THE DIGITAL DIVIDE AND HEALTH OUTCOMES: A TELERETINAL IMAGING STUDY

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ABSTRACT

The purpose of this research project was to understand, explore and describe the digital divide and the relationship between technology utilization and health outcomes. Diabetes and diabetic eye disease was used as the real-life context for understanding change and exploring the digital divide. As an investigational framework, a telemedicine intervention in the form of a diabetic eye care program that utilized web-based eye care education and retinal (teleretinal) imaging over the Internet was implemented. Research has shown that minority and underserved populations in which technology has been made available demonstrate improved their health outcomes. The participant population for this study was recruited from a Federally Qualified Health Center that serves a Federal Medically Underserved Area. Data sources included: 1) surveys using the transtheoretical model (TTM), which were used to explore behavior change as a result of the technology intervention; and 2) focus groups to further explore computer and Internet usage, and to further examine how technology impacted health and health outcomes.

Results from the TTM surveys revealed statistically significant differences in readiness to change for exercise, carbohydrate counting and smoking cessation over a three-month period. For the measure of daily self-management there was a significant difference in the transition from having no self-management plan to having a plan. There were also significant differences in decisional balance for exercise adoption and carbohydrate counting. Significant changes in TTM-based processes of change were mainly related to social interaction, such as: environmental reevaluation, which addresses the impact of the social environment on behavior; helping relationships, which involves seeking and using social support; and social liberation, which relates to recognizing changes in social norms.

Based on the focus group interviews, all participants felt that their study participation had been a positive experience. All focus group participants agreed that the retinal imaging was not invasive and provided little discomfort. Family was a key theme in the use of computers, improving eHealth literacy, and a key influence as a motivator *and* barrier for health behavior change. Family was also a key factor in the concept of

fear being a motivating factor for behavior change. Fear that they did not want to suffer from the complications of diabetes like other family members had experienced. Additionally, social support was confirmed as a key theme as a motivator for behavior change. Barriers to behavior change included the lack of support from family, food, culture and depression. The food culture of the participants was a theme that impacted the participants a great deal: the love for food; the lack of control when it came to eating; and the culturally high-fat foods that were pervasive in their environment. Symptoms of depression were also key barriers; this included low self-esteem, lack of confidence, and lack of self-motivation. Results also revealed that the lack of computer access and knowledge on use of the technology were the most common barriers in web access.

Overall, the study demonstrated that a teleretinal imaging intervention can help to improve health outcomes. The results of this study contribute to the fields of health behavior change, computer literacy, eHealth literacy, and the digital divide in an underserved, predominately Native Hawaiian population in Hawaii.

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CHAPTER 1
INTRODUCTION

1.1 Overview

Since the 1930's when radio was popularized, the influence of mass media and smart technologies have evolved at an exponential rate. This has intensified with the growth of the Internet and the proliferation of the World Wide Web (WWW). In the United States, information technologies have become integrated into everyday life. It has even been hypothesized that; people will soon no longer remember performing daily routines, social interactions and simple communications without the use of computers, email, Internet, or handheld smart devices (Hunter, 2008).

Information technology also has the potential to bridge the gap between health disparities; yet, it has the potential to widen the gap for those who lack access to the technology and the computer and literacy skills that are needed to utilize the resources. For example, health technology has been shown to improve health outcomes; however, if certain populations do not have access to the technology or the knowledge to use it, consequences may lead to increased health disparities among the "have not's." There is already evidence that the "digital divide" has negatively impacted a disproportionate burden of preventable diseases, such as diabetes, among minority and underserved populations (Baur, 2008; Eng, Maxfield, Deering, Ratzan, & Gustafson, 1998; Sarkar, Karter, Liu, Adler, Nguyen Lopez, & Shillinger, 2011). Research in usage of the Internet for healthcare has shown that minority and underserved populations are less likely to use technology, with common barriers shown to be lack of computer access and knowledge (Kruse, Koopman, R. Wakefield, B. Wakefield, Keplinger, Canfield, & Mehr, 2012). Furthermore, those who do not utilize information technology in managing their health were more likely to have poor control of their diabetes, which include blood glucose, blood pressure and lipids (Sarkar et al., 2011).

As such, a relationship has been demonstrated between technology utilization and health outcomes. Health information delivered via the Internet has shown to have a positive impact on health outcomes (Rains, 2008). Advantages of this technology include

access to health information anytime and anywhere, personalized health information tailored to the individual, access to group discussions, and social networking opportunities. Examples of how technology has improved health outcomes have been demonstrated in programs that use email-linked counseling interventions (Liebreich, Plotnikoff, Courneya, & Boule, 2009), an Internet based self-care website that included personalized feedback and peer group support modules (McKay, King, Eakin, Seeley, & Glasgow, 2001; Liebreich, Plotnikoff, Courneya, & Boule, 2009), and education via computerized information (Jones & Pearson, 1999).

To address the growing digital divide, there has been a substantial push for the development and dissemination of technology in healthcare, with a goal of removing barriers and improving access. This includes legislation that has been passed in the form of the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, which is part of the American Recovery and Reinvestment Act (ARRA) of 2009. The HITECH Act provides funding for the meaningful use of technology in healthcare, including funding for technology-related programs, such as the implementation of health information systems, electronic health records, telemedicine, and the use of HIT in clinical education. The HITECH Act also gives priority to medical practices that focus on primary care and Federally Qualified Health Centers that assist medically underserved and vulnerable populations located in rural areas (U.S. Department of Health & Human Services, 2013).

Growing momentum for programs that target minority and underserved communities suggest that there is great promise in the implementation of Internet and communication technologies for reducing health disparities and improving health outcomes among minority and rural populations (Lopez & Grant, 2012; Sequist, Thomas D., Cullen, Theresa, & Acton, Kelly J., 2011). Telemedicine is the practice of medicine over distance via telecommunications or Internet. Patient portals are web-based portal where patients can access personal medical information, education, communication with providers and other medical related data. Both of these technologies have the potential to reach the medically underserved in rural and hard to reach areas, including the ability to improve health outcomes for those with various medical conditions (Ahern, Stinson, Uebelaker, Wrobelwski, McMurray, & Eaton, 2012; McCorkle, Ercolano, Lazenby,

Schulman-Green, Schilling, Lorig, & Wagner, 2011; Quinn, Shardell, Terrin, Barr, Ballew, & Gruber-Baldini, 2011).

As technology advances and legislation for reimbursement for telemedicine becomes common practice, the potential for telemedicine technology to facilitate reduced costs, better access to care and improved quality of care becomes more of a reality (Gupta & Saot, 2011). To-date, telemedicine programs that have been successfully implemented for underserved populations in rural areas includes the following: Use of a home telemedicine system has shown to reduce blood glucose levels, lipid and blood pressure (Shea, Weinstock, Teresi, Palmas, Starren, Cimino, Lai, Field, Morin, Goland, Izquierdo, Ebner, Silver, Petkova, Kong, & Eimike, 2009); diabetes education via telemedicine (Balamurugan, Hall-Barrow, Belvins, Brech, Phillips, Holley, & Bittle, 2009); and improved pediatric patient care for rural underserved emergency departments (Heath, Salerno, Hopkins, Hertzig, & Caputo, 2009).

In Hawaii, there have been few programs, possibly due to funding challenges, that have successfully implemented telemedicine for clinical care for patients. This includes care for dialysis patients (Berman, Wada, Minatodani, Halliday, Miyamoto, Lindo & Jordan, 2011), telepsychiatry (Morland, Hynes, Mackintosh, Resick, & Chard, 2011; Chung-Do, Fukuda, Alicata, Nishimua & Else, 2012), home telemedicine monitoring of acute infections (Eron, Marineau, Baclig, Yonehara, & King, 2004), pediatric video consultations for children located in remote regions in the Pacific Basin Region (Ono & Lindsey, 2004), and remote critical care consultations (Berg, Vincent, & Hudson, 2003). There have also been successful programs that have used telemedicine to reach remote areas throughout the Pacific, predominately established by the military (Delaplain, Lindborg, Norton, & Hastings, 1993; Gunawardane, 2000).

This dissertation utilized telemedicine specific to diabetes eye care management via digital retinal imaging. Research has also shown that teleretinal imaging combined with population-based strategies has the potential to increase access to eye care and can overcome traditional barriers (Taylor, Merin, Salunga, Hepworth, Crutcher, O'Day, & Pilon, 2007). However, there has been little research on related behavior or health outcomes as a result of implementation of a teleretinal imaging program. Based on a recent literature search there were no published articles were found that examined the

impacts of telemedicine, which includes components of digital retinal imaging and diabetes self-management education, looking specifically at health behavior and health outcomes. There also are no studies published using telemedicine for diabetes management in a Native Hawaiian population. The search was conducted using Academic Search Premier, PubMed/Medline and Psychology and Behavioral Science collection databases; key words included telemedicine, diabetes, health behavior theory, retinal imaging, retinopathy, teleretinal imaging; date from 1997 through 2012; conducted January 2013.

1.3 Diabetes: The Big Problem

In an attempt to examine the relationship of technology and health, this study targeted type 2 diabetes patients. Diabetes is the seventh leading cause of death in the United States (Centers for Disease Control and Prevention, 2011). According to the Center for Disease Control and Prevention (CDC), *National Diabetes Fact Sheet, 2011,* an estimated 25.8 million children and adults have type 2 diabetes; 7 million of whom are unaware of their condition. Furthermore, it is estimated that 79 million adults have pre-diabetic conditions, which are determined by blood glucose levels higher than normal (HbA1c > 5.7%, HbA1c is a lab test that show average blood sugar over the last three months). Long-term complications related to diabetes include diabetic eye disease, nerve damage (neuropathy), heart disease, stroke, kidney failure, and peripheral vascular disease, which can result in amputations and premature death. The CDC calculates health costs related to this disease to total approximately $174 billion per year.

Over the past 10 years, the rate of newly diagnosed cases has increased more than 90%, with more than 1.9 million new cases of diabetes diagnosed every year in adults over 20 years of age (Centers for Disease Control and Prevention, 2011). In particular to Hawaii, data has shown that there is an estimated 72,000 to 100,000 people that have diabetes, including 25,000 who remain undiagnosed. Diabetes disproportionately affects Native Hawaiians, Asian Americans, and Pacific Islanders (Hirokawa, Huang, Pobutsky, Nogues, Salvail, & Nguyen, 2004). Statistics from the State of Hawaii Primary Care Needs Assessment Data Book, 2012, indicates the following: 1) Honolulu County has the highest prevalence of adults with diabetes in the state, at 9%; 2) Native Hawaiians in

particular have the highest prevalence of diabetes at 24% statewide (Schiller, Lucas, Ward, & Peregoy, 2012); and 3) statewide, the prevalence of retinopathy among adults with type 2 diabetes is 22%, with Native Hawaiians having the highest prevalence at 29% (Hirokawa et al., 2004).

Diabetic eye disease, a complication of diabetes that affects both type 1 and type 2 diabetic patients, includes diabetic retinopathy (DR), cataracts, and glaucoma. In general, the most common occurrence of the three is diabetic retinopathy, which affects 40–45% of those in the United States diagnosed with diabetes.

There are four stages of DR: mild, moderate, severe and proliferative; the latter of which, if left untreated, can result in severe blurred vision or vision loss. DR is the leading cause of adult blindness in the United States (National Eye Institute National Institutes of Health, 2013), and has been shown to be present in nearly all people diagnosed with diabetes for a duration of more than 20 years (Aiello, & Wong, 2001).

One complication of DR is diabetic macular edema (DME), or swelling of the retina. This can occur at any stage of DR without any symptoms. DME affects approximate 10% of all diabetic patients and can only be diagnosed with eye examinations; yet, left untreated, can result in moderate vision loss (Cavallerano, 2005).

Typically, there are no early warning signs of DR; however, eye examinations, which are the standard of care for diabetic patients, can detect the disease in its early stages. Both severe vision loss from proliferative DR and moderate vision loss from diabetic macular edema are preventable with timely detection, and regular clinical retinal examinations, accompanied by appropriate interventions and glycemic control. Studies have shown that the prognosis of blindness with proliferative DR within five years is more than 50%; however, with early treatment legal blindness can be reduced to 5% in five years and severe vision loss at less than 1%. Although yearly eye exams are recommended for all those diagnosed with diabetes, the primary reason for vision loss due to DR is simply the failure to do so (National Eye Institute National Institutes of Health, 2010b). Studies have shown that only 50-60% of diabetic patients have eye exams performed (Lee, Feldman, Ostermann, Brown, & Sloan, 2003), with barriers including cost, the misconception that eye exams are unnecessary, and access to care (Hartnett, Key, Loyacano, Horswell, & Desalvo, 2005).

1.4 Teleretinal Imaging Intervention

As part of the technology intervention for this study, teleretinal imaging was implemented as a method for eye examination. The community health center where participants were recruited was located in a rural area on the west side of Oahu. As previously noted, the gold standard recommendations from the American Diabetes Association is that those diagnosed with diabetes should have an eye exam at least once a year. Currently, the participant population for this study has no resident professional that can perform in-house eye examinations. Patients are required seek an eye professional outside the center. As a result, it is hypothesized that the use of telemedicine is appropriate for this population and its current circumstances.

Teleretinal imaging uses high resolution non-mydriatic (i.e., no pupil dilation needed), fundus (i.e., back of the eye, which includes retina optic disc, macula, etc.) digital cameras to image the retina and screen for diabetic eye diseases. This technology has the potential to facilitate better access to eye care, lower cost and higher patient satisfaction. Technicians can image the retina, interpret and send results to physicians for remote evaluations (i.e., teleretinal imaging). Benefits to the patient include increased access to eye examinations, reliable diagnosis of diabetic retinopathy (DR) and other nondiabetic ocular pathologies, higher satisfaction, and cost savings (Cavallerano & Conlin, 2008).

Teleretinal imaging has already been incorporated by the Veterans Health Administration (VHA), which is the largest integrated managed health care system in the US (Cavallerano & Conlin, 2008). Nearly 20% of all VHA patients with diabetes have access to teleretinal imaging services. The technology and its delivery has been validated and accepted as a clinical method of eye care for diabetic patients (Bursell, J. Cavallerano, A. Cavallerano, Clermont, Birkmire-Peters, L.P. Aiello, & L.M. Aiello, 2001; A. Cavallerano, J. Cavallerano, Tolson, L.P. Aiello, & L.M. Aiello, 2003). In collaboration with the VHA, the Joslin Diabetes Center (Boston, MA) has developed and implemented a platform to facilitate teleretinal imaging and remote image interpretation. A retrospective study conducted at the Joslin Diabetes Center has demonstrated a positive correlation between those who participated in a telehealth eye care program and later

receiving follow up standard eye care, as well as improved diabetes-related health outcomes (Fonda, Bursell, Lewis, Garren, Hock, & Cavallerano, 2007).

1.2 Purpose and Rationale

The purpose of this dissertation is to explore and describe the digital divide and the relationship between technology utilization and health outcomes. As previously discussed, technology utilization is associated with health outcomes; the higher the usage the better health outcomes that have been reported. Specifically, this research examines technology utilization and health outcomes with an underserved population in Hawaii. As a framework for understanding, this study employs a telemedicine intervention in the form of a diabetic eye care program that utilized web-based eye care education and retinal (teleretinal) imaging over the Internet. The participant population for this study was recruited from Waianae Coast Comprehensive Health Center (a Federally Qualified Health Center) that serves a federally recognized Medically Underserved Area. Research questions for this study are as follows:

1. *How does an underserved population in Hawaii react to a specific education web-based teleretinal imaging program?*

2. *What can be learned about health outcomes when telemedicine and web-based education are made available to an underserved, predominately Native Hawaiian population?*

As criteria for interpreting findings, data collection included: 1) surveys using the Transtheoretical Model of Behavior Change (TTM) were used to explore behavior change as a result of the technology intervention; and 2) focus groups to further explore computer and Internet usage and to further examine how technology impacted health and health outcomes. Focus groups, have been demonstrated to be a valuable tool since questions on not only what people believe, but also why they behave in particular ways can be explored (McLafferty, 2004; Rodriguez, Schwartz, Lahman, & Geist, 2011).

The TTM is one of the most widely used models in health behavior research and is heavily cited. In order to gain insight on how the proposed teleretinal imaging program

might affect an underserved population, transtheoretical model-based assessments were used to measure. The instruments measured behavior change for self-management of their diabetes, exercise, smoking, and carbohydrate counting. These are behaviors related to diabetes self-management.

1.5 Transtheoretical Model for Measuring Behavior Change

The transtheoretical model (TTM) is one of the leading behavioral change models used both in research and clinical practice (Glanz, Rimer, & Viswanath, 2008). The constructs and variables were developed using a comparative analysis of more than 200 existing psychological theories pertaining to behavior change (Prochaska, Redding, & Evers, 2008). The core constructs of the TTM are as follows: stages of change, which represents the temporal dimension of change; processes of change, or strategies used to progress through the stages of change; decisional balance, which represents the relative importance between the pros and cons of changing; and self-efficacy, defined as the confidence that people have to change behavior or resist situational temptations. See Table 2, page 32 for a complete description of the TTM constructs and variables. The following positive behavior changes are hypothesized:

1. Hypothesis 1: Type 2 diabetic patients who are given access to a teleretinal imaging program will make progress through the stages of change as described by the transtheoretical model at one-month and three months following baseline.

2. Hypothesis 2: Type 2 diabetic patients who are given access to a teleretinal imaging program will *increase pros of changing* by approximately one standard deviation over one month and maintain levels over three months following baseline. (This is described as the strong principle of change (Prochaska, J. O. et al., 1994) within the TTM literature.)

3. Hypothesis 3: Type 2 diabetic patients who are given access to a teleretinal imaging program will *decrease cons of changing* by approximately one-half of a standard deviation for decisional balance as dictated by the transtheoretical model over one month and sustain levels over three months following baseline. (This is described as

the weak principle of change (Prochaska, J. O. et al., 1994) within the TTM literature),

4. Hypothesis 4: Type 2 diabetic patients who are given access a teleretinal imaging program will demonstrate a linear *increase in situational self-efficacy* as over one month and sustain levels over three months following baseline.

5. Hypothesis 5: Type 2 diabetic patients who are given access to a teleretinal imaging program will *increase in their use of appropriate processes of change* in *exercise* as described by the transtheoretical model over three months following baseline.

6. Hypothesis 6: Type 2 diabetic patients who are given access to a teleretinal imaging program will *improve HbA1c* over three months.

1.6 Focus Groups for Exploring the Impact of Technology

As a follow-up to the assessments, and to gain a further understanding on the effects and use of technology and the teleretinal imaging program, focus group interviews were conducted at the completion of the study. Focus groups, guided group discussions, are becoming increasingly popular, have been demonstrated to be a valuable tool in healthcare research since the questions asking what people believe, and why they behave in particular ways can be explored (McLafferty, 2004; Rodriguez, Schwartz, Lahman, Maria, & Geist, 2011). Focus groups are also ideally suited for technology and health behavior since influences such as culture, lifestyle and family dynamics can be explored in the context of life and personal experiences. Information can be obtained between different perspectives between groups, as well as individuals. Focus groups should be conducted until data saturation is achieved and themes start to repeat. It has been suggested in the literature that the ideal number of people for a group is from seven to 10 people, with four group sessions tending to be sufficient (Nyamathi & Shuler, 1990).

For this study, four focus group sessions were held. Information on each group's perceptions and opinions were discussed. An inductive method of analysis and data collection was utilized in conducting the focus group. Moderators kept discussion focused; however, discussion was open to unanticipated areas that are relevant and provide insight into the perceptions of technology and behavior change. Areas of focus

were as follows: thoughts on the intervention of teleretinal imaging; how technology affects motivation for behavior change; obstacles in changing health behavior; the use of technology for health information, the Internet in general; as well as feedback related to study participation. See Appendix 12 for details on procedures.

CHAPTER 2
LITERATURE REVIEW

2.1 Overview

Since the 2000's there is has been a dramatic increase in the use of Internet technology. The technology is now well integrated into the daily lives of Americans and becoming an essential component; applications that are most used are email, games, news, shopping, and seeking health information (Hoffman, Novak, & Venkatesh, 2004). However, research has shown that not all Americans are equally benefiting from all available technologies. In the United States, research has shown that income is directly related to the adoption of information technology; lower income is associated with an increasing inequity in Internet usage (Pew Research Center, 2013). In addition, access to broadband technology, or high speed Internet access, has been associated with younger age, higher education, and geographic location in urban areas (Rains, 2008). Hseih and colleagues have shown that the strongest predictor of the use of information technology is one's socio-economic status (Hsieh, Rai, & Keil, 2011). This phenomenon is known as the "digital divide." The term digital divide was popularized by reports published by the National Telecommunications and Information Administration (NTIA) (National Telecommunications and Information Administration, 1995) in 1995, in which their finding exemplified a gap in the diffusion of technology based on income, race, education and geographical location (National Telecommunications and Information Administration, 1995; National Telecommunications and Information Administration, 2000; National Telecommunications and Information Administration, 1998). . There are digital divides between the rich and poor, and between urban and rural populations.

Interestingly, this trend is not universal, but unique to the United States (Martin, & Robinson, 2007). For example, the United Kingdom, which has a similar measure of income inequity and Internet uage rate to the U.S., is trending toward a decrease in inequity based on income (Martin & Robinson, 2007). There is speculation to why this trend in the United States has occurred, and not in other countries. A possibility could be that programs in the U.S. has aimed promoting Internet technology diffusion at the

"haves," such as hot spots and improved bandwidth, rather than implementing programs that benefit those who "have not" (Martin & Robinson, 2007).

2.2 Digital Divide in Healthcare

Seeking health information is one of the leading uses for the Internet and World Wide Web (WWW). Research conducted by the Pew Research Center (Pew Research Center, 2013) found that approximately 74% of adults use the Internet; 80% of those users seek information related to health (in other words, 59% of all adults surveyed use the Internet for health seeking-related activities). Searching and retrieving information on health topics is the leading purpose for health related Internet activity. This includes activities such as accessing blogs or news groups, watching online videos, reading drug or treatment reviews, and reading reviews on provider ratings (Fox, 2011). Use of the Internet for other health-related activities other than information retrieval, include tracking weight, diet and exercise, social networking with health related groups, and fundraising for medical causes (Fox, 2011).

Consistent with the digital divide in Internet usage, there are inequities in those that are utilizing Internet resources for the purpose of healthcare. This healthcare inequity has been documented for more than 15 years (Eng, Maxfield, Deering, Ratzan, & Gustafson, 1998). Several studies have shown that younger, more educated, and higher-income adults are more likely to seek electronic health information, or eHealth, on the Internet than those that are older, less educated and have lower incomes (Hsieh, Rai, & Keil, 2011; Martin, & Robinson, 2007; Koch-Weser, Bradshaw, Gualtieri, & Gallagher, 2010). This finding seems to represent a perpetuating cycle, since research has also shown that children that come from higher socioeconomic status families use computers more often than those from lower socioeconomic families. As such, children with parents with higher education used the computer and Internet more often than children from less educated parents. According to the NTIA survey in 2011, only 8.97% of those with Bachelor's degree or higher report no Internet use, whereas, 36.44% of those with a high school level of education (no college) reported no Internet use (National Telecommunications and Information Administration, 2010).

Research has also found that the amount that one benefits from the eHealth information is directly related to the level of eHealth literacy. eHealth literacy is defined as "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem" (Norman & Skinner, 2006). For example, those that are more knowledgeable and capable in accessing eHealth information also have shown to have better self-management of their health, heath behavior, and greater interaction with their physician over the Internet (Neter & Brainin, 2012). Conversely, a study conducted at Kaiser Permanente Northern California that examined utilization of a patient portal that was offered as routine care for patients with diabetes found that older adults, minority populations (African-American, Latinos and Filipinos), and those with less education were less likely to access the portal. Those who did not access the patient portal were also more likely to have poor control of their diabetes, which included HbA1c blood pressure and lipids (Sarkar, Urmimala et al., 2011). These finding are consistent with low health literacy in general, which has been associated with poor health outcomes with Japanese, Filipino and Native Hawaiians (Sentell, Baker, Onaka, & Braun, 2011).

In examining barriers to usage, the eHealth digital divide cannot be solely attributed to physical access to the technology alone. One study exploring Internet usage for primary care patients in family medicine clinics in Missouri found lower use of the Internet in patients with less education, lower income, and older age; with age being the largest factor in lack of usage (Kruse, Robin L. et al., 2012). In this study, researchers found that despite the fact that there were several places with computers to access, the most frequent barriers to usage were lack of awareness, distance, and lack of computer skills — not physical access. Another study looking at low-income adults in the Midwestern United States found that even though low-income individuals have access to the Internet, they are not going online (Jensen, King, Davis, & Guntzville, 2010). Limited knowledge on how to access health information on the WWW was not correlated with access to computers and the Internet. Researchers in this study speculate that the information retrieved on the WWW may be overwhelming and too intimidating for those with limited health and computer literacy to navigate. Fear, anxiety and embarrassment related to learning how to use the computer and Internet have also found to contribute to

their lack of use. This suggests that psychological barriers to using the Internet are also important components in perpetuating the digital divide (Stanley, 2003).

Despite barriers to using the technology, those with low eHealth and computer literacy do report a desire to learn how to utilize eHealth resources and gain eHealth literacy. Watson and colleagues explored current use of technology, receptiveness and barriers to adoption of technology with type 2 diabetic patients found that younger, more educated, and the more health aware were more likely to use computer technology; however, they study did not find any difference in the willingness to adopt information technology between current users and nonusers (Watson, Bell, Kvedar, & Grant, 2008). Related to the dissertation research question on how technology affects health outcomes, these studies demonstrate that the use of healthcare technologies has the potential to alleviate health disparities among minority and socially disadvantaged populations, especially if programs are designed to address eHealth literacy, as well as, access to the technology.

2.3 Information Technology, Internet and Diabetes Management

Several studies have been conducted exploring Internet-based healthcare for diabetes patient that have shown positive health outcomes. A study researching Internet-based care management program for veterans demonstrated improved HbA1c and reduced diabetes distress scores. A study exploring the use of a web-based diabetes self-management program that implemented online glucose monitoring and provider communication found that patients that used the program had a decrease in HbA1c (Jethwani, Ling, Mohammed, Myint, Pelletier, & Kvedar, 2012). This study used a website to track blood pressure and glucose. Patients also had access to messaging with a nurse/diabetes educator and online educational modules (Fonda, McMahon, Gomes, , Hickson, & Conlin, 2009).

Another study that examined the feasibility of a self-management website with an email-linked counseling intervention for people with type 2 diabetes showed higher levels of health satisfaction, and significant improvements in physical activity (Liebreich, Plotnikoff, Courneya, & Boule, 2009). The intervention group received weekly personalized emails and access to an online logbook and message board, all delivered via

the Internet; the control group received links to the Canadian Diabetes Association's Clinical Practice Guidelines for Physical Activity.

One paper that describes a review of 26 articles exploring the use of patient web portals for disease management targeting diabetic patients, overall consistent positive outcomes were found across the studies; patient portals enhanced patient-provider communications, improved disease management, and improved health outcomes (Osborn, Mayberry, Mulvaney, & Hess, 2010). From the provider side, information technology systems targeted toward the clinical staff that cares for diabetes patients also have shown positive outcomes. For example, implementation of a decision support system connected to a patients electronic medical record that included patient performance feedback and diabetes education show improved outcomes in HbA1c, lipids and blood pressure (Hunt, Siemienczuk, Gillanders, LeBlanc, Rozenfeld, Bonin, & Pape, 2009).

Overall, studies have also shown that the use of Internet technology in healthcare can result in improved health outcomes specifically among minority and rural populations (Lopez & Grant, 2012; Sequist, Cullen, & Acton, 2011). The IDEATel (Informatics for Diabetes Education and Telemedicine) study explored a telemedicine program targeting a diabetic population living in federally designated medically underserved area. The program incorporated home-based monitoring of blood glucose and blood pressure, videoconferencing with a diabetes educator, and web-based diabetes education. Their study found the greatest improvements in HbA1c and patient satisfaction with their Hispanic participants, whom had the lowest income, educational level, computer experience, and worst management of their diabetes, compared to the other participant groups (Weinstock, Teresi, Goland, Izquierdo, Palmas, Eimicke, Ebner, & Shea, 2011). One recent study recruited diabetic patients from a Federally Qualified Health Center in rural South Carolina to test a videoconferencing intervention to teach diabetes self-management education. Results from this study show improved glucose and LDL cholesterol for those in the intervention group (Davis, Hitch, Salaam, Herman, Zimmer-Galler, & Mayer-Davis, 2010).

Personal health portals have been used for improved health outcomes for many other conditions besides diabetes. This includes blood pressure monitoring (Ahern,

Stinson, Uebelacker, Wroblewski, McMurray, & Eaton, 2012), asthma self-management (Vandereeer, Vandenhout, Bakker, Rabe, Sterk, Assendelft, Kievit, & Sont, 2011) self-management for blood glucose control (Quinn, Shardell, Terrin, Barr, Ballew, & Gruber-Baldini, 2011) and portals for cancer patients (McCorkle, Ercolano, Lazenby, Schulman-Green, Schilling, Lorig, & Wagner, 2011). Similar to the studies discussed, uses of online portals have shown positive results. For example, a study that involved cancer patients compared computerized educational information, which incorporated data from the patient's electronic medical records to that of general information. The intervention group was able to see a summary of their medical record, information related to concepts and terms in the record, as well as general information about cancer. The control group was given general information about cancer only. Results from this study show that more patients in the intervention group felt educated; they thought that the information was relevant and reported showing computer printouts to other people. Also, patients demonstrated higher preference for the personalized information and were more likely to use the information, than those in the control group (Jones & Pearson, 1999).

2.4 Digital Retinal Imaging

This study specifically targeted diabetic eye disease, or diabetic retinopathy, which is a preventable complication of diabetes. Diabetic retinopathy is the leading cause of blindness in adults in the U.S (National Eye Health Education Program, 2008). Eye examinations, which are the standard of care for diabetic patients, can detect the disease in its early stages. Despite that yearly eye exams are recommended for all those diagnosed with diabetes, the primary reason for vision loss due to DR is the failure to have regular eye examinations (National Eye Institute National Institutes of Health, 2010b). Digital retinal imaging combined with telemedicine has the potential to reach underserved populations where specialty care is limited since a eye professional is not needed on site. Images can be sent via the Internet for remote evaluation and diagnosis. This technology has been validated as a tool for screening diabetic retinopathy. Sensitivity and specificity of results from several studies demonstrate that the digital retinal imaging is an effective method in screening for diabetic retinopathy, as well as other eye diseases (Ahmed et al., 2006; Lopez-Bastida, Cabrera-Lopez, & Serrano-

Aguilar, 2007; Bursell et al., 2001; Chow et al., 2006). Research has also validated non-mydriatic (no eye dilation) digital retinal imaging compared with dilated 35 mm retinal photography. Results have shown that the undilated digital images were comparable in determining the level of retinopathy (Bursell et al., 2001). Non-mydriatic digital imaging has the potential to provide a cost effective and more accessible method of retinopathy screening, especially for remote populations where ophthalmologists are not readily accessible (Jones & Edwards, 2010).

There have been several programs that have implemented and validated telemedicine and digital retinal imaging, no study have looked at health outcome related to the teleretinal imaging. A program in Los Angeles targeting medically underserved patients has shown the feasibility of a teleretinal imaging program (Ogunyemi, Terrien, Eccles, Patty, Fish, Teklehaimanot, Ilapakurthi, Aimiuwu, & Baker, 2011). This program successfully provided eye care to inner-city diabetic patients whose community clinics did not have the resources to provide retinal screening examinations. Another program evaluated a system call EyePACS, a license-free web-based diabetic retinopathy screening system. Their study validated the feasibility of the system and usage has expanded to over 120 primary care sites in California (Cuadros & Bresnick, 2009). Another program called the Telemedical Retinal Image Analysis and Diagnosis Network targeted underserved patients in the mid-south and southeastern U.S. This program demonstrated the feasibility of a retinal imaging infrastructure for at-risk populations (Li, Karnowski, Tobin, Giancardo, Morris, Sparrow, Garg, Fox, & Chaum, 2011). There have also been studies that have examined the frequency and adherence of eye examinations with digital retinal imaging. One study in particular examined patients' adherence to comprehensive eye care. They looked at two groups; one that was imaged with a nonmydriatic teleretinal camera and a control group that had standard dilated eye examinations. Results showed that the teleretinal imaging group had higher adherence to a follow-up dilated eye exam, within 12 months of the initial visit, than the control group. Also, the teleretinal imaging group reported a high degree of satisfaction (Conlin et al., 2006).

Based on a literature search no published articles were found that prospectively examine digital retinal imaging and diabetes self-management and health outcomes.

Databases used were Academic Search Premier, Medline and Psychology and Behavioral Science collection databases; key words included diabetes, health behavior theory, retinal imaging, retinopathy, teleretinal imaging, as keywords; date from 1997 through 2009; conducted January 2013. One retrospective study that took place at the Joslin Diabetes Center (Harvard Medical School) (n = 13,752) looked at patient clinical outcomes and teleretinal imaging. Results demonstrated a relationship between patients that received teleretinal imaging and improved HbA1c, LDL and systolic blood pressure over two years, as well as improved adherence to subsequent eye care (Fonda et al., 2007).

2.5 Theories and Models in Health Behavior

As a context for data acquisition and interpretation, the transtheoretical model was chosen to examine behavior change. The TTM is one of the most widely used models of health behavior and is easily applied to many areas in health behavior (Glanz, Rimer, & Viswanath, 2008). The TTM was designed to be generalizable across a wide variety of population and behaviors (Prochaska et al., 1994). The focus of the TTM is on individual change, versus interpersonal or community models.

As a basis for using the TTM, it is important to examine other theories of health behavior. Researchers use theories to organize, conceptualize and understand both the determinants of health behaviors and processes of health behavior change. Theories serve as a framework for research and a bridge in which to compare results across studies. In practice, theories can guide the development of interventions and promote behavior change by using key theoretical constructs as a structure in which to work. The literature suggests that theory-based interventions in health behavior are more effective than those that are not based on a theoretical constructs (Lippke & Ziegelmann, 2008; Noar & Zimmerman, 2005). Different theories may be appropriate for different situations; whether it is understanding behavior change from an individual, community or organizational point of view, or as a process, motivation or intention; hence, different theoretical models may be appropriate give the application.

Based on a review of 12 journals in health education, health behavior, and preventive medicine, published between 1999 and 2005, there were 10 top health behavior change theories and models identified that were utilized in research. The

transtheoretical model (TTM), and Social Cognitive Theory (SCT) were the top two theories (Glanz et al., 2008; Painter, Borba, Hynes, Mays, & Glanz, 2008). The other top theories included Health Belief Model (HBM), social support and social networks, patient-provider communication, and Theory of Reasoned Action/Theory of Planned Behavior (TRA/TPB), stress and coping, community organization, social ecology, and diffusion of innovations (Glanz et al., 2008; Painter et al., 2008). All of these theories have been extensively applied to diabetes.

Table 1 is a summary of the top ten health behavior models, according to the literature. Each model will be briefly discussed and examples of applications related to diabetes will be given. The theories are organized into four groups according nature of the theory. The first group, which includes the TTM, HBM, and TRA/TPB focus on the beliefs and actions of the individual. The second group focuses on interpersonal interactions and how these interactions affect health behavior. This includes SCT, social networks and social supports, stress and coping and patient-provider communication. The third group focuses on community and group approaches to creating and supporting health behavior. This includes models of community organization and theory of diffusion of innovations. The last group is ecological models. These theories focus on multiple levels that include government, policy, environment, community, and inter/intra personal levels.

Table 1. Top ten health behavior theories.

Theory	Description
Individual Health Behavior	
Transtheoretical Model (Prochaska, J. O. & Diclemente, C. C., 1983; Prochaska, J. O., Diclemente, C. C., & Norcross, J. C., 1992; Prochaska, J. O. & Velicer, W. F., 1997)	This model focuses on constructs that influence the decision making of an individual with the Stage of Change as a temporal organizing construct; behavior change occurs as a process over time.
Health Belief Model (Becker, M. H., 1974)	The main concepts of this model are that a person's perceived benefits and barriers to a behavior, cues to action and self-efficacy can explain and predict a person's health behavior.
Theory of Reasoned Action/Theory of Planned Behavior (Fishbein, M. & Ajzen, I, 1975)	Attitudes and perceived social norms act as motivational factors, towards an expected outcome of a behavior will predict behavioral intention. The TPB adds the component of perceived behavioral control.
Models of Interpersonal Health Behavior	
Social Cognitive Theory (Bandura, Albert, 1986)	People learn and operate based on their observing others; hence social experiences mold behavior and development.
Social Networks and Social Support (Barnes, J, 1954; Cassel, J., 1976)	Social relationships and affiliations as concepts and influences can describe health behavior outcomes.

Table 1. (Continued) Top ten health behavior theories

Stress and Coping (Folkman, S. & Moskowitz, J. T., 2000; Lazarus, R. S. & Folkman, S., 1984)	Stressors contribute to illness directly physiological and indirectly via maladaptive health behaviors. Coping methods for these stressors can affect health outcomes.
Patient-Provider Communication (Roter, D. L. & Hall, J., 1992)	Interpersonal communication between the patient and provider can affect health behavior (i.e., good communication between patient and clinician can lead to better health).
Community and Group Models	
Community Organization (Minkler, M. & Wallerstein, N., 2004; Walter, C., 2004)	Collective health goals from community groups, which include tasks of mobilizing resources and developing and implementing strategies for health change.
Diffusion of Innovation (Rogers, Everett, 1995)	A model that explains or promotes the spread of an innovation over time across a social system (i.e., knowledge-practice gap).
Ecological Models/Social Ecology	
Models to explain behavior (Lewin, K. & Cartwright, D., 1951) ***Models to guide behavior*** (Skinner, B. F., 1953) ***Models to guide behavior interventions*** (McLeroy, K. R., Bibeau, D., Steckler, A., & Glanz, K., 1988)	These models suggest that there are multiple layers of influence for health behavior. This may include intrapersonal, interpersonal, organizational, community, physical environment and policy.

2.5.1 Individual Health Behavior

Transtheoretical Model of Behavior Change

The TTM is one of the most widely used models in health behavior research and is heavily cited (Glanz, Karen et al., 2008). The focus of the TTM is on the cognitive constructs that predict change. The model supports the idea that interventions should be designed to fit the person's stage and readiness for change, versus interventions that treat all people the same regardless of their intentions on action. The TTM is used in this dissertation as a criteria to explore behavior change in diabetic participants, thus a more thorough discussion of the model is further examined in section 2.7 below.

Health Belief Model

The Health Belief Model (Champion & Skinner, 2008) is a widely used theoretical framework in health behavior research to both explain change and guide interventions. HBM's main constructs include the following: 1) perceived susceptibility, one's beliefs about contracting a disease or health condition; 2) perceived severity, one's feelings about the seriousness of contracting a disease or by leaving a condition untreated; 3) perceived barriers, the negative aspects of actions related to health; 4) cues to action, things that can trigger action; and 5) self-efficacy, the self-belief that once can successfully take action to produce outcomes. These constructs are used to explain, predict and influence health behavior.

There have been many studies that have utilized the HBM related to health behavior change with patients with diabetes. One study (Speer, Reddy, Lommel, Fischer, Stephens, Sohyun, & Johnson, 2008) that incorporated HBM constructs in its intervention demonstrated a significant reduction in A1c levels and an increase in physical activity in older adults from Georgia senior centers. Other studies have demonstrated relationship between the HBM's constructs and health behaviors of diabetic patients. These studies include the following: benefits and barriers constructs with regular aerobic exercise (Koch, 2002); perceived susceptibility and threat reduction with pharmaceutical care services (Pinto, Lively, Siganga, Holiday-Goodman, & Kamm, 2006); internal locus of control and self-efficacy with adherence to self-care regimes (Gillibrand & Stevenson, 2006); and perceived susceptibility, barriers, threat, intention and self-efficacy with birth

control use (Charron-Prochownik, Sereika, Becker, Jacober, Mansfield, White, Hughes, McElhinny, & Trail, 2001).

Theory of Reasoned Action/Theory of Planned Behavior

The Theory of Reasoned Action and the Theory of Planned Behavior (TRA/TPB) (Montano & Kasprzyk, 2008) focuses on the individual's motivational factors as determinants for predicting health behavior. The strongest predictor is the construct of behavioral intention, which is determined by one's attitude toward the behavior and the related social norm. The TRA/TPB is rooted in extensive work in the field of psychology in expectancy-value conceptualization. This is the concept that attitude toward an action is determined by expected beliefs and consequences of the action, hence a positive or negative outcome will affect a person's intention on performing the behavior in either direction. The Theory of Planned Behavior has the added concept of perceived behavioral control as a predictor of intention to change behavior.

Studies have used the TRA/TPB to explain correlations between patient attitude toward self-care and physical activity (Rhodes, Blanchard, Courneya, & Plotnikoff, 2009; Verderber, Rizzo, & Sherrill, 2003; Motl, Dishman, Ward, Saunders, Dowda, Felton, & Pate, 2002). One study, in which subjects were diabetic adults, found that those with higher commitment/challenge characteristics adhere to clinical recommendations of exercise better than those with higher control characteristics (Navuluri, 2003). Another study that used the TRA/TPB with diabetic patients found that an intention to brush teeth was related higher frequency of brushing and lower A1c level (Syrjala, Niskanen, & Knuuttila, 2002).

2.5.2 Models of Interpersonal Health Behavior

Social Cognitive Theory

Social Cognitive Theory (SCT) , previously known as the social learning theory (Bandura, 1977), integrates concepts from cognitive psychology (human information processing), sociology and political science (groups and societies) and humanistic psychology (self-determination, altruism and moral behavior) that explain, determine, predict and influence health behavior (McAlister, Perry., & Parcel, 2008). The key

concepts of SCT as it affects health behavior are as follows: 1) reciprocal determinism, which are environmental factors that influence behavior; 2) outcome expectations, beliefs about the likelihood of consequences of one's actions; 3) self-efficacy, the beliefs about personal ability to perform an action; 4) collective efficacy, beliefs about group actions; 5) observational learning, peer modeling; 6) incentive motivation, the use and misuse of rewards and punishments; 7) facilitation, which is providing tools for self-regulation or self-management; and 8) moral disengagement, or harmful thinking. .

Several studies in SCT have shown that increased self-efficacy can effect behavior change in people with diabetes. For example, a study testing the SCT with diabetics found that self-efficacy was the strongest factor in predicting behavior. The researchers specifically tested physical activity (Plotnikoff, Lippke, Courneya, Birkett, & Sigal, 2008). A study that examined nutritional behavior of diabetic patients found that self-efficacy was a predictor of dietary self-care (Chapman-Novakofski & Karduck, 2005; Nouwen, Law, Hussain, McGovern, & Napier, 2009). Other studies that looked at diet and diabetic patients showed self-efficacy associated with changes in strategy (Nothwehr, 2008), and spousal support as it relates to self-efficacy and reinforcement (Beverly, Miller, & Wray, 2008).

Social Networks and Social Support

The influence of social relationships on health behaviors has been used by researchers and practitioners both in creating interventions and understanding health behavior (Glanz et al., 2008). Social networks can be defined by the web of social relationships; and social support is a function of the social network that can provide support for health behaviors. This support can be categorized into four types: 1) emotional support, which includes love, trust and empathy; 2) instrumental support, involves tangible aid or services; 3) informational support, which includes advise, suggestions and information; and 4) appraisal support, which is information for self-evaluation purposes. Also, social support is intended to be helpful, rather than negative, however, whether the receiver finds it helpful is subjective (Heaney & Israel, 2008).

A study that explored meaningful interactions with young adults with diabetes found that parents provided the most reliable social support and chat friends provided

important emotional support via the Internet (Sparud-Lundin, Ohrn, & Danielson, 2010). Another study also found that the Internet provided social support for the understanding of a "normal" existence with people living with diabetes (Loader, Muncer, Burrows, Pleace, & Nettleton, 2002). A study that examined the relationships between psychosocial factors found that those with higher levels of social support and acceptance of the disease had lower perceived difficulty with self-care behaviors (Misra & Lager, 2008). Examining marital relationship factors, a study found that social support from one's spouse positively affects adherence to diabetes care regimens that include diet and exercise (Trief, Ploutz-Snyder, Britton, & Weinstock, 2004).

Stress and Coping

Stressors in people's lives affect both physical and psychological balance, which can cause illness or maladaptive behaviors. Understanding stress and coping mechanisms is important in health education, disease prevention, and in the development of effective strategies to improve health. Early work in stress and coping studied responses to stressful stimuli (Lazarus, 1993). Later, researchers focused more on potential stressful life events (Haan, 1969). The concept of stress eventually evolved to be a transactional phenomenon, dependent on the perception of the person (Grinker & Spiegel, 1945). In other words, stress is a person-environment transaction, in which the person's response to the stressor is affected by their psychological, social and cultural variables that exist for that person (Glanz & Schwartz, 2008).

There have been many studies that have examined factors of stress and coping with diabetes. A meta-analysis conducted to investigate the association between psychosocial stress and diabetes found that adverse psychosocial factors are associated with poor self-management of diabetes. Adverse psychosocial factors included stressful events, stress-prone personality and poor social support (Chida & Hamer, 2008). Another study found that some anger coping styles resulted in poorer glycemic control for people with diabetes, and may be considered a risk factor (J.P. Yi, J.C. Yi, Jean, Vitaliano, & Weinger, 2008). By examining stress at work, a Swedish study found that low decision latitude at work and low sense of coherence was associated with risk for

type 2 diabetes (Agardh, Ahlbom, Andersson, Efendic, Grill, Hallqvist, Norman, Gustenson, 2003).

Patient-Provider Communication

Interpersonal communication between the patient and health care provider has been studied for many years. Roter and Hall (1992) have identified four different categories of communication between the patient and provider: 1) paternalistic, provider exercises greater control; 2) mutuality, balance in control and participatory decision making; 3) default interaction, neither patient nor provider takes control, usually resulting in patient dissatisfaction; and 4) consumerism, when patients exercise greater control than their provider. Although there has been much research in this area, it is noted that there is not much evidence of causality of this relationship with health outcomes, research has focused more on descriptive models (Street & Epstein, 2008).

There has been a lot of research related to diabetes in this area. In a study exploring how adult females manage their diabetes, results demonstrated that patient-provider communication was the strongest factor affecting diabetes adherence to treatment regimens. Knowledge of diabetes and consequences of poor glycemic control were other major components affecting adherence (Matthews, Peden, & Rowles, 2009). Another diabetes study looking at patient-provider communication found that patients that had a longer primary care relationship with their physician or their primary care provider, which also served as their diabetes provider, reported better general communication (Piette, Schillinger, Potter, & Heisler, 2003).

2.5.3 Community and Group Models

Community Organization

Community organization is a model in which community groups identify health issues and collectively develop strategies to address these issues. The term was originally coined by American social workers in the 1800s in their efforts to coordinate services for immigrants and the poor (Garvin & Cox, 2001). The World Health Organization, in the mid-1980s, adopted this new approach by stressing community driven projects to reduce inequities and disparities among social groups. Community organization is important to

the health field since it is modeled after collectivism and community ownership. However, in research, a limitation of this model is the lack of measurement and evaluation of outcomes (Minkler, Wallerstein, & Wilson, 2008).

There have been many community-driven efforts in the area of diabetes. One effort incorporated a diabetes curriculum at a YMCA setting. The program trained community workers to administer a group-based adaptation of the Diabetes Prevention Program, which focuses diet, physical activity and weight loss to reduce rates of diabetes (Finch, Kelly, Marrero, & Ackermann, 2009). Another effort in Florida developed a free clinic to manage and educate patients with diabetes. Research results demonstrated improvements in HDL cholesterol, A1c, triglycerides and blood pressure, as well at the feasibility of a free clinic to serve diabetic patients (Soto, Bazyler, O'Toole, Brownson, & Pezzullo, 2007).

Diffusion of Innovation

The Diffusion of Innovation (DoI) model looks at the requirements needed to achieve the wide-spread dissemination and diffusion of health innovations and initiatives. This model was developed over that last fifty years, recently popularized by Everett Rodgers (1995) book, *Diffusion of Innovations*, which was first published in 1962. In health care, the DoI model has exposed the gap between knowledge and practice. Hence it is important that new effective health programs and products are widely disseminated to achieve a positive impact on public health. The DoI model has been used to understand this process and help create effective dissemination strategies. However, due to the multifaceted and fragmented nature of health care, the diffusion and dissemination of new innovation proves to be challenging (Oldenburg & Glanz, 2008).

A study using the DoI model examined six North Carolina community health centers and their adoption of a mandated diabetes registry. The study found that the involvement of the executive director and medical director was the single most influential component in the adoption and implementation of the registry. Additionally, shared problem solving and peer learning was deemed essential to the success of the program. Risk factors included lack of cross-training and employee turnover (Helfrich, Savitz, Swiger, & Weiner, 2007). Another study looking at physician organizations in the U.S.

examined organizational factors that affect the adoption of diabetes care processes. Processes included diabetic patient registries, clinical practice guidelines and case management and physician feedback. Results demonstrated that external incentives and computerized clinical systems may promote greater use of diabetes care processes (Li et al., 2004).

2.5.4 Ecological Models/Social Ecology

Ecological Models/Social Ecology

Ecological models (EM) of health behavior focus on people and their transaction with their soicocultural and physical surroundings or environment. EMs are characterized by multiple levels of influence, which include social, psychological, physical environment, organizational, community and policy. There are four core concepts to ecological models (Sallis, Owen, & Fisher, 2008): 1) multiple influences that affect intrapersonal, interpersonal, organizational, community and policy levels; 2) behavior influences interact across the different levels; 3) the model should be behavior specific, identifying influences at each level; and 4) interventions should be multi-level. The fundamental concept of EMs is that it takes a combination of environmental and individual level intervention to achieve a positive change in health behavior. Lately, there has been an increase of interest in ecological models in the with goals of population wide approaches to changing health behavior.

A study looking at high-risk urban youths with diabetes tested the ecological model. Their results showed an association between family, peers and providers can be a predictor of illness management (Sylvie, Podolski, Ellis , Frey, Maureen, & Templin, 2006). Another study looked at social capital (defined as social norms, trust and reciprocity that exist in a community for change to occur) and diabetes. Their findings suggest that people with better social support and reciprocity have lower risk for diabetes (Ahern & Hendryx, 2005). In a study conducted in the United Arab Emirates, results were consistent with the ecological model of health promotion. They found that the main barriers to weight management for women who were at risk for type 2 diabetes were lack of social support, culturally-sensitive exercise facilities and social norms that restricted outdoor exercise (Ali, Baynouna, & Bernsen, 2010).

2.6 Transtheoretical Model

The TTM was developed based on a comparative analysis of leading theories in behavior change and psychotherapy in 1984. Since then, the theory has been expanded and developed to address a broad range of health and mental health behaviors. There are four main constructs which constitutes the TTM (see Table 2 for constructs and variables). These constructs include the following: 1) stage of change; 2) decisional balance; 3) self-efficacy; and 4) processes of change;.

2.6.1 Stage of change

Stage of change is a temporal construct that looks at behavior change over time, versus a discrete event. For example, starting an exercise routine is a process that occurs over time, and not something that can be construed as a single event. The theory postulates that there are five stages in which people progress through when changing their health behavior. Note that this it typically a linear movement, but may not necessarily be so.

The first stage is *precontemplation*, this is the stage where people do not intend to change their behavior, typically measured within the next six months. People in this stage may be uninformed about health consequences, or have become demoralized about changing due to multiple failures. Typically people in the *precontemplation* stage are characterized as resistant or unmotivated to change their health behavior. The second stage is *contemplation*. At this stage people intend to change their behavior, measured typically within the next six months. People that are in the *contemplation* stage are aware of the pros and acutely aware of the cons for changing. These people are not yet ready to take immediate action. The *contemplation* stage may be a place where people stagnate for long periods of time. The next stage is *preparation*. At this stage people intend to change their behavior soon, typically within the month. For example, these people may have already joined a gym, purchased books, or consulted with clinical support. People in the preparation stage are ready to be recruited for action-oriented interventions. The *preparation* stage is followed by the *action* stage. People in the *action* stage have taken direct action to change their behavior. This may mean actively going to the gym or abstaining from smoking. The *maintenance* stage, which follows the *action* stage, is the

point where people no longer have to keep applying change processes to continue their health behavior. At this stage, they are less tempted to relapse and are more self-confident on maintaining the change. (Prochaska & Velicer, 1997; Prochaska, Redding, & Evers, 2008).

2.6.2 Decisional Balance

The decisional balance construct is the weighing of the relative pros and cons of changing health behavior. This construct was originally developed based on Janis and Mann's (1977) eight-factor model of decision making. Prochaska and colleagues have empirically consolidated those eight factors into two: pros and cons and incorporated them into the TTM (reference). TTM-based research has also shown mathematical relationships of decisional balance that have been demonstrated across 12 different studies, called the strong and weak principles of progress. The strong principle states that to progress from the contemplation stage to the action stage, the pros of changing behavior, which are lower than the cons in the precontemplation or contemplation stages, should increase by one standard deviation. The weak principle states that cons should decrease at approximately .5 standard deviations. There should be cross-over point when the cons of changing behavior and become lower than the pros of changing behavior as the participant progresses into the action stage (from precontemplation or contemplation stage) (Prochaska et al., 1994).

2.6.4 Self-Efficacy

Self-efficacy is the situational confidence that people can cope with risky or tempting situations and not relapse into negative health behaviors. This construct was taken from Bandura's (1982) self-efficacy theory. A related construct, is the concept of situations temptations. This is the opposite of self-efficacy where one get urges to engage in unhealthy behaviors (Prochaska & Velicer, 1997; Prochaska, Redding, & Evers, 2008).

2.6.2 Processes of Change

The processes of change are strategies or activities in which people engage in order to progress through the stages of change. There are 10 basic process of change that

have been identified and validated as highly reliable measures (Prochaska et al., 1988). These include the following: 1) consciousness raising, awareness about causes and consequences about behaviors; 2) dramatic relief, initial increase in emotions followed by a decrease if action is taken; 3) self-reevaluation, one's cognitive and affective self-assessment on an unhealthy behavior; 4) environmental reevaluation, how one's behavior affects the social environment; 5) self-liberation, the belief that one can change; 6) social liberation, an increase in awareness that of alternative behavior opportunities in one's society; 7) counterconditioning, or substituting positive behaviors; 8) stimulus control, removing negative cues and incorporating healthy ones; 9) contingency management, rewarding healthy behavior; and 10) helping relationships, or social support for healthy behavior change. The first five processes are based on experience and typically occurs in the early stages of change, whereas the latter five are behavioral and are used in the action stages of change (Prochaska & Velicer, 1997; Prochaska, Redding, & Evers, 2008).

Table 2. Transtheoretical model constructs (Kasila, Poskiparta, Karhila, & Kettunen, 2003; Prochaska & Velicer, 1997; Prochaska et al., 2008).

Constructs	Description
Stages of change	
Precontemplation	No intention to take action within the next 6 months
Contemplation	Intends to take action within the next 6 months
Preparation	Intends to take action within the next 30 days and has taken some behavioral steps in this direction
Action	Changed overt behavior for less than 6 months
Maintenance	Changed overt behavior for more than 6 months
Process of Change	
Consciousness raising	Finding and learning new facts, ideas, and tips that support the healthy behavior change
Dramatic relief	Experience the negative emotions (fear, anxiety, worry) that go along with unhealthy behavioral risks
Self-reevaluation	Realizing that the behavior change is an important part of one's identity as a person
Environmental reevaluation	Realizing the negative impact of the unhealthy behavior or the positive impact of the healthy behavior on one's proximal social and/or physical environment
Self-liberation	Making a firm commitment to change
Helping relationships	Seeking and using social support for the healthy behavior change
Counterconditioning	Substitution of healthier alternative behaviors and conditions for the unhealthy behavior

Table 2. (Continued) Transtheoretical model constructs

Reinforcement management	Increasing the rewards for the positive behavior change and decreasing the rewards for the unhealthy behavior
Stimulus control	Removing reminders or cues to engage in the unhealthy behavior and adding cues to reminders to engage in the health behavior
Social liberation	Realizing that social norms are changing in the direction of supporting the healthy behavior change
Decisional Balance	
Pros	Perceived benefits of changing
Cons	Perceived costs of changing
Self-Efficacy	
Confidence	Confidence that one can engage in the healthy behavior across different challenging situations
Temptation	Temptation to engage in the unhealthy behavior across different challenging situations

2.6.5 Applications of TTM

The TTM was initially applied and validated from research looking at the behavior of smokers. In studying smoking cessation, ten processes of change were found to be predictive across study populations. These processes interacted in a common pattern with the stage of change construct (Diclemente & Prochaska, 1982). In a later study examining 872 smoking subjects, the stages of change pattern again confirmed and validated relationships with the process of change variables (Prochaska & Diclemente, 1983). This model soon expanded to include research and investigation in many different areas of health behavior. Smoking cessation still remains the most common application of the TTM in intervention studies. A couple examples of application in smoking cessation include the Pathways to Change system, which is a TTM based expert system intervention. Their study results showed a cessation success rates of 22-26% (Velicer &

Prochaska, 1999). A study conducted in the U.K. tested the TTM with a self-help intervention for smoking cessation. Results showed that the TTM intervention was more effective in the precontemplation and contemplation stages (Aveyard, Massey, Parsons, Manaseki, & Griffin, 2009).

Other health areas that have heavily used the TTM as a basis for intervention includes acquired behaviors, such as alcohol abuse (DiClemente & Bellino, 1999; Prochaska et al., 2004), human immunodeficiency virus (HIV) risk (Cabral, Galavotti, Gargiullo, Armstrong, Cohen, Gielen, & Watkinson, 1996; Cabral, Cotton, Semaan, & Gielen, 2004; Galavotti, Cabral, Lansky, Grimley, Riley, & Prochaska, 1995) and drug use (Duvall, Oser, & Leukefeld, 2008; S.S. Johnson, Driskell, J.L. Johnson, Dyment, J.O. Prochaska, J.M. Prochaska, & Borne, 2006); screening behaviors, including mammography (Rakowski, Ehrich, Goldstein, Rimer, Pearlman, Clark, Velicer, & Woolverton, 1998; Pearlman, Rakowski, Clark, Ehrich, Rimer, Goldstein, Woolverton, Dube, 1997); eating behaviors, which include work in anorexia and bulimia (Jordan, Redding, Troop, Treasure, & Serpell, 2003; Touyz, Thornton, , Rieger, George, & Beumont, 2003). Other areas of TTM research include physical activity (Burbank, Reibe, Padula, & Nigg, 2002; Nigg, 2001; Bock, Marcus, Pinto, & Forsyth, 2001), weight management (Prochaska et al., 1994; Rossi et al., 2001; Vallis, Ruggiero, Greene, Jones, Zinman, S. Rossi, Edwards, J.S. Rossi, Prochaska, 2003), stress management (Mauriello, Rossi, Fava, Redding, Robbins, Prochaska, & Meier, 2007; Rooney, Hunt, Humphreys, Harding, Mullen, & Kearney, 2007), safe sun behaviors (Maddock, Redding, Rossi, & Weinstock, 2005), condom use (Prochaska et al., 1995; Evers, Harlow, Redding, & LaForge, 1998; Galavotti, Cabral, Lansky, Grimley, Riley, & Prochaska, 1995), depression (Levesque et al, 2011), and research in domestic violence offenders (Pandya, 2009; Eckhardt, & Utschig, 2007).

2.6.6 Applications of TTM to Diabetes

Within the last 20 years, there have been a multitude of studies utilizing the TTM specifically addressing diabetes, with several large-scale trials in progress (Ruggiero, 2000). Some of the studies have used the TTM to validate constructs within the model. Other studies have used the TTM to design and test interventions for improving health for

diabetic patients. Behavior change interventions that have been studied include physical activity, healthy eating and glucose measuring. There were no studies found in a literature search that used the TTM model to specifically address issues of diabetic eye disease (using PubMed, Academic Search Premier, Medline and Psychology and Behavioral Science collection databases; key words included transtheoretical, diabetes, health behavior theory, retinal imaging, retinopathy, teleretinal imaging and eye disease as keywords; date from 1997 through 2012; conducted January 2013)

There have been many studies that have validated stage-based measures on diabetic populations. For example, one study examined the validity of TTM on physical activity intervention, comparing patients with type 1 and type 2 diabetes and age. Their results validated the stage measure for physical activity for these populations. They found that there is no significant difference in stage patterns between the groups, however, age played a strong role in physical activity intention (Plotnikoff et al., 2007). Another study looked at stage of change related to healthy, low-fat eating. Their stage question asked "Do you consistently avoid eating high-fat foods?" The results of the study supported the staging algorithm; when patients moved from pre-contemplation and contemplation stages to the action stage, there was a decrease in the consumption of fat calories (Vallis et al., 2003). Another study focused on validating TTM constructs with diverse population. They looked at low income African American smokers and the constructs decisional balance and self-efficacy with smoking. Results validated the model for this population (Kohler, Fish, & Davies, 2004).

Based on the literature search, most of the intervention studies that have used TTM with diabetic patients have focused on physical activity, healthy eating, smoking, and glucose measures. A study conducted by Kirk et al (2003) evaluated a six-month effect of exercise consultation, based on the TTM, on measures of physical activity and glycemic control. A total of 70 subjects were recruited, all in either the contemplation or preparation stages. Their results demonstrated that their TTM intervention was more effective than the control group, which got a standard brochure on physical activity. A similar study, using a dietitian as a consultant, found that stage-based consultations resulted in the increase of physical activity levels (Jackson, Asimakopoulou, & Scammell, 2007). Another study conducted in South Korea evaluated a stage-matched

intervention that included counseling and exercise prescriptions (n = 45). Their results demonstrated that over a three-month period, the TTM-based counseling had significant improvements in physical activity levels and HbA1c, compared to the control group (Kim, Hwang, & Yoo, 2004).

2.7 Focus Group Interviews in Technology and Healthcare Research

To further research insights to the digital divide, health behavior change and how the teleretinal imaging program effected the participant population, focus groups were conducted as a follow-up to the TTM surveys (see Chapter 3, section 3.7 for more detail.) To provide a brief history of the use of focus group, the use of focus groups can be described as evolving from three different phases. Early use of focus groups goes back to the 1920s, when social scientists used this method for various purposes, most noteworthy for development of survey questionnaires. Social scientist also wanted strategies where results were less directed by the researcher, thus focus groups focus on the participant rather than the researcher. Though the 1970s and 80s focus groups were a popular tool for market researchers, since they enable manufacturers, media producers and sellers to understand consumer thinking, desires, and opinions at a reasonable cost. In the third phases, from the 1980s to the present, focus groups have been used in research and are now considered an important research method. The third phase was primarily delayed due to the societal preference for quantitative methods (Krueger, 1988).

Specifically in healthcare, focus groups, have been demonstrated to be a valuable tool since questions on not only what people believe, but also why they behave in particular ways can be explored (McLafferty, 2004; Rodriguez, Schwartz, Lahman, & Geist, 2011). Focus groups can also be culturally sensitive by acknowledging the participants social and cultural identities. This has shown to result in richer data since participants will be more likely to share in a context that reflects their own cultural identity (Rodriguez, Schwartz, Lahman, & Geist, 2011). Focus groups also provide an opportunity for researchers to explore social interaction between the participants (Denzin, 2000). Focus groups are ideally suited for technological and health behavior since influences such as culture, lifestyle and family dynamics can be explored in the context

of life and personal experiences. In addition, different perspectives between groups or between individuals can be explored.

The basic assumption of focus-group methodology is not the understanding of an individual, but the collective statements and shared experiences (Ivanoff & Hultberg, 2006). Focus groups share ideas with the theory of social constructivism and social cognitive theory. Social constructivism theorizes that in order to understand what happens in society, cultural and social contexts must be examined. In other words, people are active players in the construction of one's environment (Doise, 1989; Keaton, 2011). In other words, social experiences determine, predict and influence health behavior (McAlister, Perry, & Parcel, 2008). Focus groups can be used for several different purposes in health research, including instrument or measurement development; the development of educational interventions (Murdaugh, 2000, Globe, 2002); for program or software evaluation (Kirchberger, 2009); inductive method of gaining knowledge on a particular subject or experience (Nolan, 2011); as a motivational method for improving health behavior (Dellasega, 2012); or to further understand actions, perceptions and attitudes that people have about health or their health condition (Miller, 2004).

In a focus group study, related to the content of this dissertation and examining the digital divide in health information, researchers found that family member support is an important facilitator to accessing and continued use of health information technology, or patient web portals (Mayberry, Kripalani, Rothman, & Osborn, 2011). Specific to diabetes and diabetes self-management, focus groups have been used to enquire about enablers and barriers to diabetes self-management. A study, which focused on African-Americans, found that key facilitators to positive self-management behavior was linked critically to family support, the presence of a daily routine, acquisition of knowledge about diabetes self-management, and peer support in sharing and gaining knowledge. Barriers were time consumed by their diabetes, lack of self-control, pain associated with blood glucose monitoring, and forgetfulness in tasks to manage their diabetes (Chlebowy, Hood, & LaJoie, 2010). A focus group study exploring beliefs and attitudes towards diabetes in a Latino population found that the participants believed that good eating habits and exercise are needed to be healthy. Barriers to managing diabetes are life

situations, which included work and stress. Access to care and adapting to American culture were also found as key issues in their diabetes self-management (Long, Sowell, Bairan, Holtz, Curtis, Fogarty, 2012). Another study looking at facilitators and barriers to self-monitoring devices with diabetic patients found that barriers to use are knowledge, relationships with healthcare providers, and personal experience. Community programs, dieticians and pharmacists were important enablers (Chudyk, Shapiro, Russell-Minda, & Petrella, 2011).

CHAPTER 3
RESEARCH METHODOLOGY

3.1 Overview

To reiterate, the research questions focused on what can be learned about the digital divide and health outcomes among an underserved population when a teleretinal imaging program is made available. The research approach utilized a mixed method, community-based research methodology. The study implemented a telemedicine intervention in the form of a diabetic eye care program. The program consisted of retinal (teleretinal) imaging and web-based eye care education delivered over the Internet. Diabetes was used as a real-life context in which pre- and post-assessment was used to measure behavior change associated with telemedicine intervention. Focus group interviews were used to explore technology utilization (retinal imaging and web-based materials) and motivators and barriers to behavior change. Human use approvals for University of Hawaii (UH), Waianae Coast Comprehensive Health Center (WCCHC) and the office of Research Protections, Human Research Protection Office, and United States Army were obtained (see Appendices 17-19). The study's human use protocols (all three) were all closed on completion of the study. This study is sponsored by the U.S. Army Medical Research and Materiel Command and the University of Hawaii. There were no adverse events or problems pertaining to human subjects reported throughout this study.

3.2 Participants

Participants were recruited from the Primary Care Clinic of the WCCHC. This center was established in 1972 to serve the needs of Oahu's rural communities on the leeward side of the island. WCCHC serves over 26,900 patients, with more than 139,200 visits annually. Located on the Waianae coast of Oahu, WCCHC's target population is primarily Native Hawaiian (51%), with a focus on chronic disease treatment and prevention. Other populations served are Caucasian (17%), and Asian (16%). WCCHC's patients are predominately low income, with 76% of the patients having an income level of less than 200% of the Federal Poverty Level. This health center is a

Federally Qualified Health Center that serves a federal Medically Underserved Area. Less than 1% of the patients are served in a language other than English (Hawaii Primary Care Association, 2010).

The Waianae coast has a prevalence rate of diabetes of 7.1%. Native Hawaiians in particular have the highest prevalence of diabetes at 7.9%, followed by Filipinos at 7.5%, Japanese at 6.6% and Caucasian at 3.4%. Statewide, the prevalence of retinopathy among adults with type 2 diabetes is 22%, with Native Hawaiians with the highest prevalence at 28.7% (Hirokawa et al., 2004).

Qualified diabetic patients were identified from the WCCHC scheduling system as having an upcoming primary care visit within two weeks. The patients were telephoned prior to their visit to see if they were interested in participating. In addition, flyers were distributed in all WCCHC clinics and the exercise facility (see Appendix 1). Recruitment tools included referrals and directly speaking to WCCHC clients. A total of 160 participants were recruited and signed informed consent for this study (see Appendix 20 for consent form).

3.3 Study Design

This study utilized a interrupted time-series design, in which a pre -post survey model was implemented to a single cohort of participants. All participants were given the teleretinal intervention after the pre-test was administered. The same assessments were then administered at one and three months following baseline. The assessments included behavioral measures of daily self-management, exercise, smoking, and carbohydrate counting. Further detailed description will be discussed in next section. In addition to the surveys, other diabetes relevant variables were collected from each participant's electronic medical record (where available) at each of the three visits: HbA1c, body mass index, and level of retinopathy.

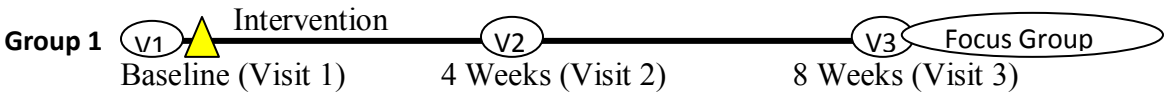


Figure 1. Study design.

Although the repetition of the assessment may have resulted in an assessment/survey affect, the design (pre, post, post-post) is stronger than a simple pre and post-test intervention. The additional assessment can be used to examine plausibility of possible alternative explanations for change (Hoyle, Harris, & Judd, 2002), and provide insight to the degree to which behavior changes may have been sustained or adopted. This approach was relevant to the study since the TTM looks at behavior change over time. This model was used for analyzing the baseline, one- and three-month follow-up data using survey results and clinical measures. Focus groups were held with participant volunteers who had completed their third and final visit, in order to obtain qualitative data on the intervention, technology, and factors related to behavior change.

3.4 Survey Instruments

All survey instruments, except for the demographics survey, were administered at all three visits. The demographics survey, which was self-administered by paper, was administered only at the baseline visit. Surveys were chosen based on their relation to managing diabetes. The following is a description of the instruments. See Appendix 2 – 11 for surveys used.

3.4.1 Stage of Change for Exercise (Appendix 2)

This measure assesses a readiness to engage in regular exercise. Participants were asked if they engage in regular exercise, which is defined as any "planned physical activity." The staging question asked the participant to rate if they exercise regularly: yes, more than 6 months ago; yes, less than 6 months; no, but intended to in the next 30 days; no, but intended to in the next 6 months; and no, did not intend to in the next 6 months (Marcus, Selby, Niaura, & Rossi, 1992b; Norman, Benisovich, Nigg, & Rossi, 1998).

3.4.2 Stage of Change for Carbohydrate Counting (Appendix 3)

Constructs for these measures have been established and validated in the Stages of Intensive Therapy Questionnaire (Jones, Cleave, Tomlinson, Hamilton, & Feig, 2006). Staging for carbohydrate counting followed this sequence. After a brief description of carbohydrate counting, participants were asked, "Do you consistently manage the amount

of carbohydrate you eat each day?" Responses included the following choices: yes, more than 6 months ago; yes, less than 6 months; no, but intend to in the next 30 days; no, but intend to in the next 6 months; and no, do not intend to in the next 6 months.

3.4.3 Stage of Change for a Diabetes Self-Management Action Plan (Appendix 4)

This measure assessed if a participant have intended to have, or do not intend to have a self-management action plan to control their health condition. A self-management plan includes the following: managing triggers that can cause symptoms; regular self-testing; and monitoring symptoms and being prepared to address symptoms. There were two questions in this measure, one that asked if the participant currently has a self-management action plan and if so, a question is asked if the plan is followed. Responses included the following choices: no, and I do not intent to in the next 6 months; no, but intend to in the next 6 months; no, but intend to in the next 30 days; and yes, I have an action plan (if yes, go to question number two). Question number two asked if the self-management plan is followed. Answers included the following: no, and I do not intend to in the next 6 months; no, but I intend to in the next 6 months; no, but I intend to in the next 30 days; yes, I have been for less than 6 months; and yes, I have been for more than 6 months. This instrument has been validated by Pro-Change Behavior Systems (Pro-Change Behavior Systems, 2010).

3.4.4 Stage of Change for Smoking Cessation (Appendix 5)

There are three items in this instrument. The first question asked if the participant is a current smoker. Answers included the following: yes, I currently smoke; no, I quit within the last 6 months; no I quit more than 6 months ago; and no, I have never smoked. If the participant selects that last choice, they are done with this instrument. Else, the following two questions are asked: in the last year how many times have you quit smoking for at least 24 hours; and are you seriously think of quitting smoking. The prior question was a fill in response; the later question had the responses available: yes, within the next 30 days; yes, within the next 6 months; and no, not thinking of quitting. This instrument, which is the short form, has been validated and determined to have high

reliability, internal validity, discriminative validity and predictive validity (Velicer et al., 1995; Diclemente & Prochaska, 1991).

3.4.5 Pros and Cons of Exercise (Appendix 6)

This measure assessed the relative importance of the advantages and disadvantages in an individual's decision to engage in regular moderate exercise. The psychometrics of the instrument have been established and validated at the University of Rhode Island and ProChange, Inc (Pro-Change Behavior Systems, 2010; Nigg, Rossi, Norman, & Benisovich, 1998). Responses were provided on a 5-point Likert scale from 1 = not important to 5 = extremely important. The psychometric properties have demonstrated good reliability and validity. Internal consistency for the pros is $\alpha = 0.87$, and $\alpha = 0.71$ for the cons, with an average loading of 0.80 on the pros and 0.62 on the cons (Sarkin et al., 2001).

3.4.6 Pros and Cons of Carbohydrate Counting (Appendix 7)

Ten items were used to assess the decisional balance, pros and cons, for managing the amount of carbohydrates consumed. Responses were based on a 5-point Likert scale from 1 = not important to 5 = extremely important. Examples of the decisional balance questions are: "My blood glucose levels will improve if I control the amount of carbohydrate I eat (Pro)" and "Eating foods that are low in carbohydrates limits my food choices (Con)." This instrument has been validated by Pro-Change Behavior Systems (Pro-Change Behavior Systems, 2010).

3.4.7 Exercise Self-Efficacy (Appendix 8)

The self-efficacy short assessment instrument was used (Benisovich, Rossi, Norman, & Nigg, 1998a; Benisovich, Rossi, Norman, & Nigg, 1998b; Marcus, Selby, Niaura, & Rossi, 1992a). For exercise, subjects were asked to rate six items on how confident they were in exercising when other things get in the way. Responses were recorded using a 5-point Likert scale: 1) Not confident at all; 2) Somewhat confident; 3) Moderately confident; 4) Very confident; and 5) Completely confident. Items included references to negative affect, excuse making, exercising alone, inconvenience, resistance

to others, and inclement weather. The scale has been rated with good psychometric properties (Sarkin, Johnson, Prochaska, & Prochaska, 2001): an average loading of 0.79, and an internal consistency coefficient is $\alpha = 0.88$.

3.4.8 Carbohydrate Counting Self Efficacy (Appendix 9)

This assessment tool consisted of 10 items that the participants answered to rate how confident they are in managing their carbohydrate intake. Responses were recorded using a 5-point Likert scale: 1) Not confident at all; 2) Somewhat confident; 3) Moderately confident; 4) Very confident; and 5) Extremely confident. Sample items on the survey inquired about managing carbohydrate intake during social events, holidays, when others are eating unhealthy foods, when blood glucose is low and when traveling. This instrument has been validated by Pro-Change Behavior Systems (Pro-Change Behavior Systems, 2010).

3.4.9 Processes of Change for Exercise (Appendix 10)

This assessment tool consisted of 28 items that rated the participant's experiences regarding exercise habits. Responses were recorded using a 5-point Likert scale: 1) Never, 2) Seldom, 3) Occasionally, 4) Often, and 5) Repeatedly. There were a few questions in each of the following process of change categories: consciousness raising, dramatic relief, environmental reevaluation, self reevaluation, social liberation, counter conditioning, helping relationships, self liberation, and stimulus control. This instrument has been validated by Pro-Change Behavior Systems (Pro-Change Behavior Systems, 2010; Nigg, Norman G.J., Rossi, & Benisovich, 1999).

3.4.10 Demographics (Appendix 11)

A demographics survey was used for descriptive purposes to examine trends, averages and variances in the participant population. The survey included demographic questions, such as age, gender, education, income, ethnic background and use of the Internet.

3.5 Personal Health Portal and Retinal Imaging

For this study, we used the Comprehensive Diabetes Management Program (CDMP) software (Estenda Solutions, Inc., 2010) as the web portal. CDMP is a Health Insurance Portability and Accountability Act (HIPAA) compliant system using a secure server maintained by Estenda Solutions, Inc. The software was implemented such that participants could access their personal retinal images and diabetic eye disease education online via a web portal. The CDMP integrates a secure Internet portal to provide patients with direct access to their personal health information and educational materials offered by their health care institution. The system integrated the participant's personal retinal images.

The digital image acquisition of the retina with the eye care system was possible using low light levels; this eliminated the need for pharmacological dilation of the pupil, making the process more comfortable and less intrusive for the patient. The retinal imaging device is Food and Drug Administration (FDA) approved. Digital retinal imaging has been validated for retinopathy assessment to be used with appropriate ophthalmological specialist referral and follow-up. However, this procedure is not meant as a substitute for retinopathy assessment by an ophthalmologist, but to provide a platform that is more readily available, accessible and comfortable for the patient. Importantly, the system allows information and images to be available for viewing by clinicians and patients in the workplace and at home, which can potentially positively impact health behaviors (Fonda, Stephanie J. et al., 2007; Bursell, S. E. et al., 2001).

The images were transferred to CDMP via the imaging technician. The images were saved on a central database where the patient and practitioner could access and view the images via a website (see Attachment 12 for screenshot). The patient educational information was created as a separate website and was linked off of the CDMP web portal. For the purposes of this study patient information was specific to retinal imaging and diabetic eye disease (see Attachment 13 for website).

3.6 Focus Group Procedures

In order to gain further insights on the impact of the web-based educational materials, and mechanisms and motivations for behavior change, four focus group

interviews were conducted. The focus groups were moderated by researchers who were familiar with this population. An inductive method of analysis and data collection was utilized in conducting the focus groups. Open-ended questions were asked to elicit responses of "how" they feel, and why" they were or were not influenced to change behavior. A procedure and script was used as a template for conducting the focus group sessions (see Attachment 12). The discussions were focused; however, discussion was guided by the flow of the participants and open to unanticipated areas that were relevant and provided insight.

Key areas of focus were as follows: thoughts on the intervention of teleretinal imaging; how technology affects motivation factors of behavior change, obstacles in changing health behavior; the use of technology for health information; motivators and barriers to behavior change as it related to diabetes; and comments on the participation in the study in general. The following questions were asked to guide the discussions.

1. Did seeing your retinal images mean anything to you?
2. How did seeing your retinal images affect your motivation to change behavior, such as exercise, diet, medication or other possible changes?
3. What are motivating factors or obstacles that affected your decisions regarding managing your diabetes? This could include family, friends, community, your own health concerns, etc…
4. What motivated you to participate in the study?
5. Do you use the Internet for obtaining information on health care?
6. What do you feel was the most beneficial aspect of the program?
7. What do you feel was the least beneficial aspect of the program?
8. How could we improve the program?

A description analysis of the focus groups was used since data does not address any quantitative research questions. The aim was to explore eHealth literacy and factors involved in behavior change. Data analysis included examining written notes, and listening to the audio taped sessions multiple times in conjunction with the notes to further get a sense of the interview as a whole. In doing this, themes were identified and indexed in conjunction with the written notes. In addition, relevant quotes were

highlighted and sorted such that comparisons could be made between the focus group interviews. At this point, the data was ready to be analyzed. The context of topics, frequency of comments and intensity of comments were considered in the analysis. For this analysis, the sessions were replayed multiple times to parse out data in conjunction with the research notes (Steward et al., 2007; Rabiee, 2004). In sum, data was analyzed utilizing the analysis continuum of 1) examining raw data, i.e. flip charts and audio recordings, 2) using descriptions of context, and then 3) interpreting or analyzing the data within the context of the research questions (Krueger, 1988).

The moderator was also the one conducting the data analysis, which has been supported in the literature, based on the assumption that first hand exposure to the discussion and interaction is important in interpretation of the data (Krueger, 1988). Audio was analyzed taking into context the social interactions, intonations, emotions and cultural inflections. In addition, the focus groups were well planned with focus questions accompanied with field notes, which in some circumstances may enhance the reliability, validity and transparency, rather than hinder it (Clausen, 2012).

3.7 Pre-Post Study Procedures

A community-based research method was used, in which the intervention, methods and results were developed, implemented and approved by the Waianae Coast Comprehensive Health Center (WCCHC). In the process, several meetings with the staff and Director of the Preventive Health Department to discuss the research proposal were conducted. An application was submitted to the WCCHC research committee; the research committee assessed how the study would impact the community participants. Benefits to the community and community involvement, further described in Chapter 7, section 7.3, were reviewed, and resources required by the health center were discussed. On completion of the study, the results were presented at a “report to community” forum, to which all participants were invited. The event was also open to all clients of WCCHC. Flyers were distributed advertising the event (see Attachment 1). The report to the community was done with the intention of receiving feedback from the community regarding the study results and the value of the intervention to the community. In

addition, an end of study presentation was also given to the research committee at WCCHC for their feedback and comments.

3.7.1 Inclusion and Exclusion Criteria

The following was inclusion criteria for all participants.

- Ages 18 - 75 (upper age limit is due to age related imaging quality)
- English speaking
- Able to understand and sign informed consent
- Referred from and a patient of WCCHC
- Diagnosis of T2D using America Diabetes Association criteria 30
- HbA1c measured within 3 months of screening
- Client of WCCHC

The following exclusion criterion was used.

- Subject in either the Action or Maintenance Stages for all areas (exercise, carbohydrate counting, smoking and daily self-management).

3.7.2 Data Collection

The study duration for participants was between two to four months. All study participants provided written informed consent after having the study explained to them. The study consisted of three visits: a demographics survey (see Attachment 11) and teleretinal imaging intervention were administered at visit one (baseline). The TTM health behavior surveys were administered three times: at baseline, after one month and three months (Appendix 2-11). In addition to the surveys, other variables collected from the patient's electronic medical record included the patients HbA1c, body mass index, and level of retinopathy. All data collected were pooled into aggregate data, with no way to match individual survey scores or other variables to specific study participants.

The TTM surveys were administered via voice-recorded PowerPoint slides, whereby each question was read to the participant via the integrated recording; the responses were collected via a wireless card key input. Participant were required to press a number on the card that best reflected their response. Participants' responses were automatically

recorded by the software. This method of survey administration facilitated standardization of the survey administration, and allowed for multiple participants to take the survey at the same time, and preserved anonymity of the participants. After the initial visit, individual follow-up survey assessments were conducted over the telephone if the participant could not come into the clinic; slides were read to the participants over the phone, and using the same software, the research assistant logged the responses by the card key.

The following is a detailed description of the visits.

Visit 1 - Baseline (approximately 1 hour). All patients completed a demographic survey (Appendix 11) and baseline stage of change assessment surveys (Appendix 2 - 5). After the surveys, all patient's were given the teleretinal imaging intervention, which included their retinas being imaged and access to the personal health portal; this also included educational information on diabetic eye disease (See Appendix 14). A printed handout of the retinal images and educational website was also given to the patient. Based on the survey results, participants that fell in the precontemplation, contemplation, or preparation stages of change for any of the health behaviors were eligible to continue and complete visit 2 and visit 3 of the study. These patients will be asked to return in four to eight weeks for a second follow-up visit.

Those that did not fall into the precontemplation, contemplation, or preparation stage categories were excluded from the study at this time. We had no participants that were excluded. If their participation in the study ended at this time, they would have received $15 compensation for their time and inconvenience ($15 was given as compensation for every office visit, to a maximum of three visits.)

Visit : 4 to 8 weeks later (approximately 1 hour) After four to eight weeks from the baseline visit the participants were administered the assessment surveys again.. If it was not possible to have the participant come to the clinic to take the surveys in person, they were administered over the telephone. After Visit 2 was completed, all participants were asked if they were willing to attend a focus group interview at Visit 3. If they agreed, they were telephone and given an option of tentative dates within their Visit 3 window.

Follow-up: 4 to 8 weeks later (approximately 30 minutes) Again after four to eight weeks from visit 2, the participants were administered the follow-up assessment surveys. If it was not possible to have the participant come to the clinic to take the surveys in person, they were administered over the telephone. If the participant agreed to, and was available to attend a focus group interview, they were scheduled to do the last assessment in at the clinic, with the focus group interview following the completion of the surveys. On completion of this last visit, the participants were compensated $45 for their time completing all three visits. After the allotted time windows, if the participants did not complete all three visits, they were compensated $15 for each of the visits they completed.

During scheduling of the third study visit, all participants were asked if they were willing to participate in a focus group interview to discuss their opinions and experience in the study. Based on scheduling and availability we were able to recruit five to eight participants for four focus group interviews. All focus group interviews were conducted in the administrative conference room at the Waianae Coast Comprehensive Health Center and lasted one hour. Prior to the focus group, all participants completed their third survey visit. At the start of each focus group, a brief introduction on what was expected during the session was explained, as well as some basic ground rules in participating. Moderators introduced themselves followed by each member introducing themselves and where they are from. As an icebreaker willing participants were asked to share something personal. Lunch was provided after the group interviews.

Flipcharts were created with each of the topic questions already written at the top of the chart. This was used to help focus the topics and allow the participant see the topic questions throughout the sessions. As discussion ensued, responses to the topic question were recorded on the flipchart. Comments were added throughout the session. Check marks were applied when responses were repeated. When the moderator was not clear of a response, the participant was asked to clarify so that the flipchart notes were accurately recorded. In addition to the flipchart notes, all participants gave informed consent to have the group interview audio recorded and photos taken.

3.8 Statistical Analysis

3.8.1 Sample Size Calculation

The sample size was calculated using pros from the decisional balance scale as the outcome variable. This variable was chosen since with the given the time frame, this is where there is the greatest potential to demonstrate early stage change. The sample size was calculated using a predicted increase in 1.0 standard deviation of the mean pros scores from the precontemplation to preparation stages of change, as predicted by the strong principle of change (Prochaska, 1994). A Statistical power of 80% (alpha .05, two-tailed) was calculated with a medium population effect size. Effect size was based on Cohen's guidelines and empirical data from the literature (Velicer et al., 2008; Cohen, 1988). Results from a power analysis gives a total of 85 participants (n = 85) that was needed to demonstrate change, with a significance level of 5%. A total of 213 participants were calculated to be recruited for this study. This accounts for 50% attrition (n = 85). This was assumed due to the number of times the participant would have to fill out the surveys. An additional 20% (n = 43) attrition was calculated on top of the 50% for patients falling into the action or maintenance stages (Jones, Edwards, Vallis, Ruggiero, L. Rossi, S.R. Rossi, Greene, Prochaska, & Zimman, 2003), in which they will not qualify for the study. The final sample size was a total of 125 participants that finished the study, which exceeded the sample power calculation.

3.8.2 Descriptive Statistics

Means, standard deviations, frequencies, proportions, and graphical displays were analyzed for all study variables. In addition, plots of longitudinally measured variables are constructed to understand their general trends over the study period. A descriptive cross-sectional comparison was charted for the stage of change and decisional balance (pros and cons) variables. In order to qualitatively demonstrate the TTM, the literature suggests that to progress from the contemplation to the action stage of change, the pros of changing behavior, which are lower than the cons in the precontemplation or contemplation stages, should increase by one standard deviation and the cons should decrease at approximately .5 standard deviation. There should be cross-over point when the cons and become lower than the pros as the participant progresses into the action

stage (from pre-contemplation or contemplation stage) (Prochaska, Redding, & Evers, 2008). In order to demonstrate if this happens, we conducted a cross-problem comparison using the results from the decisional balance instruments (*Exercise Regularly: Pros and cons* and *Carbohydrate Decisional Balance)*. Scores were converted into standard (T) scores as independent variables. Dependent variables that consist of the staging instruments (exercise, carbohydrate counting and self-management), results were charted. Prochaska (Prochaska et al., 1994) suggests that a change in stage in exercise or carbohydrate counting (i.e., progression from pre-contemplation or contemplation to action stage), there should also be demonstrated be a cross over between increase in pros and decrease in cons.

3.8.3 Statistical Analysis

For the main analysis in examining the baseline, post-intervention and three-month follow-up longitudinal data, Person's chi-squared test were used for the categorical variables dependent variables of stage of change for daily self-management, exercise, carbohydrate counting and smoking (from pre-action stage to action or maintenance stages). An one-way analysis of variance was used for the continuous dependent variables of self-efficacy for exercise and carbohydrate counting; decisional balance for exercise and carbohydrate counting.

3.8.4 Clinical Measures

A paired-sample t-test was conducted to compare the baseline HbA1c to the post-intervention HbA1c values

3.8.5 Post-hoc Sheffé Test

Since a significant differences in the analyses were detected ($p < 0.05$ significance level), post-hoc tests were conducted to determine the source of the differences between the dependent variables. Sheffé pairwise comparisons between means were used to test significant main and interaction effects between dependent variables. This test was chosen due to the versatility and conservative nature of the test (Pedhazur, Elazar J. & Schmelkin, Liora Pedhazur, 1991).

Table 3. Summary of analyses related to research question.

Statistical Model	Variables *Independent Variable (IV)* *Dependent Variable (DV)*	Related Hypothesis
Descriptive Statistics	• *Demographics Survey*	
	Cross-sectional comparison of staging versus decisional balance (pros and cons) (charts) *Stage of Change for Exercise* • *Carbohydrate Staging* • *Staging for Self-Management Action Plan* • *Smoking Stage of ChangeExercise Regularly: Pros and Cons* • *Carbohydrate Decisional Balance*	
Statistical Model	**Variables** ***Independent Variable (IV)*** ***Dependent Variable (DV)***	**Related Hypothesis**
Chi Square	**IV – Visit 1, Visit 2, Visit 3**	
	DV - Stage of Change Surveys • *Stage of Change for Exercise* • *Carbohydrate Staging* • *Staging for Self-Management Action Plan* • *Smoking Stage of Change*	Hypothesis 1: Type 2 diabetic patients who are given access to the teleretinal imaging intervention will progress to a *higher stage of change* as dictated by the transtheoretical model over one month and three months.

Table 3. (Continued) Summary of analyses related to research question.

Statistical Model	Variables *Independent Variable (IV)* *Dependent Variable (DV)*	Related Hypothesis
ANOVA	**DV - Decisional Balance Surveys** • *Exercise Regularly: Pros and Cons* • *Carbohydrate Decisional Balance*	Hypothesis 2: Type 2 diabetic patients who are given access to teleretinal imaging intervention will *increase pros for decisional balance* by approximately one standard deviation over one month and maintain levels over three months.
	DV - Decisional Balance Surveys • *Exercise Regularly: Pros and Cons* • *Carbohydrate Decisional Balance*	Hypothesis 3: Type 2 diabetic patients who are given access to teleretinal imaging intervention will *decrease cons for decisional balance* by approximately one-half of a standard deviation for decisional balance as dictated by the transtheoretical model over one month and sustain levels over three months.
	DV - Self-Efficacy Surveys • *Exercise Regularly: Self-Efficacy* • *Carbohydrate Self Efficacy*	Hypothesis 4: Type 2 diabetic patients who are given access to teleretinal imaging intervention will demonstrate a linear *increase in situation-specific confidence (self-efficacy)* as over one month and sustain levels over three months.
	DV - Process of Change Survey • *Process of Change for Exercise*	Hypothesis 5: Type 2 diabetic patients who are given access to their retinal images and PHP will *increase in their use of appropriate processes of change* in *exercise* as dictated by the transtheoretical model over three months.

Table 3. (Continued) Summary of analyses related to research question.

Statistical Model	Variables *Independent Variable (IV)* *Dependent Variable (DV)*	Related Hypothesis
Post-hoc Analysis	Post-hoc Sheffé Test will be conducted on all the analyses above that result in $p < 0.05$ significance level.	
T-Test	**IV – Visit 1, Visit 3** **DV -** HbA1c	Hypothesis 6: Type 2 diabetic patients who are given access to their retinal images and PHP will *improve clinical measures* over three months.
Chi-Square	**IV – Visit 1, Visit 3** **DV -** Level of Retinopathy	

CHAPTER 4
SURVEY RESULTS

4.1 Overview

This chapter is an in depth analysis of the TTM survey results. As part of the examination of the technology and the digital divide, it is important to examine related health outcomes that could be a potential benefit to the participant and community. Hence, as part of the research on the reaction to the teleretinal imaging program, health behavior changes are examined via the TTM surveys.

4.2 Participant Characteristics

One-hundred and sixty participants signed informed consent, with 125 participants completing all three assessment visits. The retention rate was 78%, which exceeded the sample size calculation. The overall participant demographics are as follows: n=160; mean age=53, range 24 – 78, SD=11.9; mean BMI=38.8, range 23 – 101; 49% female; 46% married; 14% attended "some college"; 55% Native Hawaiian.

The participant demographic for those that completed all three visits are as follows: n=125; mean age=53, range 27 – 77, SD=11.1; mean BMI=39.3, range 23 – 101; 50.4% female; 57% married; 16% attended "some college"; 60% Native Hawaiian. See Table 4 for more detailed demographic data on the participant population.

Table 4. Demographic data on participant population (n = 125).

	Mean	*SD*	*N*
Age	52.54	11.13	125
BMI	39.28	11.58	125
HbA1c			
Baseline	8.59	2.50	111
Visit 3	8.22	2.24	53
Level of Retinopathy			
Nonproliferic	6	4.8	125
Proliferic	15	12.0	125
No Evidence	80	64.0	125
Ungradable	24	19.2	125
	Frequency	*Percentage*	
Gender			
Male	62	49.6	
Female	63	50.4	
Ethnicity			
Native Hawaiian	75	60.0	
Filipino	13	10.4	
Caucasian	11	8.8	
Samoan	7	5.6	
Japanese	4	3.2	
Portuguese	4	3.2	
Micronesian	4	3.2	
Other	7	5.6	
Marital Status	57	45.6	
Married	51	40.8	
Not Married	4	3.2	
Widowed	13	10.4	
Divorced			
Education			
High School	105	84.0	
Some College	16	12.8	
2+ years College	4	3.2	

Table 4. (Continued) Demographic Data on Participant Population (n = 125).

Employment Status		
Unemployed	57	45.6
Employed Part-time	15	12.0
Employed Full-time	21	16.8
Retired	30	24.0
Family Income		
$0 - 9,999	5	4.0
$10,000 - 19,000	41	32.8
$20,000 - 29,000	31	24.8
$30,000 - 39,000	15	12.0
Above $40,000	7	5.6

4.3 Survey Results

In this section, each of the survey results is examined individually. Figures 2-7 below are graphs displaying the results for each instrument across all three visits for those who completed the study (n = 125). The purpose in displaying the results longitudinally across the three visits is to demonstrate general trends over the study period. The variables displayed are the stages of change for daily self-management, exercise, carbohydrate counting and smoking cessation. In addition, the mean score results across all three visits for exercise pros and cons, carbohydrate counting pros and cons, and processes of change for exercise are displayed.

4.3.1 Stage of Change

Stage distributions and comparisons for the participant populations are displayed for daily self-management, exercise, carbohydrate counting and smoking cessation below. Overall, the trend from visit one to visit three across all four measures can be generalized as: an increase percentage of those in the contemplation stage; a decrease in percentage of those in the preparation stage; and an increase in percentage of those in action or maintenance stages.

Because of the small sample size, results have been dichotimized and are presented as pre-action (at risk) and action (no risk) categories, since the main goal for healthy behavior is to advance into the action stages. Pre-action consists of the precontemplation, contemplation and preparation stages; these are stages in which the participant is not yet acting upon the healthy behavior. The latter category consists of action and maintenance stages; this is the category where the participant is participating or acting upon the healthy behavior.

Figure 2 below show the survey results for daily self-management. As shown in the graph, 24.8% of the subject population were in the pre-action, or risk stages of precontemplation, contemplation and preparation, at visit one. By visit three, there was actually an increase in number of participants reporting to be in the pre-action stages, at 47%. This may be explained by the large amount of those, 68.8%, that started with no plan at visit one, and having developed a self-management plan by visit three (8.8% had no plan at visit three). Hence those with no self-management plan at visit one, may have moved to the pre-action stages of having a daily self-management plan, but not yet ready for action. A chi-squared test showed that there were significant differences between the three visits, $\chi^2(4, n = 375) = 149.767$, $p < .0005$.

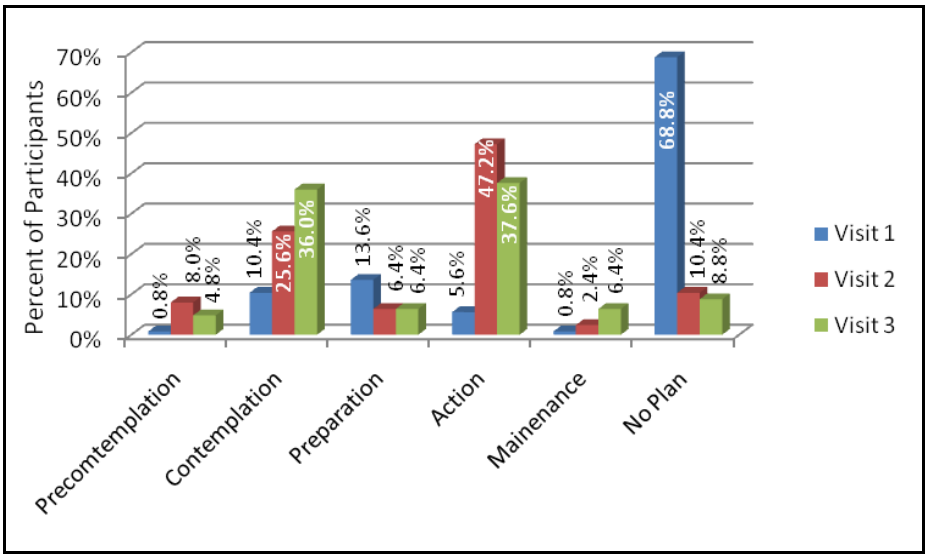


Figure 2. Percent of participants distribution of stage for daily self-management stage of change across three visits (n = 125).

For regular exercise behavior at visit one, 82.4% of participants were in the pre-action stages (see Figure 3 below). By visit three, 46.4% reported still being in the pre-action stages for regular exercise. This is indicates that there was a 36% change in participants from pre-action into the action stages. A chi-squared test showed that there were significant differences between the three visits, $\chi^2(2, n = 375) = 41.177$, $p < .0005$.

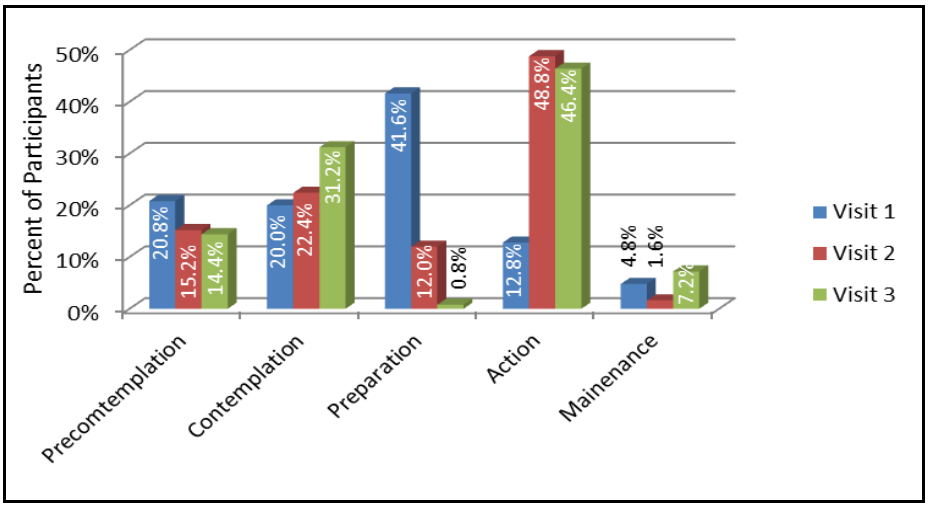


Figure 3. Percent of participants distribution of stage for exercise stage of change across three visits (n = 125).

Figure 4 below shows the stage distribution for carbohydrate counting. For this behavior, 80.8% of the participants reported being in the pre-action stages at visit one. At visit three 52% reported being in the pre-action stages. This indicates that there was a 28.8% change in participants from pre-action to action. A chi-squared test showed that there were significant differences between the three visits, $\chi^2(2, n = 375) = 29.978$, $p < .0005$.

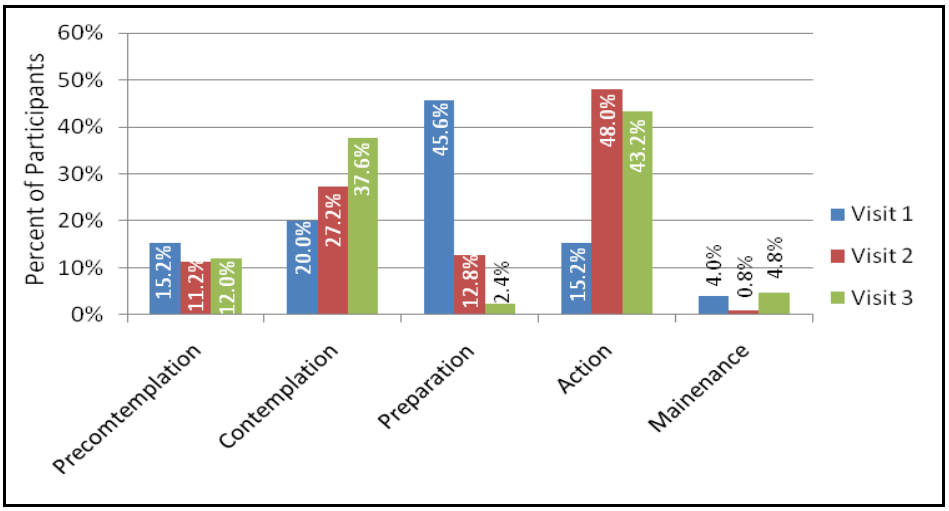


Figure 4. Percent of participants distribution of stage for carbohydrate counting stage of change across three Visits (n = 125).

For smoking cessation, 91.2% of participants at visit one were in the pre-action stages. At visit three, 83.2% of participants reported being in the pre-action stages. This indicates that there was a 8% change from pre-action to action stages of change for smoking cessation. A chi-squared test showed that there were significant differences between the three visits, $\chi^2(4, n = 375) = 9.900$, $p = .042$.

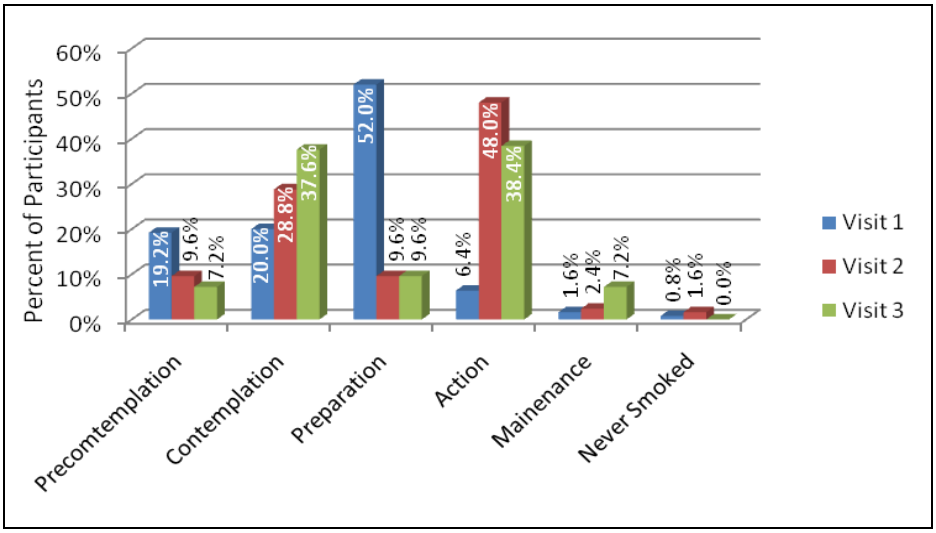


Figure 5. Percent of participants distribution of stage for smoking cessation stage of change across three visits (n = 125).

4.3.2 Decisional Balance (Pros and Cons)

Decisional balance for exercise is the measure of relative importance of the advantages and disadvantages in an individual's decision to engage in regular moderate exercise. Figure 6 shows the means distribution for exercise pros and exercise cons across the three visits. As shown, there is a trend in the increase scores for pros and decrease of scores for cons across over the three time points.

A one-way ANOVA was used to test the difference between the three visits. Scores significantly differed across the three visits for both exercise pros, $F(2, 372) = 5.567$, $p = .004$, and exercise cons, $F(2, 372) = 9.844$, $p < .005$. Turkey post-hoc comparisons of the three visits indicate that there was a significant difference between only visit one ($M = 12.15$, $SD = 4.008$) and visit three ($M = 13.98$, $SD = 4.662$) at $p = .03$ for exercise pros. For exercise cons, the Turkey post-hoc comparison showed s significant difference between visit one ($M = 10.92$, $SD = 4.667$) and visit two ($M = 9.18$, $SD = 4.247$) at $p = .003$; and a significant difference between visit one and visit three ($M = 8.70$, $SD = 3.515$) at $p < .005$.

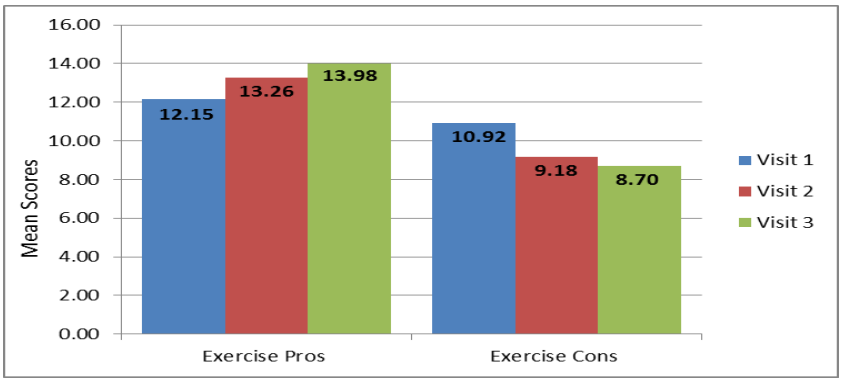


Figure 6. Means score distribution for exercise pros and cons across three visits (n = 125).

Decisional balance for carbohydrate counting is the measure of the pros and cons in an individual's management of carbohydrates consumed. Figure 7 shows the means distribution for exercise pros and exercise cons across the three visits. As shown, there is a trend in the increase scores for pros for carbohydrate counting across the three visits; however there is also an increase in mean of scores for cons from visit one to visit three. Possible reasons for this will be discussed in the analysis of results section.

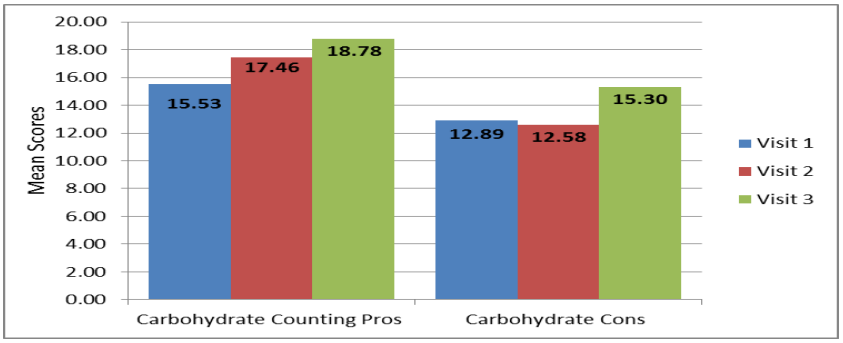


Figure 7. Means score distribution for carbohydrate counting pros and cons across three visits (n = 125).

A one-way ANOVA was used to test the difference between the three visits. Scores significantly differed across the three visits for both exercise pros, $F(2, 372) = 11.166$, $p < .005$, and exercise cons, $F(2, 372) = 8.555$, $p < .005$. Turkey post-hoc comparisons of the three visits indicate that there was a significant difference between visit one ($M = 15.53$, $SD = 5.271$) and visit two ($M = 17.46$, $SD = 5.580$) at $p = .015$, and visit one and visit three ($M = 17.78$, $SD = 5.544$) for carbohydrate counting pros at $p < .005$. For carbohydrate counting cons, the Turkey post-hoc comparison showed a significant difference between visit one ($M = 12.89$, $SD = 4.742$) and visit three ($M = 15.3$, $SD = 6.652$) at $p = .003$; and a significant difference between visit 2 ($M = 12.58$, $SD = 5.567$) and visit 3 at $p < .005$.

The literature suggests that to progress from the contemplation stage to the action stage, the pros of changing behavior should increase by one standard deviation and the cons should decrease approximately one-half standard deviation. This is known as the strong and weak principles of progress. In analyzing for these principles, the sum scores are converted to standard T scores, with a mean of 50 and a standard deviation of 10. Standardizing the scores to T-scores controls for the difference in rating pros versus cons, since it is easier for a participant to rate questions related to pros, rather than cons (Prochaska, 2008a).

In analyzing the data, we examine the maximum amount of increase in T-score in the pros for changing and the maximum decrease in T-scores for cons across the stages.

Just taking the difference of scores between the precontemplation and action stages would not be a clear gauge since change may peak in the pre-action stages and level off or decline in the action stages (Prochaska et al., 1994).

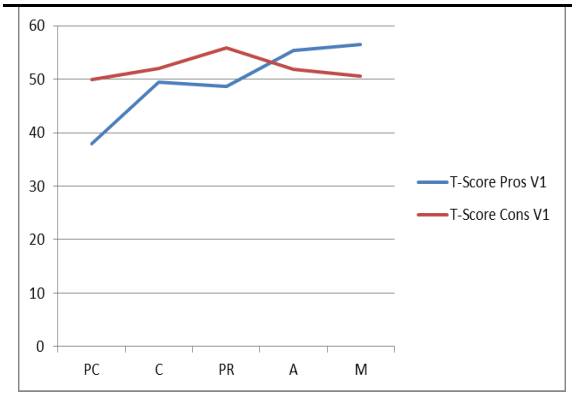
As demonstrated in Table 6, the mean maximum increase in the pros for exercise across all three visits is a T-score of 8.82. This is off by .1 SD, which is very close to the prediction. The maximum decrease in cons for exercise is mean T-score of -3.25, which is off of by 1.75 T-score points, or in other words, .175 SD. This is also very close to the prediction. The maximum mean T-score for carbohydrate counting is 10.53, which is .053 SD off of the prediction. The maximum mean decrease in cons is -.6.59, which is .159 SD off from the prediction. Overall, the decisional balance results obtained agree with the strong and weak principles, which further validate the efficacy of the decisional balance instruments on this particular study's participant population.

Table 5. Maximum increase in T-scores in the pros of healthy behavior change and the maximum decrease in the cons of not changing behaviors for exercise and carbohydrate counting.

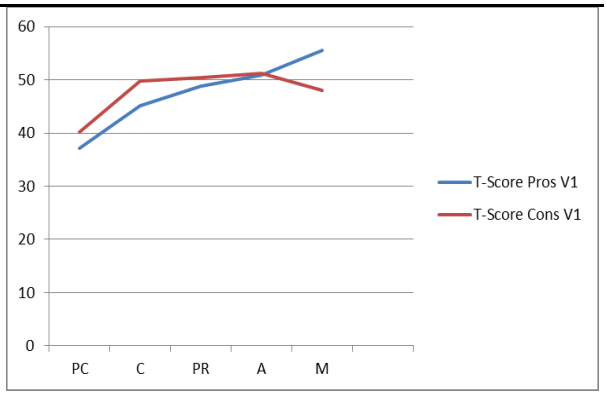
	Maximum Increase	Maximum Decrease
Exercise Visit 1	11.53	-4.08
Exercise Visit 2	6.13	0.82
Exercise Visit 3	8.81	-6.5
Mean for Exercise	*8.82*	*-3.25*
	(2.70)	*(3.73)*
Carb Counting Visit 1	8.03	0.75
Carb Counting Visit 2	11.77	-6.58
Carb Counting Visit 3	11.78	-13.95
Mean for Carb Counting	*10.53*	*-6.59*
	(2.16)	*(4.23)*

In further analysis of the decisional balance results, a descriptive cross-sectional comparison is charted with the stage of change. Study results support the predictable patterns and relationships observed for the acquisition of health behavior from various

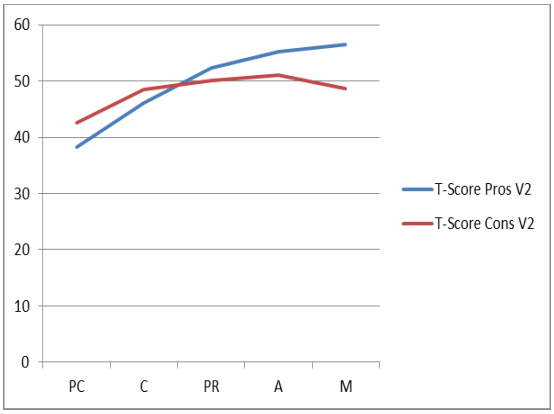
other studies that have used decisional balance measures (Prochaska et al., 1994). This further validates the use of the TTM framework on this participant population. As seen in the graphs below in Figure 8a-f, in the precontemplation stages, the cons of changing, across all visits and both measures, outweigh the pros. At around the contemplation and preparation stages, the pros and cons are close to equal. As predicted, there is a cross-over point when the cons and become lower than the pros as the participant progresses into the action stage (Prochaska et al., 2008). Note, the sum scores are converted to standard T scores, with a mean of 50 and a standard deviation of 10 as further discussed below.



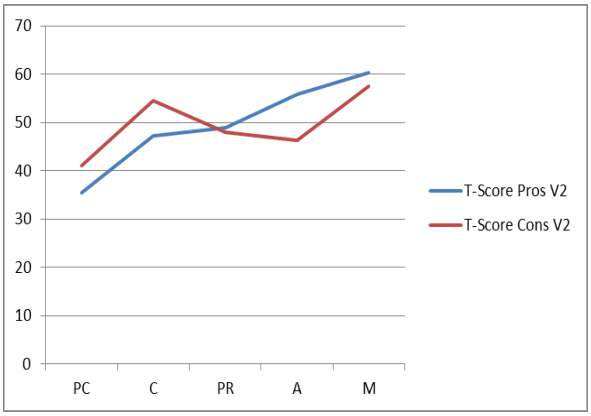
a. Exercise Visit1



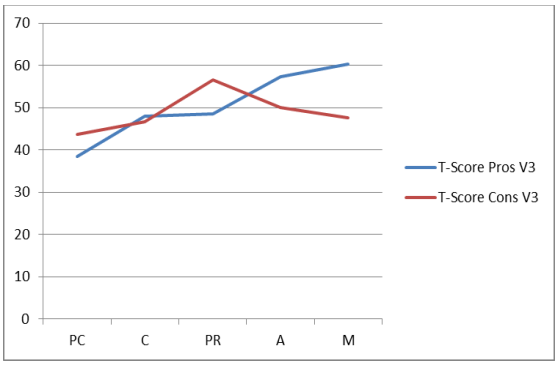
d. Carbohydrate Counting Visit 1



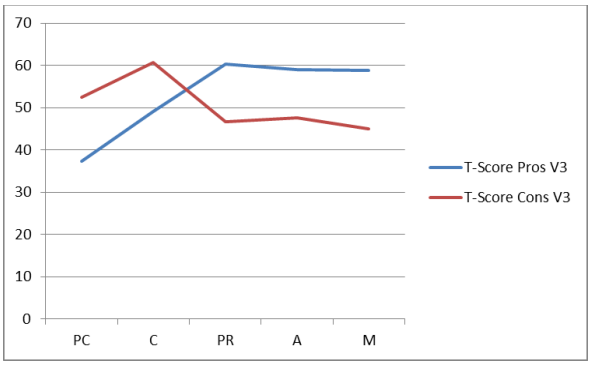
b. Exercise Visit 2



e. Carbohydrate Counting Visit2



c. Exercise Visit 3



f. Carbohydrate Counting Visit 3

Figure 8. The relationship between stage and the decisional balance exercise and carbohydrate counting.

4.3.3 Self-Efficacy

The instruments for self-efficacy measures how confident one is in exercising when other things get in the way, and how confident one is in managing their carbohydrate intake.

For both measures examining exercise and carbohydrate counting self-efficacy, there was no apparent trend demonstrated across the three visits. In a repeated measures one-way analysis of variance (ANOVA) to compare the mean self-efficacy scores, there was no statistical significant interaction across the three visits for either exercise, $F(1.922, 238.315) = .248$, $p = .772$, or carbohydrate counting, $F(1.867, 231.551) = 2.254$, $p = .111$.

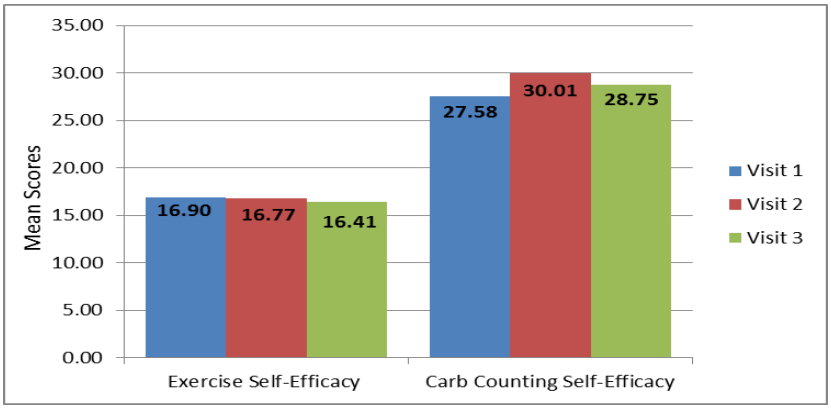


Figure 9. Means distribution for exercise and carbohydrate counting self-efficacy across three visits (n = 125).

4.3.4 Process of Change for Exercise

The processes of change construct are activities that people engage in order to progress through the stages of change. There were 10 basic processes of change that were identified and validated as highly reliable measures (Prochaska, Diclemente, & Fava, 1988). These include the following: 1) consciousness raising, which is awareness about causes and consequences about behaviors; 2) dramatic relief, initial increase in emotions followed by a decrease if action is taken; 3) self-reevaluation, one's cognitive and affective self-assessment on an unhealthy behavior; 4) environmental reevaluation, how one's behavior affects the social environment; 5) self-liberation, the belief that one

can change; 6) social liberation, and increase in social opportunities for those that are deprived; 7) counterconditioning, which is positive substitute behaviors; 8) stimulus control, removing negative cues and incorporating healthy one; 9) contingency management, consequences in either healthy or unhealthy behavior; and 10) helping relationships, which is positive support for healthy behavior change (Prochaska & Velicer, 1997; Prochaska et al., 2008).

The results for processes of change for regular exercise are shown in Figure 10 below. Theory suggests that in the earlier stages of change people apply conscious raising, dramatic relief self-reevaluation and environmental reevaluation (Glanz et al., 2008) (the cognitive processes). As people progress to the action and maintenance stages, people apply self-liberation, helping relationships, counterconditioning, stimulus control and social liberation processes (the experiential processes).

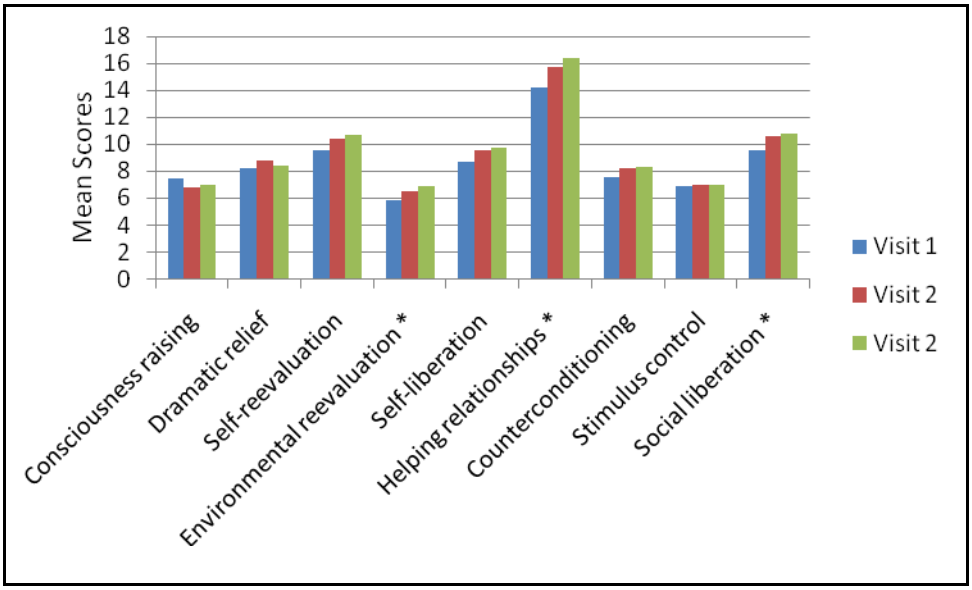


Figure 10. Mean score distribution for processes of change for exercise across three visits.

An analysis of variance demonstrates that the effects for environmental reevaluation, $F(2,371) = 5.632$, $p < .005$, helping relationships, $F(2, 3367) = 4.469$, $p < .05$, and social liberation, $F(2, 371) = 5.448$, $p < .05$ were significantly different across the three visits. Interestingly, these processes all were related to social components;

environmental reevaluation looking at impact of behavior on the social environment; helping relationships seek and use social support; and social liberation, which relates to social norms.

4.3.5 Clinical Measures

The clinical measures were obtained via a review of the participant's electronic health record. The following analyses are of the clinical measures, HbA1c and Level of Retinopathy. Analysis of lipids was not conducted due to the lack of data. Less than 5% of participants had lipid panel laboratory results for either baseline or post-intervention in their electronic health record.

4.3.6 HbA1c

In examining the clinical measures from patient medical records, we were able to obtain 111 of the participant's laboratory data for HbA1c. Only 53 of those patients had a post-intervention HbA1c lab available. A paired-sample t-test was conducted to compare the baseline HbA1c to the post-intervention HbA1c values. Although the HbA1c values decreased, there was no significant difference between the baseline HbA1c ($M = 8.417$, $SD = 2.119$) and the post-intervention HbA1c ($M=8.215$, $SD=2.24$), $t(52)=1.076$, $p > .05$. A one-way between subjects analysis of variance was conducted to compare the effect of HbA1c pre- and post-intervention with all four of the stage of change variables (daily self-management, exercise, carbohydrate counting and smoking cessation) categorized as pre-action and action stages at visit number 3. There was no significant effect of HbA1c on daily self-management, exercise, or carbohydrate counting. The results did show a significant effect on smoking risk and HbA1c, $F(2, 108) = 4.438$, $p < .05$. A post hoc analysis Tukey HSD test showed the mean HbA1c for those that were in the pre-action stage of quitting smoking ($M = 8.066$, SD 2.008) was significantly different than those that reported never have smoked ($M = 9.209$, SD 2.744) at $p < .05$ level of significance.

4.3.7Diagnosis of Diabetic Retinopathy

Results of the non-mydriatic retinal imaging ($n = 125$) diagnosed 16 people with nonproliferative retinopathy and 15 people were diagnosed with proliferative retinopathy.

An average of 6.5% of the images were ungradable by the eye care professional. This could be due to factors, such as, age, presence of central cataract, pupil diameter, iris color, or imager error. None of the patients were diagnosed with macular edema. A chi-square test of independence was performed to examine the relation between retinopathy diagnosis and stage of change for daily self-management, exercise, carbohydrate counting and smoking. There were no significant relations between these variables.

CHAPTER 5
DISCUSSION OF SURVEY RESULTS

5.1 Overview

This section is a discussion of the TTM survey results as it pertains directly to the stated hypotheses regarding behavior change. Again, behavior change is used as a context and measure to how the teleretinal imaging program affected the participants and their diabetes condition.

5.2 Stage of Change

As revealed in the results section, there were statistical significant differences between the visits in all of the stage of change measures (daily self-management, exercise, carbohydrate counting, and smoking cessation.) In this section, the stage of change measures will be further evaluated, specifically addressing Hypothesis 1 below.

Hypothesis 1: Type 2 diabetic patients who are given access to the teleretinal imaging intervention will progress to a *higher stage of change* as dictated by the transtheoretical model over one month and three months.

When promoting health behavior the main goal for healthy behavior is to advance into the action stages. In analyzing the data for the stage of change hypothesis the results are discussed as participants either changing behavior or not yet changing. We categorize this as pre-action, the stages of precontemplation, contemplation, and preparation, or post-action stages, the action and maintenance stages. The results only report those that were in the pre-action stages at visit one. All those in the action stages at visit one are excluded from this analysis.

5.2.1 Daily Self-Management

To reiterate, the daily self-management stage of change instrument assesses if a participant has, intend to have or do not intend to have a self-management action plan to control their diabetes. As shown below in Figure 11 below, by visit three, there was

actually an increase in number of participants reporting to be in the pre-action stages, at 47.7%. This may be due to the large amount of those, 91.9%, that started with no plan at visit one, and having developed a self-management plan by visit three (8.1% had no plan at visit three). Hence those with no self-management plan at visit one, may have moved to the pre-action stages of having a daily self-management plan, but not yet ready for action.

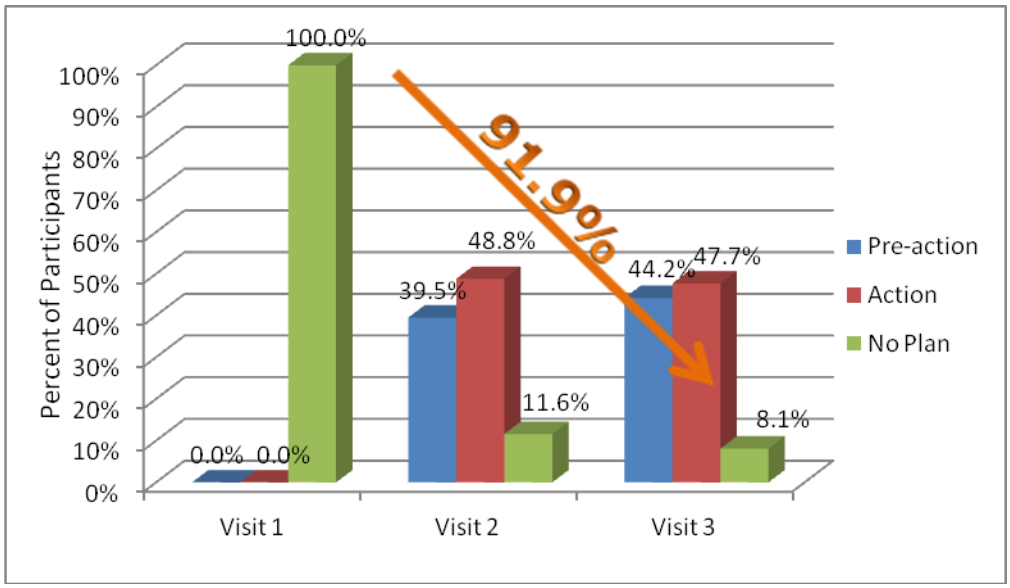


Figure 11. Distribution for pre-action and action stages for daily self-management across three visits.

Looking at the distribution of those that report belonging to the action stages, from visit one to visit two, there is an increase of 48.8%, however, from visit 2 to visit three the frequency of those in the action stages drops 5.6%. A chi-square tests showed that there was significant differences detected, $\chi^2(4, N = 258) = 194.609$, $p < .005$.

Thus, in addressing Hypothesis 1 for the category of daily self-management, we can refute the null hypothesis that that Type 2 diabetic patients who are given access to the teleretinal imaging intervention will not progress to a *later stage of change* as dictated by the transtheoretical model over one month and three months.

5.2.2 Exercise

The stage of change measure for exercise assesses a readiness of one to engage in regular exercise. Overall, the general trend for the measure was an increase in those in the action stages and a decrease of those in the pre-action stages across the three visits. From visit one to visit two, there was a 47.6% increase in the action stages, and from visit two to visit three, there was a 3.9% increase in frequency. From visit one to visit three results showed that 50.5% of participants progressed from pre-action into the action stages (see Figure 12).

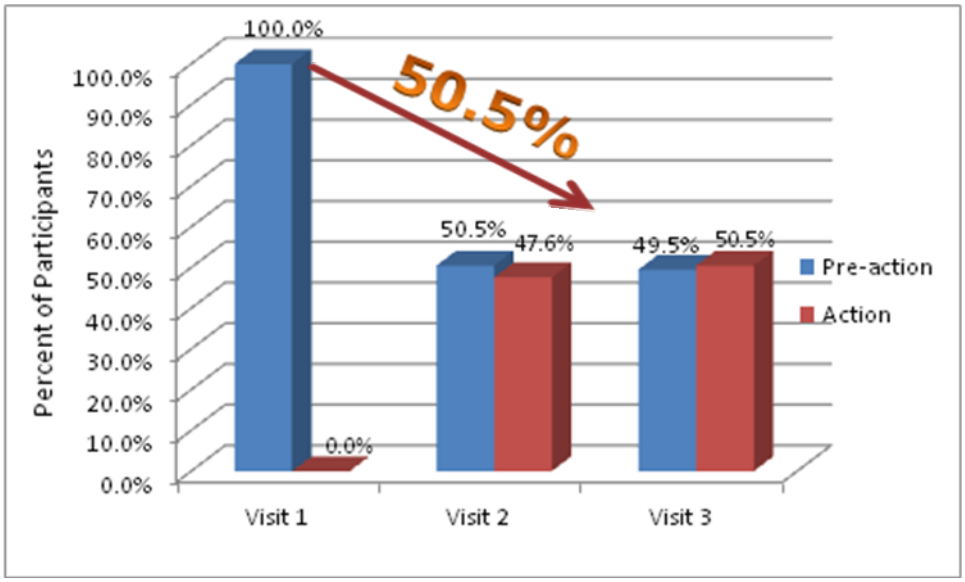


Figure 12. Distribution for pre-action and action stages for exercise across three visits.

a chi-square tests showed that there were significant differences detected, $\chi^2(2, N = 309) = 75.222$, $p < .005$, for visit one to visit three a statically difference was detected.

Thus, in addressing Hypothesis 1 for the category of exercise, we can refute the null hypothesis that that Type 2 diabetic patients who are given access to the teleretinal imaging intervention will not progress to a *later stage of change* as dictated by the transtheoretical model over one month and three months.

5.2.3 Carbohydrate Counting

The survey for stage of change for carbohydrate counting focuses on the management of carbohydrate intake. Figure 13 shows the stage distribution for

carbohydrate counting. Similar to the previous stage of change results, there is statistically significant differences detected, $\chi^2(2, N = 303) = 264.109$, $p < .005$. Overall, from visit one to visit three there was a total percentage increase of those in the action stages of 45.5%. Thus, we can refute the null hypothesis that that Type 2 diabetic patients who are given access to the teleretinal imaging intervention will not progress to a *higher stage of change* as dictated by the transtheoretical model over one month and three months.

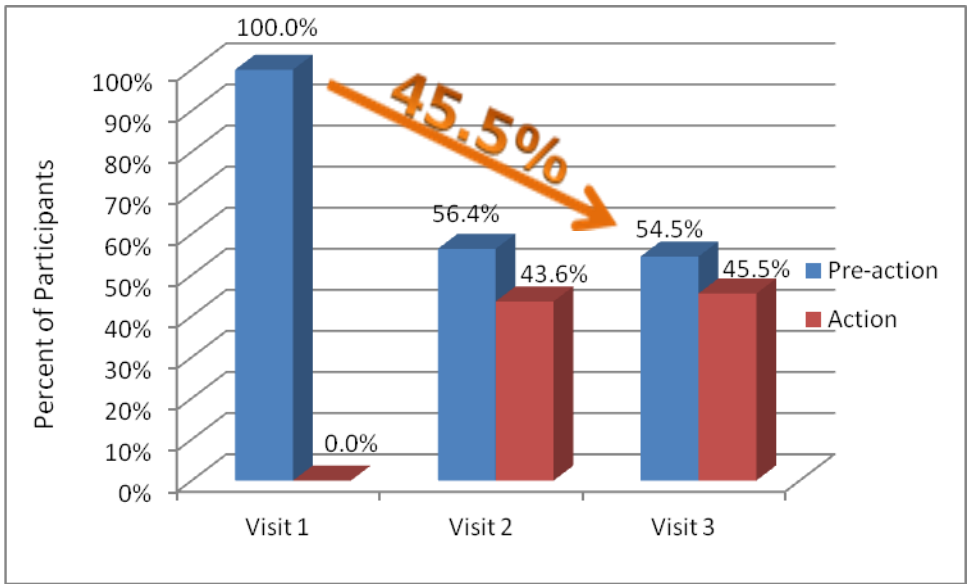


Figure 13. Distribution for pre-action and action stages for carbohydrate counting across three visits.

5.2.4 Smoking Cessation

The smoking cessation stage of change measures the readiness to quit smoking. As seen in Figure 14, there was large decrease of 37% of those in the pre-action stage from visit one to visit two. Looking at the differences between visit one to visit two and visit two to visit there, there was no statistical difference found; however, a statistical difference between visits one and visits three, $\chi^2(2, N = 250) = 9.536$, $p = .008$, was detected.

Since there was no statistical significance between visit one to visit two ($p = .120$), we cannot refute the null hypothesis that that Type 2 diabetic patients who are

given access to the teleretinal imaging intervention will not progress to a *higher stage of change* as dictated by the transtheoretical model over one month and three months.

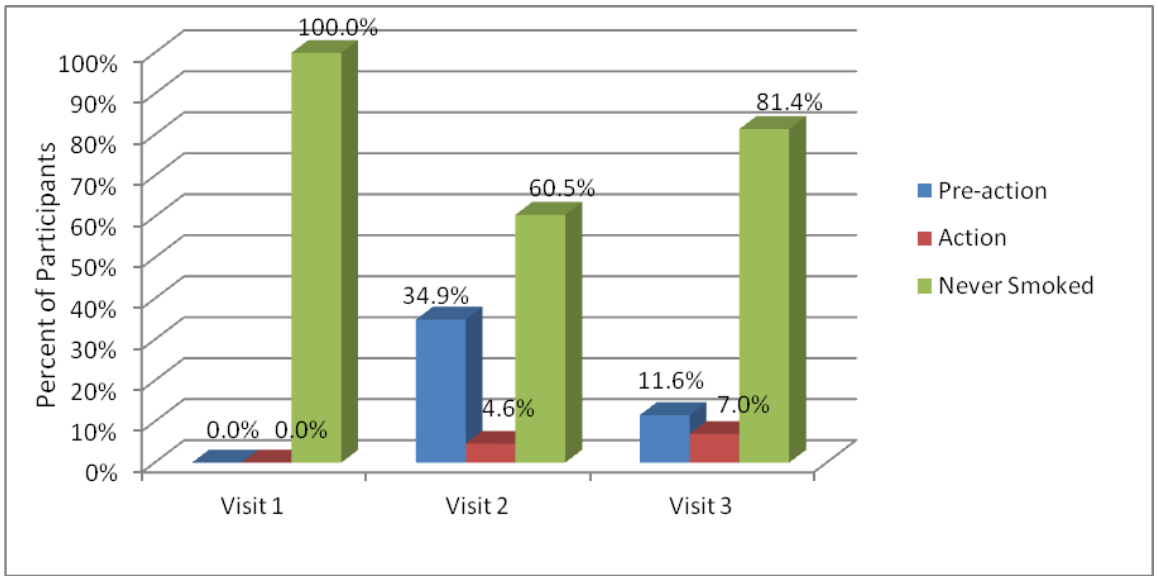


Figure 14. Distribution for pre-action and action stages for smoking cessation across three visits.

5.3 Decisional Balance (Pros and Cons)

Table 7 below displays the mean T-scores for exercise and carbohydrate decisional balance. These measures examine the pros and cons for changing behavior. This study looked at exercise and carbohydrate counting. The decisional balance measures pertain to Hypothesis 2 and Hypothesis 3.

Hypothesis 2: Type 2 diabetic patients who are given access to teleretinal imaging intervention will increase pros for decisional balance by approximately one standard deviation over one month and maintain levels over three months.

Hypothesis 3: Type 2 diabetic patients who are given access to teleretinal imaging intervention will decrease cons for decisional balance by approximately one-half of a standard deviation for decisional balance as dictated by the

transtheoretical model over one month and sustain levels over three months.

Table 6. Mean T-scores for pros and cons across the visits.

	Mean T-Score V1	Mean T-Score V2	Mean T-Score V3
Exercise Pros*	47.78	50.30	51.92
	(9.09)	(9.92)	(10.57)
Exercise Cons*	53.10	49.01	47.89
	(10.94)	(9.95)	(8.23)
Carb Counting Pros*	46.92	50.37	52.71
	(9.39)	(9.94)	(9.88)
Carb Counting Cons*	48.80	48.26	52.95
	(8.15)	(9.56)	(11.43)

* $p < .0005$.

5.3.1 Exercise Pros

In examining the mean T-scores for exercise pros from Visit 1 to Visit 2, there is a T-score increase of 2.52 points. With this being a standard deviation of .252, this does not support the hypothesis, thus the null hypothesis that diabetic patients who are given access to teleretinal imaging intervention will not increase pros for decisional balance by approximately one standard deviation over one month and maintain levels over three months cannot be refuted. However, in a repeated measure ANOVA examining the difference between the mean scores across the three visits, the difference between the visits was statistical significant ($F(1.987, 246.390) = 8.187, p < .005$). Post hoc tests using the Bonferroni correction revealed that the mean T-scores from visit 1 to visit 2 ($p = .038$) and visit 1 to visit 3 ($p = .001$) were statistically significant. Sum scores from visit 2 to visit 3 were not statistically significant. Despite that the change over one month was not one standard deviation, the results do partially support the prediction of Hypothesis 2 that change will occur within the first month.

5.3.2 Exercise Cons

In examining the mean T-scores for exercise cons from Visit 1 to Visit 2, there is a T-score decrease of 4.09 points. This is a standard deviation of .409, which is .091 off of the predicted *approximate* one-half standard deviation. Additionally, from Visit 2 to Visit 3, there is a 1.12 point decrease in mean T-scores. With this being said, we can refute the null hypothesis that diabetic patients who are given access to teleretinal imaging intervention will not decrease cons for decisional balance by approximately one-half of a standard deviation for decisional balance as dictated by the transtheoretical model over one month and sustain levels over three months. Furthermore, in a repeated measure ANOVA examining the difference between the mean scores across the three visits, the difference between the visits was statistical significant ($F(1.872, 232.095) = 11.731$, $p < .005$). Post hoc tests using the Bonferroni correction revealed that the mean T-scores from visit 1 to visit 2 ($p = .005$) and visit 1 to visit 3 ($p < .005$) were statistically significant. Sum scores from visit 2 to visit 3 were not statistically significant, with supports the idea of Hypothesis 3 that change will occur within the first month.

5.3.3 Carbohydrate Pros

In examining the mean T-scores for carbohydrate pros from Visit 1 to Visit 2, there is a T-score increase of 3.45 points. With this being a standard deviation of .345, this does not support the hypothesis, thus the null hypothesis that diabetic patients who are given access to teleretinal imaging intervention will NOT increase pros for decisional balance by approximately one standard deviation over one month and maintain levels over three months cannot be refuted. However, in a repeated measure ANOVA examining the difference between the mean scores across the three visits, the difference between the visits was statistical significant *($F(1.838, 227.925) = 13.954$, $p < .005$)*. Post hoc tests using the Bonferroni correction revealed that the mean T-scores between all three visits were statistically significant ($p < .005$).

5.3.4 Carbohydrate Cons

In examining the mean T-scores for carbohydrate cons from Visit 1 to Visit 2, there is a T-score decrease of 0.54 points. This is a standard deviation of .054, which is

not close to the predicted *approximate* one-half standard deviation. Hence, we cannot refute the null hypothesis that diabetic patients who are given access to teleretinal imaging intervention will not decrease cons for decisional balance by approximately one-half of a standard deviation for decisional balance as dictated by the transtheoretical model over one month and sustain levels over three months. However, in a repeated measure ANOVA examining the difference between the mean scores across the three visits, the difference between the visits was statistical *significant* $(F(1.977, 245.150) = 8.794, p < .005)$. Post hoc tests using the Bonferroni correction revealed that the mean T-scores from visit 1 to visit 2 was not statistically significant, yet differences from visit 1 to visit 3 ($p = .004$), and from visit 2 to 3 ($p = .001$) were statistically significant.

5.4 Self-Efficacy (Exercise and Carbohydrate Counting)

The self-efficacy instruments measured how confident the participant is in exercising when other things get in the way, and how confident they are in managing their carbohydrate intake. These surveys address Hypothesis 4 as follows.

Hypothesis 4: Type 2 diabetic patients who are given access to teleretinal imaging intervention will demonstrate a linear *increase in situation-specific confidence (self-efficacy)* as over one month and sustain levels over three months.

In conducting repeated measures ANOVA, there was no statistical significance detected for neither exercise self-efficacy, nor carbohydrate counting self-efficacy, across the three visits, thus the null for self-efficacy cannot be refuted for either exercise or carbohydrate. The means and standard deviations for all three visits are displayed in Table 8.

Table 7. Means for self-efficacy by visit number.

	Visit 1	*Visit 2*	*Visit 3*	*N*
Exercise Self Efficacy	16.90 (5.82)	16.77 (6.82)	16.41 (8.07)	125
Carb Counting Self Efficacy	27.58 (10.07)	30.01 (10.10)	28.75 (11..69)	125

5.4 Processes of Change (Exercise)

The results for processes of change address the following hypothesis.

Hypothesis 5: Type 2 diabetic patients who are given access to their retinal images and PHP will *increase in their use of appropriate processes of change* in *exercise* as dictated by the transtheoretical model over three months.

In examining the appropriate processes of change, a previous study has shown that in minority populations, specifically Native Hawaiian, the role of social support is important (Mau, 2001). As shown in the study results, the processes related to social components all had significant differences across the three visits: environmental reevaluation, $F(2,371) = 5.632$, $p < .005$, helping relationships, $F(2, 3367) = 4.469$, $p < .05$, and social liberation, $F(2, 371) = 5.448$, $p < .05$. These results further support the importance of social support.

Based on the assumption that social support is relevant to the study population, we can conclude that the null hypothesis, Type 2 diabetic patients who are given access to their retinal images and PHP will not increase in their use of appropriate processes of change in exercise as dictated by the transtheoretical model over three months, can be refuted.

5.5 Clinical Measure HbA1c

The following is the relevant hypothesis for the clinical measure of HbA1c.

Hypothesis 6: Type 2 diabetic patients who are given access to their retinal images and PHP will *improve clinical measures* over three months.

As stated previously, results for clinical measures were obtained from the participants electronic health record, only 111 of the participant's laboratory data for HbA1c was available within three months prior of the intervention. Only 53 of those patients had a post-intervention HbA1c lab available. A paired-sample t-test was conducted to compare the baseline HbA1c to the post-intervention HbA1c values. Although the HbA1c values decreased, as stated in the results section, there was no significant difference between the baseline HbA1c ($M = 8.417$, $SD = 2.119$) and the post-intervention HbA1c ($M=8.215$, $SD=2.24$), $t(52)=1.076$, $p > .05$. Thus, the null hypothesis for Hypothesis 6 cannot be refuted.

CHAPTER 6
AN ANALYSIS OF THE FOCUS GROUPS

6.1 Overview

Focus groups were used as a follow-up to the TTM surveys. They also further explored computer and Internet usage and how the teleretinal imaging program affected health behavior. Focus groups were conducted until data saturation was achieved and themes start to repeat. It has been suggested in the literature that the ideal number of people for a group is from seven to ten people and four group sessions tend to be sufficient (Nyamathi & Shuler, 1990). For this dissertation, four focus group sessions were held. All focus groups were held in the administrative conference room at the Waianae Coast Comprehensive Health Center (WCCHC). The sessions were limited to approximately one hour. Lunch was provided for all participants after the group session. The focus group participants were generally homogenous and most did not know each other. Because participants were all diabetic patients at the Waianae Coast Comprehensive Health Center, there was a general feeling of solidarity and openness to sharing. This included in the discussions food, culture, computer use and struggles with diabetes.

6.2 Participant Characteristics

A description of all consented study participants is described in Chapter 5. The following is a description of the participants that volunteered to participant in a focus group session. Overall, there were 25 volunteers that participated, 50% female, mean age 56, mean education level is 12th grade, mean BMI 36.9, 44% Native Hawaiian, 44% unemployed, 6% retired.

Group One

Seven participants attended the first focus group interview on Tuesday, August 30th, 2011, from 11am until 12:00 noon. The participant demographics are as follows: n=7; mean age=49 (ages 27, 39, 44, 50, 53, 63 and 66), four females, three males; six Native Hawaiian, one Portuguese. Six of the participants reported highest level of

education is 12th grade, and one had some college. Three reported retired, two unemployed, one homemaker, and one unknown employment status. Seven self-reported health status as *Good*, one reported health status as *Fair*.

Group Two

Eight participants attended the second focus group interview on October 11th, 2011, from11am until 12 noon. The participant demographics are as follows: n=8, mean age=50 (ages 38, 42. 43, 47, 53, 57, 58 and 61), four females and four males, five Native Hawaiian, two Caucasian and one reported other. All participants reported 12th grade as highest level of education. Five reported unemployed and three reported retired. Four self-reported health status as *Good*, one reported *Very Good* and two reported *Fair*.

Group Three

Five participants attended the second focus group interview on November 13th, 2011, from 11am until 12 noon. The participant demographics are as follows: n=5, mean age=58 (ages 41, 53, 54, 63 and 77), three females and two males, all reported primary ethnic background as Native Hawaiian. Four participants reported 12th grade as highest level of education, one reported some college. Two reported unemployed, two reported retired and one reported working full-time. Four self-reported health status as *Good* and one reported *Very Good*.

Group Four

Five participants attended the second focus group interview on January 9th, 2012, from 11am until 12 noon. The participant demographics are as follows: n=5, mean age=64 (ages 59, 61, 62, 70 and 70), three females and two males, one reported primary ethnic background as Native Hawaiian, two Caucasian, one Filipino, and one Japanese. Four participants reported 12th grade as highest level of education, one reported some college. Four reported unemployed and one reported retired. Two self-reported health status as *Good*, two reported *Very Good* and one reported *Fair*.

6.3 Results

Key areas that were focused on were as follows: thoughts on the intervention of teleretinal imaging; how technology affects motivation factors of behavior change, obstacles in changing health behavior; the use of technology for health information; motivators and barriers to behavior change as it related to diabetes; and comments on the participation in the study in general. Several key themes emerged from the focus group discussions, which can be categorized into three different areas: 1) computer technology, includes Internet, eHealth, and digital retinal imaging; 2) motivators for behavior change in diabetes management; and 3) barriers to behavior change in diabetes management. See Table 9 for an overview of the themes based on category.

Table 8. Categories and key themes.

Category	Key Themes
Computers, Internet, eHealth, digital retinal imaging	*Access to Computers, Internet, eHealth* • **Cost Barrier** • **Low Computer and eHealth Literacy** • **Family Encouragement to Learn** • **Knowledge is good** *Digital retinal imaging* • **Learned from imaging process** – empowered by being able to take action • **Easy, no discomfort**
Motivators for behavior change	• **Family** – grandchildren, not to be a burden on others, encouragement/support • **Social Support –** WCCHC**,** group support, socializing, getting out, meeting new people • **Fear** – dialysis, losing legs, losing sight, quality of life
Barriers to behavior change	• **Family** - lack of support, enablers • **Depression** – state of mind, depression, lazy, low self-esteem, lack of confidence, lack of self-motivation, boredom, no time • **Food and Culture**– love for food, culture

6.3.1 Computer Technology and Retinal Imaging

Access to Technology

Of the 25 total focus group participants 15 (60%) of the participants reported having no computers at their home. The overall results from the demographics survey, revealed that of all the study participants 66.4% of the study participants (n = 125) stated that they have access to the Internet in their home. It was not differentiated if this access was via a computer or cellular phone. Despite that the majority of participants responded that they have Internet access, according to the access logs for the online patient portal and educational material, only six participants accessed the portal (n = 125), which is only 5% of the participant population. One person accessed it twice; the remaining four only accessed the portal only one time. Results from the demographics survey showed no statistical difference detected between home Internet access when compared with variables of employment, sex, ethnic background, educational level, income level, self-reported health status, or BMI.

When the barriers to access were discussed, many participants felt that it was difficult to obtain access to computers and the Internet. It was mentioned that that the Waianae Public Library has access to computers and the Internet, however, lines for use are long. Many stated that they had relatives that owned computers, but they do not utilize them regularly. There were no other known places in Waianae for public access to the Internet. Cost of equipment and Internet access, and having broken computers were discussed as barriers. The Waianae Coast Comprehensive Health Center does not provide any computer or Internet access.

Computer and eHealth Literacy

One of the predominant themes that came out when discussing Internet access and surfing the web, was the lack of knowledge on how to surf the web. This could explain the lack of participants that accessed the study portal. Of the ten focus group participants that reported having a computer with Internet available to them, four reported that they do not know how to access the Internet. It was discussed that children or grandchildren use the computer surf the net, but they do not know how to themselves. This may be reflected on the participant population. From the demographics survey, a chi-square tests

showed that there was a significant differences detected between surfing the Internet and employment status, $\chi^2(28, N = 123) = 51.737$, $p = .004$, 87% of those that never surf the web reported being either unemployed or retired. Of the focus group participants, only one reported as being employed full-time. All others were either unemployed or retired, with one participant having an unknown employment status (n = 25). Overall, 42.4% (n = 123) of the participants answered that they never surf the Internet. There was also no statistical difference detected between surfing the web when compared with variables of sex, ethnic background, educational level, income level, self-reported health status, or BMI.

This reveals that access to technology was not always associated to lack of use. Of all the focus group participants (n = 25), only two of the participants discussed regularly going on the WWW. These two also enthusiastically stated that they obtain health information from various sources, such as WebMD.com. A few of the participants stated that they have Internet on their cellular phone. Of them, only one of the focus group participants stated that they use their cellular phone for access the WWW, but only to gamble. One participant stated that he tried access health information on the Internet, but could not find anything. Overall, the majority of participants discussed either not having access to the Internet, or not knowing how to access the WWW.

However consistent across all participants was the willingness to learn and become more literate with both the computer and eHealth information. Participants were enthusiastic about the information that they have learned from the study. Participants also stated that if courses were available, they are willing to attend. Several participants stated that family members encourage the use of the Internet, especially children and grandchildren. The few that did access found the information to be helpful and empowering. For those that did say that they surf the WWW, there were positive statements.

Table 9. Participant's statements on barriers to Internet usage.

Key Theme	**Participant Statements**
Cost Barrier	• *"I don't have money [if had computer], would love it"* (Female, 47 years old) • *"Yeah…I'm illiterate to that… It cost money, that stuff..."* (Male, 72 years old)
Computer and eHealth Literacy Barrier	• *"I went on with my sister once, only my sister know how to work it."* (Female, 40 years old) • *"I have a computer but only my grandson uses it, I don't know how."* (Female, 62 years old) • *"Don't know how to use… only know how to play texas holdum."* (Female, 54 years old) • *"I have a phone you can go on the Internet but don't know how to use."* (Female, 54 years old) • *"I don't know I was looking it up and it shut off… I looking for the eye stuff and any part of the diabetes stuff… nothing came up…I never click on um."* (Male, 27 years old) • *"Maybe it's a good idea, but, I don't know, for me I get the old style, I don't bother."* (Male, 72 years old)
Family encouragement	• *"Yeah, I would go classes if someone gave me a computer."* (Male, 72 years old) • *"My son says, Dad you gotta learn… you gotta do it yourself and learn the computer."* (Male, 54 years old) • *"I don't have computers, but my brother has two or three… but you never know I might end up …over there and trying to look up diabetes."* (Male, 66 years old)

Table 9. (Continued) Participant's statements on barriers to Internet usage

Knowledge is good	• *"With modern technology everyone is being aware, and for those that are programs like us, we are be taught that alcohol does have an effect on our eyes."* (Male, 54 years old) • *"I did and I shared it with my family and kids, so I made it aware to them, said look, if you don't take care of yourself this is what could happen, if you don't want that to happen, these are these are the step you have to take… also from other places [websites]."* (Male, 50 years old) • *"The computer it helps a lot, because, I mean for myself, the more information I got, I can balance the scales, because now I'm retaining more information than before, so now the more information I get, I can tweak my plan and my train of thought in how I'm going to make things easier for me…so the more knowledge I'm gaining, the more it is motivating me to work in different ways, instead of the same, same."* (Male, 51 years old)

Digital Retinal Imaging

Overall, all the participants had positive comments about the digital retinal imaging. Participants commented that they liked that the imaging did not cause any discomfort and was a motivating factor in their diabetes management. Many commented that they were relieved that the results of the image showed no signs of eye disease. Hence, a common theme was the idea that doing the digital retinal imaging was a form of empowerment; a way to take responsibility for their health. Undertaking the retinal imaging procedure is a form of taking charge and seen as a positive step in diabetes management. This was especially pertinent since several of the participants stated this in conjunction with family having suffered from diabetic eye disease.

"Taking the images of my eyes was an active procedure, you know, I have to scrub my feet and go to the doctors and take the tests, but those are outward physical things, I know one day they may cut off my feet if I don't take care of it. But it is really hard to get up in the morning and take care of yourself…it is double breath in the morning ...having the actual test done it for me kinda made me think more of my body …once I lose my eye ...you know."(Male, 53 years of age)

"My dad he died from diabetes and then he had both cataract surgeries in both of his eyes, so by me seeing the pictures of my own eyes and seeing the different stages as I progress in getting older gives me an advantage and let me know how well I'm doing as far as fighting the battle and making sure my eyes and the rest of my body stays good, so its important." (Male, 50 years of age)

"My dad has diabetes, he had two surgeries on his eye, so when I see my images, at least it tell me if I have a problem and I can prevent it from getting worse and control my diabetes, so it is very interesting to learn." (Female, 39 years of age)

As part of the study procedure, all the patients received a copy of their retinal images. When discussed, the impact that seeing their images had on them was very minimal. Most stated that it was good; there was no other strong comment on the images.

6.3.2 Motivators to behavior change

There were several different motivating factors for behavior change discussed in the focus groups. Three key themes that emerged were family, social support and fear. This concurs with the TTM results in the processes of change, where social components were revealed to have an influence with this population. Other motivating factors that the participants discussed included progress in diet and weight loss, obtaining medical

insurance, improved medication, getting off medication, awareness and knowledge, and new procedures and medical possibilities.

Family

When discussing motivating factors for behavior change in positively managing their diabetes, one of the most prominent themes was the influence of family. All the participants had family member that have suffered from complications of diabetes. Participants discussed how experiencing family member debilitated from diabetes complications influenced them to take care better of their own health. They discussed not wanting to end up with similar health problems. Many also discussed having parents or family members who died from diabetes and other health related chronic diseases. On the positive side, a large number of participants were motivated by being able enjoy their grandchildren. Many also stated that they do not want to be burden on family, and they wanted to be a good example. Also, there were many statements on the positive encouragement that family members have given them to improve and manage their diabetes. This included encouragement to exercise, reminders to take medication and check blood sugar, and encouragement to eat healthy.

Social Support

Social support was another key theme that emerged as a motivating factor for behavior change. Several participants discussed that the group participation was helpful and encouraging. It reminded them that they are not alone in their struggles. Seeing others improve their health is also motivating, it gave them hope that they also can improve. The participants overwhelming stated that they enjoyed the study and meeting new people. The staff and programs at the Waianae Coast Comprehensive Health Center were also well received. This included support and encouragement from the staff (trainers, counselors, and administrators), the fitness center and wellness programs, and support from the clinical providers (physicians, nurses and dieticians).

Fear

Another theme in the focus group discussions that was a motivating factor for change was fear. This included fear as a result of seeing family members suffer and die,

as well as, fear that their health will degrade in such a way. Several people stated that they cared for family member or friends whom lost toes and legs, lost sight, and had serious debilitating health problems due complications. There was fear that they would go down this same path and suffer. Many stated that they wanted to live; they did not want to die.

Table 10. Motivators for behavior change.

Key Theme	Participant Statements
Family	• *"I have 14 grandchildren and I don't want to miss anything."* (Female, 61 years old) • *"After I had one granddaughter, my whole life changed, so I can see her."* (Female, 39 years of age) • ***"****Family they don't want to see you going around with one leg gone, two legs… man that is worse they have to do all the work for you, for me."* (Male, 72 years old) • *"I did know about as far as the cataracts or glaucoma and stuff like that until my Dad started getting sick. So once my dad starting getting sick.. as they starting getting more advance and more technical and then when they started offering taking pictures of the eyes and stuff, I really started to get into that because I was concerned about my eyes, because my Dad also wore glasses, now since they have it, I want to make sure that you know I get my pictures done every year so if something comes up at least they can spot it right away always and take control of the situation."* (Male, 50 years old) • *"My old man changed me, he's the one that motivates me…he works, he's a carpenter, we get up 4:30-4:00 o'clock in the morning, we get up and do our walk, then he takes a bath and goes to work. If he can do it, I can do it… If I start to slow down he pushes me."* (Female, 53 years old)

Table 10. (Continued) Motivators for behavior change

	• *"My mom had diabetes, my dad had diabetes… now me and him [son], I gotta take care of him and myself, so it's good to learn."*(Female, 63 years old)
Social Support	• *"I love meeting people on the road… you know it's awesome."* (Male, 41 years old) • *"We should have more of this kind, group session; it's good to learn from each other."* (Female, 44) • *"Sure like the small group, sharing and discussing, its like when I go exercise, I didn't start because of the fear of you know how I look and I can't do it, I look strong, but hey how come this guy looks strong but only lifted 10 lbs, hey I'm just starting off… but I love small groups and helps that I see people share, it gives me the confidence the confidence to manage more in my life… I'm not alone."(*Male, 53 years old)
Fear	• *"I should be worried…My mom had diabetes, and by the time she passed away she had no sight, she had no hearing…she cut off her limbs, her finger fell off, big hole on her butt on the left side came off, and gangrene on her vagina and butt hole, and then she died…I don't want to be that way." "I don't want to be where my mom was."(*Female, 53 years old) • **"***My family has bad diabetes, my aunty lost her eye sight, my uncle lost his leg, my grandma … died."* (Female, 47 years old) • *"My eating habits changed when I took the test, because I run a narcotics anonymous meeting, and I have this one blind guy that comes, and I don't want to lose my sight, so I better start eating right*."(Female, 42 years old) • *"I lost my mom to diabetes, I saw her die…. She was only 66."(*Male, 53 years old)

Table 10. (Continued) Motivators for behavior change

	• *"What motivated me to exercise was seeing all the negative that can happen to a diabetic person, you know, unfortunate people you know they lose their toes amputation, they kidneys fail, they look sickly, it's the diabetes controlling them, I'm going to control my diabetes and not let it kill me… I really have a problem with my food, buy I say hey I don't want to lose a part of my body… have a hard time controlling my food."* (Male, 50 years of age)

6.3.3 Barriers to behavior change

In discussing barriers to change, four key themes emerged: family; lack of support; depression and life situations; and food and culture. Other barriers to change that were discussed include misleading information, lack of transportation, cost of medications, lack of knowledge, insurance issues and other health issues.

Family

Family stood out to be not only a strong motivator for behavior change, but also a strong barrier to behavior change. Several participants commented on how family members are discouraging factors and even enabling factors for bad behavior. For example this includes being forced to eat food during childhood, influencing bad behaviors such as drugs and alcohol abuse, and having no control since it runs it the family. Several participants discussed how their family members suffered or died from the complication of diabetes and the thought that this would be their fate since they have inherited the disease.

Depression

Depression in many forms emerged as a barrier to behavior change. This included depression from hardships in life, setback in health status or other health issues, and fear of what other think. Many participants discussed feeling discouraged and beaten by the disease at some point. However, most all the participants in the focus groups talked about the need to struggle through this mental state and to move forward.

Food and Culture

Hawaii and Native Hawaiians have a rich culture that includes family gatherings and plenty of food. Most all participants enthusiastically expressed their love for good food. During the discussion the feel of the conversation lightened up when the participants discussed the food they loved and described the different recipes and foods they ate which now, they admitted, have contributed to their decline in health. Many discussed how they now have to restrict their diets because of their diagnosis of diabetes.

Table 11. Barriers for behavior change.

Key Theme	Participant Statements
Family	• "*My husband…discourages me, he calls me like names and stuff…"* (Female, 42 years of age) • "*Same thing, my friend doesn't support me in my exercise"* (Female, 57 years of age) • "*We're all ohana, we all go down together."* (Female, 63 years of age)
Depression	• *"sometimes for me is when hardship and despair comes, you know, when situations comes in your life, and I've been poking myself and you know taking my medicines, then I go to the doctor, you put yourself in a state a mind… I don't want to change… so I know I need to go back to the positive."* (Female, 38 years of age)

Table 11. (Continued) Barriers for Behavior change

Food and Culture	• *"to me today it is all about what you eat, you know for your diabetes, cause us guys were raised don't waste your food…you don't eat you get a [smack]"* (Female, 53) • *"I'm really really stubborn when it comes to food…I have a dietician and her and I don't get along because I can tell her that I can eat two pack of bacon and she tell me just to have two pieces, I say you touch my food and I'm not going to be happy…when it comes to food, I get hard hard time… I really struggle with my food…"* (Female, 39 years old) • *"When I found out I had diabetes, the big change in my eating was I cut half of the eating down, before if I don't have diabetes, hoo, hana hou, big plate, Mt. Ka'ala size…now only one small plate or bowl."* (Female, 39 years of age) • *"I eat the fat in laulau…if you don't eat the fat they go ohhh"* (Female, 39 years of age) • *"You take the laulau and fry it in butter…yumm..Waianae side we eat."* (Female, 39 years old) • *"I'm um struggling along, like I said, I didn't know I had diabetes till I was in my fifty's, so I ate everything, ate anything, and today like trying to put on the brakes is like holy craps, but I'm really working on it, trying."* (Female, 63 years old) • *"Bad habit, I love my cookies, my ice cream, I love my ice cream."* (Female, 53 years old) • *"Did you know vegetables are so good, I never knew that, I never knew that… I was never a vegetable eater… put the meat and rice in front of me and that's it"* (Female, 53 years old) • *"I could sit down and put away two large pizzas, just by myself..ahhh."* (Male, 50 years of age)

6.4 Discussion

Several key themes emerged though all four of the focus group discussions. Overall the general feel was that the intervention of the digital retinal imaging, health portal and educational material was a positive experience. Despite the lack of accessing the Internet and web portal, all participants discussed how learning about digital imaging and diabetic disease was an encouraging component in taking personal responsibility for their health. It is a source of empowerment. Many of the participants stated that they are in the process of learning diabetes self-management and would like to learn more. This enthusiasm to learn is consistent with other studies specifically looking at the health literacy and utilizing patient web portals, which found that despite the lack of use of Internet technology, people are enthusiastic and would like to learn and utilize health information technology for diabetes care (Watson, Bell, Kvedar, & Grant, 2008).

Based on the focus group discussions, a general low eHealth literacy rate was detected. This was demonstrated by the lack of knowledge in both accessing the Internet and accessing information on the Internet. Only one participant was able to discuss specific websites where health information is available. Very few participants were familiar and able to search for health information on the Internet at all; this was consistent with those that also had a computer available to them. Other research studies that examined underserved populations also found this to be true. For example, a study looking at low-income adults in the Midwestern United States also found that limited health literacy was not correlated with access to computers and the Internet. This study found that low-income individuals have access to the Internet, but are not to utilizing this resource (Jensen, 2010). Researchers in this study speculate that the information retrieved on the WWW may be overwhelming and too daunting for those with limited health literacy to navigate. In this study's focus group discussions that asked about surfing the web, there also was some confusion on how to search for information; many not knowing how to get on the Internet all together.

Key themes in both barriers to and motivators for changing health behavior were prominent in the discussions. This included family, social support and community. This is not surprising since in Native Hawaiian culture, the family, or *'ohana* is an integral part of health and wellness. Family in this context extends to relationships to members in

the community, outside of direct relations, that have shared values, beliefs, expectations and goals. *'Ohana* is also a key source for support and identity (Mcubbin, 2006), and has been associated with improved health behavior (Mau, 2001). The importance of *'ohana* has also been demonstrated with focus groups used to investigate other issues with Native Hawaiians. A focus group study conducted to examine the supports and obstacles to cancer survival for Native Hawaiians found family, friends and the community as key themes. Religion, spiritual support, and the desire to help others were also social components that were found to be important. In contrast, one study found that lack of support as a key obstacle for Native Hawaiians (Braun, 2002). Another focus group study exploring barriers and supports for smoking cessation in a Native Hawaiian population found that social support was a key motivating factor and barrier for smoking cessation (Kaholokula, 2008).

Similarly, with other minority groups in the United States, family or social support was found to be important. A study examining the facilitators and barriers to diabetes self-management with African-American adults using focus groups found that key facilitators to positive self-management behavior was linked critically to family support, the presence of a daily routine, acquisition of knowledge about diabetes self-management, and peer support in sharing and gaining knowledge. Barriers were time consumed managing their diabetes, lack of self-control, pain associated with blood glucose monitoring, and forgetfulness in tasks to manage their diabetes (Chlebowy, Hood, & LaJoie, 2010). It has also been found that including family support as a tool for improving diabetes can be effective (Keogh, 2011).

Thus there has been a strong push for community oriented support networks for managing diabetes. A paper conducting a systematic review of diabetes interventions, focusing on socially disadvantaged adults with type 1 or type 2 diabetes, demonstrated that tailoring programs culturally, utilizing lay people or community educators leading the intervention, has shown to improve diabetes care among socially disadvantaged populations (Glazier, Bajcar, Kennie, & Willson, 2006). With the wide usage and improved applications of social networking technology there is the potential for community support to be offered over the Internet. This may be especially advantageous for those who live in rural, hard to reach areas. Tools, such as Facebook, are already

being used to share information, offer guidance, and used as a tool for emotional support for those living with diabetes (Green, 2010). Opportunities with applications of the Internet and the WWW for diabetes management cannot be ignored. Thus future efforts need to further address the digital divide and programs need to be implemented to close the gap.

CHAPTER 7
OVERALL DISCUSSION AND CONCLUSIONS

7.1 Summary of Results

Overall, based on the focus group interview, all the participants felt that the participating in the study was a positive experience. All were enthusiastic about learning more about diabetes and how technology can be used as a tool to improve their health. All the focus group participants agreed that the retinal imaging was not invasive and provided little discomfort. Participants in the focus groups discussed how learning about digital imaging and diabetic eye disease was a component to taking responsibility for their health; the need to learn more about diabetes and diabetes self-management were common themes. Results from the demographic survey, focus groups and access logs for the health portal showed that the participants were not regular users of the Internet. From the demographic survey, only 12.8% of the participants answered that they surf the WWW every day; 42.4% stated that they never surf the WWW. Cost, access to computers and low computer literacy was revealed to be barriers to using eHealth technology. Despite that the use of computers and eHealth literacy was low, all participants in the focus groups had positive reactions to the intervention and were enthusiastic to learn more about computers, the Internet, and eHealth information.

Family was a key theme in the use of computers, improving eHealth literacy, and a key influence as a motivator *and* barrier for health behavior change. Family was also a key factor in the concept of fear being a motivating factor for behavior change. Fear that they did not want to suffer from the complications of diabetes like other family members had experienced. Additionally, social support was a key theme as a motivator for behavior change. Participants enjoyed communicating with each other; they had positive comments about group interaction and the feeling that they were not alone in their diabetes struggle. Barriers to behavior change included the lack of support from family, food, culture and depression. The food culture of the participants was a theme that impacted the participants a great deal: the love for food; the lack of control when it came to food; and the culturally high fat foods that they loved. Depression was also a

key barrier; this included low self-esteem, lack of confidence, and lack of self-motivation.

Results from the TTM surveys revealed statistically significant differences in the transition from pre-action to action stages of exercise, carbohydrate counting and smoking cessation using the TTM stages of change. For the measure of daily self-management there was a significant difference in the transition from no self-management plan to having a plan. There were significant differences in the pros for changing and the cons of changes for exercise and carbohydrate counting. The processes related to social interaction all had significant differences across the three visits, this included the following variables: environmental reevaluation, which looked at impact of behavior on the social environment; helping relationships, which involves seeking and using social support; and social liberation, which relates to following social norms. There were no differences over the visits in self-efficacy in exercise and carbohydrate counting.

The TTM surveys were further validated on this population supporting the predictable patterns and relationships observed for the acquisition of health behavior from various other studies that have used decisional balance measures (Prochaska et al., 1994). This was demonstrated a cross-problem comparison using the results from the decisional balance instruments. As expected, since there was progression from pre-action to action stages of change in exercise and carbohydrate counting, the change was also demonstrated by the cross over between increase in pros and decrease in cons.

Results of the non-mydriatic retinal imaging (n = 125) found that overall 21 participants, or 16.8%, were referred to their primary care physician for further investigation. There were 31 images diagnosed with retinopathy, for some, diagnosis may have been both on the right and left eye. These results from the retinal imaging were consistent with other studies that utilized digital retinal imaging. For example in a large study of 1,943 patients that were screened for diabetic retinopathy, 416, or 21% of the patients receiving a recommendation for referral to specialty care, and between 3% and 12.2% of the images were not gradable (Ogunyemi et al., 2011), another study found the incidence of diabetic retinopathy diagnosis was 14.8% (Li et al., 2011).

7.2 Discussion of Overall Results

The following discussion addresses the research question.

1. *How does this population react to a specific education web-based teleretinal imaging program?*

This study demonstrated that a teleretinal imaging intervention can potentially improve health outcomes. As revealed by the TTM surveys, positive behavior outcomes were demonstrated. There was a positive change in health behavior for exercise, carbohydrate counting, smoking cessation, and daily self-management as it related to their diabetes. It cannot be concluded that these changes were due directly to the intervention, since the majority of the participants did not access the online materials, however, it is speculated that the overall experience, which included the retinal imaging and having to discuss diabetes with the imager and the clinic staff for at least three research visits, may have had an impact.

All the participants had their retinas digitally imaged and were given access to the patient portal. They were also given a printed copy of their retinal images and educational materials. They were able to discuss the images with the clinic imager; she was trained not to give any clinical diagnosis, but was able to answer question on the images themselves. This may have included why they were taking the images, where in the eye it was imaging and why it is important. The procedure for the clinic research staff was not to advise or educate the participants in diabetes self-management, however, in a clinic setting; discussions tend to focus on health issues, problems and questions. This study interaction, in itself, may have acted as a form of social support.

Discussions in the focus group revealed that all participants did understand that the images were of their retinas and taking the images is an important component in managing their diabetes. None of the participants asked questions or cared to discuss details of the images, such as pathologies revealed in the images or how the images are diagnosed. The primary concern of the participants was the diagnosis results of the retinal images. This revealed that participants had some knowledge on diabetic eye disease, or gained the knowledge from this study. They were able to discuss the images,

knowing that it is a component to diabetes management. As such, despite that their role was only to image and administer the surveys, they seemed to have positive relations with the participants. The clinic research assistants all received positive feedback from the focus group participants. As such, other studies have shown that underserved diabetic patients that are mentored by culturally sensitive community health workers can improve health outcomes (Spencer, Rosland, Kieffer, Sinco, Valerio, Palmisano, Anderson, Guzman, & Heisler, 2011; Swider, 2002).

The following discussion addresses the research question.

2. *What insights can be learned about the digital divide and health outcomes when web education, is made available to an underserved, predominately Native Hawaiian population?*

Focus group results revealed that the lack of computer access and knowledge on use of the technology were the most common barriers in web access. This is consistent with other studies that have examined the digital divide amongst underserved populations (Kruse et al., 2012). Additionally, participants revealed that greater usage was linked to their family members facilitating access, by helping them navigate and encouraging them to learn. This is also consistent with other studies (Mayberry, Kripalani, Rothman, & Osborn, 2011). Thus, results have further validated the importance of family and the positive role of social support. The influence of the family has many affects, from encouragement to learn more about computer technology, to acting as a motivating factor for changing health behavior. The importance of family or '*Ohana* is consistent with other research results targeting this population (Mau et al., 2001).

As revealed in the focus group sessions, neither the retinal images nor the patient portal seemed to have a large direct impact on the participants. There was very low access to the online portal. Discussions with the retinal imager at the clinic revealed that there was little interest in the patient portal or images themselves. It is speculated that the lack of interest may be due to general low computer literacy and health literacy in diabetes eye care. However, despite that the population had low computer access and eHealth literacy, all participants in the focus groups desired to learn more about accessing

the WWW. There were no negative comments about the digital retinal imaging procedure. All participants appreciated the imaging and agreed that the non-mydriatic imaging adds convenience and is a less invasive method for retinal imaging.

From the overall demographics survey, 66.4% of the study participants (n = 125) stated that they have access to the Internet in their home. Thus, access to technology may not be the primary barrier to usage. Studies involving other minority populations had similar results where other barriers were revealed as components to the lack of usage. For example, a study conducted in Los Angeles (Jung, Peng, Moran, Jin, McLaughlin, Cody, Jordan-Marsh, Albright, & Silverstein, 2010) found that with low-income minority seniors psychological variables related to anxiety were a stronger predictor for computer usage than experience. Hence, those with less anxiety were more likely to enroll in a computer course than those that had higher anxiety with more computer experience.

As stated previously, this study population had a an enthusiasm to learn, this also consistent with other studies examining technology utilization with minority populations; despite the lack of use of Internet technology, people are enthusiastic and would like to learn and utilize health information technology (Watson et al., 2008). A study specifically examining attitudes toward technology utilization (Shieh, Chang, & Liu, 2010) found that with low income women, after attending a computer course anxiety levels and attitudes toward computers greatly improved. As such, this is the idea of perceived usefulness and social support. As revealed with this dissertation's participant population, the role of the social environment, as shown in the TTM study results looking at environmental reevaluation, helping relationships, and social liberation, is a large influence. For example, people would probably be more inclined to learn and utilize technology if friends, family and community are positive influences (Donate, Brandtweiner, & Kerschbaum, 2009).

Future research in this area is needed to specifically address and parse out the variables that impact underserved minorities and computer and technology utilization. This includes social support, computer access and literacy, eHealth literacy and education. Additionally, as technology access changes, such as with the availability of cell phones with Internet access, the digital divide may change from a gap to access, to a differentiation in the patterns of usage, i.e. for information, education, or entertainment.

Access to data, such as access to databases, social networks, and news and information, versus access to the technology may become the new digital divide. Other embedded issues also need to be examined. For example, a study examining the digital divide with African-American students (Payton, 2003), found that access to technology was not so much of a problem. The young minority participants had many concerns on lack of social networks to help them succeed in a digital world. Who would be their role models and mentors when trends in technology utilization favor those outside their social group?

7.3 Contribution to the Community

Community-based research is an approach to research whereby the community has an integral part in the design, implementation and dissemination of the research. This contrasts from traditional research in the past where subjects, in particular minority populations, were exploited and described in publications in an unflattering way, and situations in the past where research provided little benefit to the community (Green & Mercer, 2001). When utilizing community-based research theory, the community has a vested interest in the intervention and outcomes, thus making the research a stronger contribution to both the community and the ability to decrease health disparities. This is especially important in research among minority populations since the community can both provide valuable insight to the needs of the population, as well as, provide insight to what interventions would or would not work (De las Nueces, Hacker, DiGirolamo, & Hicks, 2012).

For this research study, an application was submitted to the WCCHC research board. The board reviewed the study to determine if this study was in the best interest of the community. In addition, as part of the application, the study had to demonstrate that the researchers had been working with the community in designing the study. Involvement of the community needed to be an integral part of the study design. The application had to also demonstrate that the impact to WCCHC was minimal to their regular operations, and that there was no financial cost to the clinic. Thus, a close relationship with the Director of Preventative Health was formed; the study was aided by the fact the Director of Preventative Health supported the efforts and felt that there was a benefit to the community. In other words, there was internal buy in and support from a

clinic director. After the research board approved the study, a requirement of the clinic was to obtain approval from their committee on human use. Human use approvals from University of Hawaii, WCCHC, and the U.S. Army (funder) were obtained.

At the end of the research study, prior to publication of results, it was suggested that the results be presented to both the community and the research board at WCCHC. This gives them an opportunity to provide feedback, ask questions and review the results. A presentation was conducted at the WCCHC café, whereby all the participants in the study were invited. General flyers were also posted around the center. Feedback from the attendees was positive and many asked for more opportunities to access the retinal imaging. Several administrative personnel that attended also had positive feedback. A primary care physician at the clinic was very interested in the digital retinal imaging and how the program can be offered to patients on a regular basis. At the post-study presentation to the research board, the study received positive feedback and the board was happy with both the study results and learning positive points to a digital retinal imaging program at the clinic.

For the patients, the contribution to the community included free digital retinal imaging and diagnosis for 160 participants. The study also further demonstrated the value and feasibility of having a digital retinal imaging program for the patients, clinical staff, and administration. Additionally, a contribution to the community was to further knowledge that a digital divide exists within the WCCHC community. The need for community programs for both diabetes self-management and computer literacy is apparent. Hopefully, future programs can use the knowledge gained to both better understand and develop effective programs to address the health and computer literacy disparities in Hawaii.

7.4 Contributions to Knowledge

This dissertation study has many components that contribute to the knowledge in retinal imaging, eHealth literacy, and diabetes care. The following are unique to this study.

- In a literature search (using ScienceDirect and EbscoHost (databases – Academic Search Premier, PubMed/Medline, Psychology and Behavioral Science collection,

Computer Source databases), key words included Hawaii and digital divide, eHealth, computer literacy, from 2000 through 2012) conducted February 2013, there were no published articles were found that explored eHealth literacy, computer literacy or the digital divide with a predominately Native Hawaiian underserved populations in Hawaii. This study further provides evidence that the digital divide does exist.

- There have been no studies examining digital retinal imaging with Native Hawaiian or underserved populations in Hawaii. Overall, the digital retinal imaging system is a feasible option for screening and diagnosis of retinopathy in remote and underserved areas. Both clinic staff and physicians were enthusiastic and felt the need to implement the digital retinal imaging as part of their standard clinical care.
- There have been no prospective studies on the effects of digital retinal imagining and health outcomes. This study found prospectively that a teleretinal imaging intervention resulted in positive health behavior changes in exercise, carbohydrate counting, smoking cessation, and daily self-management as it related to their diabetes. In general, behavior change is a very challenging area; this study has contributed to knowledge in diabetes management.
- The TTM surveys supported the predictable patterns and relationships using stage of change and the decisional balance measures. This was demonstrated by charting a cross-problem comparison using the results from the decisional balance instruments and stage of change. In compliance with other studies, there was a progression from pre-action to action stages of change in exercise and carbohydrate counting, which was also patterned by a crossover between the increase in pros and decrease in cons. This further validates the TTM surveys.

Overall, as a case study, the results from this can contribute to the understanding of health behaviors, computer literacy and the digital divide with underserved populations in Hawaii. Results can also contribute to developing future more effective interventions in improving diabetes care.

7.5 Limitations to the Study

There were several limitations to this study that should be noted. Foremost, the lack of computer resources was unknown at the beginning of the study. Since there were no published research articles on the digital divide or eHealth literacy with this population, it was assumed that the participant population would have access to computers and the Internet. However, results showed low access and low usage of computer technology. This is a limitation to the study since it was designed to explore usage; however it is also a key finding and confirms that the eHealth digital divide does exist within this population.

Another limitation to this study was that the majority of the focus group participants were either unemployed or retired. As demonstrated in the demographics survey, there was a significant difference detected between surfing the Internet and employment status. In other words, those that were unemployed were less likely to surf the Internet. This lack of Internet usage may be reflected in the focus group results, and thus may not be representative to the participant population at whole. Future research needs to include more diverse participant populations, which includes input from those that are employed and have experience using the Internet. In addition, the use of focus groups can be subjective both in the participant discussion and in analysis of the data, thus results may not be generalizable to the targeted population.

Not having a control group or conducting randomization is another limitation. Because there was no control group it is difficult to determine if the changes were due to the teleretinal intervention or other factors, such as social support previously discussed. In other words, the changes in behavior may have occurred by the interaction of clinic staff, regardless of the retinal imaging and patient portal. However, the TTM surveys have been previously validated and the design is stronger than a simple pre and post-test intervention. The sample population was a convenient sample that consisted of diabetic volunteer patients from the Waianae Coast Comprehensive Health Center. Thus, it is possible that patients that volunteered are already in the pre-action stage of wanting to improve their health in general and may not be representative of the WCCHC community or underserved populations in Hawaii. Nonetheless, the participant population was

consistent with the demographics of the area at large. This includes income level, ethnic breakdown and educational level.

The TTM surveys looks at change over time, utilizing six month as a guide. For this study, due to funding and time constraints, we were only able to assess the participant over a three month period. Despite that change was detected, results may have been stronger if the population was surveyed over a longer period of time, such as one year. This would be more appropriate for the TTM surveys. Additionally, the validated TTM surveys were self-reported and focused only on exercise, daily self-management and smoking cessation. There were no validated TTM surveys available that specifically addressed diabetes health risks. Additionally, the self-reported surveys may have resulted in socially perceived appropriate responses.

Lastly, regarding the clinical data, the data was obtained via a patient chart review and was not mandated by the study design. Not all the patients had lab results, and not all corresponded precisely with the study timeline. HbA1c lab results were logged if there were within three months of the baseline visit and within six month after the baseline visit. There were no significant differences in HbA1c detected.

7.6 Further Research

This study examined the use of a teleretinal imaging program that integrated an online patient portal that included diabetic eye disease education. Results showed improved health outcomes. Future research is needed to parse out the different components that may have effects. This could be the retinal imaging alone, the surveys as an assessment effect or the study as a social support mechanism. Results also revealed the lack of Internet usage and computer availability to the participants. There is a dearth of research on the digital divide, computer and eHealth literacy, and the use of Internet technology with health disparate populations in Hawaii. Research is needed to explore eHealth literacy in rural communities in Hawaii and how increased literacy can affect health outcomes. The connection between health disparities and access to technology would also be an interesting area to explore.

The following are further research ideas that can be carried forward tying on to the results of this dissertation work.

- Results from this study support the idea that there is digital divide, which includes barriers to access and low eHealth literacy levels. In order for health technologies to be useful and aid in improving health and health outcomes for underserved populations, specific research is need to investigate the digital divide in Hawaii. This would include investigating access to technology, computer literacy, and essence of Internet usage as it relates to health conditions. Essence of use includes socio-cultural components, user's computer skill level, health literacy level, and relevant cultural context.
- The results of this study showed that an intervention that consists of teleretinal imaging and a patient portal can affect behavior outcomes. To parse out the retinal imaging from the online educational component, an interesting study would be to offer the retinal imaging as standard of care, with the educational component as the intervention. An annual dilated eye exam is standard of care for those diagnosed with diabetes (Cabral et al., 1996; Cabral, Cotton, Semaan, & Gielen, 2004; National Eye Institute National Institutes of Health, 2013); and teleretinal imaging has been validated and accepted as a clinical method of eye care for diabetic patients (Bursell et al., 2001; Cavallerano et al., 2003). The control group would receive the teleretinal imaging and the intervention group would receive the retinal imaging plus the online educational materials. From a community standpoint, all patients are still benefiting from the teleretinal imaging, which can further validate the use of teleretinal imaging as an alternative for dilated eye examinations. Measured outcomes could be health behavior and/or HbA1c lab results.
- This study resulted in improved health outcomes and change in health behaviors for diabetics. Positively changing one's health behavior is a very challenging endeavor, any insights on the mechanisms of behavior change is useful. Further research is needed in developing effective interventions for diabetes self-management and further validating the TTM model on Native Hawaiian and other health disparate populations.

7.7 Conclusion

Despite the limitations to the study, the results of this study are a contribution to the overall knowledge in health behavior change, computer literacy, eHealth literacy, and the digital divide in an underserved, predominately Native Hawaiian population in Hawaii. Utilizing a community based approach, a good relationship was developed with the Waianae Coast Comprehensive Health Center. A clear understanding of the needs and requirements to conduct research at the clinic was obtained. This is a valuable accomplishment in the potential to conduct future research at the clinic. Limitations to the study are noted, however they will aid in designing stronger studies in the future. Based on the report to the community and to the WCCHC research committee, a regular program for digital retinal imaging would be a valuable asset to the clinic. Benefits of using telemedicine for this proposed study included increased access to eye examinations with reliable diagnosis of diabetic retinopathy, and increased access to relevant educational materials.

In Hawaii, there are many healthcare challenges. Chronic diseases such as diabetes, heart disease and hypertension disproportionately affect Native Hawaiians, Asian Americans and Pacific Islanders. Infectious diseases, such as HIV/AIDS, also disproportionally affect Native Hawaiians/Pacific Islanders; this has been documented at a rate of over two and half times that of White Americans (CDC, 2012). Native Hawaiians in particular have the highest percentage rate of obesity (42.8%) compared to any other racial/ethnic group in the United States (Schiller et al., 2012). In particular, on the island of Oahu, the Waianae coast that has the largest percentage of individuals that fall below 100% of the Federal Poverty Level (18.7%), with an average per capita income of $17,300. The Waianae coast also has the highest unemployment rate (8.9%). Statewide, Waianae has the highest obesity rate in the state at 43.5%, the largest percentage of those that smoke (26.0%), and highest percent of those that have been diagnosed with diabetes (13.7%) (Family Health Services Division Hawaii Department of Health, 2012).

There is growing evidence that the use of healthcare technologies can potentially ameliorate these health disparities. Telemedicine and Internet-based interventions have the potential to address access and quality of care by reaching a broader population base.

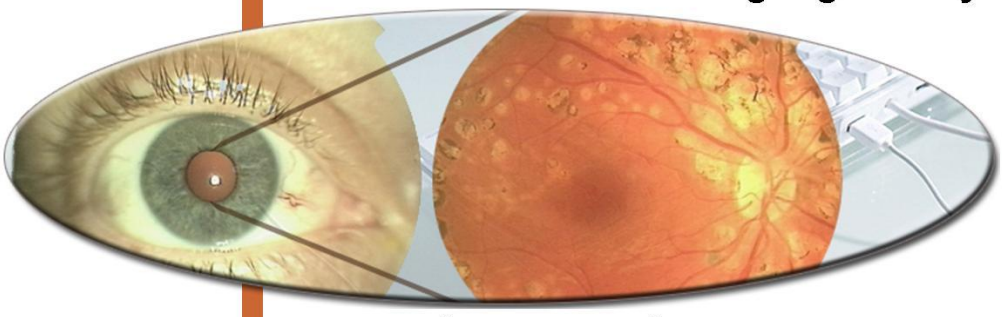
Because Internet-based interventions are available 24 hours a day, they can be used to manage chronic diseases at the convenience of the patient, which can be an effective tool in managing chronic diseases. Educational, web-based applications can be tailored to the population, and can deliver culturally appropriate education and communications. The personalization of information, which is information tailored to the particular user, provides relevance and context for the intended recipient. This can results in a stronger impact than a once-size-fits-all approach.

However, as discussed, there exists disparities in access to technology, disparities in those that use eHealth information, and disparities in the literacy skills needed to access the information. From a governmental standpoint, there is a large push for the development and dissemination of technology in health care to both remove barriers to care and improve access. And to a large extent, it is a public health issue that people are excluded from accessing the Internet and denied the use of technology that can help manage and improve health conditions (Baur, 2008). As such, in order to close the digital divide, computer literacy and eHealth literacy must accompany access to computers (Stanley, 2003). Programs are needed to educate and implement computer technology in underserved areas. Further research and investigation is needed to address access issues and computer and eHealth disparities. Lastly, as technology advances and legislation addresses the need to close the digital divide, the potential for technology to facilitate reduced costs, better access to care and improved quality of care can become more of a reality.

APPENDIX 1

STUDY FLYER

Diabetes Retinal Imaging Study



VOLUNTEERS NEEDED

Be part of an important diabetes research study

Please call Maurice Kalaau or Ashley Jardin at (808) 697-3558 for more information

- Are you between 18 and 75 years of age?
- Have you been diagnosed with Type 2 diabetes?
- Do you want to learn about diabetic eye disease?
- Are you a patient of the Waianae Coast Comprehensive Health Center?

If you answered YES to these questions, you may be eligible to participate in a diabetes research study.

The purpose of this research study is to use digital retinal imaging as a tool in managing Type 2 diabetes. Benefits include digital retinal imaging of your eyes (NO pupil dilation needed), results of the images and educational information about diabetic eye disease. Participants will receive an incentive payment. There is NO cost to participate and NO medications will be given.

This study is being conducted at the *Waianae Cost Comprehensive Health Center*, *Malama Ola Clinic*, 86-260 Farrington Highway, Waianae, Hawaii

This study is sponsored by the U.S. Army Medical Research and Material Command and the University of Hawaii.

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD, 21702-5014, is the awarding and administering acquisition office, through award no. W81XWH-09-2-0166

APPENDIX 2

STAGE OF CHANGE FOR EXERCISE

Please answer the following questions based on your present situation.

Please select the best response from the choices and mark or circle the correct answer.

Regular Exercise is any *planned* physical activity (e.g., brisk walking, aerobics, jogging, bicycling, swimming, rowing, etc.) performed to increase physical fitness. Such activity should be performed *3 to 5 times* per week for *20-60 minutes* per session. Exercise does not have to be painful to be effective but should be done at a level that increases your breathing rate and causes you to break a sweat.

Do you engage in regular exercise according to the previous definition?

- ☐ No, and I do not intend to in the next 6 months.
- ☐ No, but I intend to in the next 6 months.
- ☐ No, but I intend to in the next 30 days.
- ☐ Yes, I have been for less than 6 months.
- ☐ Yes, I have been for more than 6 months.

APPENDIX 3
CARBOHYDRATE STAGING

The next set of questions asks about your carbohydrate intake. While all foods raise blood glucose, CARBOHYDRATES raise it the most. CARBOHYDRATES are found in most foods. Meats, fats, and oils have little carbohydrate. Starchy vegetables, such as corn, peas, and potatoes; breads; rice; cereal; pasta; fruit juice; fruit; and milk have about 12-15 grams of carbohydrate per serving (in one portion). Soda and fruit drinks, as well as sugar and sweets, are usually 100% carbohydrate.

Managing carbohydrates involves both keeping track of the amount of carbohydrate you eat and keeping the amount you eat consistent at meals and snacks (i.e., not eating more than you need at any one time). Keeping track does not have to be complicated. It can be as easy as counting servings, or portions, of foods with carbohydrates (e.g., 1 slice of toast or 1 bread "exchange").

1. **Do you CONSISTENTLY manage the amount of carbohydrate you eat each day**?

- ☐ No, and I do not intend to in the next 6 months.
- ☐ No, but I intend to in the next 6 months.
- ☐ No, but I intend to in the next 30 days.
- ☐ Yes, I have been for less than 6 months.
- ☐ Yes, I have been for more than 6 months.

APPENDIX 4
STAGING FOR SELF-MANAGEMENT ACTION PLAN

Self-management means taking the necessary steps that allow you to control your health condition(s). A verbal or written action plan helps you do this.

A self-management action plan often includes:

- Managing triggers that can cause symptoms

  Some examples:

  - *If you have asthma, avoiding cigarette smoke*
  - *If you have high blood pressure, avoiding foods high in sodium*
  - *If you know stress can make your condition worse, avoiding stressful situations*
- Regular self-testing

  Some examples:

  - *If you have diabetes, glucose testing before and after meals*
  - *If you have diabetes, checking your feet regularly*
  - *If you have congestive heart failure, checking your body weight daily*
- Monitoring symptoms and being prepared to address urgent symptoms

  Some examples:

  - *If you have diabetes, noticing symptoms of low blood sugar, such as hunger, sweating, dizziness or confusion*
  - *If you have COPD, monitoring shortness of breath*
  - *If you have allergies, having an Epipen with you*
  - *If you have a cardiac condition, carrying Nitroglycerine tablets if appropriate*

1. Do you currently have a self-management action plan?

   1=No, and I do not intend to in the next 6 months. (Skip to next section)

   2=No, but I intend to in the next 6 months. (Skip to next section)

   3=No, but I intend to in the next 30 days. (Skip to next section)

4=Yes, I have an action plan. (Go to Question 2)

2. Do you follow your self-management action plan?

   1=No, and I do not intend to in the next 6 months.

   2=No, but I intend to in the next 6 months.

   3=No, but I intend to in the next 30 days.

   4=Yes, I have been for less than 6 months.

   5=Yes, I have been for more than 6 months.

APPENDIX 5

SMOKING: STAGE OF CHANGE

1. **Are you currently a smoker?**

   * Yes, I currently smoke (Answer question 2 and 3)

   * No, I quit within the last 6 months (Answer question 2 and 3))

   * No, I quit more than 6 months ago (Answer question 2 and 3))

   * No, I have never smoked (Skip to next section)

2. **In the last year, how many times have you quit smoking for at least 24 hours? _____**

3. **Are you seriously thinking of quitting smoking**?

   * Yes, within the next 30 days

   * Yes, within the next 6 months

   * No, not thinking of quitting

APPENDIX 6

EXERCISE REGULARLY: PROS AND CONS

This section looks at positive and negative aspects of exercise. Read the following items and indicate how important each statement is with respect to your decision to exercise or not to exercise in your leisure time. Please answer using the following 5-point scale:

Your answer choices are: **1 = Not important**
2 = A little important
3 = Moderately important
4 = Very important
5 = Extremely important

If the statement does not apply to you, you should respond Not important.

1. I would have more energy for my family and friends if I exercised regularly.
   - ☐ Not Important
   - ☐ A Little Important
   - ☐ Moderately Important
   - ☐ Very Important
   - ☐ Extremely Important

2. I would feel embarrassed if people saw me exercising.
   - ☐ Not Important
   - ☐ A Little Important
   - ☐ Moderately Important
   - ☐ Very Important
   - ☐ Extremely Important

3. I would feel less stressed if I exercised regularly.
   - ☐ Not Important
   - ☐ A Little Important
   - ☐ Moderately Important

- ☐ Very Important
- ☐ Extremely Important

4. Exercise prevents me from spending time with my friends.
   - ☐ Not Important
   - ☐ A Little Important
   - ☐ Moderately Important
   - ☐ Very Important
   - ☐ Extremely Important
5. Exercising puts me in a better mood for the rest of the day.
   - ☐ Not Important
   - ☐ A Little Important
   - ☐ Moderately Important
   - ☐ Very Important
   - ☐ Extremely Important

6. I feel uncomfortable or embarrassed in exercise clothes.
   - ☐ Not Important
   - ☐ A Little Important
   - ☐ Moderately Important
   - ☐ Very Important
   - ☐ Extremely Important

7. I would feel more comfortable with my body if I exercised regularly.
   - ☐ Not Important
   - ☐ A Little Important
   - ☐ Moderately Important
   - ☐ Very Important
   - ☐ Extremely Important

8. There is too much I would have to learn to exercise.

- ☐ Not Important
- ☐ A Little Important
- ☐ Moderately Important
- ☐ Very Important
- ☐ Extremely Important

9. Regular exercise would help me have a more positive outlook on life.
   - ☐ Not Important
   - ☐ A Little Important
   - ☐ Moderately Important
   - ☐ Very Important
   - ☐ Extremely Important

10. Exercise puts an extra burden on my significant other.
    - ☐ Not Important
    - ☐ A Little Important
    - ☐ Moderately Important
    - ☐ Very Important
    - ☐ Extremely Important

APPENDIX 7

CARBOHYDRATE DECISIONAL BALANCE

The following statements represent different opinions about managing the amount of carbohydrate that you eat. Please rate HOW IMPORTANT each of the following would is in your decision to manage carbohydrates, according to the following 5-point scale.

1. My blood glucose levels will improve if I control the amount of carbohydrate I eat.

   ☐ Not Important
   ☐ A Little Important
   ☐ Moderately Important
   ☐ Very Important
   ☐ Extremely Important

2. Eating foods that are low in carbohydrates limits my food choices.

   ☐ Not Important
   ☐ A Little Important
   ☐ Moderately Important
   ☐ Very Important
   ☐ Extremely Important

3. I feel better about myself when I control my carbohydrate intake.

   ☐ Not Important
   ☐ A Little Important
   ☐ Moderately Important
   ☐ Very Important
   ☐ Extremely Important

4. Controlling the amount of carbohydrate I eat takes too much time.

- ☐ Not Important
- ☐ A Little Important
- ☐ Moderately Important
- ☐ Very Important
- ☐ Extremely Important

5. My diabetes care team would be pleased if I controlled my carbohydrate intake.

- ☐ Not Important
- ☐ A Little Important
- ☐ Moderately Important
- ☐ Very Important
- ☐ Extremely Important

6. Figuring out how my blood glucose responds to different amounts of carbohydrate takes too much effort.

- ☐ Not Important
- ☐ A Little Important
- ☐ Moderately Important
- ☐ Very Important
- ☐ Extremely Important

7. Controlling carbohydrates is a good way to help me manage my weight.

- ☐ Not Important
- ☐ A Little Important
- ☐ Moderately Important
- ☐ Very Important
- ☐ Extremely Important

8. Low carbohydrate foods are less appealing.

- ☐ Not Important
- ☐ A Little Important
- ☐ Moderately Important
- ☐ Very Important
- ☐ Extremely Important

9. I feel healthier when I eat fewer carbohydrates.

- ☐ Not Important
- ☐ A Little Important
- ☐ Moderately Important
- ☐ Very Important
- ☐ Extremely Important

10. Having to control carbohydrates makes me feel like my life is ruled by food.

- ☐ Not Important
- ☐ A Little Important
- ☐ Moderately Important
- ☐ Very Important
- ☐ Extremely Important

APPENDIX 8

EXERCISE REGULARLY: SELF-EFFICACY

This part looks at how confident you are to exercise when other things get in the way. Read the following items enter in the box the number that best expresses how each item relates to you in your leisure time. Please answer using the following 5-point scale:

Your answer choices are: **1 = Not at all confident**
2 = A little confident
3 = Moderately confident
4 = Very confident
5 = Completely confident

1. I am under a lot of stress.
2. I feel I don't have the time.
3. I have to exercise alone.
4. I don't have access to exercise equipment.
5. I am spending time with friends or family who do not exercise.
6. It's raining or snowing.

APPENDIX 9

CARBOHYDRATE SELF-EFFICACY

Please rate how confident you are that you would manage the amount of carbohydrates you eat in the following situations using the 5-point scale: How confident are you that you would manage carbohydrates in the following situations?

1. If I am frustrated with my diabetes.
   - ☐ Not at all confident
   - ☐ Not very confident
   - ☐ Moderately confident
   - ☐ Very confident
   - ☐ Extremely confident

2. At social events.
   - ☐ Not at all confident
   - ☐ Not very confident
   - ☐ Moderately confident
   - ☐ Very confident
   - ☐ Extremely confident

3. When I crave a high carbohydrate snack.
   - ☐ Not at all confident
   - ☐ Not very confident
   - ☐ Moderately confident
   - ☐ Very confident
   - ☐ Extremely confident

4. During the holidays.
   - ☐ Not at all confident
   - ☐ Not very confident
   - ☐ Moderately confident

- ☐ Very confident
- ☐ Extremely confident

5. When others are eating unhealthy foods.
   - ☐ Not at all confident
   - ☐ Not very confident
   - ☐ Moderately confident
   - ☐ Very confident
   - ☐ Extremely confident
6. If my blood glucose is low.
   - ☐ Not at all confident
   - ☐ Not very confident
   - ☐ Moderately confident
   - ☐ Very confident
   - ☐ Extremely confident

7. While watching TV. $
   - ☐ Not at all confident
   - ☐ Not very confident
   - ☐ Moderately confident
   - ☐ Very confident
   - ☐ Extremely confident

8. If I am traveling.
   - ☐ Not at all confident
   - ☐ Not very confident
   - ☐ Moderately confident
   - ☐ Very confident
   - ☐ Extremely confident

9. When I have skipped a meal.

- ☐ Not at all confident
- ☐ Not very confident
- ☐ Moderately confident
- ☐ Very confident
- ☐ Extremely confident

10. Over the weekend.
    - ☐ Not at all confident
    - ☐ Not very confident
    - ☐ Moderately confident
    - ☐ Very confident
    - ☐ Extremely confident

APPENDIX 10

EXERCISE REGULARLY: PROCESSES OF CHANGE

The next section asks about experiences that can affect whether or not people engage in *regular exercise*.

The following experiences can affect the exercise habits of some people. Think of similar experiences you may be currently having or have had during the past month. Then rate how frequently the event occurs by selecting the appropriate number. Please answer using the following

Your answer choices are: **1 = Never**
2 = Seldom
3 = Occasionally
4 = Often
5 = Repeatedly

1. I read articles about exercise in an attempt to learn more about it.
2. I look for information related to exercise.
3. I find out about new methods of exercising.
4. I get upset when I see people who would benefit from exercise but choose not to exercise.
5. I am afraid of the consequences to my health if I do not exercise.
6. I get upset when I realize that people I love would have better health if they exercised.
7. I realize that if I don't exercise regularly, I may get ill and be a burden to others. I think that my exercising regularly will prevent me from being a burden to the healthcare system.
8. I think that regular exercise plays a role in reducing health care costs.
9. I feel more confident when I exercise regularly.
10. I believe that regular exercise will make me a healthier, happier person.
11. I feel better about myself when I exercise.
12. I have noticed that many people know that exercise is good for them.
13. I am aware of more and more people who are making exercise a part of their lives.

14. I have noticed that famous people often advertise the fact that they exercise regularly.
15. When I feel tired, I make myself exercise anyway because I know I will feel better afterwards.
16. Instead of taking a nap after work, I exercise.
17. Instead of relaxing by watching TV or eating, I take a walk or exercise.
18. I have a friend who encourages me to exercise when I don't feel up to it. I have someone who encourages me to exercise.
19. My friends encourage me to exercise.
20. One of the rewards of regular exercise is that it improves my mood.
21. I try to think of exercise as a time to clear my mind as well as a workout for my body.
22. If I engage in regular exercise, I find that I get the benefit of having more energy.
23. I tell myself that I can keep exercising if I try hard enough.
24. I make commitments to exercise.
25. I believe that I can exercise regularly.
26. I keep a set of exercise clothes conveniently located so I can exercise whenever I get the time.
27. I use my calendar to schedule my exercise time.
28. I make sure I always have a clean set of exercise clothes.

APPENDIX 11

DEMOGRAPHICS SURVEY

Tell us about yourself: Please answer the following questions based on your present situation. Please select the best response from the choices and mark or circle the correct answer.

1. □ Female □ Male

2. Please circle the highest grade of school that you completed.

1	2	3	4	5	6	7	8	9	10	11	12

College/University	1	2	3	4	5+
Graduate School	1	2	3	4	5+

3. When were you born? _____ (month) _____ (day) _____(year)

4. How much do you weigh (choose one)? _____ (lbs.) _____(kgs.)

5. How tall are you (choose one)? ____ (ft.) _____ (in.) _____ (cms.)

6. Would you say your general health is:

□ Excellent □ Very Good □ Good □ Fair □ Poor

7. What is your marital status?

□ Married □ Widowed □ Separated □Divorced

□ Not Married □ Not married, but living with a partner

8. Do you have Internet access at your home? □ Yes □ No

If no, do you have Internet access elsewhere? □ Yes (Where? _____) □ No

9. How frequently do you browse the Internet (World Wide Web) or send/receive email?

- □ Every Day
- □ Several times a week
- □ About once a week
- □ Several times a month
- □ About once a month
- □ Less than once a month
- □ Never

10. What is your ethnic background? (Please choose the category that best describes you)

- ☐ Native Hawaiian
- ☐ Samoan/American Samoan
- ☐ Guamanian
- ☐ Tongan
- ☐ Micronesian
- ☐ Fijian
- ☐ Maori
- ☐ Niuean
- ☐ Tuvaluan
- ☐ Uveans
- ☐ Tahitian
- ☐ Tuamotuan
- ☐ Marquesan
- ☐ Chamorro
- ☐ Cook Islander
- ☐ Other Pacific Islander

(please specify) _____

- ☐ Caucasian
- ☐ Chinese
- ☐ Filipino
- ☐ Japanese
- ☐ Korean
- ☐ Cambodian
- ☐ Indian (India)
- ☐ Indonesian
- ☐ Laotian
- ☐ Malaysian
- ☐ Other Asian Alaskan Native
- ☐ African American / Black
- ☐ Hispanic/Latino
- ☐ Native American
- ☐ Don't Know
- ☐ Other

(please specify) _____

11. Which of the following best describes your current employment status?

- □ Employed full-time
- □ Unemployed
- □ Homemaker
- □ Retired
- □ Student
- □ Employed part-time (# hrs./wk.) _____

12. What is your total yearly household/family income from all sources?

- □ $0-9,999
- □ $10,000-19,999
- □ $20,000-29,999
- □ $30,000-39,999
- □ $40,000-49,999
- □ $50,000-59,999
- □ $60,000-69,999
- □ $70,000-79,999
- □ $80,000+
- □ Don't know
- □ Prefer not to say

13. What is your zip code? _____

14. Would you say your health is:

- □ Excellent
- □ Very Good
- □ Good
- □ Fair
- □ Poor

APPENDIX 12
FOCUS GROUP PROCEDURES

Three to six focus groups will be conducted with subjects that represent the spectrum of results. Group discussion will be recorded using field notes and tape-recorded. Information on the group's perceptions and opinions will be discussed. This can potentially explain the mechanisms of behavior change as a result of the retinal imaging intervention. An inductive method of analysis and data collection will be utilized in conducting the focus group. Open-ended questions will be developed to elicit responses of "how" they feel towards retinal imaging, and why" they were or were not influenced to change behavior. The moderators will keep the discussion focused; however, discussion will be open to unanticipated areas that are relevant and provide insight into the mechanisms of behavior change. Analysis will include both the content of the discussions and participant characteristics, which may include body language and/or mood.

The following are the procedures for the focus group discussion.

- 6-10 people (12 people will be selected to participant to include an attrition rate of ~10-20%)
- Sessions will last approximately 45-90 minutes
- Name tents will be provided with a number for anonymous identification of comments
- Refreshments will be provided
- Moderator and assistant moderator will facilitate discussion (see Attachment 1 for introduction script)
    1. Welcome
    2. Purpose
    3. Ground rules
    4. Questions
- The following questions will be asked.
    1. Did seeing your retinal images mean anything to you?

2. How did seeing your retinal images affect your motivation to change behavior, such as exercise, diet, medication or other possible changes?
3. Do you access information regarding your health over the Internet? How did it affect your motivation to change behavior, such as exercise or diet?
4. Were there other factors that affected your decisions regarding managing your diabetes? This could include family, friends, community, your own health concerns, etc…
5. Is there anything additional you would like to say regarding retinal imaging?
6. What motivated you to participate in the study?
7. What do you feel was the most beneficial aspect of the program?
8. What do you feel was the lease beneficial aspect of the program?
9. How could we improve the program?
10. What do you think would really motivate you to increase your exercise?
11. What do you think would really motivate you to improve your diet?

Focus Group Introduction Script

Hello and welcome to our group session. Thank you for taking the time to join our discussion on the retinal imaging study. My name is Kathleen Connolly and I represent University of Hawaii. Assisting, also from the WWCCHC we have _____. We are attempting to gain information about the effects of the retinal images and feedback of the study. We have invited you to participate in our study because you reflect a wide range of our results, and are very interested in your feedback.

Today we will be discussing the study and how retinal imaging has affected the management of your diabetes. There are no right or wrong answers but rather individual points of view. Please feel free to share your experience, whether it differs or is similar to what others have said.

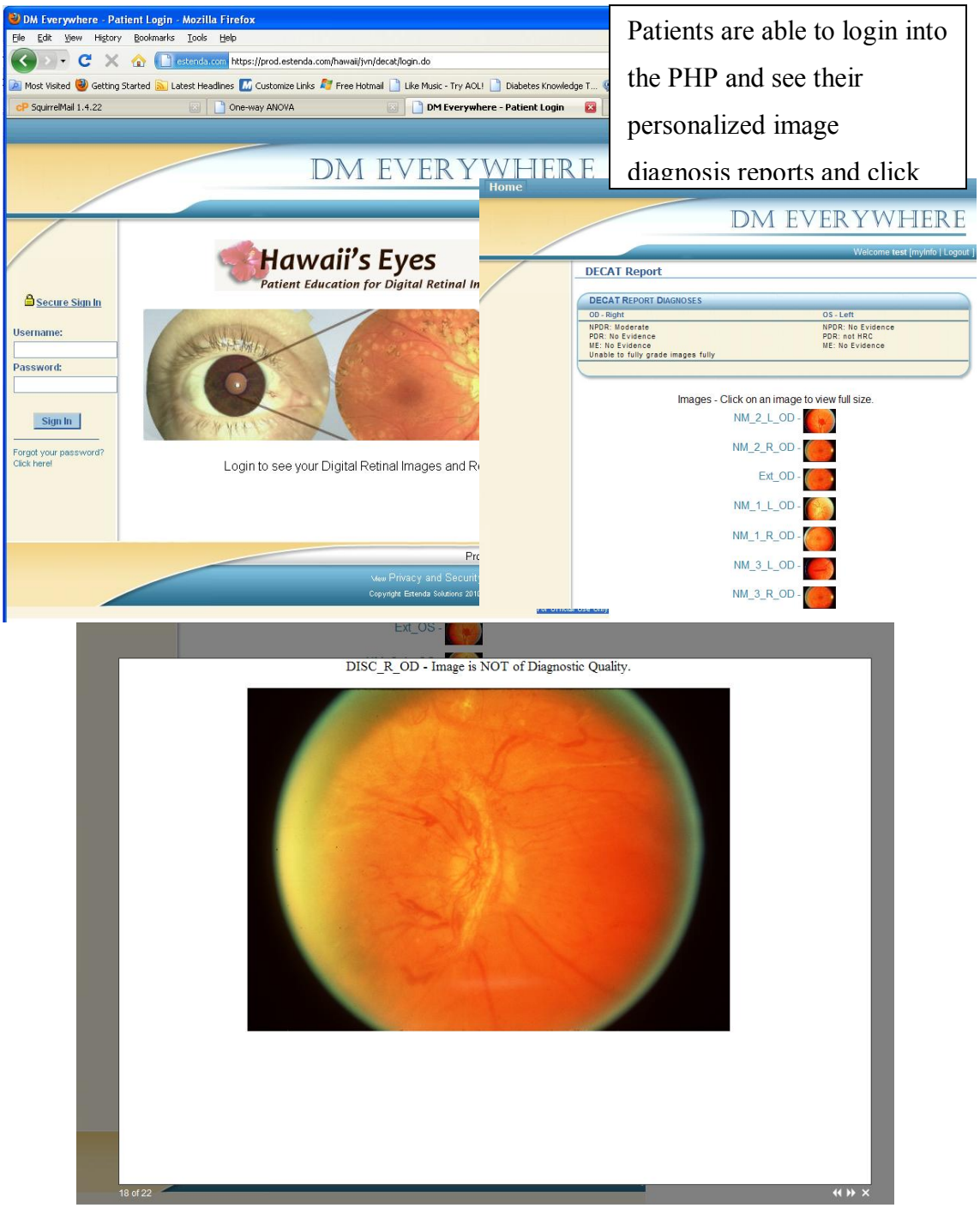
Before we begin, let me remind you of some ground rules. Please speak up so others can hear clearly. Also, please, only one person should talk at a time. We will be on a first name basis tonight, however, in our notes, only the number that is on your name tent will be attached to comments.

You may be assured of complete confidentiality. Keep in mind that we're interested in negative comments as well as positive comments; sometimes the negative comments are the most helpful.

Our session will last about an hour; we will not be taking any breaks. However, feel free to step out if you need a break; also feel free to grab some snacks or drinks while the discussion is in progress. Okay, let's begin. We've placed name cards on the table in front of you to help us remember each other's names. Let's find out some more about each other by going around the room one at a time. Tell us your name and where you live, also if you have any questions up front. After that we will open discussion with topic questions.

APPENDIX 13

PATIENT PORTAL

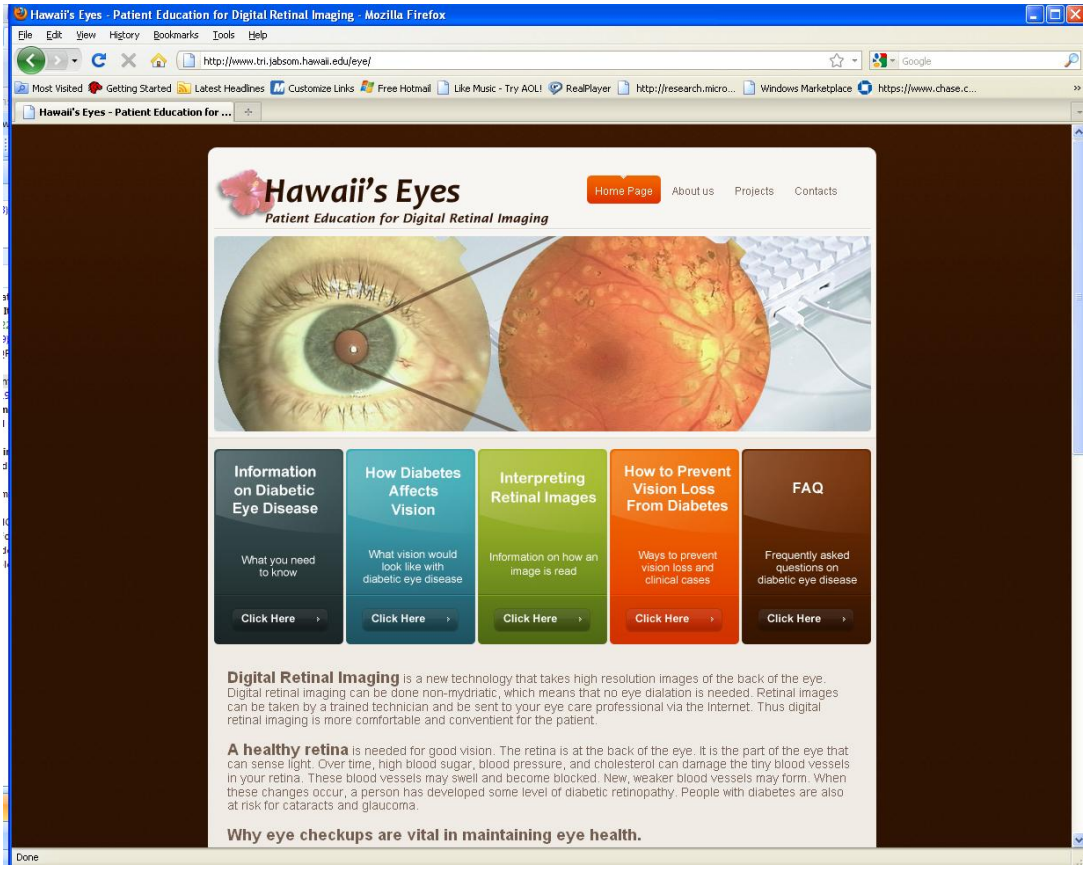


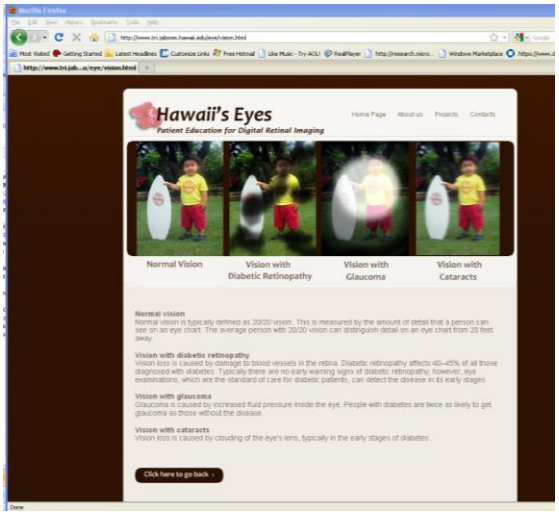
Patients are able to login into the PHP and see their personalized image diagnosis reports and click

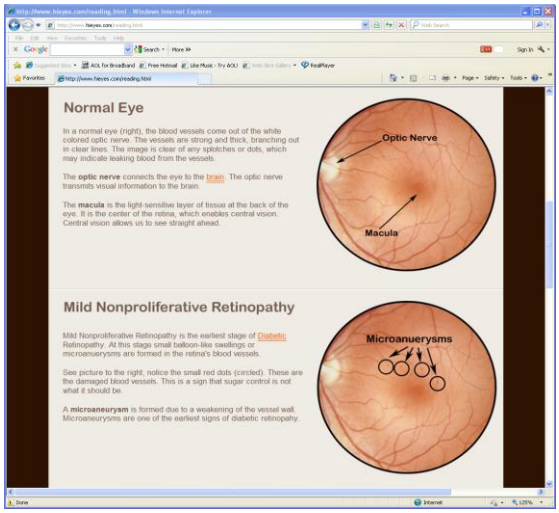
APPENDIX 14

EDUCATIONAL WEBSITE

SCREENSHOT AND CONTENTS







Retinal Imaging

(National Eye Health Education Program, 2008)

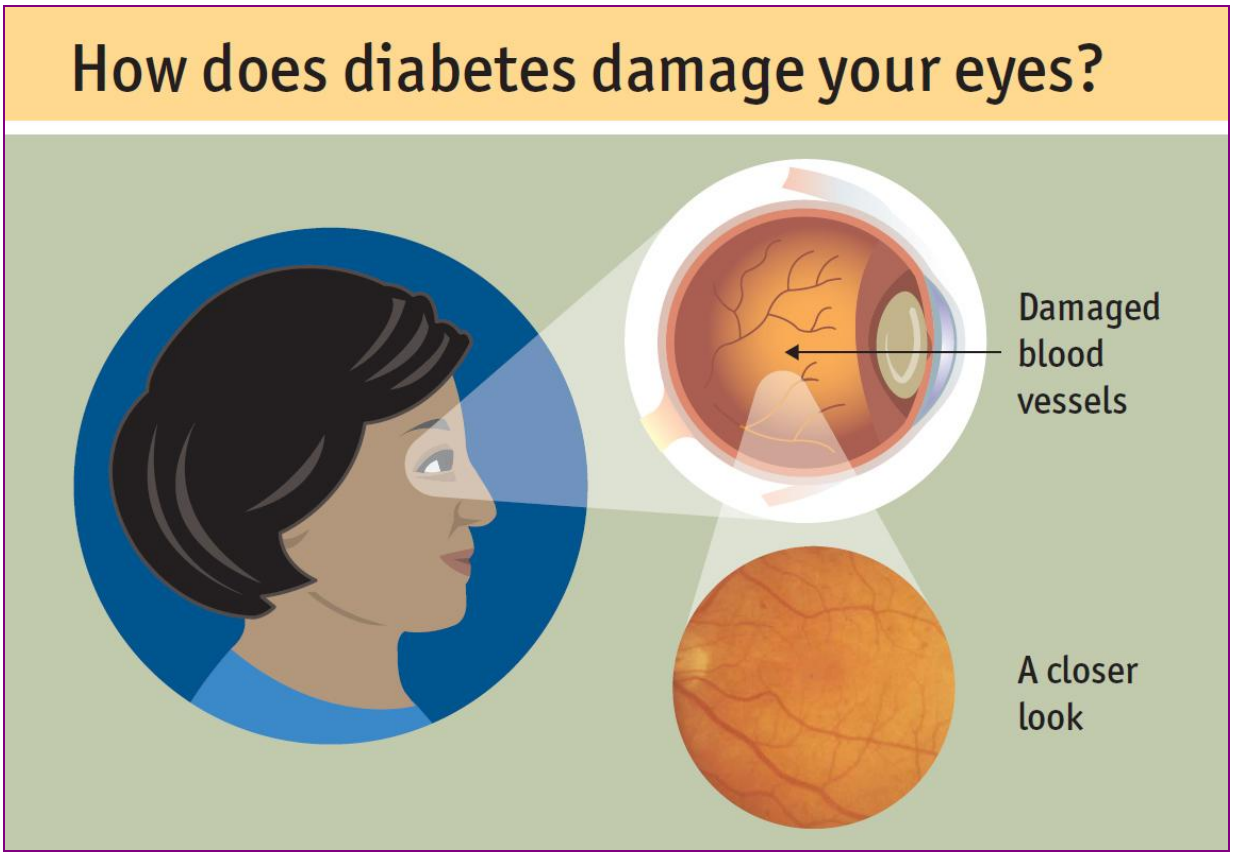
A healthy retina is needed for good vision. The retina is at the back of the eye. It is the part of the eye that can sense light. Over time, high blood sugar, blood pressure, and cholesterol can damage the tiny blood vessels in your retina. These blood vessels may swell and become blocked. New, weaker blood vessels may form. When these changes occur, a person has developed some level of diabetic retinopathy. People with diabetes are also at risk for cataracts and glaucoma.

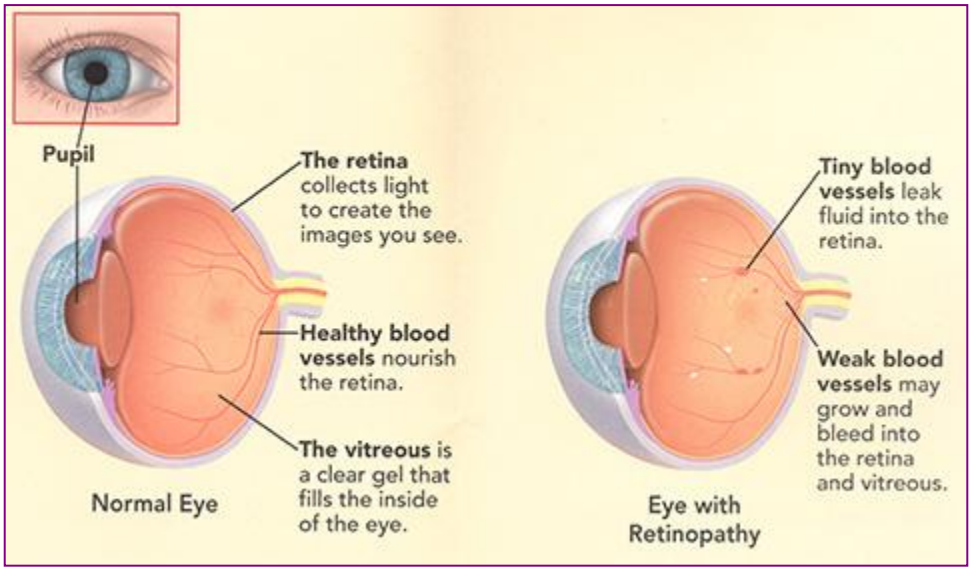
- Diabetic retinopathy can damage your eyes even before you see changes in your vision. Left untreated, diabetic retinopathy can cause vision loss.

- There are no warning signs for diabetic retinopathy. A dilated eye exam or retinal imaging allows the eye care professional to see the early signs of the disease and help you before your vision is affected.

- Finding and treating diabetic retinopathy early can help protect your vision.

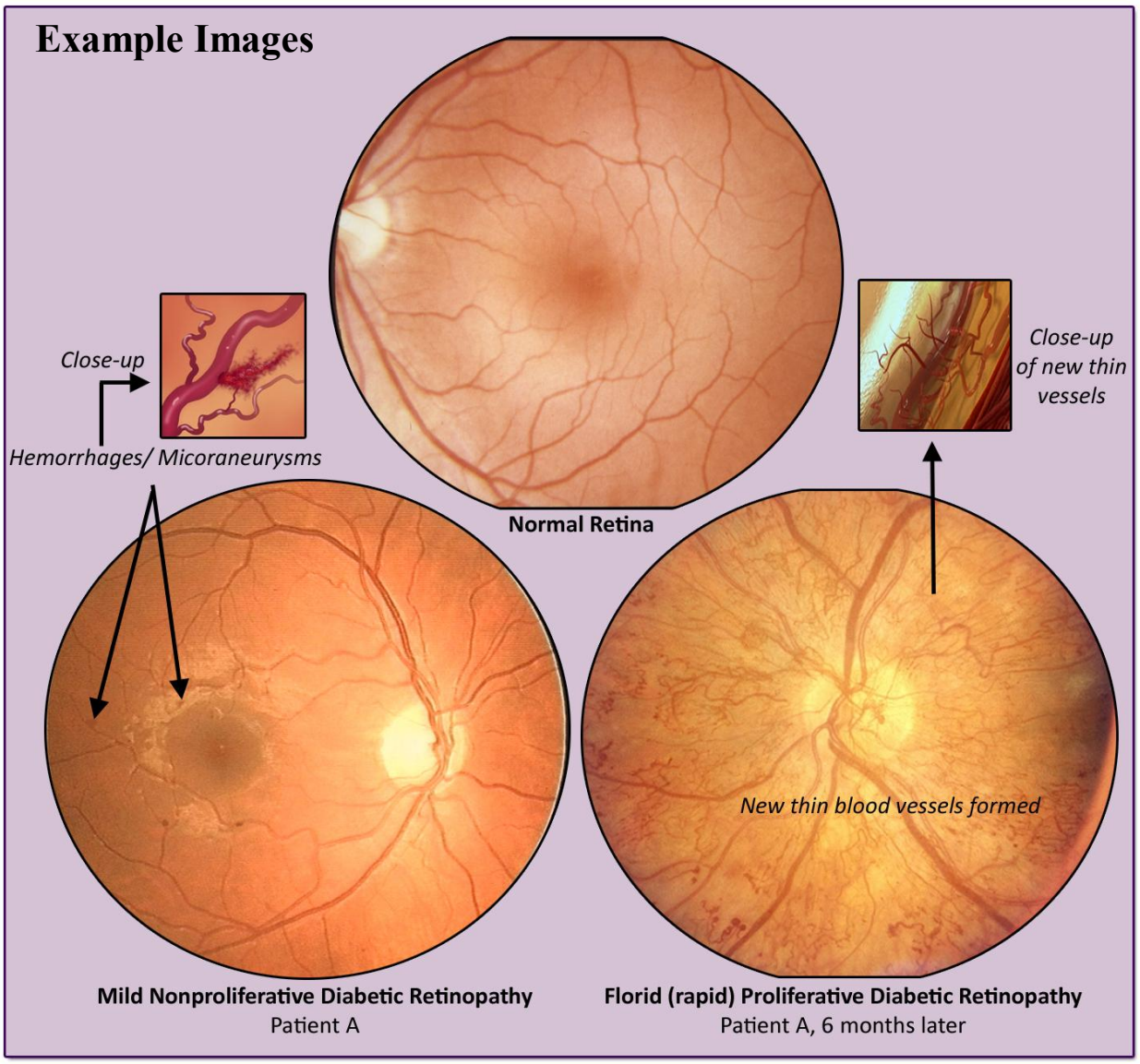
- If you develop diabetic retinopathy, your eye care professional will know when and how to treat the damage to your eyes. Often, laser surgery (using a special beam of light) is performed to treat the damaged blood vessels inside the eye.





http://www.merhieyeclinic.com/Images/DiabeticRetinopathy.jpg

Viewing Your Retinal Images



Above are example images of a normal retina (top), early stage (mild nonproliferative) and a severe forth stage proliferative diabetic retinopathy (see Facts for information on stages).

Notice the normal retina has clear strong blood vessels. The mild case of diabetic retinopathy has tiny hemorrhages or microaneurysms. This is cause by weakening of the blood vessel walls, which forms the bubbling out of the walls.

- The detection of micoraneurysms is the earliest detectable sign of diabetic retinopathy.
- Microaneurysms appear as small red dots in the retinal layers.

- Ruptures of the microaneurysms produce hemmorages, they appear similar to microaneurysms.

If the diabetic condition is left untreated, eventually the retina is triggered to produce more new vessels (see image above, bottom right), which are thin and weak. If the new vessels are not surgically removed, vision impairment and blindness may occur.(Bhavsar, Abdhish R & Drouilhet, John H, 2009)

The above sample images are from an extreme rare case where progression of the disease from mild to sever proliferative diabetic retinopathy occurred over 6 months.

The following percentages are typical of the disease.(Bhavsar, Abdhish R, Atebara, Neal H, & Drouilhet, John H, 2009)

Patients with Type 1 diabetes

- In 10 – 15 years, 25 - 50% of patients show signs of retinopathy
- After 15 years, 75 -95% of patients show signs of retinopathy
- After 30 year of diabetes, 100% show signs of retinopathy

Patients with Type 2 diabetes

- After 11 – 13 years, 23% show signs of retinopathy
- After 14 – 16 years, 41% show signs of retinopathy
- After 16 years, 60% show signs of retinopathy

Facts About Diabetic Eye Disease Information

(National Eye Institute National Institutes of Health, 2010b; National Eye Institute National Institutes of Health, 2010a; Centers for Disease Control and Prevention, 2008; Aiello, L. P., Cahill, M. T., & Wong, J. S., 2001)

What is diabetic eye disease?

Diabetic eye disease, which affects both type 1 and type 2 diabetic patients, is a group of eye problems that are complications of diabetes. This includes diabetic retinopathy (DR), cataracts and glaucoma, which all can cause severe vision loss or blindness.

Download NIH information flyer on diabetic retinopathy (PDF, 474 KB)

Download NIH information flyer on cataracts (PDF, 201 KB)

Download NIH information flyer on glaucoma (PDF, 390 KB)

What is diabetic retinopathy?

Diabetic retinopathy, which is changes in the retina, is caused by changes in the blood vessels. This is a result of diabetes which affects the circulatory system of the retina over time.

There are four stages of DR:

- ***Mild*** – earliest stage, small balloon-like swelling in the retina's blood vessels.
- ***Moderate*** – blood vessels in the retina are blocked
- **Severe** – more blood vessels are blocked, body sends signal to grow more new blood vessels for nourishment.
- ***Proliferative*** – advanced stage, new blood vessels that are formed are abnormal and fragile. These vessels have thin, fragile walls that my leak.

How is diabetic retinopathy treated?

For the first three stages, no treatment is needed, unless macular edema exists. To prevent progression, blood sugar, blood pressure and blood cholesterol must be controlled.

With proliferative diabetic retinopathy, laser surgery is used to shrink the abnormal blood vessels. Two or more sessions of surgery are typically needed to complete the treatment. There may be some vision loss, but complete vision

loss can usually be prevented. Laser treatment works best before the new blood vessels start to bleed.

For severe bleeding, a surgical procedure called a vitrectomy is performed, whereby blood is removed from the eye. A vitrectomy is when an incision is made in the eye to remove the blood.

What is macular edema?

Macular edema is when the part of the retina that provides central vision swells from leaking fluid.

How is macular edema treated?

Laser surgery is used to slow the leakage of fluid and reduce the amount of fluid in the retina.

What is a cateract?

A cateract is a clouding of the lens, which is the part of the eye that helps focus light on the retina, that affects vision.

How are cateracts treated?

Early symptoms of cataract may be treated with new eyeglasses, brighter lighting or magnifying lenses. Cataracts may be removed by surgery if every day activities are impaired.

What is glaucoma?

Glaucoma is a group of diseases that can damager the eye's optic nerve by pressure buildup in the eye fluid. When the optic nerve is damaged vision loss or blindness may occur.

How is glaucoma treated?

Early stages of glaucoma can be treated to delay the progression by medication, surgery, or a combination of both.

More FACTS

- DR can develop without symptoms; however there is high risk for vision loss.
- DR is the leading cause of adult blindness in the United States.
- DR has shown to be present in nearly all persons diagnosed with diabetes for duration of more than 20 years.
- Both severe vision loss from DR and moderate vision loss from diabetic macular edema are preventable with timely detection, regular clinical retinal examinations, accompanied by appropriate interventions and glycemic control.
- People with diabetes are 60% more likely to develop cataracts.
- People with diabetes are 40% more likely to suffer from glaucoma.
- Risk for diabetes eye disease also increases with age.

How You Would See With Diabetic Eye Disease

Normal vision

Vision with diabetic retinopathy

- Vision loss is caused by damage to blood vessels in the retina.
- Diabetic retinopathy affects 40–45% of all those diagnosed with diabetes.
- Typically there are no early warning signs of diabetic retinopathy; however, eye examinations, which are the standard of care for diabetic patients, can detect the disease in its early stages.

Vision with cataracts

- Vision loss is caused by clouding of the eye's lens, typically in the early stages of diabetes.

Vision with glaucoma

- Glaucoma is caused by increased fluid pressure inside the eye.
- People with diabetes are twice as likely to get glaucoma as those without the disease.

For Additional Information

American Diabetes Association

http://www.diabetes.org/home.jsp

EyeCare America

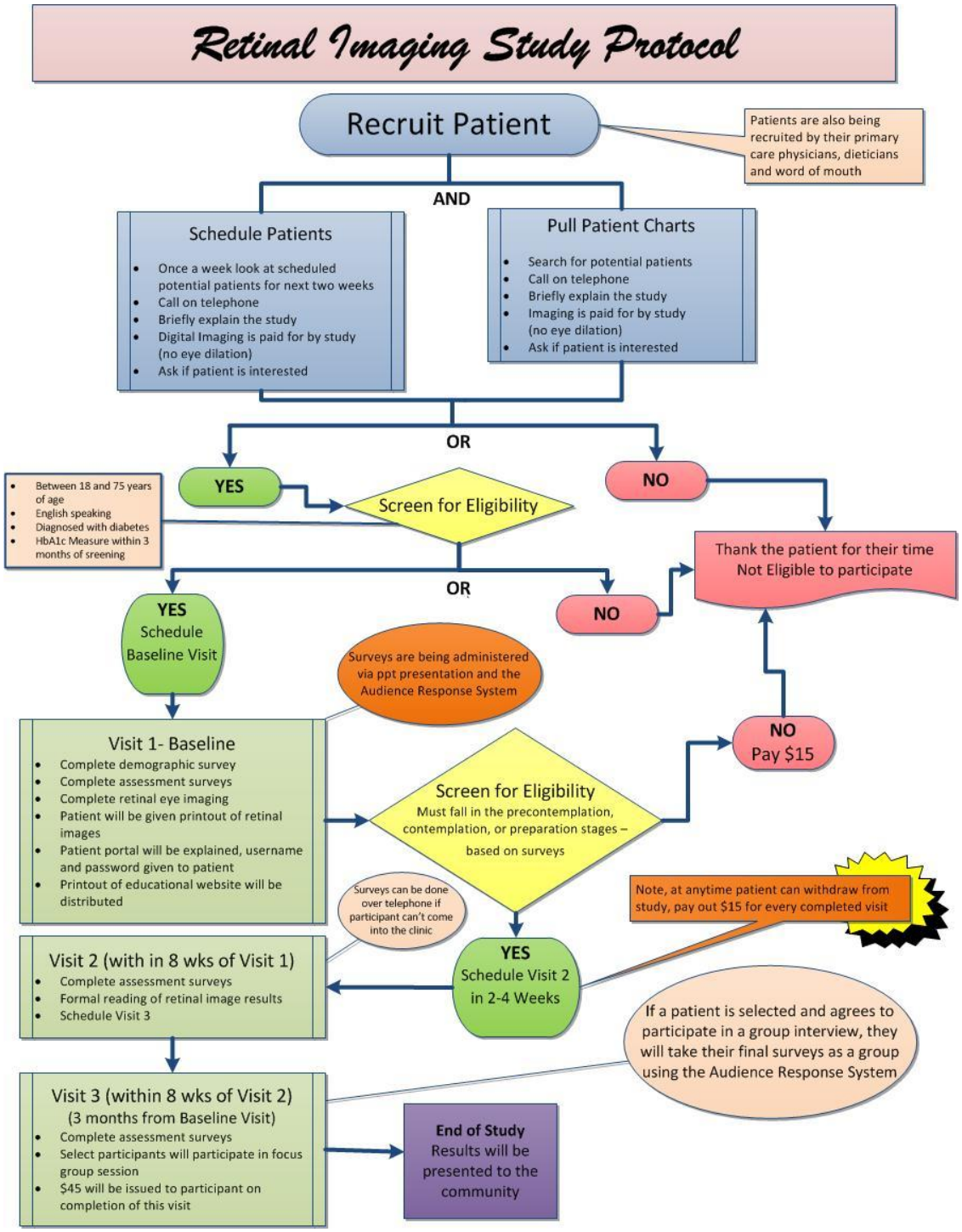
http://www.eyecareamerica.org/eyecare/

National Eye Institute (NEI)

http://www.nei.nih.gov

APPENDIX 15

STUDY FLOW



APPENDIX 16

REPORT TO COMMUNITY FLYER

For more information
and to RSVP,
please contact
Kathleen Connolly
(808) 692-1089
kihmm@hawaii.edu

This study is sponsored by the U.S. Army Medical Research and Material Command and the University of Hawaii

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD, 21702-5014, is the awarding and administering acquisition office, through award no. W81XWH-09-2-0166.

The Content of this brochure does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred.

Diabetes Retinal Imaging Study

Results Are In!

You are invited
to come and learn the results of this study.

Where:
KA'AHA'AINA CAFE
Waianae Cost Comprehensive Health Center
86-260 Farrington Highway
Waianae, Hawaii 96792

When:
Tuesday, July 17th, 2012
4pm—5pm Presentation
5pm—6pm Refreshments

Please RSVP by July 11th

APPENDIX 17

UNIVERSITY OF HAWAII INSTITUTIONAL REVIEW BOARD APPROVAL

UNIVERSITY OF HAWAI'I

Committee on Human Studies

MEMORANDUM

October 20, 2010

TO: Deborah Birkmire-Peters, Ph.D.
Principal Investigator
Telehealth Research Institute

FROM: Nancy R. King
Director

SUBJECT: CHS #17909 – "Does a Personalized Health Portal for Diabetes Retinal Imaging Positively Affect Motivational Readiness to Change?"

Your application for CHS approval of the proposed change within the current approval period was approved by the Committee on Human Studies (CHS) on October 19, 2010 for the study identified above. The approved changes were to the protocol and consent form.
This application qualified for Expedited Review under CFR 46.110 and 21 CFR 56.110, Category (b).

If future revisions to your study are required, please seek CHS approval prior to their implementation. If a change is necessary to protect the safety or welfare of study participants, it is permissible to make the change without prior approval. However, you must notify the CHS as soon as possible, requesting approval for the change.

When seeking approval to modify a CHS-approved document, please submit the document using "Track Changes" to identify the proposed modifications. Clearly explain the reason for the change on the CHS Status Report form.

Please contact the CHS office at 956-5007 if you have any questions or require assistance.

1960 East-West Road, Biomedical B104, Honolulu, Hawaii 96822-2303
Telephone: (808) 956-5007, Facsimile: (808) 956-8683, Website: www.hawaii.edu/irb

APPENDIX 18

WCCHC INSTITUTIONAL REVIEW BOARD APPROVAL

WAIANAE COAST COMPREHENSIVE

HEALTH CENTER

DATE: August 11, 2010

TO: Deborah Peters, PhD

FROM: Rachelle Enos, Chair
Waianae District Comprehensive Health and Hospital Board, IRB (WCCHC)
IRB # 00006399

SUBJECT: 10–WCCHC–01-Hawaii: **Does a Personalized Health Portal for Diabetes Retinal Imaging Positively Affect Motivational Readiness to Change?**

PI: Deborah Peters, PhD

Your response to the WCCHC IRB request for clarification and required revisions has been determined satisfactory; therefore, your project is approved to proceed. The Assurance ID for this project is attached.

This assurance must be renewed annually, and the WCCHC IRB must be notified immediately if there are any changes in the study protocol or management, or in the case of any adverse or unanticipated events.

Please contact me if you have any questions. We are pleased to be collaborating with you on this innovative project.

Sincerely,

Rachelle Enos, MPH
Chair, WCCHC IRB

86-260 Farrington Highway, Waianae, Hawaii 96792 • Telephone: (808) 696-7081 • Fax: (808) 696-7093
Visit our website at: www.wcchc.com

APPENDIX 19

ARMY INSTITUTIONAL REVIEW BOARD APPROVAL

From: Brosch, Laura R Dr CIV USA MEDCOM USAMRMC [Laura.Brosch@us.army.mil]
Sent: Monday, September 20, 2010 9:14 AM
To: Deborah P. Peters
Cc: Bennett, Jodi H Ms CIV USA MEDCOM USAMRMC; brigit.ciccarello@tatrc.org; sherry.labella@amedd.army.mil; Kathleen Kihmm Connolly; stanley.saiki@tatrc.org; Brosch, Laura R Dr CIV USA MEDCOM USAMRMC; Duchesneau, Caryn L Ms CIV USA MEDCOM USAMRMC; Mizell, Stephanie B CTR US USA MEDCOM USAMRMC; Katopol, Kristen R Ms CTR US USA MEDCOM USAMRMC
Subject: A-15721.b HRPO Approval Memorandum (Proposal No. 08113006, Award No. W81XWH-09-2-0166) Site: WCCHC (UNCLASSIFIED)

Classification: UNCLASSIFIED
Caveats: NONE

SUBJECT: Initial Approval for the Protocol, "Does a Personalized Health Portal for Diabetes Retinal Imaging Positively Affect Motivational Readiness to Change," Submitted by Deborah P. Peters, University of Hawaii, Honolulu, Hawaii, Proposal Log Number 08113006, Award Number W81XWH-09-2-0166, HRPO Log Number A-15721.b (Site: Waianae Coast Comprehensive Health Center)

1. The subject protocol (dated 4 March 2010) was approved by the Waianae District Comprehensive Health and Hospital Board (WCCHC) Institutional Review Board (IRB) on 24 March 2010. This protocol was reviewed by the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) and found to comply with applicable DOD, U.S.
Army, and USAMRMC human subjects protection requirements.

2. This no greater than minimal risk study is approved for the enrollment of 213 subjects total (at the WCCHC and the University of Hawaii sites.)

3. The following are reporting requirements and responsibilities of the Principal Investigator to the HRPO. Failure to comply could result in suspension of funding.

a. Major modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. Major modifications include a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change in age range or change in/addition to the study population, or a change that could potentially increase risks to subjects.

b. All unanticipated problems involving risk to subjects or others must be promptly reported by telephone (301-619-2165), by email (hsrrb@amedd.army.mil), or by facsimile (301-619-7803) to the HRPO. A complete written report will follow the initial notification. In addition to the methods above, the complete report can be sent to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RP, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

c. Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the Sponsor, or regulatory agencies will be promptly reported to the USAMRMC ORP HRPO.

d. Any deviation to the protocol that may have an adverse effect on the safety or rights of the subject or the integrity of the study must be reported to the HRPO as soon as the deviation is identified.

e. A copy of the continuing review approval notification by the WCCHC IRB must be submitted to the HRPO as soon as possible after receipt of approval. According to our records, it appears the next continuing review by the WCCHC IRB is due no later than 23 March 2011.
Please note that the HRPO also conducts random audits at the time of continuing review and additional information and documentation may be requested at that time.

f. The final study report submitted to the WCCHC IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.

g. The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research; the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies including legal or medical actions; and any instances of serious or continuing noncompliance with the regulations or requirements must be reported immediately to the HRPO.

4. Please Note: The USAMRMC ORP HRPO conducts random site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

5. Do not construe this correspondence as approval for any contract funding. Only the Contracting Officer or Grants Officer can authorize expenditure of funds. It is recommended that you contact the appropriate contract specialist or contracting officer regarding the expenditure of funds for your project.

6. The HRPO point of contact for this study is Stephanie Mizell RN, BSN, MPH, Human Subjects Protection Scientist, at 301-619-1032/Stephanie.mizell@amedd.army.mil

LAURA RUSE BROSCH, RN, PhD
Director, Office of Research Protections Human Research Protection Office U.S. Army Medical Research and Materiel Command

Note: The official copy of this approval memo is housed with the protocol file at the Office of Research Protections, Human Research Protection Office, 504 Scott Street, Fort Detrick, MD 21702. Signed copies will be provided upon request.
Classification: UNCLASSIFIED
Caveats: NONE

APPENDIX 20

INFORMED CONSENT

UNIVERSITY OF HAWAII at Manoa

Informed Consent Form

Subject's Name:

Principal Investigator: *Deborah Birkmire-Peters, Ph.D.*

Co-Investigators: *Kathleen Kihmm Connolly, M.S.*

Sven-Erik Bursell, Ph.D.

Project Title: *Does a Personalized Health Portal for Diabetes Retinal Imaging Positively Affect Motivational Readiness to Change?*

This Portion To Be Reviewed and Signed by Subject:

This consent form may contain words that I do not understand. I will ask the study investigator or a member of the staff to explain any words or information that I do not understand.

PURPOSE OF PROJECT:

You have been asked to participate in this research study because you have been diagnosed with type 2 diabetes and have been referred by a primary care physician for retinal imaging (eye examination). The purpose of this research study is to look at how you feel about diabetes self-management behaviors. This study is being sponsored (paid for) by funding from the United States Department of Defense.

VOLUNTARY:

Your participation in this study is voluntary. You may refuse to participate or even withdraw once the study has started. You will not be penalized or lose any benefits to which you are otherwise entitled.

The study staff or the study sponsor may stop your participation if you do not follow the study schedule or if there is a change in your medical condition.

If any new information is learned about the study procedures that may change your mind about staying in the study, it will be given to you.

ALTERNATIVE METHODS:

You may choose not to participate in this study. You do not have to participate in this study to receive treatment for your diabetes. Participation in this study is not a substitute for your usual ongoing medical care by your regular doctor or specialist.

STUDY PROCEDURES:

You will be one of approximately 213 subjects who will participate in this study. You are eligible to participate because:

You are a patient of the Waianae Coast Comprehensive Health Center (WCCHC)
You have been diagnosed with type 2 diabetes by a physician
You are at least 18 years old, but younger than 75 years old
Your are comfortable reading and/or speaking English
You have had an A1c test within the last 3 months

You will make a total of three visits to the WCCHC for this study. Each visit will last about 1 hour. You may be chosen to participate in a focus group discussion that will be part of your third visit. If you are chosen and agree to be part of the focus group, the third visit will take about an hour and a half. Your total participation is about 3 months after the first study visit.

During each visit you will fill out questionnaires about yourself, including your background, ways in which you take care for yourself, and how you feel about caring for your diabetes. During the first visit, you will also have an eye exam where photographs of the retinas of your eyes will be taken. During the second visit a staff member will discuss the results of your eye exam. When we schedule your third visit, which will be about 3 months after our fist visit, we will let you know if you have been chosen for the focus group. There will be refreshments provided at the focus group discussion.

As part of the study but not part of the visits:

The study will review your medical records to obtain your most recent A1c measure (a measure of my blood sugar control over a short period of time), Body Mass Index (BMI), and blood pressure.

RISKS AND/OR DISCOMFORT:

There are no known risks to your participation in this study, however you understand that there may be unforeseeable risks related to this study and if you are injured in the course of this research procedure, you alone may be responsible for the costs of treating your injuries.

Coming to WCCHC three times and completing the questionnaires may be time-consuming and inconvenient for you.

IMPORTANT INFORMATION:

It is not the policy of the Waianae Coast Comprehensive Health Center to provide free medical treatment or financial compensation for such things as lost wages, disability, and discomfort as a result of such event or injury.

BENEFITS:

There is no guarantee that you will benefit by participating in this study. However, you and patients with diabetes may benefit from this medical research in the future.

COST/PAYMENT:

You will not be charged for any of the study procedures.

On your completion of the study, you will receive $15 for each visit you qualify for and complete ($45 maximum) to compensate for time and inconvenience associated with participation in research activities at WCCHC. It is anticipated that the time you will spend will be approximately three hours participating in the research study. If you are chosen to participate in a focus group during the third visit, approximate and additional 30 mintues of your time (refreshments will be served).

You will receive compensation on your final visit of the study. If you voluntarily choose to drop out prior to your final visit, please contact kathleen Connolly, Project Coordinator at (808) 692-1089 to arrange compensation for completed visit.

CONFIDENTIALITY:

Medical data collected from your participation in the study will be subject to the Institutional Review Boards of the University of Hawaii and the WCCHC and will not be revealed or disclosed to anyone other than the members of the study staff and representatives of the U.S. Army Medical Research and Materiel Command (MRMC). Representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research protocols as part of their responsibility to protect human subjects in research.

However there is a risk of breach of confidentiality that cannot be totally eliminated. To minimize that risk, study records will be kept in restricted areas at the WCCHC and at the University of Hawaii. Computer access will be restricted by a password known only to authorized members of the staff at the WCCHC and the University of Hawaii. Information that could identify you, such as name, will be maintained in a file separated from all study information. All questionnaires you complete will not have your name on them. Instead, they will be labeled with a number. All study records will be destroyed five years after the end of the overall study.

In spite of these efforts to protect the confidentiality of information about you, there is a risk that sensitive information may be obtained by others or discovered or inferred by members of your family.

The results of this study may be published in scientific journals or presented at medical meetings, but your identity will remain confidential.

AUTHORIZATION TO OBTAIN/UTILIZE IMAGES:

Sometimes an image and/or part of a videotape clearly shows a particular feature or detail that would be helpful in teaching or when presenting the study results at a scientific presentation or in a publication.

By signing this consent form you acknowledge that you are over 18 years of ages and hereby grant permission to the University of Hawaii and its affiliates and subsidiaries to

be photographed, and to allow the University of Hawaii and its affiliates and subsidiaries to use and/or permit others to use the images in which you may appear in for teaching, scientific presentations and/or publications with the understanding that you will not be identified by name.

If you would like to withdraw consent for use of images in which you appear to be used, please check the following.

☐ No, I do not consent to use my images.

QUESTIONS:

In the event of a research-related injury, or if you have any questions at any time about the research study, Dr. Peters or her associates will be glad to speak to you at (808) 692-1090 during the hours of 8am - 5pm, Monday through Friday HI time. Or you can write to the following address:

Telehealth Research Institute
John A. Burns School of Medicine
651 Ilalo Street, MEB, Suite 212
Honolulu, HI 96813

If you have questions about your legal rights as a research subject, or would like to report an adverse event related to participation in this research study, you may contact the following:

Rachelle Enos
WCCHC Research Coordinator/IRB Chair
86-260 Farrinton Highway
Waianae, Hawaii 96792
(808) 697-3330

Committee on Human Studies
University of Hawaii
1960 East-West Rd./ Biomed B-104
Honolulu, HI 96822
(808) 956-5007

CONSENT:

You will be given a copy of this consent form to keep. By signing this consent form, you are not waiving any of your legal rights, claims, or remedies.

I have read (or someone has read to me) the information in this consent form. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. By signing this consent form, I willingly agree to participate in this study.

_____ _____

Signature of Subject *Date*

_____

Permanent Street Address of Subject

_____

City and Postal Code of Subject

This Portion to be Completed by Investigator (or Representative):

I have explained to the above-named subject the nature and purpose of the procedures described above and such foreseeable discomfort, risks, and benefits that may result. I have considered and rejected alternative procedures for obtaining this information. I have asked the subject if any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

_____ _____

Signature of Investigator (or Representative) *Date*

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