or type 2 diabetes**
 - **Must be a patient at the participating clinics/centers**
 - **Duration of diabetes > 2 years**
 - **Comfortable with English**
 - **18+ years of age**



Plan

Covariates:

- Age
- Gender
- Ethnicity and race
- Educational attainment
- Insurance status
- Number of household members supported on household income
- Household income
- Health conditions as noted in medical record

Product
Line
Review

*Distance
Medicine*

17 January 2006



Plan

Concurrent Criterion-Related Measures:

- Seven day food diaries
- Seven day physical activity diaries
- Physical measurements
- SF-36 Short Form
- Center for Epidemiologic Studies – Depression (CES-D) scale (abbreviated, validated form)
- Social Provisions Survey (SPS)
- Summary of Diabetes Self-care Activities Questionnaire (SDSCA-Revised)
- Salivary cotinine

Product
Line
Review

*Distance
Medicine*

17 January 2006



Plan

Procedures:

- **Screening and Informed Consent**
- **Data Collection Visit**
 - **Collect physical activity and food logs**
 - **Complete study questionnaires**
 - Social demographics
 - BAT
 - Criterion instruments
- **6 and 12 month medical record review**

Product
Line
Review

*Distance
Medicine*

17 January 2006



Plan

Data Analyses:

- To determine concurrent validity scores from sub-sections of the BAT will be correlated with corresponding questionnaires, logs, anthropometrics, and medical record data
- Predictive validity will be measured by correlational analysis and regressing health factors on scores from sub-sections of the BAT
- Combination of data from all the participating study sites and replicating analyses described above

Product
Line
Review

*Distance
Medicine*

17 January 2006

Appendix J

**Presentation to the University of Hawaii Bioinformatics Graduate Class
(ICS 614)**



Diabetes Care and Treatment Program: A Joslin Telemedicine Initiative

**Deborah Birkmire-Peters, PhD
Telehealth Research Institute
John A. Burns School of Medicine**

**Rick Walsh
Estenda Solutions, Inc.**

**Presentation to Bioinformatics
(ICS 614)
October 31, 2006**



Background

- Project initiated in 1999
- Initial project congressionally funded for five years
- Sponsor: USA Telemedicine and Technology Research Center (TATRC)
- Consortium:
 - Joslin Diabetes Center
 - New England VA
 - Tripler Army Medical Center
 - Walter Reed Army Medical Center
 - Indian Health Service



Background

- **Joslin Vision Network (JVN) retinal imaging of diabetic patients in Ophthalmology Service**
- **Reading Center established**
- **Patient education project**



JVN Retinal Imaging





Digital Retinal Images





JVN Imaging: Number of Patients

TAMC

HILO

KAHULUI

1999	11		
2000	482		
2001	560		
2002	652	102	91
2003	687	102	90
2004	356	43	27
TOTAL	2748	247	208



Successes to Date

- JVN imaging of diabetic patients standard of care
- Number of patients receiving JVN imaging: 3203
- Research studies completed
 - Reading Center Certification
 - JVN Imaging vs. Dilated Eye Exam
 - DOIT: Patient Education



Transition

- New project congressionally funded for additional five years
- Sponsor: USA Telemedicine and Technology Research Center (TATRC)
- Consortium:
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 - Estenda Solutions, Inc.
- Development of the Comprehensive Diabetes Management Program (CDMP)



Transition

- Originally planned to implement CDMP at Tripler Army Medical Center
- CDMP was to interface with existing database, i.e., ICDB
- Accelerated adoption of AHLTA (CHCS II) at TAMC delayed implementation of CDMP indefinitely
- Project transitioned into Hawaii community health centers



Waianae Coast Comprehensive Health Center (WCCHC)

- **Four communities**
 - Nanakuli
 - Maili
 - Waianae
 - Makaha

- **10 miles of coastline and 5 miles inland**



Waianae Coast Comprehensive Health Center (WCCHC)

➤ Population: 42,259*

- 41% Multiracial
- 29% Native Hawaiian or other Pacific Islander
- 17% Asian
- 11% Caucasian

■ Largest population of Native Hawaiians in state

*2000 Census



Waianae Coast Comprehensive Health Center (WCCHC)

Most economically disadvantaged on island of Oahu:

- **Highest percentage of population on Oahu below 200% of federal poverty level**
- **Highest percentage of households receiving financial aid (23.1% in Waianae vs 4.9% in state)**
- **Highest percentage of households using food stamps (45.3% in Waianae vs 12.9% in state)**



Waianae Coast Comprehensive Health Center (WCCHC)

- **Five clinics on Waianae Coast and in Kapolei and Waipahu**
- **Services:**
 - Primary care
 - Emergent care (24 hours)
 - Some specialty care
 - Laboratory (24 hours)
 - Radiology (24 hours)
 - Dental
 - Pharmacy
 - Preventative health/health education
 - Medical nutrition therapy/WIC
 - Case management and homeless outreach
 - Chronic disease management
 - Native Hawaiian healing
 - Integrative/alternative medicine
 - Lifestyle enhancement
 - Adult day care
 - Behavioral health



Waianae Coast Comprehensive Health Center (WCCHC)

- **Total number of individuals seen for services in 2003 was 23,943**
- **Total number of encounters in 2003 was 125,642**
- **Clinic population:**
 - **77% Asian Pacific Islanders (51% of which were Native Hawaiians)**
 - **65% were below 100% federal poverty level**
 - **1500 individuals diagnosed with diabetes seen in 2003 (6.29% of total number seen at WCCHC)**



Waianae Coast Comprehensive Health Center (WCCHC)





Waianae Coast Comprehensive Health Center (WCCHC)





Waianae Coast Comprehensive Health Center (WCCHC)





Waianae Coast Comprehensive Health Center (WCCHC)





Waianae Coast Comprehensive Health Center (WCCHC)

- **Electronic medical record (NextGen)**
- **Research projects:**
 - **Waianae Cancer Research Project**
 - **Hawaii Diet Study**
 - **Intimate Partner Violent Pilot Study**



The Physicians Center at Mililani

- **Outpatient clinic for residents and faculty of the University of Hawaii Family Practice Residency Program**
- **Mission to provide optimal health care to underserved communities in Hawaii and the Pacific Basin**
- **Large number of indigent patients on state-funded health insurance or with no insurance**



The Physicians Center at Mililani

- **Population:**
 - **1% African American**
 - **18% Caucasian**
 - **30% Asian**
 - **9% Native Hawaiian**
 - **6% Pacific Islander**
 - **31% Filipino**
 - **5% Other**
- **Approximately 300 patients diagnosed with diabetes**
- **No electronic medical record**
- **Beta site for VISTA**



The Physicians Center at Mililani





Molokai General Hospital

- **Located on the island of Molokai which is the most rural and underdeveloped of the major islands in the Hawaiian chain**
- **Total population under 7500**



Molokai General Hospital

Population largely economically disadvantaged:

- **47.6% of the population more than 200% under the federal poverty level (1998)**
- **The civilian unemployment rate was 11.3% in 2003**
- **24.5% of the population using food stamps (2003)**



Molokai General Hospital





Molokai General Hospital





Molokai General Hospital





Molokai General Hospital





Molokai General Hospital

- **11 bed facility**
- **Rural Health Clinic co-located with Molokai General Hospital**
- **Healthcare providers wear multiple hats**
- **No resident specialists**
- **Eye care specialty care available on itinerant basis**
- **No electronic medical record**



CDMP

- **Clinical and behavioral decision support**
- **Based on Joslin Diabetes Center treatment guidelines and risk profiling**
- **Includes reference, education, and care planning tools**
- **Secure, web-based and HIPAA compliant**
- **Site and provider customizable**



Care Provider Home Page

CDMP - User Home - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address http://localhost:8080/cdmp/userHome.do?task=getHome Go

Comprehensive Diabetes Management Program

Home | Status Center | Message Boards | Private Msgs | Search
Add Patient | User Pref | Admin | Help | Log Out

user3 user3 Home Page

Patient Search

Last Name
Find

Today's Patients

- 8:00 Haverback, Chester
- 9:00 Snyder, Joyce
- 14:00 Lewis, George
- 16:00 Lewis, George

View New All Open All Red Close Print Filter is OFF

Close	Status	Level	Patient Name	Alert	Origin Date	Days Old	Count
☐	Open	YELLOW	Salvo, Robert	No Foot Exam	05/03/2004	31	3
☐	Open	YELLOW	Salvo, Robert	Triglycerides	05/10/2004	24	1
☐	Open	RED	Salvo, Robert	No Foot Exam	05/10/2004	24	2
☐	Open	RED	Salvo, Robert	No A/C Ratio Test	05/10/2004	24	2
☐	Open	RED	Salvo, Robert	No PCP Visit	05/10/2004	24	2
☐	Open	YELLOW	Salvo, Robert	Care Plan Expiration OR No Care Plan	05/10/2004	24	2

Reminders for All days All Close Print

Close	Patient Name	Category	Reminder	Assigned To	Due Date
☐	Salvo, Robert	Care Plan	Schedule Depression Screening - Salvo needs to see his shrink for therapeutic holistic help of the left side of his brain.		05/21/2004
☐	Salvo, Robert	Behavior Assessment	Call Patient to schedule a new BAT	User One	07/03/2004

User: user3
Teams: WVRAMC

Contact Administrator

Local intranet



Patient Home Page

CDMP - Patient Home - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address http://localhost:8080/cdmp/patientHome.do?patientId=10115&patientFirstName=Robert&patientLastName=Salvo Go

Comprehensive Diabetes Management Program

Home | Status Center | Message Boards | Private Msgs | Search
Add Patient | User Pref | Admin | Help | Log Out

open all | close all

Patient Home: Robert Salvo [✓ DME] Team: WRAMC

Current History Close Print Filter is OFF

Close	Status	Level	Alert	Origin Date	Days Old	Count
☐	Open	YELLOW	No Foot Exam	05/03/2004	31	3
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Reminders for All Days History All days Add New Close Print

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Patient Snapshot

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Address http://localhost:8080/cdmp/patientSnapshot.do?patientId=10115&patientLastName=Salvo&patientFirstName=Robert Go

Comprehensive Diabetes Management Program

Home | Status Center | Message Boards | Private Msgs | Search
Add Patient | User Pref | Admin | Help | Log Out

open all | close all

Patient Snapshot: Robert Salvo

Gender:	MALE	Diabetes Type:	1	Ethnicity:	White
Age:	57	Diabetes Onset:	01/01/1972	Taking Aspirin:	No

Patient Status Data

Red Alerts: 3 Open, 31 in last 90 days
Yellow Alerts: 3 Open, 28 in last 90 days

Care Plan: last updated 9/1/03, planned end date: 12/31/03

Foot Exam: No exam in last 365 days
Eye Exam: No exam in last 365 days
JVN: No JVN exam
BAT: 06/01/2004
NAT: None

Procedures: 7 in last 365 days, last on 04/28/2004
Admissions: 0 in last 365 days

Risk Profile (View)

Glycemic Control	High
Cardiac	High
PVD/Peripheral Neuropathy	Medium
Retinopathy	High
Nephropathy	High

BAT Scores (06/01/2004)

(Summary | Detail)

Psycho-Social	1 (1 - 30)	Low
Physical Wellness	2 (1 - 33)	Low
Self-Management / Lifestyle	3 (1 - 24)	Low

Ed. Assessment (05/25/2004)

Nutrition	No Education
Process	No Education

Labs and Vital Signs

Lab	Date	Value/Trend
HbA1c%	09/16/2003	6.2 =
Triglycerides	04/29/2004	301 +
LDL	06/05/2003	101 =
Serum Creatinine	09/13/2003	2.60 =
Fasting Glucose	09/13/2003	221
Random Glucose	No Results Found	
A/C ratio	09/16/2003	74.1 =
Protein on dipstick	No Results Found	
Protein in urine	09/13/2003	NEGATIVE

Medications

Name	Prescribed	Refills
GLUCOPHAGE XR	04/28/2004	0
GLUCOPHAGE XR	04/04/2004	2
ZESTORETIC	09/13/2003	0
TERAZOSIN HCL	09/13/2003	3
SYNTHROID	09/13/2003	3
HUMULIN N	09/13/2003	3
HUMALOG	09/13/2003	6
ZESTORETIC	09/13/2003	3
EUPROSEME	09/13/2003	2

Chronic Problems Listing

(View Complete List)

- Diabetic Retinopathy
- Diabetic Retinopathy
- ESRD
- ESRD
- High Blood Pressure
- High Blood Pressure
- Hypoglycemia
- Hypoglycemia
- Kidney disease

Done

Local intranet



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- ESRD
- High Blood Pressure
- High Blood Pressure
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- Hypoglycemia
- Kidney disease

Done

Local intranet



Contact Information

- **Deborah Birkmire-Peters, PhD**
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John A. Burns School of Medicine
808-780-1090
dbpeters@hawaii.edu
- **Rick Walsh**
Estenda Solutions, Inc.
808-692-1085
FWalsh@estenda.com

Appendix K

**Presentation to COL Karl Friedl, Director, TATRC, on the Diabetes Care and
Treatment Project**

Diabetes Care and Treatment Program: A Joslin Telemedicine Initiative

**Deborah Birkmire-Peters, PhD
Telehealth Research Institute
John A. Burns School of Medicine**

February 14, 2007





Background

- Project initiated in 1999
- Initial project congressionally funded for five years
- Sponsor: USA Telemedicine and Technology Research Center (TATRC)- COR COL Ron Poropatich
- Consortium:
 - Joslin Diabetes Center
 - New England VA
 - Tripler Army Medical Center
 - Walter Reed Army Medical Center
 - Indian Health Service



JVN Retinal Imaging





Digital Retinal Images





JVN Imaging: Number of Patients

TAMC

HILO

KAHULUI

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Successes to Date

- JVN imaging of diabetic patients standard of care
- Number of patients receiving JVN imaging: 3203
- Research studies completed
 - Reading Center Certification
 - JVN Imaging vs. Dilated Eye Exam
 - DOIT: Patient Education



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- Development of the Comprehensive Diabetes Management Program (CDMP)



Transition

- Originally planned to implement CDMP at Tripler Army Medical Center
- CDMP was to interface with existing database, i.e., ICDB
- Accelerated adoption of AHLTA (CHCS II) at TAMC delayed implementation of CDMP indefinitely
- Project transitioned into Hawaii community health centers



Community Health Centers

- **Waianae Coast Comprehensive Health Center**
- **The Physicians Center at Mililani**
- **Molokai General Hospital**



CDMP

- **Clinical and behavioral decision support**
- **Based on Joslin Diabetes Center treatment guidelines and risk profiling**
- **Includes reference, education, and care planning tools**
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user3 user3 Home Page

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Today's Patients

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Teams: vWRAMC

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Local intranet



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Local intranet



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Comprehensive Diabetes Management Program

Home | Status Center | Message Boards | Private Msgs | Search
Add Patient | User Pref | Admin | Help | Log Out

open all | close all

Patient Snapshot: Robert Salvo

Gender:	MALE	Diabetes Type:	1	Ethnicity:	White
Age:	57	Diabetes Onset:	01/01/1972	Taking Aspirin:	No

Patient Status Data

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(Summary | Detail)

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HUMALOG	09/13/2003	6
ZESTORETIC	09/13/2003	3
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Chronic Problems Listing

(View Complete List)

- Diabetic Retinopathy
- Diabetic Retinopathy
- ESRD
- ESRD
- High Blood Pressure
- High Blood Pressure
- Hypoglycemia
- Hypoglycemia
- Kidney disease

Done

Local intranet



CDMP

Adapted for:

- **Chronic kidney disease – local affiliate of the National Kidney Foundation**
- **Liver disease (Hepatitis B and C) – HMSA Foundation grant**
- **Bariatric surgery – Springfield General Hospital**



Military Relevance

- **Cost of treating diabetes and other chronic diseases significant to the military healthcare system**
- **CDMP model for DOD chronic disease management with reduction in healthcare costs**
- **DM Everywhere model for Personal Health Record**
- **JVN imaging can be adapted for use in field for rapid evaluation of eye injuries**
- **JVN imaging can be used for medical exams for returning service members**



Take Home Message

Widespread adoption of healthcare information technologies, such as the CDMP, require the empirical demonstration of their safety, efficacy and cost effectiveness. The proposed CDMP studies are critical to obtaining that data.

Appendix L

2007 CDC Diabetes Translation Conference Presentation



Test-Retest Reliability of a New Screening Questionnaire for People with Diabetes

J Garren¹, S Fonda¹, S Bursell¹, P Conlin², R Vigersky³, D Birkmire-Peters⁴

¹ Beetham Eye Institute, Joslin Diabetes Center, Boston, MA

² Veterans Administration Medical Center, Boston, MA

³ Walter Reed Army Medical Center, Washington, DC

⁴ John A. Burns School of Medicine, University of Hawaii, Manoa, HI



INTRODUCTION:

Daily self-care behaviors carried out by the person with diabetes are of central importance in attaining good blood glucose control. This is achieved through patient adherence to:

- A healthy diet
- Regular exercise
- Appropriate use of diabetes medications (insulin and oral agents)
- Regular self-monitoring of blood glucose (SMBG) to guide daily management decisions
- Hypoglycemia management and prevention
- Foot care, clinic visits, diabetes education, and various necessary medical screenings

Many environmental and patient factors can influence implementation of the diabetes treatment plan by the patient. Typically little time is spent in busy, primary care settings (not specializing in diabetes) assessing each patient's factors and current behaviors that can influence their diabetes treatment/self-management plan. The opportunity to implement a tailored care management approach with diabetes patients is lost.

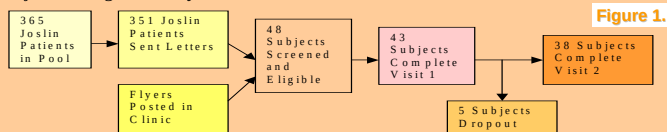
Thus, a consortium of diabetes experts from the Joslin Diabetes Center, Veterans Affairs, the Department of Defense, and the Indian Health Service developed a screening instrument to be used in busy clinical settings to quickly assess patient's factors and behaviors. The BAT draws key questions from other validated assessments and is intended to generate further evaluation and/or referrals.

Since this instrument is new, we are conducting studies to evaluate its test-retest reliability, criterion validity, and predictive validity. This study reports on the test-retest reliability of the BAT.

MATERIALS AND METHODS:

Study Design:

This is an observational study with two measurements per study subject taking place 2 to 4 weeks apart. The study subjects were recruited using flyers and mass mailings to potential subjects identified through medical record review. Figure 1 shows the flow of subjects through the study.



Site and Subjects:

Recruitment for study subjects occurred at Joslin Diabetes Center (Boston), a tertiary care specialty hospital. Subjects were considered eligible if they had diabetes for 2 years or more, were 18 years old or older, and comfortable speaking and reading English.

Measures:

At both visits the subject completed a blood glucose test, a test of cognitive functioning, and the BAT questionnaire. Social-demographic data were collected during the first visit as well. Basic health data was gathered from the subjects' medical records at the end of the study.

Table 1 shows the BAT questionnaire questions along with their variable names. Certain questions are “flagged” to indicate that they were intended to result in clinician follow-up or referral. These are the questions we examined the test-retest reliability of.

Table 1. Behavioral Assessment Tool

Question	Variable name
Is English your native language?	english
When you learn something new, does it help to hear it in your native language?	learnlang
Would you like someone who speaks your native language to help you complete this survey?	speaklang
Do you have problems reading and understanding written materials?	readwrite
Would you like someone to read the survey questions to you?	readques
When were you first told you have diabetes?	whendiagnose
On a typical day, how many servings of fruits and vegetables do you eat?	servfruitveg
During the past 7 days, how often did you eat 3 meals a day (that is, you did not skip a meal)?	eat3meals
How many times in the past 7 days have you eaten food prepared in a restaurant or cafeteria?	restaurant
How would you describe your physical activity level?	physactivity
In the last 7 days, how many times were you moderately to very physically active for 30 minutes or more?	modtoستن
How often do you check your blood sugar?	smbg
In the last 7 days, how often did you miss taking your diabetes pills or insulin?	missmeds
During the past month have you often been bothered by feeling down, depressed, or hopeless?	depressed
During the past month have you often had little interest or pleasure in doing things?	nopleasure
Do you drink alcohol?	alcohol
Are you concerned about your drinking?	concernalc
Do you smoke cigarettes, cigars, a pipe, or chew tobacco?	smoke
In general, would you say your health is:	selfratehealth
Have you been examined by an eye doctor in the last 12 months?	eyeexam
How often do you check your feet for sores, cuts, or bruises?	checkfeet
Have your feet been examined by a doctor in the last 12 months?	footexam
Do you use other healing methods or remedies in addition to those prescribed for	altmeds
Do you have family and friends you can ask for help?	havefamfrinds
Do your family and friends live in your house or nearby?	famfrindsnear
Do you agree with the following statement? My family and friends support me by encouraging me to do things to improve my health.	support
Do you have problems getting to the clinic?	probgetclinic
How long does it usually take you to get to the clinic?	timetoclinic
How do you usually get to the clinic?	howclinic
How do you like to learn about new things?	video, read, othershow, discussions, listening, computers, class, otherways
How much have you learned about diabetes from reading materials, visits with nurses, or attending classes?	howmuchlearn
Would you like to learn more about taking care of your diabetes?	learnmore
Which BEST describes you? (Choose only one answer.)	employoft, employoft, disabled, retired, student, lookwork, otherwork
Do you have any vision problems?	vision
Do you have any hearing problems?	hearing
Do you have any problems walking?	walking
Do you have problems remembering things?	remembering
Do you have any money issues that affect your ability to take care of any of the following items?	probpaymeds, probpayfood, probpaytransport, probpaysmbg
Did you complete these questions with help from another person?	hadhelp

* / * questions represent questions that have clinical relevance for follow-up or referral.

Statistical Analysis:

Demographic characteristics of the sample are presented as descriptive statistics. Spearman rank coefficients (ordinal) or Cramér's V (nominal) and agreement percentages were calculated to examine the test-retest reliability of the “flagged” BAT questions. The BAT questions' reliability were also compared against other reliable instruments for questions about nutrition, physical activity, blood glucose monitoring, alcohol use, mood, and social support. Statistical analysis was carried out using the statistical package SAS 9.1.

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RESULTS:

The majority of the sample was female, white, and had type 2 diabetes (70%, 84%, and 70% respectively). The average age of the subjects was 61 ± 13 years. Eighty-eight percent of the subjects completed the study; dropouts were not significantly different demographically from completed subjects. Table 2 list the demographics of the population for this study, i.e. age group, gender, race/ethnicity, education, diabetes type, and income.

Overall test-retest reliability ranged from -0.06 to 1.0 with seventy percent of all BAT questions having an acceptable test-retest reliability ($r \geq 0.50$). Among the BAT questions being compared against other reliable questionnaires the overall test-retest reliability ranged from 0.27 to 0.98 with eighty percent of the BAT questions having an acceptable test-retest reliability.

Table 3 list all of the percent agreements and Spearman rank coefficient or Cramér's V with p-values for the BAT questionnaire questions.

Table 2. Demographics			Table 3. Test-retest Reliability			
Parameters	#	%	BAT Variable	% Agree	r	p
Age Group			servfruitveg	89	0.71	<0.0001
≤ 49 years	9	20.93%	eat3meals	68	0.37	0.0224
50-59 years	14	32.56%	restaurant	74	0.78	<0.0001
60-69 years	9	20.93%	physactivity	79	0.59	0.0001
70+ years	11	25.58%	modtoستن	58	0.58	0.0001
Female	30	69.77%	smbg	92	0.93	<0.0001
Race/Ethnicity			missmeds	76	0.27	0.0983
Asian	2	4.65%	depressed	87	0.64	<0.0001
Black of African American	1	2.33%	nopleasure	92	0.71	<0.0001
White or Caucasian	36	83.72%	alcohol	97	0.95	<0.0001
Other	4	9.30%	concernalc	97	0.98	<0.0001
Education			smoke	95	0.96	<0.0001
Less than high school	2	4.65%	selfratehealth	79	0.83	<0.0001
High school diploma (including GED)	5	11.63%	eyeexam	100	-	-
Some College to College Grad	20	46.51%	checkfeet	68	0.42	0.008
Post College	16	37.21%	footexam	97	0.81	<0.0001
Type 2 Diabetes	30	70.00%	havefamfrinds	97	-	-
Income			famfrindsnear	87	0.55	0.0034
Less than \$5,000 - \$39,000	9	20.93%	support	61	0.58	0.0001
\$40,000 - \$59,000	10	23.26%	vision	68	0.29	0.1946
\$60,000 - \$99,000	9	20.93%	hearing	95	0.81	<0.0001
\$100,000+	8	18.60%	walking	97	0.97	<0.0001
Don't know	7	16.28%	remembering	87	0.79	<0.0001
			probpaymeds	0.95	0.84	<0.0001
			probpayfood	0.92	0.37	0.0233
			probpaytransport	0.89	0.62	0.0001
			probpaysmbg	0.95	0.75	<0.0001

CONCLUSION:

For most BAT questions, test-retest reliability is acceptable and suitable for clinical use ($r \geq 0.50$). However, it is lower for the questions “eat3meals” ($r = 0.37$), “missmeds” ($r = 0.27$), “checkfeet” ($r = 0.42$), “vision” ($r = 0.29$), and “probpayfood” ($r = 0.37$).

Further study is required to determine: a) whether the low reliability is specific to this sample; and b) possible reasons for the low reliability scores, such as question wording. Data collected from other sites might shed light on the first issue, and ongoing studies of the BAT's validity may address the issue of question wording.