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Associations Among Measures of Engagement with KP.Org and Clinical Outcomes

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ASSOCIATIONS AMONG MEASURES OF ENGAGEMENT WITH KP.ORG AND
CLINICAL OUTCOMES

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A DISSERTATION

Submitted to the graduate faculty of The University of Alabama at Birmingham,
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USING MEASURES OF ENGAGEMENT WITH KP.ORG TO DETERMINE
ASSOCIATIONS WITH SELECTED CLINICAL OUTCOMES

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ABSTRACT

Introduction

The purpose of this retrospective cohort study was to examine patterns of use of an electronic personal health record among adults diagnosed with diabetes, hypertension or hyperlipidemia. Intermediate behavioral measures (medication possession ratios) and physiological measures of metabolic control for diabetes (hemoglobinA1c), hypertension (blood pressure) and hyperlipidemia (low density lipoprotein) were examined.

Methods

Administrative data from Kaiser Permanente Georgia were analyzed. Adult members of with selected chronic diseases of diabetes, hypertension or hyperlipidemia who used the Kaiser Permanente electronic personal health record (KP.Org) during calendar year 2008 were included (n = 9504). The cohort was assessed for a period of 6 months prior to initial KP.Org logon to establish baseline information, and was followed forward in time for a period of up to 14 months to establish post-exposure outcomes. Logon to KP.Org was measured as a frequency tabulation using quartiles of use calculated via univariate analysis. Quartile 1 was set as the lowest frequency of use and served as the referent group. Use functions within KP.Org included secure messaging, encounter details, lab results, medical advice and medications. Intermediate behavioral measures of adherence, medication possession ratios, were calculated by taking the total days of supply of

medications dispensed, divided by the total number of days between the first and last prescription refill. Physiological clinical outcome measures included hemoglobinA1c, blood pressure and low density lipoprotein. Logistic and multiple regression analyses were conducted controlling for the covariates of age, gender, percent African American and Geostrata quartile (a proxy measure of socioeconomic status).

Results

There was a statistically significant association between highest logon to KP.Org and medication possession ratios among participants stratified by diabetes (p <.0001), hypertension (0.0076) and hyperlipidemia (0.0002). There was a statistically significant association between increased use of KP.Org primary outcome variables of HbA1c (p<.0001), blood pressure (p<.0001) and low density lipoprotein (p<.0001).

Conclusion

Increased use of KP.Org was associated with improvements in physiological outcome measures and with medication possession ratios. Medication possession ratios were a significant indicator of improved outcome measures among diabetics and hyperlipidemics, but not among hypertensives.

Keywords: electronic personal heath record, nursing informatics, secure messaging, provider patient communication, patient engagement in chronic disease management, nursing research

DEDICATION

This dissertation is dedicated to my parents, Edward and Barbara Sobko, whose unconditional love, unwavering support and ongoing encouragement made this possible. And to my sister Leslie, who never stopped believing in me even amidst many challenges and barriers. I also dedicate this dissertation to Aristotle, who was my constant companion and a wonderful source of great joy and happiness. I love you all eternally.

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LIST OF ABBREVIATIONS

PHR   Personal Health record

ARRA   American Reinvestment and Recovery Act

ONC   Office of the National Coordinator

DHHS   U.S. Department of Health and Human Services

HIE   Health Information Exchange

USB   Universal Serial Bus

ASTM   American Society for Testing and Materials, International

CCR   Continuity of Care Record

HIMSS   Health Information Management Systems Society

ADA   American Diabetes Association

CDC   Centers for Disease Control and Prevention

AHA   American Heart Association

EHR   Electronic Health Record

HMO   Health Maintenance Organization

CMS   Centers for Medicare and Medicaid Services

KP   Kaiser Permanente

KPGA   Kaiser Permanente, Georgia

Kp.Org   Kaiser Permanente Personal health Record System

NHANES   National Health And Nutrition Examination Survey

HEDIS   Healthcare Effectiveness and Data Information Set

NCQA	National Committee for Quality Assurance
NQF	National Quality Forum
HbA1c	Hemoglobin A1c
BP	Blood Pressure
LDL	Low Density Lipoprotein
SES	Socioeconomic Status
% African American	Percent African American
CINAHL	Cumulative Index in Nursing and Allied health Literature
NIH	National Institutes of Health
HIPAA	Health Insurance Portability and Accountability Act
ECPA	Electronic Communications Primacy Act
AMA	American Medical Association
CITL	Center for Information technology Leadership
AHIMA	American Health Information Management Association
AHRQ	Agency for Healthcare Research and Quality
NTIA	National Telecommunications and Information Administration
NEHTA	National E-Health Transition Authority
FCC	Federal Communications Commission
BRFSS	Behavioral Risk Factor Surveillance System
WHO	World Health Organization
NHLBI	National Heart, Lung and Blood Institute
NIDDK	National Institute of Diabetes and Digestive Kidney Diseases
CSFII	Continuing Survey of Food Intakes by Individuals

USDA/ARS	United States Department of Agriculture/ Agricultural Research Service
HDL	High Density Lipoprotein
ARIC	Atherosclerosis Risk In Communities
CHS	Cardiovascular Health Study
NIA	National Institute on Aging
CHD	Coronary Heart Disease
JNC-7	Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure

CHAPTER 1

INTRODUCTION

There is growing support for the use of innovative technologies to improve the

delivery of healthcare by increasing patient engagement in decision-making processes,

improving communication between patients and providers, and improving processes for

access to healthcare and health-related information (Ahern, Phalen, & Mockenhaupt,

2003; Allen, Lezzoni, Huang, Huang, & Leveille, 2008; Botts & Horan, 2007; Ferrante,

2005; Kuhn, Giuse, Lapao, & Wurst, 2007). In *Crossing the Quality Chasm*, the Institute

of Medicine emphasized that patient care should not only occur within the constructs of

face-to-face meetings with providers, but "access to care should be provided over the

Internet, by telephone and by other means in addition to face-to-face visits " to foster

continuous healing relationships (Institute of Medicine, 2001, p. 4). Subsequent reports

have promoted the use of electronic tools such as Personal Health Records (PHRs) that

enable patients to take a more active role in managing their own health (Tang, 2006).

New objectives in the recently released Healthy People 2020 set forth by the

United States Department of Health and Human Services (2010), include developmental

goals to increase the proportion of persons who use electronic personal health

management tools, increase the proportion of persons who use the Internet to keep track

of personal health information, and increase the proportion of persons who use the

Internet to communicate with their provider (Department of Health and Human Services,

2010, December). Federal funding has been allocated to promote activities that will

support working toward these goals as part of the American Recovery and Reinvestment Act of 2009, (111th Congress, 2009). The Centers for Medicare and Medicaid Services (CMS) and the Department of Veterans Affairs (VA) have been using variations of the electronic PHR for several years as a strategy to improve the delivery of healthcare for their respective members (Endsley, 2006). However, these strategies have only begun to be evaluated, and initial findings are highly variable (Greene, 2008; Kahn, Aulakh, & Bosworth, 2009; Middleton, 2009). There is a need to comprehensively evaluate whether use of an electronic PHR is associated with improvement in health outcomes.

The Office of the National Coordinator (ONC) within the United States Department of Health and Human Services (DHHS) is supporting the development of a Health Information Exchange (HIE), a mechanism for sharing relevant patient health information among providers across institutions for the purpose of improving the efficiency and safety of healthcare delivery (Office of the National Coordinator of Health Information Technology, 2010). Although the idea of HIE is not new, the processes involved in establishing this type of network are highly complex and will require significant expertise, multi-disciplinary collaborations and extensive resources (Frisse, 2010). If successful, an HIE could serve as a catalyst for widespread adoption of electronic patient-centered PHRs by supporting the use of electronic mechanisms for information exchange between providers and patients (Fruhling, 2010).

Defining Personal Health Records

The online PHR is a technological innovation designed to provide continuous access to patient-specific relevant information. The technological capabilities and novel applications of electronic PHRs are evolving rapidly, and previous studies have revealed varied levels of success in the implementation of different types of PHR structures and functionalities (Endsley, 2006). To date, there is no universally accepted definition of a PHR. However, several distinct approaches to the electronic PHR have emerged.

One version of the electronic PHR is a provider-owned and provider-maintained digital summary of relevant clinical information that can be viewed by patients. This variation of the electronic PHR is a 'read-only' record for the patient (the patient cannot edit the record by altering, adding or deleting any information). The provider (individual or organization) supplies, controls and maintains the data, and can make limited sets of information such as laboratory test results, medication lists, or appointments available to patients for viewing. Typically, viewing of the electronic data occurs via a password-protected Web site or a patient portal. Some organizations are also making data on claims processing, prescriptions, medication refills and imaging studies available for their members (Tang, 2009).

A second version of electronic PHR is a patient-owned software program that allows individuals to input their own health information into the program (Greenhalgh, 2010). Patients manage the PHR and can notate concerns, problems, symptoms, contact information, medication lists, and so forth. Patients may choose to share their PHR with their provider(s) via email or by creating a printed version. The PHR software usually resides on an individual's computer. Alternatively, the PHR can be accessed via Web-

link, in which case the site is maintained by a third-party host. This format is similar to systems used by financial institutions that maintain password-protected, secure sites containing individual financial information. Microsoft Health Vault[©] and Google Health[©] utilize this kind of structure. One of the limitations of this version of electronic PHR is that it requires a great deal of data entry by the patient, making it time and labor intensive. To remain useful for patients and providers, the information in this type of PHR structure requires ongoing updates and input of data. For individuals with complex health needs, multiple medications, frequent visits to numerous providers, or frequent changes in medication regimes, maintenance of this type of PHR structure may be overly burdensome.

A third version of the electronic PHR is a portable digital file that contains selected, clinically relevant health data which can be managed, secured, and transferred between computers (Flatley-Brennan, 2007). The portable digital file can be transferred using a USB (universal serial bus) -compatible device such as a smart card, personal digital assistant or cellular phone, which can be plugged in to a computer (Ellingsen & Monteiro, 2008). This version of the PHR corresponds very closely to the ASTM International[®] (formerly known as the American Society for Testing and Materials) E-2369-05 standard specification for Continuity of Care Record (CCR). Developed collaboratively by medical and nursing experts and health information technology vendors, the CCR includes elements such as personal and demographic information, emergency contact information, insurance information, allergies, medications, surgeries, hospitalizations, advanced directive forms, problem lists, care plans, immunizations,

laboratory tests and results, spiritual affiliations and cultural considerations (Endsley, 2006).

In addition to these three basic versions of the electronic PHR, definitions of electronic PHRs and recommendations for optimal PHR structure have been set forth by organizations that specialize in health information technology. For example, the Healthcare Information Management Systems Society (HIMSS) suggests that an effective electronic PHR should be universally accessible, easy to understand, and should serve as a lifelong tool for managing relevant health information, promoting health maintenance and assisting with chronic disease management via an interactive, common set of electronic tools (Healthcare Information Management Systems Society, 2007) . Similarly, other health information experts suggest the optimal PHR should include an internet-based tool kit that provides individuals with the opportunity to access and manage their lifelong health information, (Markle Foundation, 2006). The American Health Information Management Association (AHIMA) recommends that the ideal PHR should offer more than a static repository for storing patient data and should provide functions that combine data, knowledge, and tools to assist patients in becoming active participants in their own care (Burrington-Brown, 2005). Using the definitions of these leaders in the development of technologies to enhance healthcare delivery, the PHR has the potential to represent a viable tool for the promotion and maintenance of health by encouraging engagement between patients, providers, and the healthcare system.

Background and Significance

In addition to storing patient health information, the patient-centered PHR can also include decision-support capabilities that may be especially effective in assisting patients with their own management of chronic health conditions, such as diabetes, hypertension and hyperlipidemia. These chronic health conditions often require more frequent contact with providers, ongoing monitoring of medications and frequent laboratory testing for effective management, and may be particularly conducive to web-based electronic tools, such as the PHR. There is a great need to find effective mechanisms to address the alarming growth rate of these pervasive chronic health conditions while supporting self-management strategies for patients (Institute of Medicine, 2001).

Prevalence of Diabetes, Hypertension and Hyperlipidemia

The prevalence of diabetes, hypertension and hyperlipidemia among all age groups in the United States is approaching epidemic proportions. Recent estimates indicate more than 25.8 million people, 8.3% of the U.S. population, have diabetes (Centers for Disease Control and Prevention, 2011b). Further, according to the National Health Statistics Reports 2003- 2006, among the U.S. population age 20 and older, approximately 31% have a diagnosis of hypertension, and nearly 42% of women and 34% of men have a diagnosis of hyperlipidemia (Centers for Disease Control and Prevention, 2007). This constitutes an extremely pervasive problem among American adults.

The total economic cost of diabetes in America in 2007 was estimated to be $174 billion. Medical expenditures totaled $116 billion; comprised of $27 billion for diabetes care, $58 billion for chronic diabetes-related complications, and $31 billion for excess general medical costs (American Diabetes Association, 2008). These economic costs and health consequences cannot be sustained. Of great concern are research reports that reveal only 50% of patients diagnosed with diabetes adhere to their treatment regimes, leading to serious health complications, emergency hospitalizations and costly medical interventions (Delamater, 2006).

Similarly, studies evaluating causal factors of heart disease, the number one cause of death in the United States, indicate that diabetes, hypertension and hyperlipidemia often cluster together and significantly increase the risk of premature death and comorbid health complications (McDonald, 2008; Riegel, 2009). Research shows that while hyperlipidemia is a major modifiable risk factor for heart disease and diabetes, less than 50% of patients who are prescribed cholesterol-lowering medications take these medications as instructed (Senior, 2004), and an estimated 60,000 deaths occur annually in the United States as a result of failure to effectively manage high cholesterol (Kohn, 2000). Clearly there is a need to develop tools for patients to better manage chronic diseases such as diabetes, hypertension and hyperlipidemia.

Potential Benefits of Electronic PHRs

Use of electronic tools such as PHRs may promote improved monitoring and management of blood glucose, blood pressure and cholesterol levels by providing automatically generated alerts to patients to schedule lab tests, make an appointment with

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the physician, or refill medications. Electronic PHRs can also provide descriptions of tests, links to appropriate patient-centered health information, and general interpretation of laboratory results. Patients experiencing chronic illnesses can utilize PHRs to track their diseases in conjunction with their healthcare providers which may potentially reduce communication barriers between patients and their providers (Grant, et al., 2008).

In March, 2010, Kaiser Permanente completed the implementation of the largest Electronic Health Record (EHR) system in the world, connecting more than 450 medical offices and 35 hospitals across nine states and Washington D.C. (Scott, 2011). The system, called HealthConnect[©], was designed to coordinate care among multiple providers across various medical care settings, and includes a secure messaging component for enhanced communication between patients and their providers. Recent reports from Kaiser Permanente reveal more than 700,000 emails are exchanged each month between patients and providers within the HealthConnect[©] system (Scott, 2011).

Improved provider-patient communication may serve to facilitate earlier interventions and shared decision-making when complications or problems are encountered, supporting a streamlined system of healthcare delivery that is continuous rather than episodic (Zhou, Kanter, Wang, & Garrido, 2010). For example, electronic tools designed to connect patients with their providers via monitoring of glucose levels, blood pressure and cardiac rhythms transmitted through secure phone lines or via wireless technologies have shown a reduction in acute emergencies and hospital readmissions associated with diabetes and congestive heart failure (Chumbler, 2007; Jha, 2008; Wright, 2008).

Early systems, primarily controlled by healthcare professionals, have been effectively used to remotely monitor patient status and provide instructions to patients in a traditional 'rescue intervention model' (Piette, 2010). In this model, providers are electronically alerted when pre-established parameters of glucose, blood pressure or heart rates fluctuate outside the appropriate range, and may contact the patient for the purpose of adjusting the prescribed treatment regime to address these fluctuations. While these technologies have demonstrated high levels of effective early notification to providers, they have also been labor intensive and costly (Bierman, 2006). To date, evidence of increased patient engagement in decision-making associated with utilization of provider-controlled remote monitoring tools is lacking.

Researchers evaluating electronic PHRs developed from a more patient-centered approach have received positive feedback regarding effectiveness in meeting patient and provider needs (Grossman, Zayas-Caban, & Kemper, 2009). Patients and providers have reported improvements in communication and information-sharing as well as increases in effective diabetes medication adjustments when using systems that are managed collaboratively between patients and providers (Grant, et al., 2008; Kahn, et al., 2009). These types of applications include notification to patients when potential complications of chronic illness occur. Patients receive automatically-generated alerts and are encouraged to take appropriate action in following their pre-established care plans developed in advance with their provider. Further research is needed to better understand the relationship between electronic PHR use and chronic illness management (Mandl, 2007).

It is important to recognize that having access to the Internet and possessing the necessary skills for effective utilization of electronic PHRs are not universal. Although PHRs have the potential to increase the quality and effectiveness of healthcare delivery, not all patients will have access to PHRs, and those with access may or may not effectively utilize the available tools. A two year cohort study to assess rates of PHR use among individuals ages 25-59 participating in a Health Maintenance Organization (HMO) in a southern metropolitan city, found significant differences in access to PHRs by race, even when controlling for education and income, suggesting a possible unintended consequence of increasing health disparities due to unequal use and access (Roblin, 2008). Further, there may be considerable variation among individuals in their ability and willingness to take on the role of managing personal health and attending to personal health needs (Pagliari, et al., 2005).

The U.S. Secretary of Health and Human Services, the National Coordinator for Health Information Technology, and the Administrator of the Centers for Medicare and Medicaid Services (CMS) have all identified PHRs as a priority, resulting in a substantial increase in activity surrounding the use of PHR systems for patients and providers (Centers for Medicare and Medicaid Services, 2010; CMS, 2010; Tang, 2006). One PHR system that has achieved high levels of acceptance is the PHR developed and implemented by Kaiser Permanente.

<div align="center">Kaiser Permanente</div>

Founded in 1945, Kaiser Permanente (KP) is one of the nation's largest not-for-profit health plans, serving more than 8.6 million members. Kaiser Permanente evolved

from industrial health care programs for construction, shipyard, and steel mill workers for

the Kaiser industrial companies during the late 1930s and 1940s. It was opened to public

enrollment in October 1945 and comprises The Kaiser Foundation Health Plan, Inc.,

Kaiser Foundation Hospitals and their subsidiaries, and The Permanente Medical Groups.

As a national program, Kaiser Permanente provides healthcare services to its members in

multiple states (see Figure 1), and regions (see Table 1).

Figure 1. Kaiser Permanente Service Regions Map
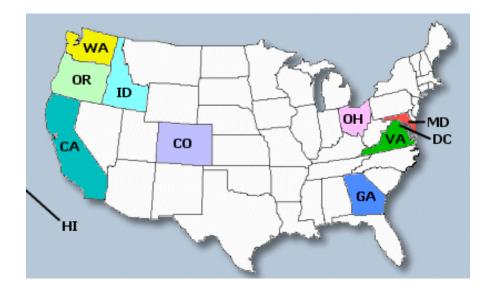
Table 1. Kaiser Permanente Service Regions

Colorado	Denver, Colorado Springs, Boulder
Georgia	Atlanta
Hawaii	Oahu, Kauai, Hawaii, Maui
Mid-Atlantic States	Washington, D.C., Northern Virginia, Suburban Maryland, Baltimore
Northern California	East Bay, Golden Gate, South Bay, Valley, Fresno, North East Bay, Stanislaus County
Northwest	Portland, Salem, Vancouver, Washington, Longview/Kelso

Ohio	Cleveland, Akron
Southern California	Coachella Valley, Kern County, Orange County, the Valleys, western Ventura County, Inland Empire, metropolitan Los Angeles/West Los Angeles

Table 2. Kaiser Permanente Membership by Region (data as of December 31, 2008)

Colorado	479,800
Georgia	268,802
Hawaii	222, 594
Mid-Atlantic States (Virginia, Maryland, Washington, D.C.)	485,401
Northern California	3, 285,068
Northwest (Oregon/Washington)	472,555
Ohio	137,669
Southern California	3,281,915
Total Membership	8,633,804

Table 3. Kaiser Permanente Medical Facilities and Staff (data as of December 31, 2008)

Medical Centers	35
Medical Office	431
Physicians (approximate, representing all specialties)	14, 600
Employees (approximate, representing technical, administrative and clerical employees and caregivers)	167, 300

Table 4. Kaiser Permanente Annual Operating Revenues 2005-2008

2005	$ 31.1 billion
2006	$ 34.4 billion
2007	$ 37.8 billion
2008	$ 40.3 billion

KP.Org

The Kaiser Permanente Healthcare Network utilizes a centralized electronic medical record and documentation system, Kaiser Permanente HealthConnect®. Because Kaiser Permanente (KP) serves as both provider and payer linked through this electronic system, data generated from this system provides a unique opportunity to examine health status, health behaviors and health outcomes in a variety of ways. The structure of the KP HealthConnect® system creates data that can be examined at the national, regional, local or individual level. All data are linked via a unique patient medical record identifier. Providers throughout the entire KP Healthcare Network have access to and interact with this system. The personal health record portion of the system that provides patients with electronic access to their electronic medical record (KP.Org) is described as follows.

Kaiser Permanente first launched KP.Org in 2005. Today, more than 8.6 million Kaiser Permanente members have activated their electronic PHR, making KP.Org one of the most actively used electronic PHRs in the world. KP.Org provides care teams with access to patient information and up to date best practice guidelines to enhance patient safety and quality care while increasing convenience and coordination of services (Oldenburg, 2009).

In addition to increasing communication and sharing best-practice guidelines among care teams and providers, KP.Org also empowers patients to manage their own health and provides secure access to tools designed to assist patients in connecting to the people and services they need to remain healthy. KP members send more than 700,000 secure e-mail messages each month to KP doctors and clinicians (Kahn, et al., 2009;

Scott, 2011), potentially preventing inconvenience of waiting for a phone call or making an unnecessary trip to the doctor's office (Institute of Medicine, 2001). Timely communication and current information can also potentially decrease redundancies in healthcare services and overuse of the system because patient needs are being met more efficiently (Cass, 2009). KP.Org presents a single online entry point for members to access online features and tools such as medication information and prescription refills, timely access to lab test results, summaries of their health conditions, summaries of visits with their provider, health information, and appointment setting for laboratory tests and provider visits.

Structure of KP.Org

The KP.Org web portal uses an open source Epic Common platform with the ability to implement regional differences as needed. This provides a basic platform for all regions so that individual modules can be developed and utilized in accordance with the specific goals of each location and facility in the KP system. Priorities and health goals of particular regions are algorithmically derived from a variety of data sources and disease registries including National Health and Nutrition Examination Survey (NHANES) managed by the Centers for Disease Control and Prevention (CDC), and the Healthcare Effectiveness and Data Information Set (HEDIS) and Quality Measurement, managed by the National Committee for Quality Assurance (NCQA) and endorsed by the National Quality Forum (NQF). Data are examined in parallel with information generated by the Kaiser Care Management Institute, the epicenter of the Kaiser Permanente research activities. Goals and health priorities are examined in an ongoing

fashion to ensure that each service region within the Kaiser network is addressing the most important health priorities for its participants at any given time within any particular region (Oldenburg, 2009).

Since its original deployment in 2005, use of the KP.Org system has greater than 150,000 daily users, more than eight million active on-line users and approximately 55,000 new users per month (Scott, 2011). However, there is limited information to ascertain whether use of PHRs may influence patient behaviors and in turn, improve patient health outcomes. There is a need to establish objective evidence of the efficiency and effectiveness of PHRs before widespread adoption will likely occur.

Intuitively, PHRs may potentially influence health outcomes by facilitating more active engagement of individuals in managing their health. Zhou and colleagues conducted a retrospective longitudinal study using administrative data to examine whether use of secure messaging between patients and their providers was associated with improved performance on HEDIS measures and found a statistically significant effect for each measure (Zhou, et al., 2010). Further research is needed to investigate the potential mechanisms by which secure system e-mail exchange between patients and providers might improve the delivery of healthcare and the healthcare experience.

Statement of the Problem

To substantiate the value of technological tools such as the electronic PHR, there is a need to examine whether scientifically derived health-related outcomes are associated with PHR use. There is also a need to understand potential associations between PHR use and health behaviors in working the improvement of chronic disease management.

Purpose of the Study

The purpose of this study was to determine if use of an electronic PHR resulted in better self-management of chronic conditions, measured by selected physiological outcomes in patients diagnosed with one or more selected diseases (diabetes, hypertension or hyperlipidemia), and if individual characteristics of patients impact their use of the system. The three specific aims of this study were to: (1) define and calculate PHR use measures of specific functions within the KP.Org system; (2) define and calculate intermediate patient-centered process measures (medication possession ratios); (3) determine if PHR use influences physiologic measures of metabolic control of hemoglobin A1c (HbA1c), blood pressure (BP) and calculated low density lipoprotein (LDL). Covariates of age, gender, Geostrata code (indicative of socioeconomic status), % African American of the geographic tract associated with the Geostrata code, number of comorbidities (limited to diabetes, hypertension and hyperlipidemia), and calculated body mass index (BMI) were included.

Description of Use Measures of KP.Org

The functions listed in Aim 1 that served as measures of use of KP.Org were defined as follows. Logon to KP.Org and all other use measures within KP.Org were measured as a frequency count indicating that an individual first registered with the Kp.Org electronic PHR system and logged on (signed in to the system) at least one time in addition to going through the online registration process. If the individual used any of the selected functions (clicked on any of the selected pages) within KP.Org, each such action was tabulated as a frequency. The selected measures of use of KP.Org included the

following: logon (described above), viewing the encounter details page, viewing lab results, using the medical advice function, viewing medications, and using the secure messaging function. Operational definitions of each of these functions are provided in Appendix A.

<div align="center">Description of Additional Variables</div>

Medication Possession Ratios

As an indicator of chronic disease management behavior, medication possession ratios were used to gauge how well an individual was following a prescribed medication regime. Medication possession ratios were calculated by taking the total days of supply of medications dispensed, divided by the total number of days between the first and last prescription refill for each medication prescribed for an individual with a known diagnosis of diabetes, hypertension or hyperlipidemia. Only medications specific to these diagnoses were included in the analysis.

Geostrata Code (SES)

The Geostrata code is a numerical value assigned to represent quartiles of the socioeconomic status (SES) index within a given neighborhood based on zip code and census tract data. This system of analysis was developed by Kaiser Permanente, Georgia (KPGA) and has been used to capture socioeconomic status for KPGA membership since 2005. Patient level reported characteristics were used to develop an SES index, which was analyzed and divided into quartiles assigned numeric values of one through four. The first quartile corresponds to the lowest range of SES, representative of areas that are the

most economically deprived. The second quartile corresponds to the lower-middle range

of SES; the third quartile corresponds to the higher middle range of SES; and the fourth

quartile corresponds to the highest SES from among the zip codes, census tract and

patient level reported data included in the analysis. The calculation of the Geostrata code

has been shown to correlate highly with other methods of calculating or measuring SES

(Roblin, 2011). However, the Geostrata coding system is not without limitations. For

example, individuals with low socioeconomic status may be living in neighborhoods

assigned the highest Geostrata code, and vice versa.

Percent African American

A preliminary review of demographics from KPGA sample data revealed that

variables of race and ethnicity were captured for only 40% of members in the existing

data set for this analysis. Therefore, data generated from census tract and block

information was used to indicate the percent of African Americans within a given

geographic block matched with Geostrata codes. This variable was developed and

validated by researchers at KPGA (Roblin, 2010) as a strategy to overcome the issue of

missing data on member race, as race is not a required field in the KPGA database, but is

optional. The variable % African American is intended to provide an estimate of the

percent of African Americans living within a given neighborhood included in the KPGA

service area, but is not a direct measure of race. The value of this variable can range from

0 to 1. Research shows that this measure is a reliable proxy of KPGA membership in the

region for which the sample was selected for use in this study (Roblin, 2011).

Body Mass Index

Body mass index (BMI), a key index for relating a person's body weight to their height, was calculated using the formula: BMI = weight (in pounds)/height (in inches)^2 × 703. The National Institutes of Health (NIH) now defines normal weight, overweight, and obesity according to the BMI rather than the traditional height/weight charts (Centers for Disease Control and Prevention, 2011a). Since the BMI describes the body weight relative to height, it correlates strongly (in adults) with the total body <u>fat</u> content, which is also highly correlated with diabetes, hypercholesterolemia and hypertension (Diabetes Prevention Program Research Group, 2007).

Research Questions

Among adult enrollees of Kaiser Permanente Georgia (age 21 or older) who were diagnosed with one or more specific chronic condition (diabetes, hypertension, hyperlipidemia) who logged on to the KP.Org system at least one time during calendar year 2008, and who were members of KP.Org at least 6 months prior to and 14 months following initial KP.Org logon:

1. What were the frequencies of use of the following functions within Kp.Org?
    a. Logon to KP.Org
    b. Encounter Details
    c. Appointment Details
    d. Lab Results
    e. Medical Advice

      f. Medication

      g. Secure Messaging

2. Was there an association between frequency of use and intermediate behavioral measures of adherence (medication possession ratios)?

3. Was there an association between frequency of use and improvement in physiologic measures of metabolic control (HbA1c, LDL, BP)?

4. Was there an association between frequency of use, intermediate behavioral measures of adherence (medication possession ratios) and physiologic measures of metabolic control (HbA1c, LDL, BP)?

5. Did the covariates of age, gender, Geostrata score (a proxy measuer of SES), % African American, comorbidities, or calculated BMI explain differences between frequency of use, measures of adherence (medication possession ratios), and physiologic measures of metabolic control (HbA1c, LDL, BP)?

Hypotheses

Among adult users (age 21 or older) of KP.Org who were diagnosed with one or more selected chronic disease (diabetes, hypertension, hyperlipidemia), who logged on to KP.Org at least one time during calendar year 2008:

Hypothesis 1: Increased use of KP.Org will be associated with improved intermediate patient-centered process measures of adherence (medication possession ratios), from the time six months prior to the first KP.Org logon in calendar year 2008 up to the time 14 months following initial KP.Org logon.
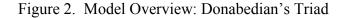
Hypothesis 2: Increased use of KP.Org will be associated with improved

physiologic metabolic control measures including: (a) HbA1c, (b) BP (c) LDL from the

time six months prior to the first KP.Org logon in calendar year 2008 up to the time 14

months following initial KP.Org logon.
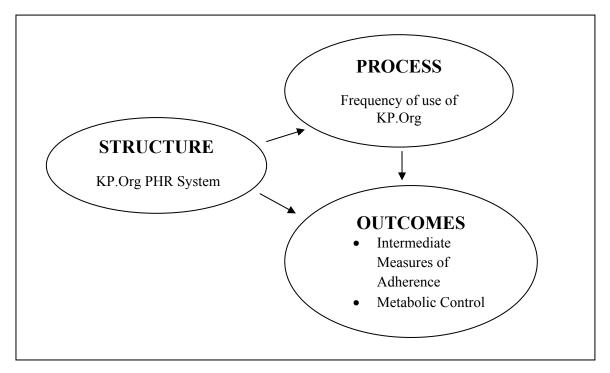
Conceptual Framework

The conceptual framework for this study is derived from the triad model proposed

by Donabedian (1974), which expresses three core constructs: structure, process and

outcomes (Figure 2). According to the model, outcome is a measure of the effect of a

delivered service. Structure and process contain indirect measures that influence

outcomes. Donabedian's premise is that all elements in the model are linked with each

other. Insight into just one of the elements is insufficient for effective evaluation of the

phenomenon. Outcome indicators may provide the best view of performance, but

research shows that process indicators are far more sensitive and unequivocal in the

measurement of changes in performance values (Donabedian, 1992). Donabedian's

partitioning makes it possible to specifically determine relationships between several

indicators that in turn, influence outcomes.

In this model, *Structure* is represented by the KP.Org system, including all the

structural components associated with the system (hardware, software, physical structure,

the environment and physical location of the system, monitors for viewing the system,

keyboards for operating the system, etc). *Process* is represented by the frequency of use

of the KP.Org PHR, including the interactive processes between users of the system to

access information available within the system. *Outcomes* are represented by two

different potential mechanisms: intermediate behavioral measures of adherence (such as those associated with medication possession ratios) and physiological outcome measures of metabolic control, such as laboratory values indicative of diabetes, hypertension and cholesterol (HbA1c, BP, LDL).

Figure 2. Model Overview: Donabedian's Triad

Proposed Conceptual Model

The proposed model is a variation of Donabedian's Triad with the inclusion of an intermediate step between processes and outcomes. The proposed model identifies the KP.Org as the structure component. *Structure* of the system includes the system itself, the components and information within the system, and the mechanisms that enable the operation of the system, and internal linkages within the system that provide connectivity to equipment and other tools that are sources of data viewed within the system. ith the

KP.Org system, and includes the six most frequently accessed functions within the

Kp.Org system within this data set: logon to the system, use of the encounter details,

viewing lab results, using medical advice, viewing medication, and the use of secure

messaging.
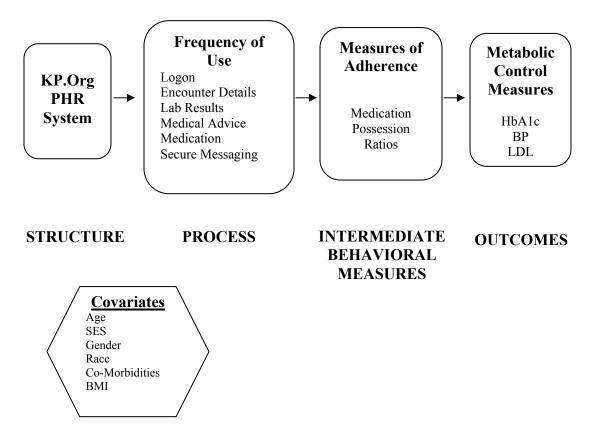
Figure 3. Proposed Conceptual Model Including Study Variables and Covariates

KP.Org PHR System	Frequency of Use Logon Encounter Details Lab Results Medical Advice Medication Secure Messaging	Measures of Adherence Medication Possession Ratios	Metabolic Control Measures HbA1c BP LDL

STRUCTURE   **PROCESS**   **INTERMEDIATE BEHAVIORAL MEASURES**   **OUTCOMES**

Covariates
Age
SES
Gender
Race
Co-Morbidities
BMI

In Donabedian's original model, use of KP.Org could lead directly to outcome

measures. However, use of KP.Org is a measure of frequency of logging onto and

visiting various pages within the PHR system. It is not possible to know whether or how

an individual might have actually used the information on the page. Thus, this measure

cannot be directly linked to physiological outcomes in an informative or meaningful way.

Intermediate Behavioral Measures of adherence represent a necessary step in moving from processes (use of KP.Org) to outcomes (physiologic measures of metabolic control). These behavior measures are an intermediate-level addition to the original triad model proposed by Donabedian, and include medication possession ratios, empirical measures of behavior that can be evaluated over time and compared with frequency and patterns of use of the system. *Outcomes* are represented by physiological measures of metabolic control, and include HbA1c, BP and LDL. The model is intended to show that increased use of KP.Org has the potential to increase medication possession ratios, which are believed to impact physiological measures of metabolic control including HbA1c, BP and LDL.

Study Design

This is a retrospective cohort study using secondary data from Kaiser Permanente Georgia, a federally-qualified group and network model HMO that provides comprehensive medical services to approximately 275,000 residents in the Atlanta metropolitan area. The cohort for this study was comprised of adult enrollees of KPGA, age 21 or older, who utilized the selected PHR at least once during the calendar year 2008 and who had a diagnosis of one or more selected chronic diseases (diabetes, hypertension, hyperlipidemia). Each individual in the cohort served as his/her own control within the analysis.

Methods

Initial logon to KP.Org at any point during calendar year 2008 was the median

point. The cohort was assessed for a period of six months prior to initial KP.Org logon to

establish baseline information. The cohort was then followed forward in time from initial

KP.Org logon for a period of up to 14 months following initial logon (which in some

cases extends to 2010) to assess post-exposure outcomes of adherence (measured by

calculated medication possession ratios) and metabolic control measures of HbA1c,

blood pressure and calculated LDL. Logon to KP.Org was measured as a frequency

tabulation using Quartiles of Use that were calculated using univariate analyses. Quartile

1 (lowest use) served as the referent for all analyses. Quartile 2, Quartile 3 and Quartile 4

represent lower moderate, upper moderate and highest Logon to KP.Org respectively.

Patterns of KP.Org use were evaluated by examining frequency counts of use of

each selected function including the following: encounter details, lab results, medical

advice, medication and secure messaging. Medication possession ratios were calculated

by taking the total days of supply of medications dispensed and dividing that number by

the total number of days between the first and last prescription refill.

Data for the laboratory tests was obtained from the LAB_SERV Database and the

MEDICATIONS Database. Physiological clinical outcome measures were collected for

each participant from the LAB-SERV database (HbA1c and LDL) and from the

VITAL_SIGNS database (BP). These three clinical outcome measures represent the gold

standard in clinical evaluations of diabetes (HbA1c), hypertension (BP), and

hyperlipidemia (LDL) (Corbett, 2008).

Correlation tests were performed on all variables to determine whether the variables displayed associations, and to quantify existing relationships between two or more variables including the strength and direction of the relationship. Results were used to develop models for analyses. Logistic and multiple regression analyses were utilized to explain associations among the variables of interest.

The covariates of age, gender, % African American, and Geostrata score (a representation of socioeconomic status) were examined to determine if these variables explained differences between patterns of use, measures of adherence (medication possession ratios), and physiologic measures of metabolic control (HbA1c, BP, LDL).

Data were cleaned, organized and checked for accuracy and consistency. Sample data (N = 500) were used for the purpose of programming all variables and analyses models using Statistical Analysis Software (SAS), version 9.2 . SAS is a modular, integrated, and hardware-independent system of statistical software, and is the program of choice because it is known to be a particularly powerful tool for the type of analysis required to answer the research questions in this proposal. Correlation matrices were conducted between all individual participation measures to determine appropriateness for inclusion in the model and to check for collinearity. Bivariate correlations greater than .89 were excluded from the model (O'Rourke, 2005) The models were tested using sample data. Errors were addressed prior to using the program for analysis of the complete data set.

Mediation analysis was performed to evaluate whether medication possession ratio served as a mediator between frequency of Logon to KP.Org and the primary outcomes of change in HbA1c, BP or LDL using the four steps of mediation analysis set

forth by Barron and Kenny (1986) and MacKinnon, Fairchild and Fritz (2007) (Barron, 1986; MacKinnon, 2007) . For all models used in mediation analysis, the main independent variable was a dichotomous indicator of logon frequency equal to zero for the bottom (lowest) quartile of KP.Org logon frequency, and 1 for all other quartiles of KP.Org logon.

First, each mediation variable (medication possession ratio for specific diagnosis of diabetes, hypertension or hyperlipidemia) was regressed on the independent variable logon to KP.Org set as a dichotomous variable (Model 1). Next, each dependent variable (primary outcome measure of change in HbA1c, BP or LDL) was regressed on the mediator variable (medication possession ratio) with the independent variable (logon to KP.Org) on the outcome (Model 2). Finally, each dependent variable (primary outcome measure) was regressed on the independent variable (Logon to KP.) to determine the total effect (Model 3) (Barron, 1986; MacKinnon, 2007) .

The indirect effect, or mediated effect, of the independent variable (Logon to KP.Org) on the outcome variable (change in HbA1c, BP or LDL) via the mediator (mediation possession ratio) was calculated as a product of the coefficient for the mediator (Model 2) and the coefficient for the independent variable (Model 1) for each of the three outcomes (Hba1c, BP and LDL). The statistical significance of the indirect effect was calculated using the Sobel test (Fritz, 2007). To complete the mediation analysis, the proportion mediated was reported as the indirect effect divided by the total effect (the sum of the direct and indirect effects). All mediation models were run without adjustments for covariates, and then repeated with adjustments for age, gender, percent

African American and Geostrata quartiles (a proxy measure of SES). Final calculations of the total effect, direct effect, indirect effect and proportion mediated were performed.

Logistic and multiple regression analyses were conducted without adjustments for covariates, and were repeated with adjustments for age, gender, percent African American and Geostrata quartiles (a proxy measure of SES) using the primary independent variable logon to KP.Org and primary outcome measures of HbA1c, BP and LDL. Additional logistic and regression analyses were performed using secondary independent variables of specific functions of use within KP.Org (Secure Messaging, Medical Advice, Lab Results, Medication and Encounter Details) and primary outcome measures of HbA1c, BP and LDL to determine associations and relationships among these variables and to complete the analysis for the study.

Protection of Human Subjects

KPGA Research Committee Approval and Institutional Review Board Approval from both Kaiser Permanente Georgia and University of Alabama at Birmingham were obtained. A Data Use Agreement between Kaiser Permanante Georgia and the investigator was executed and filed. De-identified data used for this study was strictly used for scientific purposes. Data were maintained securely at all times to the fullest extent possible. Data storage and analysis occurred on a KPGA-authorized, secure and encrypted computer. The storage and management of the data was supervised by the investigator's primary research mentor, Thomas K. Houston, MD, MPH, and by Douglas Roblin, PhD, Senior Research Scientist, Kaiser Permanente, Georgia.

This research study strictly followed the ethical principles expressed in the Belmont Report as appropriate for all research involving the use of human subjects. The investigator and all responsible parties (including academic advisors and research mentors guiding the investigator in this project) were compliant with the policies of the Institutional Review Board and Data Use Agreement through coordination of activities including the exercise of prudent and ethical judgment for the protection of data at all times, and acted in a knowledgeable manner in accordance with federal, state and local laws and institutional policies. The investigator determined that risks to subjects were minimized, and that the research plan made adequate provisions for monitoring the data to ensure the safety of information including the protection of the privacy and confidentiality of the data.

Study Contributions

This study provides an initial indication of the role of PHR use on intermediate behavioral outcomes (adherence measures) and physiological metabolic control measures. Results provide valuable information regarding how patients are using an existing PHR and how use of the PHR may enhance patient behaviors in working toward improved management of health associated with selected chronic conditions including diabetes, hypertension and hyperlipidemia. Information generated from this study may influence the design of current and future electronic PHRs that support patient-provider collaboration in managing health more effectively. The information generated by this study makes a meaningful contribution to what is currently known about PHR use and

adds to the body of scientific knowledge by providing important information regarding

significant links between use of technology and selected physiological health outcomes.

Assumptions

1. A selection effect in the analysis was anticipated. Presumably, people who were
   more active using the PHR were behaviorally different than those who did not use
   the PHR system. People who did not use the PHR system at least one time during
   calendar year 2008 were not included in the sample.

2. It was assumed that when patients requested a prescription refill, they were
   actually taking medicines as prescribed.

3. It was assumed that the metabolic control measures used for analysis in this study
   as outcome variables, represent consistent measures taken of all patients in the
   PHR system and that the values were a reflection of the patient's health behaviors
   and not the result of other physiological limitations.

Limitations

1. It cannot be assumed that data are without error. However, individuals
   entering data into the EHR were trained to a minimal level of proficiency and
   tested regarding their ability to understand and appropriately use the system
   for data entry.

2. Secondary data cannot be modified or altered after the fact – the study was
   limited to data that were already collected and available within the database.

3. People who take the extra time to utilize an electronic tool related to their healthcare (such as a personal health record), may be better at self-managing their health in general.

4. Participants with incomplete data or data ranges outside the clinical scope considered appropriate for life (such as LDL > 600, HbA1c of 200) were excluded from the entire analysis, as verification of appropriate values within the de-identified dataset was not possible.

5. There are additional physical and psychosocial factors that could have influenced the outcomes that were not assessed in this study.

CHAPTER 2

REVIEW OF THE LITERATURE

This chapter explores the concepts as found in the literature that are congruent

with the proposed conceptual model introduced in Chapter 1, and discusses what is

currently known about the relationships among and between the selected study variables.

Factors that represent measures of KP.Org use, intermediate behavioral variables of

adherence, physiological clinical outcome measures (HbA1c, LDL, BP), the selected

chronic diseases (diabetes, hyperlipidemia, hypertension), and the covariates age, gender,

Geostrata code (a proxy measure of SES), % African American, number of co-

morbidities and calculated BMI are included. The literature review resulted from an

examination of the Cumulative Index in Nursing and Allied Health Literature (CINAHL),

PsycINFO, The Cochrane Database of Systematic Reviews, Web of Science, Medscape,

and PubMed Databases.

Background

The changing architecture of the American Health Care System has become a

national priority as evidenced by the billions of dollars the U.S. federal government has

committed to address the inefficiencies and associated rising costs in the current system

(111th Congress, 2009; National Institutes of Health, 2004). Although there are many

factors that contribute to rising health care costs, some of the inefficiencies within the

system are the result of sub-optimal exchange of patient information within the context of

care delivery. While support for improved health communication between providers and patients is well documented (American Health Information Management Association & American Medical Informatics Association, 2008; Atkinson, Saperstein, & Pleis, 2009; Blobel & Pharow, 2009; Houston, Sands, Nash, & Ford, 2003; Sciamanna, Rogers, Shenassa, & Houston, 2007) , there is also a need to understand how electronic tools designed to increase patient access to health information might be of value in the delivery of healthcare (Houston, Sands, Jenckes, & Ford, 2004; Quantin, 2010; Sands, 2004).

New objectives in the recently released Healthy People 2020 include developmental goals to increase the proportion of persons who use electronic personal health management tools, the proportion of persons who use the Internet to keep track of personal health information, and the proportion of persons who use the Internet to communicate with their provider (United States Department of Health and Human Services, 2010). Federal funding has been allocated to promote activities that will support working toward these goals as part of the American Recovery and Reinvestment Act (111th Congress, 2009).

The Centers for Medicare and Medicaid Services and the Department of Veterans Affairs have been using variations of the electronic PHR for several years as a strategy to improve the delivery of healthcare for their respective members (Endsley, 2006). However, these strategies have only begun to be evaluated, and initial findings are highly variable (Greene, 2008; Kahn, et al., 2009; Middleton, 2009). There is a need to comprehensively evaluate whether use of an electronic PHR is associated with improvement in health outcomes.

The Office of the National Coordinator (ONC) within the United States

Department of Health and Human Services (DHHS) is supporting the development of a

Health Information Exchange (HIE), a mechanism for sharing relevant patient health

information among providers across institutions for the purpose of improving the

efficiency and safety of the healthcare delivery (Office of the National Coordinator of

Health Information Technology, 2010). Although the idea of HIE is not new, the

processes involved in establishing this type of network are highly complex and will

require significant expertise, multi-disciplinary collaborations and extensive resources

(Frisse, 2010). If successful, an HIE could serve as a catalyst for widespread adoption of

electronic patient-centered PHRs by supporting the use of electronic mechanisms for

information exchange between providers and patients (Fruhling, 2010).

Health Communication

Defined as "the study and use of methods to inform and influence individual and

community decisions that enhance health" (Freimuth & Quinn, 2004, p. 2053) health

communication is a primary construct in the delivery of healthcare and the development

of a cooperative relationship between patients and providers. The concept of a

cooperative provider-patient relationship is supported by the Institute of Medicine in the

landmark report, *Crossing the Quality Chasm,* which sets forth the precedent that

"patients should receive care whenever they need it and in many forms, not just face-to

face visits" (Committee on Quality of Health Care in America, 2001, p. 15). This

includes providing access over the internet, by telephone and via other means. The

electronic PHR presents an opportunity for improving patient access to individualized personal health information while supporting improved provider patient communication.

Potential advantages of improved provider-patient health communications include an increase in patient satisfaction and quality of care, improvement in patient adherence to treatment regimes, increased levels of patient autonomy, improved health outcomes, medication safety, and cost savings (Allen, et al., 2008; Baker, 2003; Bierman, 2006; Scott, 2011). Technological tools designed to enhance provider-patient health communication may be especially useful for patients with chronic illnesses such as diabetes, hypertension and hyperlipidemia, which often have complex treatment regimes and may require more frequent monitoring (Kaushal, et al., 2009; Zhou, 2010).

Structure: The Electronic Personal Health Record (PHR)

Definition of Electronic PHRs

PHRs overlap with but are not the same as electronic health records (EHRs). EHRs do not allow patient access or patient control of information. PHRs are designed for patient control and are also unique in that they can be accessed through the Internet from myriad locations. PHRs can be implemented within the context of an existing electronic health record, or can be stand-alone systems. Integrated PHRs have the advantage of leveraging existing detailed clinical information (laboratory test results, medication information, requests for prescription refills, requests for medical advice) via access to the PHR. Although evidence for the effectiveness of PHRs for improving health outcomes is limited, their perceived value and demand is increasing.

The online personal health record is a technological innovation designed to provide continuous access to patient-specific relevant information. One application of the electronic PHR is similar to electronic banking, wherein individuals keep their private information in a secure electronic database and decide what information to include and who may have access to it. The Microsoft HealthVault® and Google Health® utilize this configuration. Another model of the electronic PHR includes read-only access for an individual patient, in which care providers enter information into the record and patients can view the information. In this model, discrepancies are discussed between patient and provider, but actual data input occurs at the provider level. A variation of this model may include certain portions of the PHR that are available for data input from patients. For example, the patient might enter daily weights, glucose measures, exercise, or diet information into the PHR so that their provider(s) can review the data. In this model, data may be labeled as 'patient-entered' to distinguish between sources of information. There is variability in the potential uses of the electronic PHR, and different models may have different advantages and disadvantages depending upon the goals of the users.

Several accepted definitions of the electronic PHR can be found in the literature. For example, HIMSS defines an electronic PHR as "a universally accessible, layperson comprehensible, lifelong tool for managing relevant health information, promoting health maintenance and assisting with chronic disease management via an interactive, common data set of electronic health information and e-health tools" (Healthcare Information Management Systems Society, 2007, p. 16). Comparatively, in *Connecting for Health*, the Markle Foundation defines the PHR as "an Internet-based set of tools that allows individuals to access and coordinate their lifelong health information and make

appropriate parts of the record available to those who need it" (Markle Foundation, 2006, p. 3). Based on these examples, the ideal PHR presents a viable technological tool for the promotion of health and health maintenance by establishing access and connectivity between patients, providers and the health care system.

Potential Benefits.

Perhaps the greatest benefit of the PHR may be its ability to enhance patient engagement in their own healthcare management via alerts and reminders (Tang, 2005), improved medication management (Tang, 2006), the ability to schedule appointments for recommended screenings, immunizations and preventive care (Pagliari, 2007; Tripathi, Delano, Lund, & Rudolph, 2009) and an increased sense of autonomy, particularly in the management of chronic diseases such as, diabetes, hyperlipidemia and hypertension, among others(Allen, et al., 2008; Anderson, 2007; Burkow, et al., 2008; Fuji, Galt, & Serocca, 2008; Kahn, et al., 2009; Nahm, et al., 2008).

PHRs also have the potential to reach disadvantaged and underserved populations because of the flexibility in access and the wide variation in functionality. Intervention studies targeting the underserved have begun to show great promise in engaging patients in the process of disease management among low-income, disadvantaged and vulnerable populations (American Health Information Management Association & American Medical Informatics Association, 2008; Botts & Horan, 2007; Chang, et al., 2004; Gibbons, 2005; Koivunen, Valimaki, Pitkanen, & Kuosmanen, 2007; Liaw & Humphreys, 2006). Yet, critical barriers exist regarding usability of electronic PHRs, including low health literacy, limited access to technologies, and legal and ethical

concerns (Bodie & Dutta, 2008; Cashen, Dykes, & Gerber, 2004; Koch, 2006; Miller, 2007; Viswanath & Kreuter, 2007; Wangberg, et al., 2008). The need for research relating PHR use to patient outcomes has been identified as a necessary step in working toward addressing these issues (Atienza, et al., 2007; Beaudoin, Rocha, & Tse, 2005; Bott, 2007; Hesse & Shneiderman, 2007; Jadad & Enkin, 2006).

Current Trends of Electronic PHRs

Current estimates show as many as 200 PHR products in the United States. The diverse number of applications and platforms contributes to the nebulous definition of this technology, which is further complicated by the vast number of stakeholders including patients, providers, payers, employers and more recently, third party organizations (e.g., Google Health[©], Microsoft HealthVault[©]). Experts assert that the success of PHRs is dependent upon several factors including business value for stakeholders, provider adoption, and patient use (Ahern, et al., 2003; Blobel, 2008; Fonda, 2010). For example, a comprehensive analysis conducted by the Center for Information Technology Leadership (CITL) in 2008 distinguished between potential PHR functions and applications, finding that the benefits and value of PHRs are directly associated with the types of functions supported by the PHRs (Kaelber, 2008). From a business perspective, this report makes a major contribution to the available literature in building a case for PHRs based on economic value of the PHR (American Health Information Management Association & American Medical Informatics Association, 2008; Kaelber, Jha, Johnston, Middleton, & Bates, 2008). Limitations of the CITL study include evaluating only web-based access to PHRs (exclusion of alternative methods of

accessing and interacting with the PHR such as cellular phone technologies, text-based

architectures, and USB drive-based applications), lack of inclusion regarding hybrid PHR

taxonomies and architectures, variations in security infrastructures, data conversion costs,

and comprehensive applications within the PHR. However, this study was the first

attempt to quantify expenditures and potential financial benefits associated with the

development, implementation and adoption of PHRs in the United States.

PHR Use

Nearly six in ten Americans report they would utilize a PHR if given the

opportunity, (Markle Foundation, 2006), approximately 75% state they would

communicate electronically with their provider (Sciamanna, et al., 2007), 60% report

they would look up laboratory and test reports and would review medications through a

PHR if these functions were made available (Zayas-Caban & Valdez, 2007), and nearly

70% believe PHRs would significantly improve the quality and delivery of healthcare

(Kaushal, et al., 2009). Although the evidence demonstrates the potential consumer

demand for PHRs, and nearly 70 million people in the US currently have access to some

form of a PHR, only 10% of individuals are actually using these tools (Heubusch, 2007;

Tang, 2009). There is a need to understand this variation in self-reported patient

preferences and actual patient behaviors.

In the dynamic PHR marketplace, it is unclear how many PHRs of any architecture

actually exist or how many hybrid architectures may be in use within specific

organizations or clinics. Of these, there is tremendous variation in the functional

capabilities of PHRs and within organizations, different functions may be available and

utilized differently. For example, there are nearly one hundred potential applications in the KP.Org PHR, but availability of these functions varies within individual clinics, and more than half of the functions have not yet been made available in any clinic setting (Oldenburg, 2009).

Most PHR systems are not interoperable (cannot communicate with other healthcare systems). Yet, patients, on average, have four outpatient visits per year, and typically these visits are not with the same provider (Ahern, 2007). There is a need for the development and adoption of standards for interoperable PHRs to ultimately be successful and provide meaningful benefit for patients, providers and payers (Blobel & Pharow, 2006).

The Kaiser Permanente Electronic PHR: KP.Org

In its current implementation, KP.Org offers registrants a range of functions: make appointments, refill prescriptions, secure message with primary care providers, view selected laboratory test results, complete a health risk appraisal (from which selected information is entered into the patient's medical history), and obtain health information on a range of topics. KP.Org has been available to patients enrolled in Kaiser Permanente Georgia (KPGA) since 2005. Information about KP.Org is disseminated through patient mailings, provider recommendations, and notes in post-visit summaries which are printed and provided to patients.

Secure Messaging

Provider-patient secure messaging is an electronic form of communication exchange (e-mail) that flows through a secure point at the level of access for both providers and patients via KP.Org logon. There is ample research describing the benefits and barriers to the implementation and effective use of provider-patient secure messaging(Collins, Murphy, & Strecher, 2007; Couchman, 2005; Hobbs, 2003; Houston, et al., 2004; Zhou, 2010). However, issues of privacy, confidentiality and security are only beginning to be examined and are anecdotal in nature with somewhat mixed results. This notable gap in the literature may be the result of the limited number of patients and providers actually using secure messaging to communicate with one another, and the relatively brief period of time that these types of services have been available for use in healthcare.

There are several obvious advantages to the use of electronic secure messaging: it is legible, fast and efficient (Schillinger, 2009); it can provide automatic documentation (Silber, 2004); it can verify receipt of messages (Siteman, et al., 2006); it can enhance scheduling, confirming or sending reminders about appointments (Tang, 2005); and it can be used to report laboratory results or provide patient education materials (Scott, 2011). Health care facilities utilizing secure messaging to follow-up with discharged patients and monitor patient progress have reported favorable results (Austin, 2006). If the *Healthy People 2020* goal of increasing internet access to 80% of all households is realized, this type of growth will likely serve as a catalyst to bolster the use of secure messaging as an integral component of the delivery and management of healthcare.

In 2001, approximately 175 million people in the United States had access to the internet (Gaster, 2003), and studies show that nearly 85% of surveyed patients believe e-mail via secure messaging would be an excellent way to communicate with the health care provider (Leong, 2005). It is interesting to note that while providers report favorable attitudes toward the use of secure messaging with patients (Zhou, 2010), and the majority of primary care patients who have internet access desire to use secure messaging to communicate with their healthcare team (Houston, 2004), only 6% of patients have actually used secure messaging to communicate with their provider (Williams, 2008). There is a great need for research to examine this phenomenon of high desirability but less than expected usage.

Conventional e-mail is the most common form of electronic communication, and although it is familiar, inexpensive, and can be accessed from any location with Internet access, it is also unstructured and poorly designed for health care applications such as completing forms for referrals, prescription renewals, or automatically routing messages (Delbanco, 2008). Further, there is tremendous variability in the safety, security, and privacy of different electronic messaging tools. Secure messaging portals and encryption software packages address some of these issues and can provide security through mechanisms similar to that of financial industries. To address these issues, steps have been taken to develop comprehensive guidelines that support the implementation of secure messaging between patients and providers (American Medical Association, 2004a; Blobel & Pharow, 2008; Bovi, 2003; Centers for Medicare and Medicaid Services, 2010; Hine, Petersen, Pluke, & Sund, 2008; Kane, 1998; National E-Health Transition

Authority, 2009). However, standardization and consensus of the guidelines and priorities has not yet been achieved.

Privacy, Security and Confidentiality

The development of the internet and rapid increase in capabilities and applications of web-based communication within the past decade have made it a viable option for health communication between patients and providers. The delivery of healthcare services using telecommunications such as the internet is recognized by the United States Federal Communications Commission (FCC) as the delivery of health care to individual patients and the transmission of health information over distance using telecommunication technologies including: (1) direct clinical, preventive, diagnostic, and therapeutic services and treatment; (2) consultation and follow-up services; (3) remote monitoring of patients; (4) rehabilitation services; and (5) patient education (Centers for Medicare and Medicaid Services, 2010; National Telecommunications & Information Administration, 2008).

There are several obvious advantages to the use of web-based communications including increased speed, legibility and efficiency, while providing the ability for automatic documentation and the verification of receipt of information via data logs. However, three categories of issues emerge as major barriers to widespread implementation of web-based health communications: issues of privacy, issues of confidentiality, and issues of security.

Privacy

Privacy in healthcare is the right and desire of a person to control the disclosure of personal health information (Frisse, 2010). The literature on privacy offers several moral justifications for the rules of privacy including the principle of respect for autonomy, which allows patients to discuss sensitive and private information freely with their provider(s). Privacy is also associated with the potential for economic damages to patients, such as loss of insurance or employment, and includes social or psychological damages that may result from breach of patient privacy. An examination of law pertaining to issues of privacy in telemedicine found that "to the extent that ethical justifications for privacy rely on the damage that might occur if the rules are not observed, privacy has instrumental value" (Ranson, 2007, p. 358). Intrinsic values are those values that are valued for their own sake such as acceptance and approval, recognition, positive relationships, gratitude, appreciation, respect, achievement, and so on (Dwyer, 2002). Intrinsic values are sometimes referred to as final or terminal values, because they cannot easily be evaluated or 'tested' for goodness or level of value, as each individual may experience and define these concepts differently (Walsh, Passerini, Varshney, & Fjermestad, 2008). It is important to understand that the law recognizes the instrumental value of health (in contrast to the intrinsic value of health). Instrumental values are valued only because they are perceived to be the key to protecting or fulfilling instrinsic values. As such, they provide a mechanism by which privacy can be recognized and protected within the legal system (Dwyer, 2002).

While the U.S. Constitution provides some minimum levels of protection for the privacy of information, the right to privacy is restricted to state action and does not

include the private industry (Office of the National Coordinator of Health Information Technology, 2010). The issue is further complicated by the variety of policies in place at the state level, which may be centralized or decentralized. Centralized policies are those regulations and policies governing e-mail that are either implemented by all state agencies, or serve as a comprehensive guideline for individual agencies' policy development. In comparison, decentralized policies allow each state agency to develop its own policy with varying oversight or direction from the state-level government (National Telecommunications & Information Administration, 2008). A comprehensive report conducted in 2008 revealed that twenty-seven states have centralized policies and twenty three have decentralized policies, with a vast degree of variability (Ahmed, 2008). Until standardized oversight and protections are achieved, variability of policies for provider-patient e-mail communication will likely continue to be a significant barrier to widespread adoption. Further, it is the responsibility of each health-care provider that utilizes web-based provider-patient communications to be knowledgeable of the policies and regulations, and to participate in educating patients about the risks associated with the use of these communication strategies. For many providers, this presents an additional barrier to implementing web-based communications with patients.

On April 14, 2003, the Health Insurance Portability and Accountability Act (HIPAA) went into effect, for the purpose of helping to ensure patient privacy and to increase patients' control of their personal health information. HIPPA has a distinct rule for privacy (Public Law 104-191), and one for security (45 CFR Part 150 and Part 164, Subparts A and C). To meet the requirements of HIPAA, electronic exchange of information between patients and providers must have password protection, encryption,

and authentication in transmission of patient information over an open network (United States Department of Health and Human Services, 1996a). Failure to adhere to HIPAA may result in severe civil and criminal penalties for providers as well as the entities they represent. Many states are instituting their own privacy regulations which may be more stringent than HIPAA and generally supersede federal regulations (Ahmed, 2008).

The Electronic Communications Privacy Act (ECPA) of 1986, enacted originally to protect against government eavesdropping on telephone conversations, is currently the only law that provides any legal protection for communications that occur electronically (National Telecommunications & Information Administration, 2008). The law was initially developed with consideration for the conflicting needs of law enforcement agencies, the corporate world, and academia (Goode, 2008), and was later extended to include cellular phones, satellite television, paging devices, electronic surveillance and all forms of digital and electronic communications including e-mail (Callens & Cierkens, 2008). Under the ECPA, there is privacy protection against the interception of e-mail during transmission and against unauthorized access to e-mail stored on a computer system or electronic device. However, exceptions exist that give employers and the government the right to monitor e-mail content. While the ECPA prohibits outside interception of e-mail without proper authorization, it does not cover interceptions by persons inside the organization, because according to this law, those who own the system also own the mail sent on it (Ahmed, 2008). Further, the US Patriot Act has greatly expanded the government's authority to monitor electronic communications (110th Congress, 2001) .

Clearly there are numerous issues regarding electronic communication strategies that may create concerns for providers and patients. From the provider perspective, there is the professional, moral, legal and ethical obligation to protect patient privacy. From the patient perspective, there is an expectation that the electronic exchange of personal information is protected under the same rules as in-person discussions and consultations in the context of the patient-provider contract. It is critically important that policies and laws be developed to provide privacy protections, and mechanisms of enforcing those protections. Further, patients should be educated about the current state of the legal limitations regarding privacy protections when using web-based modes to communicate personal health information with providers.

Security

Security is defined as a collection of policies, procedures and safeguards that help to maintain the integrity and availability of information systems and to control access to the contents of information systems(United States Department of Health and Human Services, 1996b). Within this definition, integrity means to ensure that patient data cannot be changed or deleted by unauthorized individuals or parties, and availability means that upon demand, the patient data can be accessed and used by authorized individuals (Van der Haak, 2003).

Security measures can include such things as alerts, reminders, firewalls, encryption, passwords, and numerous other administrative or technical interventions used for the purpose of protecting information. Effective safeguards require explicit policies that detail acceptable and appropriate uses of information. Well-developed policies that

enhance information security also include a statement of institutional philosophy and specific goals regarding privacy; a classification of information assets by type; standards for information system design, implementation and operation; standards for administering, controlling and monitoring information by type; and specific procedures for detecting and managing or handling issues of abuse or breach of security (Callens & Cierkens, 2008; United States Department of Health and Human Services, 1996b). These concerns must be appropriately addressed to create an environment where patients, providers (and institutions) are protected when utilizing information technologies such as web-based applications to communicate with one another.

Ambiguity exists in current policies, procedures and security measures, as well as privacy and confidentiality issues that relate to ethical considerations of electronic healthcare information exchange between providers and patients. Questions regarding ownership of personal health information, access to information, uses of personal health information, and information exchanged across state lines, between health care organizations (either by the patient or the provider or both) generate major concerns about liabilities if a breach should occur, whether intentional or unintentional. There are also issues regarding the responsibility of providing appropriate patient education for electronic information exchange with providers and web-based communication etiquette. It is important that patients who are novel users to electronic modes of communication understand the limits and purposes of the technology; what it can and cannot do.

Patients or providers who use electronic communications in the workplace for medical information interchange are not assured of confidentiality. Patients who use home computers may lack privacy and security from spouses, children or parents if they

are not diligent in closing web-based applications when moving away from the computer. It is interesting to note that while electronic communications must be protected from unauthorized interlopers, the majority of electronic data violations are actually committed by authorized persons (DeVille, 2002). Currently, electronic communications may be vulnerable to outside access, such as being intercepted, forwarded to unauthorized individuals, altered or falsified without detection, printed, or even stored by unauthorized individuals.

High- profile breaches of individual's health information have fueled feelings of anxiety regarding the use of electronic communication to share health information with providers. Well-publicized incidents within the past few years involving human error, such as the attachment of an electronic file containing the names and addresses of 6500 HIV/AIDS patients to an e-mail in a county health department (Daugherty, 2005), have heightened concerns about confidentiality and ethical considerations. There is a need for research regarding the security, privacy and confidentiality issues surrounding the use of electronic-communication between patients and providers so that effective policies and guidelines can be developed and implemented that address the health and communication needs of providers and their patients.

Utilizing secure messaging within a PHR provides an additional layer of privacy, security and confidentiality because the exchange of information can only occur within the PHR itself, and is therefore not transmitted across an open network. While this minimizes the risks for a potential breach, individual users (both patients and providers) must exercise appropriate measures to safeguard patient information by closing applications containing private information when walking away from the computer,

engaging in private information exchange in private settings to avoid on-lookers, and by remaining cognizant of potential risks.

Confidentiality

The controlled release of personal health information to a care provider or surrogate with an agreement that limits the extent and conditions for which information may be used or further released is 'confidentiality' (United States Department of Health and Human Services, 1997). Confidentiality ensures that patient data are not made available or disclosed to unauthorized individuals (Van der Haak, 2003). Several types of threats to the confidentiality of patient's healthcare information may occur, including those originating within the patient care institution, those within secondary user settings, or outsider intrusion into medical information systems. Primary confidentiality breaches include accidental disclosures, insider curiosity, or insider subornation. Breaches of patient confidentiality within secondary user settings include unauthorized use of patient information by supportive care personnel or use of information without patient consent for data-mining or research. Outsider intrusion (hacking) into medical information systems can also compromise patient confidentiality. There are few reports of this type of breach in the healthcare setting, possibly because these incidents are handled internally as part of risk management, or perhaps because there is limited transfer of un-encrypted patient information. It may also be that incidents go un-reported in an attempt to avoid litigation. Another possible explanation may be the under-use of electronic communication between providers and patients.

Patient Use

The literature reveals that nearly 69% of adults in the United States use a computer either at home 51%, at work 47%, or at a college, library or other location 26% averaging nearly fifteen hours per week on the computer with an average of six hours per week using the Internet (Harris Interactive, 2001; Hassol, 2004). Approximately 102 million Americans use e-mail, and an estimated 52 million use instant messaging (Ferrante, 2005). Of these, nearly ten million Americans aged 65 and older use the Internet, and women in this age group are the fastest growing group of Internet users (Reinhardt, 2004). Male Internet users over the age of 65 have grown to over 5 million users, a 30% increase since 2003, and Internet users ages 55 to 64 increased 15% to nearly 16 million (Hassol, 2004). In comparison, the largest number of American Internet users, those aged 25 to 49 have shown average yearly increases of 3%, demonstrating a significant shift in the growth patterns of Internet use from younger users to those aged 65and older (Koch, 2008), a trend that has also been reported in studies conducted in other countries (Mykkanen, Korhonen, Porrasmaa, Tuomainen, & Ensio, 2007). This is particularly significant for potential health care applications using Internet and electronic messaging tools, as the number of individuals aged 65 and older are more likely to have chronic health issues and comorbidities that require more frequent communication and engagement with providers (Goroll, Simon, Tripathi, Ascenzo, & Bates, 2009).

However, one study that examined mail utilization patterns and attitudes among primary care physicians and their ambulatory outpatient clinic patients found that among 248 patient-participants who used e-mail, 60% were female, 55% had college or

postgraduate-level education, 41% earned an annual income ≥ $75,000, and 80% self-reported being in good or very good health (Moyer, 2002). These data suggest that early adopters of e-mail appear to be healthier, younger, more educated, and less likely to use clinical resources such as clinic visits than non-email users. Unfortunately, these early adopters are likely not the patients with the greatest need for access to healthcare and improved communication with healthcare providers.

Provider Use

Survey data reveal that the majority of physicians use a computer or the Internet for business as well as personal reasons. A survey conducted by the American College of Physicians American Society of Internal Medicine found that 69% of physicians used the Internet on a weekly or daily basis from the office, but less than 7% reported using secure e-mail daily or weekly to communicate with patients (Lacher, 2000). The American Medical Association (AMA) conducted a survey of physician electronic communication use in 2004, and found that 70% of physicians reported using the e-mail communication tools, but only 25% reported using e-mail to communicate with patients (American Medical Association, 2004b). A more recent survey conducted by Harris Interactive found that 93% physicians reported using the Internet, with 87% reporting use at home, 56% at the office and 40% in the clinical work area. In this survey, 55% physicians reported using e-mail to communicate with colleagues, and 34% reported frequent e-mail communication with support staff. However, only 14% reported utilizing secure messaging communication strategies with patients to send specific health-related clinical

information, and only 13% reported communicating with patients via secure messaging (Harris Interactive, 2010).

<center>Function of Electronic Communication</center>

The primary function of provider-patient electronic communication is to augment the in-person communication between patients and their providers for the improvement of health care delivery and management of patient health needs. While this may seem a simple endeavor, research shows that the issue is wrought with complications including legal, sociocultural and health literacy concerns (Ahmed, 2008; De Meyer, 2008). In addition, there are barriers to technological access for vulnerable and disadvantaged populations which present a unique set of ethical concerns and a phenomenon coined 'the digital divide' (Chang, et al., 2004; Roblin, 2008). The unique perspective of both patients and providers must be considered in evaluating the utility of electronic communication if the potential of this tool is to be realized.

Patient Perspectives

Numerous studies show that patients who currently have access to and use e-mail indicate a strong willingness and desire to communicate with their primary care providers using electronic communication (Couchman, 2005; Delbanco, 2008; Sciamanna, et al., 2007). Some studies have reported that patients' desire to e-mail their providers is so strong, they would be willing to pay for this service (Bryce, et al., 2008; Winter, 2008). Yet, studies evaluating both patient and provider use of e-mail to communicate reveal very low percentage of utilization.

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It is interesting to note that patient indicators of desire to communicate with providers electronically is consistently correlated with specific tasks or functions that patients perceive to be advantageous. For example, in a study evaluating the likelihood of patients using e-mail for selected general clinical services, patients most wanted to communicate requests for prescription refills 83% followed by the ability to communicate questions and concerns directly with their physician for non-urgent consultations 82% or to obtain routine laboratory results or test reports 80%. In this study, making or canceling appointments was reported as the least interest to patients (Couchman, 2005). These findings are consistent with reports from similar studies that examined patient priorities regarding use of electronic communication with providers (Sittig, 2001; Taylor, 2004).

When asked about their expectations, 57% of online users expect better coordination of health services using the Internet to communicate with the clinic; 60% report they often have questions following a clinic visit that could be addressed without a return visit if e-mail were utilized, and 8% indicate they would like follow-up e-mails, appointment reminders, and information about preventive care based on their medical history if it could be sent via e-mail (Hesse & Shneiderman, 2007). Patients also reveal that they expect a timely response from providers when using electronic communication, although 'timely' may range from 8 to 48 hours based on several studies (Sillence, Briggs, Harris, & Fishwick, 2007; Sittig, 2001).

The asynchronous communication inherent in electronic communication allows users to send and read messages in a convenient manner and may avoid problems associated with 'telephone tag'. E-mail communication can be stored electronically or

printed for personal record-keeping, functions patients have endorsed as highly beneficial to them (Liederman, 2003). However, patients have expressed concerns about the routing of messages to the correct provider/recipient, length of time it may take to get a response, and the privacy of their health information when communicating electronically (Leong, 2005). Additional concerns identified by patients include questionable effectiveness and efficiency of e-mail communication, the desire to speak with someone 'in person', and ease and familiarity of telephone use versus computer use (Moyer, 2002). While the numbers of patients who indicate they would prefer electronic communication with their providers, there is a need to understand the relatively low use of this technological tool.

Provider Perspectives

Benefits and risks associated with patient electronic communication from providers' perspectives are well documented (American Health Information Management Association & American Medical Informatics Association, 2008; American Medical Association, 2004b; Booth, 2006; Delbanco, 2008). Rapid, inexpensive, convenient, simple and asynchronous communication are benefits that have the potential to reduce the number of non-urgent clinic visits and telephone calls, increase patient engagement in clinical decision-making, and enhance linkages to patient educational materials and information (Flynn, Gregory, Makki, & Gabbay, 2009).

Studies show that physicians in general believe that e-mail is a good way for patients to reach them, is an effective tool for handling administrative tasks, and do not mind receiving messages from patients (Moyer, 2002). However, other studies report

provider concerns regarding increase in non-reimbursable workload, fear of being

overwhelmed or inundated with trivial patient messages, not having enough time to

respond to patient messages, and potential scheduling pressures associated with patient e-

mail communications (Neupert & Mundie, 2009; Taylor, 2004). One study found that e-

mail communication did, in fact, increase communication burden on clinicians and staff,

did not substitute for telephone consultations, and was of limited use in improving

clinical efficiency and care effectiveness (Car, 2004).

In March, 2010, Kaiser Permanente completed the implementation of the largest

Electronic Health Record (EHR) system in the world, connecting more than 450 medical

offices and 35 hospitals across nine states and Washington D.C. (Scott, 2011). The

system, called HealthConnect©, was designed to coordinate care among multiple

providers across various medical care settings, including a secure messaging component

for enhanced communication between patients and their providers. Recent reports from

Kaiser Permanente reveal more than 700,000 emails are being exchanged each month

between patients and providers within HealthConnect©, with reported favorable responses

(Scott, 2011). It is anticipated that the implementation of reimbursement mechanisms for

provider engagement with patients in an online format will have a result in a large

upsurge in the use of this kind of communication tool for the delivery of healthcare

(Kaushal, et al., 2009; Zhou, 2010).

Disadvantages

Despite the potential benefits of electronic communication between patients and

providers, there are also potential drawbacks. Asynchronous electronic communication

may be more convenient for users, but it is a less robust form of communication and is absent the visual cues of face-to-face communication, the audio cues of telephone conversations, and the interactive style of 'real-time' contact. Thus, electronic communication may not be optimal for conveying sensitive health information, complex issues, or critical issues. While electronic communication may threaten patient privacy and confidentiality, this issue appears to be of far greater concern to providers than to patients, perhaps because of potential liability issues (Adibi & Agnew, 2008; Callens & Cierkens, 2008).

Selected Chronic Illnesses: Diabetes, Hypertension and Hyperlipidemia

Background and Significance

The prevalence rates of diabetes, hypertension and hyperlipidemia among all age groups in the United States are approaching epidemic proportions. Recent estimates provided by the American Diabetes Association (ADA) and the United States Centers for Disease Control and Prevention (CDC) indicate more than 23.6 million people, or greater than 8% of the population, have diabetes (American Diabetes Association, 2007; Centers for Disease Control and Prevention, 2011b). Further, according to the National Health Statistics Reports 2003- 2006, among the U.S. population age 20 and older, approximately 31% have a diagnosis of hypertension, and nearly 42% of women and 34% of men have a diagnosis of hyperlipidemia (Centers for Disease Control and Prevention, 2007). These trends demonstrate significant and pervasive health concerns among very large numbers of American adults.

Studies evaluating causal factors of heart disease, the number one cause of death in the United States, indicate that diabetes, hypertension and hyperlipidemia often cluster together and create increased risk of premature death and comorbid health complications (Cobain, 2007). Hyperlipidemia is a major (but modifiable) risk factor for heart disease and diabetes. Unfortunately, less than 50% of patients who are prescribed cholesterol-lowering medications take these medications as instructed (Chapman, 2008), and an estimated 60,000 deaths occur annually in the United States as a result of failure to effectively manage hyperlipidemia (Keevil, 2007).

There is a need to develop tools for patients to better manage chronic diseases such as diabetes, hypertension and hyperlipidemia. Use of health management tools such as electronic PHRs may promote closer monitoring of glucose fluctuations, weight control, medication management, and follow-up with a provider when problems or deviations occur. Patients experiencing chronic illnesses could utilize PHRs to track their diseases in conjunction with their healthcare providers, potentially reducing communication barriers between patients and their caregivers (Grant, et al., 2008; Scott, 2011). Improved provider-patient communication may also serve to facilitate earlier interventions and shared decision-making when complications or problems are encountered, creating a streamlined system of healthcare delivery that is more continuous and less episodic (Zhou, 2010). Although diabetes, hypertension and hyperlipidemia are often diagnosed in combination, each of these chronic illnesses has a unique set of issues, concerns, risks and consequences which are described in the following sections.

Diabetes

Diabetes mellitus is a condition in which the pancreas no longer produces enough insulin, or cells stop responding to the insulin that is produced, such that life-essential glucose in the blood cannot be absorbed into the cells of the body (American Diabetes Association, 2007). Symptoms of diabetes include frequent urination, lethargy, excessive thirst, and hunger (Centers for Disease Control and Prevention, 2007). Treatment may include changes in diet, oral medications, and in some cases, daily injections of insulin. Known risk factors for the development of diabetes include: age over 45 years, familial history of diabetes, gestational diabetes or delivering a baby weighing more than 9 pounds, heart disease, high blood cholesterol level, obesity, lack of adequate daily exercise, polycystic ovary disease (in women), previous impaired glucose tolerance (Agency for Healthcare Research and Quality, 2009). Certain ethnic groups, particularly African Americans, Native Americans, Asians, Pacific Islanders, and Hispanic Americans, have been shown to be at greater risk for the development of diabetes and associated complications (Natarajan, 2004; Paeratakul, 2002).

Diabetes: Morbidity and Mortality

Overall, the risk for death among people with diabetes is about twice that of people without diabetes of similar age (Agency for Healthcare Research and Quality, 2009). Diabetes was the seventh leading cause of death listed on U.S. death certificates in 2006. This ranking is based on the 72,507 death certificates in 2006 in which diabetes was listed as the underlying cause of death. According to death certificate reports, diabetes contributed to a total of 233,619 deaths in 2005, the latest year for which data on

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contributing causes of death were available (Centers for Disease Control and Prevention, 2007). Further, diabetes is likely to be underreported as a cause of death. Studies have found that only 35% to 40% of decedents with diabetes had it listed anywhere on the death certificate and only about 10% to 15% had it listed as the underlying cause of death (Middleton, 2009). The prevalence of both diagnosed and undiagnosed diabetes among adults in the United Sates varies by age, gender, race/ethnicity, geographic location, socioeconomic status (SES) and body mass index (BMI) (Centers for Disease Control and Prevention, 2011b).

Diabetes and Age

Nearly 1.6 million new cases of diabetes are diagnosed in people aged 20 years and older each year, and the number of older persons with diabetes is expected to grow as the elderly population increases in number (Centers for Disease Control and Prevention, 2011b). According to the American Diabetes Association, approximately 18.3%, or 8.6 million Americans age 60 and older have diabetes (American Diabetes Association, 2007).

As shown in Figure 4, the National Health and Nutrition Examination Survey III (NHANES III) reported that among the population over age 65, between 18% and 20% have diabetes, and as many as 40% have its precursor form of impaired glucose tolerance (McDonald, 2008).
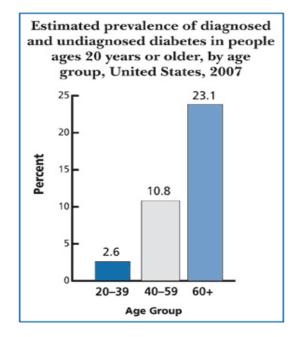
Figure 4. Estimates of Diabetes Prevalence (NHANES, 2007)

Estimated prevalence of diagnosed and undiagnosed diabetes in people ages 20 years or older, by age group, United States, 2007

Source: 2003–2006 National Health and Nutrition Examination Survey estimates of total prevalence (both diagnosed and undiagnosed) were projected to year 2007.

Diabetes Prevalence and Gender

The prevalence of diabetes among adults in the United States varies slightly by gender. Information released by the Centers for Disease Control and Prevention in 2009 estimates approximately 12 million or 11.2% of all men ages 20 years or older have diabetes, and 11.5 million, or 10.2% of all women ages 20 years or older have diabetes.

Diabetes and Race/Ethnicity

After adjusting for population age differences, 2004 to 2006 national survey data for people ages 20 years or older indicate that 6.6% of non-Hispanic Whites, 7.5% of Asian Americans, 10.4% of Hispanics, and 11.8% of non-Hispanic blacks had diagnosed

diabetes. Estimates reveal that 3.2 million African Americans currently have diabetes, indicating that African Americans are at a significantly higher risk for developing diabetes than other racial and ethnic group (National Institute of Diabetes and Digestive and Kidney Diseases, 2005). It is projected that this number will triple by the year 2050, far exceeding the rate of increased incidence of diabetes among other racial groups (Venkat-Narayan, 2006).

Recently, researchers explored beliefs about prescription medications among 806 non-Hispanic black and non-Hispanic white adults who have been diagnosed with diabetes. Findings reveal that non-Hispanic black patients perceive greater serious concerns about treatment for diabetes including concerns about racial discrimination, mistrust in providers and lack of trust in the safety and efficacy of generic medications (Piette, 2010). This study also reveals that non-Hispanic black patients consistently had greater dissatisfaction with treatment related information, significantly lower rates of medication adherence, more limited educational attainment, lower incomes, and higher averages of hemoglobin A1c than their non-Hispanic white counterparts (Piette, 2010). These findings support the notion that the experience of living with diabetes is highly variable between racial groups. There is a need to better understand these variations and to develop tools and interventions that can effectively address racial and ethnic gaps in disease prevalence and disease treatment.

Diabetes and SES

Socioeconomic status has long been of interest to researchers in examining health outcomes, health behaviors, adherence to treatment regimes and successful management

of chronic diseases. Socioeconomically vulnerable patients may be more fatalistic about

their disease trajectory and may therefore be less motivated to treat their illness

aggressively (Egede, 2003). Intensive treatment may also be overly burdensome and

excessively costly for socioeconomically deprived individuals, making it more difficult

for them to effectively equate a benefit from following complex treatment regimes in the

context of economic limitations.

It has been shown that diabetes patients often struggle with the costs of their

medicines, leading to potentially serious implications regarding adherence and health

status (Natarajan, 2004). After adjusting for cost burdens and socioeconomic status,

some studies have found higher rates of cost-related adherence problems among African

Americans with diabetes than among Whites with diabetes (Kurlander, 2009).

Issues of confounding between race/ethnicity and socioeconomic status (i.e.,

health status varies by race and health status varies by SES) have been described in the

literature (Williams, 2005). Researchers at the Johns Hopkins Center for Health

Disparities Solutions examined race and socioeconomic disparities among black and

white Americans with diabetes and found that when blacks and whites live in similar risk

environments, where there are no race differences in SES as measured by median income

and level of education, health outcomes are more similar (LaVeist, 2009). The findings of

this study suggest that prevalence differences between blacks and whites with diabetes

may have more to do with socioeconomic status than race differences.

Similarly, a community-based epidemiologic survey of 5503 Boston residents

aged 30-79 years (1767 Black participants, 1877 Hispanics, 1859 whites) found that

socioeconomic status had a much stronger association with diabetes prevalence than

race/ethnicity (Ure, et al., 2007). Future research directed at examining health disparities within samples that account for socioeconomic and environmental factors might be highly beneficial.

Diabetes and Geostrata Score

The Geostrata score is a numerical value assigned to represent quartiles of the socioeconomic status (SES) index within a given neighborhood based on zip code and census tract data. Research scientists at Kaiser Permanente Georgia (KPGA) developed an equation for assigning member patients of their network a Geostrata score as part of their effort to assess available services among KPGA members within the Atlanta metropolitan area. The Geostrata score has also been used to gather information about KPGA members including available resources, environmental safety, and health concerns of specific communities and to identify adverse conditions of neighborhoods and housing based on geographic location.

Studies reveal that the distance from a healthcare provider and the quality and safety of the living environment can influence health status and disease vulnerability in many ways. Recent work by Schootman and colleagues (2007) identified several potential mediating mechanisms by which adverse conditions of neighborhoods and housing may promote the development of diabetes (Schootman, 2007). Individuals may be at increased risk for diabetes through the adoption and maintenance of behaviors such as lack of participation in physical activity (Kriska, 2003), greater use of tobacco products (Kahn, 2009), poor nutrition (Franz, 2004), and alcohol consumption (Djousse, 2007). Research reveals that these behaviors are more prevalent among men and women

residing in areas affected by adverse neighborhood and housing conditions. Adverse

neighborhood and housing conditions may also affect the development of diabetes

through influence on other health conditions such as obesity, hypertension and other

comorbid conditions (Strodl, 2006).

In a small prospective analysis of urban middle-aged African Americans living in

St. Louis, Missouri, adverse housing conditions were positively associated with increased

risk of diabetes (Schootman, 2007). Further, a cross-sectional analysis of black and white

adults participating in the Coronary Artery Risk Development in Young Adults study

found that neighborhood deprivation was associated with the development of insulin

resistance, a precursor to diabetes (Kershaw, 2010). Other studies have shown a

relationship between improved neighborhood resources for physical activity and healthy

foods and a reduction in the incidence of diabetes (Auchincloss, 2009).

Knowledge of environmental and housing conditions as well as location of

residence may promote development of health interventions that meet the needs of

individuals living in communities where adverse conditions prevail. The Geostrata score

can be of great benefit in obtaining information about environmental safety, housing and

resources that might otherwise be difficult to capture.

Diabetes and Comorbidities

The number and type of comorbid conditions among individuals with diabetes is

highly complex, and effective treatment can be extremely challenging. In many cases

there is a bi-directional relationship between comorbid diseases. For example, adults

suffering from diabetes are at increased risk for numerous comorbid conditions, while

numerous comorbid conditions can increase the risk of developing diabetes (American Diabetes Association, 2007).

Several comorbid conditions have been shown to consistently cluster together, for example, diabetes, heart disease, and stroke. Diabetes doubles the risk of vascular problems, including cardiovascular disease (Agency for Healthcare Research and Quality, 2009).   In 2004, diabetes-related death certificates noted heart disease as a comorbid condition on 68% of death certificates, and stroke on 16% of death certificates among people aged 65 years or older, indicating that adults with diabetes have heart disease death rates and risk of stroke about two to four times higher than adults without diabetes (National Institute of Diabetes and Digestive and Kidney Diseases, 2005).

Studies reveal that 75% of adults with diabetes also have blood pressure greater than or equal to 130/80 mmHg, or used prescription medications for hypertension (American Heart Association, 2010). Blood pressure control reduces the risk of cardiovascular disease (i.e., heart disease or stroke) among people with diabetes by 33% to 50% and the risk of microvascular complications (eye, kidney, and nerve diseases) by approximately 33%. In general, for every 10 mm Hg reduction in systolic blood pressure, the risk for any complication related to diabetes is reduced by 12 percent (American Diabetes Association, 2007).

A study conducted by researchers from the Brigham and Women's Hospital, Harvard Medical School and the Harvard School of Public Health followed over 38,000 female health professionals for ten years and found that women with hypertension were three times more likely to develop diabetes compared with women who had optimal BP

after adjusting for various factors such as age, ethnicity, smoking, alcohol intake, body mass index (BMI), exercise, and family history of diabetes (Conen, 2007).

A secondary analysis performed using 2007 data from the Behavioral Risk Factor Surveillance System (BRFSS) found that diabetes was 2.36 times more likely to be present in respondents with hypertension (95% CI, 2.23-2.51) and 1.94 times more likely among those with hyperlipidemia (95% CI, 1.84-2.05). Results of this study also reveal that hypertension and/or hyperlipidemia significantly increased the odds of having coexisting diabetes (Yang, 2009). The findings of this analysis support the positions of the American Heart Association and the American Diabetes Association that hypertension, hyperlipidemia and diabetes frequently coexist and should be treated in unison (American Diabetes Association, 2008; American Heart Association, 2010).

Diabetes and BMI

Body Mass Index (BMI) is an index measure that is useful for measuring overweight and obesity in adults. BMI is calculated as the weight in kilograms divided by height in meters squared. An alternative calculation using pounds and inches takes weight multiplied by 704.5 divided by height in inches, and that result divided by height in inches again. The BMI is the measurement of choice for health researchers because it is a direct calculation based on simultaneous use of height and weight, is not gender specific, can be easily assessed through a medical exam or via self-report, and is less prone to measurement error (Biggs, 2010). BMI does not directly measure percent of

body fat, but it provides a more accurate measure of overweight and obesity than relying on weight alone.[1]

The National Institutes of Health (NIH) identify overweight as a BMI of 25-29.9 kg/m^2, and obesity as a BMI of 30 kg/m^2 or greater. However, overweight and obesity are not mutually exclusive, since obese persons are also overweight. Defining overweight as a BMI of 25 or greater is consistent with the recommendations of the World Health Organization (WHO) and most other countries (World Health Organization, 2003).

In 1995, the WHO recommended a classification for three "grades" of overweight using BMI cutoff points of 25, 30, and 40 (World Health Organization, 1995). The International Obesity Task Force suggested an additional cutoff point of 35 and slightly different terminology. Two organizations within NIH, the National Heart, Lung, and Blood Institute (NHLBI) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), convened an expert panel whose report, released in June 1998, provided definitions for overweight and obesity in agreement with those used by the World Health Organization. The panel identifies overweight as a BMI 25 to less than 30, and obesity as a BMI ≥30. These definitions are based on evidence that health risks increase more steeply in individuals with a BMI 25 (World Health Organization, 2003).

BMI cutoff points are a guide for definitions of overweight and obesity and are useful for comparative purposes across populations and over time. However,

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[1] The multiplier 704.5 is used by the National Institutes of health. Other organizations may use a slightly different multiplier; for example, the American Dietetic Association suggests multiplying by 700. The variation in outcome (a few tenths) is insignificant.

the health risks associated with overweight and obesity do not conform to rigid cutoff points. For example, an overweight individual with a BMI of 29 does not instantly acquire all of the health consequences of obesity after crossing the threshold of a BMI of 30. Health risks increase gradually as BMI increases. Regardless of the definitions used for overweight and obesity, studies have shown that the number of overweight individuals in the United States continues to rise for all age groups (Centers for Disease Control and Prevention, 2011a).

Overweight and obesity are found worldwide, and the prevalence of these conditions in the United States ranks high along with other developed nations. Approximately 280,000 adult deaths in the United States each year are attributable to obesity (Allison, 1999). Most studies show an increase in mortality rate associated with obesity (BMI $\geq$30). Obese individuals have a 50-100 percent increased risk of death from all causes, compared with normal-weight individuals (BMI 20-25), with most of the increased risk attributable to cardiovascular causes (American Heart Association, 2010).

Results from a study examining the obesity-related chronic conditions in the US adult population found that the specific level of risk associated with a given level of obesity may vary depending on race, gender and socioeconomic status (Cobain, 2007). Using multivariate analysis on 9643 participants from the Continuing Survey of Food Intakes by Individuals (CSFII), a database provided by the US Department of Agriculture/Agricultural Research Service (USDA/ARS), researchers observed an incremental increase in the odds ratio of diabetes, hypertension and hyperlipidemia with increasing body weight after adjusting for age, race, gender, income, education

and smoking. They also noted and significantly higher risk of diabetes, hypertension

and hyperlipidemia for both overweight and obese individuals compared to normal

weight individuals (Paeratakul, 2002).

Trends of obesity prevalence have been shown to increase with advancing age

until a person reaches his or her sixties, when obesity prevalence begins to decline

(Flegal, 1998). From 1991 to 1998, obesity increased in every state of the United

States, in both genders, and across all races/ethnicities, age groups, educational

levels, and smoking statuses (Ford, 2010). Age adjusted prevalence of combined

obesity and overweight in the United States are depicted in Table 5.

Table 5 . Age Adjusted Prevalence of Combined Obesity and Overweight in the
U.S. (Source: Healthy People, 2020)

Age	United States Population	Normal Weight BMI 20 to < 25	Overweight BMI 25 to < 30	Obese BMI > 30
All Ages	Total Population	< 50%	> 50%	~ 25%
20+	Total Population	73 million, 41%	97 million, 55%	40 million, 22%
20+	Women	40 million, 44%	47 million, 51%	23 million, 25%
20+	Men	33 million, 39%	50 million, 59%	17 million, 20%

The age-adjusted prevalence of combined overweight and obesity in

racial and ethnic minorities, particularly for minority women, is generally higher

than in whites in the United States (Flegal, 2010). Table 6 is a representation of

findings published by Flegal and colleagues' from their examination of trends in

overweight and obesity among U.S. adults from 1999-2008.

Table 6. Prevalence of Combined Overweight and Obesity in U.S.by Race, Age and Gender (1999-2008)

Race	Age	Gender	Percent
African American	20+	Women	65.8
Mexican American	20+	Women	65.9
White	20+	Women	49.2
African American	20+	Men	56.5
Mexican American	20+	Men	63.9
White	20+	Men	61.0

The relationship between elevated BMI and diabetes is well documented in the literature. Among persons who have been diagnosed with Type 2 (noninsulin-dependent) diabetes, 67% have a BMI of 27, while 46% have a BMI of 30 (American Diabetes Association, 2007). An estimated 15.6 million adults in the U.S. (8% of men and women age 20 or older) have diabetes, with Type 2 diabetes accounting for about 90-95% of these cases (Centers for Disease Control and Prevention, 2011a). The relative risk of diabetes increases by approximately 25% for each additional unit of BMI greater than 22 (Yang, 2009).

Although high measures of BMI have been consistently shown to predict the onset of diabetes, the mechanisms for this relationship are not fully understood. One hypothesis suggests that the release of fatty acids and cytokines from increased amounts of lipids into the portal circulation affects hepatic metabolism of insulin and inflammatory markers (Diabetes Prevention Program Research Group, 2007).

Hypertension

Hypertension is defined as a repeatedly elevated blood pressure exceeding 140 over 90 mmHg a systolic pressure above 140 with a diastolic pressure above 90 (American Heart Association, 2010). Individuals taking prescribed anti-hypertensive medications are frequently included as hypertensive in research studies, whether their blood pressure is well-controlled or not, which can sometimes present special challenges in making accurate estimations of the prevalence of hypertension among the population. Guidelines established within the context of best-practice recommendations in working toward Healthy People 2020 goals suggest that lowering the threshold of systolic blood pressure from 140 mmHg to 130 mmHg may be preferred for initiating early interventions for blood pressure reduction (Fuzhong, 2009; United States Department of Health and Human Services, 2010).

Hypertension: Significance and Prevalence

Hypertension affects approximately 65 million individuals in the United States (Riegel, 2009). Approximately 60% of American adults have pre-hypertension or hypertension, but elders, African Americans, individuals with low SES and those with overweight or obesity are disproportionately affected (Ong, 2007). The prevalence of hypertension has increased by approximately ten percentage points during the past decade (United States Department of Health and Human Services, 2010). Because hypertension is often asymptomatic, many individuals with hypertension do not seek medical care and may be unaware they have high blood pressure. Research indicates that the awareness and appropriate management of hypertension remains unacceptably low (Carretero,

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2000). Data from the National Health and Nutrition Examination Survey (1999-2004) evaluating blood pressure for 14, 653 US adults reveals that 31% were not aware of their disease, only two thirds 66% were told by health professionals to adopt lifestyle modifications or take drugs to control hypertension, and only 31% controlled their hypertension (Fields, 2004a).

Hypertension and Age

There is a natural tendency for blood pressure to rise with age due to the reduced elasticity of the arterial system. In a study evaluating blood pressure of 4800 African-American and white men and women with known hypertension, age was associated with a significant increase in the prevalence of systolic hypertension after 60 years of age, and increased obesity between the ages of 30 and 50 years was associated with significant increases in diastolic pressure regardless of race (Anderson, 1999). A community based cohort study using data from the Framingham Heart Study found that among those older than age 80, the prevalence of hypertension exceeds 70%, fewer than 10% have normal blood pressure levels, and only 38% of men and 23% of women had controlled blood pressure levels less than 140/90 mmHg (Lloyd-Jones, 2005).

Whereas average diastolic pressure increases until approximately age 55 years and then decreases throughout the remaining lifespan, average systolic blood pressure increases linearly with age until the end of life (Fields, 2004b; Franklin, 2006). Thus, older individuals have a high incidence and prevalence of systolic hypertension. According to experts, it is rare to escape the development of hypertension with aging (American Heart Association, 2010). In fact, even for individuals who are not

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hypertensive at age 65, the remaining lifetime risk of developing hypertension is approximately 90% (Cobain, 2007).

Hypertension and Gender

Women, on average, develop hypertension later than men (Murasko, 2006). From ages 35 to 44, approximately 23% of men and 18% of women have some form of cardiovascular risk including heart disease, stroke or hypertension. By ages 45-55, prevalence rates for hypertension and associated cardiovascular risk factors are about 36% for both men and women. However, after age 55, women surpass men in prevalence of hypertension (American Heart Association, 2010). Studies have shown that women have a higher prevalence of hypertension with a slightly later onset than men, regardless of their race/ethnicity (Fields, 2004a; Ong, 2007). The prevalence of high blood pressure for post-menopausal women has consistently shown a steep rise; however, the mechanisms related to alterations in hormone balance and potential coexisting issues among post-menopausal women is not clearly understood (National Institute on Aging, 2005).

Hypertension and Race/Ethnicity

It is well known that hypertension is more prevalent among African Americans than for any other race/ethnic group in the United States (American Heart Association, 2010; Green, 2005). Excess hypertension prevalence among US Blacks compared to US Whites contributes to racial disparities, but is not fully understood (Collins, et al., 2007). Using data from the Multi-Ethnic Study of Atherosclerosis (MESA), researchers

examined multiple factors to explain variation in hypertension prevalence among blacks and whites and observed that hypertension was more prevalent among blacks born in southern states, possibly attributable to diet and exercise norms, educational attainment and per capita income, which have traditionally been lower in the South than in other parts of the country (Kershaw, 2010). However, additional research is needed to fully understand the complexities of geographic differences across racial/ethnic groups.

Hypertension and SES

Access to quality health care is associated with better prevention, detection and management of chronic disease processes such as hypertension, and consequently, better outcomes (Geronimus, 2007; Keevil, 2007). Access to healthcare has been evaluated using health insurance status to examine the relationship between health insurance and hypertension and other chronic diseases (Borrell, 2009). A secondary analysis of data from the National Medical Expenditure Survey revealed a positive effect of insurance coverage on hypertension among groups most likely to utilize public health insurance coverage, including ethnic minorities, suggesting that health outcomes such as improved control of hypertension may be related to health insurance by improving access to consistent care (Moy, 1995). Thus, being poor and uninsured likely limits access to healthcare and may reduce the opportunity to address chronic diseases such as hypertension (Rooks, 2009).

Hypertension and Geostrata Score

Recent studies have indicated that the socioeconomic characteristics of a neighborhood can affect health status independent of the socioeconomic status of an individual (Kershaw, 2010). Neighborhood environment can influence diet and physical activity, important behaviors associated with prevention and control of hypertension, through the availability of grocery stores, recreational facilities, and educational resources (Moore, 2008). Neighborhood environments also vary regarding noise, violence, pollution and poverty, chronic stressors that have been shown to influence development of hypertension (Sundquist, 2001).

A group of scientists conducted a study to examine the interaction effects between person and environment on blood pressure among 1145 adults ages 50-75 from 120 different neighborhoods. Findings reveal that individuals living in neighborhoods with well developed walkable areas (paths/sidewalks, street connectivity, amount of open/green spaces, safety features for pedestrians) demonstrated improvement in blood pressure over time, while neighborhoods with low walkability and high density of fast food establishments were significantly related to increases in systolic and diastolic blood pressure over time. The negative effect of fast food restaurants was diminished among high-walkable neighborhoods (Vongjaturapat, 2009). Results of this study together with information available from Geostrata scoring techniques can provide insight for urban planning and public health efforts, particularly with regard to promoting healthy blood pressure among community residents.

Hypertension and Comorbidities

In addition to being the single greatest predictor of heart disease, hypertension is an important risk factor for the development and worsening of many co-morbid conditions, including complications of diabetes such as diabetic eye disease and kidney disease. Hypertension affects up to 60% of people with diabetes, and having diabetes increases the risk of developing high blood pressure and other cardiovascular problems, by adversely impacting arteries, predisposing them to atherosclerosis (American Heart Association, 2010). Atherosclerosis can lead to high blood pressure, which if not treated, can lead to blood vessel damage, stroke, heart failure, heart attack, or kidney failure among many other health consequences. The lack of symptoms associated with hypertension have earned it the pseudonym 'silent killer' (Anderson, 1999).

Hypertension and BMI

The age-adjusted prevalence of hypertension in overweight U.S. adults (BMI 25 to < 30) is 23.9% for men and 23.0% for women, compared with 18.2% for men and 16.5% for women who are not overweight (BMI < 25). The prevalence for obese adults is 38.4% for men and 32.2% for women (Centers for Disease Control and Prevention, 2011a). Guidelines established within the context of best-practice recommendations in working toward Healthy People 2020 goals suggest that lowering the threshold of systolic blood pressure and maintaining a healthy weight are the preferred early interventions for blood pressure reduction (United States Department of Health and Human Services, 2010).

Hyperlipidemia

Hyperlipidemia is an elevation of lipids (fats) in the bloodstream, including cholesterol, cholesterol esters (compounds), phospholipids and triglycerides (American Heart Association, 2010). The term hyperlipidemia in this review of literature is intended to include all elements of elevated lipids in the blood stream and is used in the broader context than the term hypercholesterolemia or high cholesterol. The prevalence of hyperlipidemia refers to the estimated population of people who are managing hyperlipidemia (including high cholesterol and hypertriglyceridemia) at any given time.

Hyperlipidemia, in general, can be divided into two subcategories: hypercholesterolemia, in which there is a high level of cholesterol, and hypertriglyceridemia, in which there is a high level of triglycerides. The fat-protein complexes in the blood are called lipoproteins, of which the best known are LDL (low density lipoprotein) and HDL (high density lipoprotein). Excess LDL cholesterol contributes to the blockage of arteries, and can increase risk of many other heart and vascular complications including heart attack (Vogel, 2009). Population studies have clearly shown that the higher the level of LDL cholesterol, the greater the risk of heart disease (Corbett, 2008). This is true in men and women, in different racial and ethnic groups, and among all adult age groups (American Heart Association, 2010). According to experts at the Mayo Clinic, the optimal LDL level is below 100 mg/dL, and a measure of 160-189 mg/dL is considered to be high (Cassar, 2009).

Hyperlipidemia: Significance and Prevalence

Blood lipid levels are highly heritable traits, and research studies have attempted to identify particular alleles that may confer increased or decreased risk of hyperlipidemia (Morris, 2010). For example, recent analyses using genetic mapping on ancestral lipid phenotypes reveal that inter-ethnic variation in lipid traits can be attributed to genetic variants that have different frequencies in diverse populations (Deo, 2009). These findings have prompted increased research efforts to better understand the growing trend of elevated lipids among adults in the United States and the potential role of genetics in the development of hyperlipidemia.

Hyperlipidemia and Age

The literature reveals patterns between age and hyperlipidemia that consistently vary by gender. Interestingly, a steady rise in both men and women in hyperlipidemia has been noted after age 20, and a decline in hyperlipidemia has been noted in men after age 55 and in women after age 75 (Wong, 2009). This could be due to the fact that fewer men over age 55 and fewer women over the age of 75 may still be alive with hyperlipidemia, as it is highly associated with cardiovascular disease, the leading cause of death in the United States.

In general, hyperlipidemia is more prevalent among women than men. Today, about a quarter of all American women have blood cholesterol levels high enough to pose a serious risk for heart disease. From a clinical perspective, more than half of the women over age 55 would benefit from lower blood cholesterol levels (Morris, 2010). Middle-aged men, however, may be at increased risk for the development of hypertension in the

presence of hyperlipidemia. According to published results from the Physician's Health

Study, total cholesterol (HDL-cholesterol and LDL- cholesterol combined) accurately

predicted onset of hypertension in 3110 men without self-reported hypertension over a

seven year time period, suggesting that hypertension may be a consequence of

hyperlipidemia among middle-aged men (Laaksonen, 2008).

Table 7. Prevalence of Hyperlipidemia in U.S. by Age and Gender

Age group	Men	Women
20-34	11.0%	9.3%
35-44	21.1%	12.8%
45-54	22.9%	23.7%
55-64	16.5%	26.2%
65-74	19.2%	37.4%
over 75	10.1%	27.6%

Source: Health United States, 2008, National Center for Health Statistics
Gender and Hyperlipidemia

Hyperlipidemia and Race/Ethnicity

Racial and ethnic disparities regarding prevalence or incidence of hyperlipidemia

have not been substantiated in the literature (Kirchhoff, 2008). However, African

Americans are more likely to have poor cardiovascular outcomes than whites (Morris,

2009). Although the reasons for excess cardiovascular morbidity and mortality in

African-Americans is not fully understood, a large part can be accounted for by increased

prevalence of individual risk factors, and risk-factor clustering, including all variations of

hyperlipidemia (Morris, 2010). Data from the Behavioral Risk Factor Surveillance

System (BRFSS) indicates that the prevalence of certain risk factors for cardiovascular

disease such as diabetes, hypertension and obesity (particularly in women) appear to be significantly more prevalent in African Americans than in whites (Centers for Disease Control and Prevention Office of Minority Health, 2009).

Analysis of 14,162 participants in the Atherosclerosis Risk In Communities (ARIC) study demonstrated that greater than 90% of cardiovascular events in African Americans could be explained by elevated risk factors, compared to approximately 70% in white participants (Howaza, 2007). While research has also shown that African Americans do not necessarily differ from whites in the receipt of medical management for hyperlipidemia, African Americans as a group are less likely to engage in the recommended lifestyle changes for reducing blood lipid levels than whites, and are also more likely to report barriers to recommended changes (Davis, 2008).

Although hyperlipidemia is a significant risk factor for the development of cardiovascular disease, and African Americans continue to have the highest death rate from cardiovascular disease (Lloyd-Jones, 2005), African-Americans may present with a more favorable lipid profile than their white counterparts, which could partially explain variations in the literature regarding racial differences and prevalence of hyperlipidemia (Morris, 2010). For example, low density lipoprotein (LDL) levels of African- American men are consistently similar or lower compared with white men, and measures of high-density lipoprotein are consistently higher, resulting in a lower overall cholesterol level and a healthier ratio of LDL to HDL (Laaksonen, 2008). There is evidence that these differences may be owing to lower hepatic lipase activity among African Americans (Vega, 2004). However, further research is needed to better understand these potential mechanisms of action within the context of overall risk factors. A more desirable lipid

profile should not be interpreted as a protective mechanism against cardiovascular

disease in the presence of other individual risk factors.

Hyperlipidemia and SES

Disparities in the availability, affordability, timely use and effectiveness of

healthcare services influence health outcomes. This can be especially true for individuals

with hyperlipidemia who may be socioeconomically disadvantaged and are prescribed

numerous medications for the control and maintenance of elevated cholesterol

(Kirchhoff, 2008). Further, effective management of hyperlipidemia also requires

frequent laboratory testing to evaluate the efficacy of medication treatments and to detect

any side effects of the medicines (such as hepatic or renal complications), to determine

appropriate medication levels, and to measure change or improvement in cholesterol

levels. For many, the measures necessary for effective control of hyperlipidemia may be

overly burdensome and costly. Socioeconomic factors such as unemployment, poverty,

low educational level and income inequality have been shown to negatively impact health

status and health outcomes as well as creating barriers to health access for individuals

with hyperlipidemia or other chronic diseases (Sharma, 2004). While numerous studies

have established associations between hyperlipidemia and various indicators of SES,

education has been shown to be the strongest SES measure associated with risk factors

for hyperlipidemia (Sundquist, 2001). It has been hypothesized that poor detection and

management of hyperlipidemia in individuals with low levels of education may explain

some of this association (Merkin, 2007). Education influences knowledge about disease

risk factors, the health system, and the ability to access and utilize health care services

(Sabates, 2008). Thus, education may influence rates of screening, awareness, treatment alternatives and follow-through with health regimens for hyperlipidemia. An analysis of men and women over the age of 20 who participated in the National Health and Nutrition Examination Survey (NHANES) between 1999 and 2002 revealed a significant association between education and screening for hyperlipidemia. The study also revealed that the odds of not being screened for hyperlipidemia were 2.5 times greater for individuals with the lowest levels of education compared to those with the highest levels of education, and that these trends persisted across racial and ethnic differences (Merkin, 2007).

Hyperlipidemia and Comorbidities

Hyperlipidemia is recognized as a major contributing factor for the initiation and progression of atherosclerosis, hypertension, diabetes, heart disease, stroke, and many other diseases (American Heart Association, 2010). Hyperlipidemia is especially problematic when it co-occurs with other risk factors, increasing risk for health complications and particularly of acute and critical cardiac events. A sub-analysis using data from the Cardiovascular Health Study (CHS), a longitudinal epidemiologic study, found that among the 4,311 participants included in the analysis, the risk for experiencing a sudden cardiovascular event was as high as (80%) among persons with both hyperlipidemia and hypertension (Wong, 2009).

Research shows that improved control of LDL cholesterol among individuals with diabetes can reduce cardiovascular complications by 20% to 50%, and improved LDL in conjunction with other risk factors consistently reduces overall health risk (Sundquist,

2001). However, recent information published from analyses using the National Health

and Nutrition Examination Surveys shows that the prevalence of undiagnosed

hyperlipidemia remains extremely high 56%, and individuals may be at risk for

complications related to comorbid disease associated with hyperlipidemia without

awareness of these risks (Kuklina, 2009). Although between 1999 and 2006

improvements in screening and early detection of hyperlipidemia have been noted,

control of hyperlipidemia remains poor (Ford, 2010).

Hylerlipidemia and BMI

The age-adjusted prevalence of hyperlipidemia in overweight U.S. adults (BMI

between 25 and 30), is 19% for men and 28% for women, compared with 15% for men

and 16% for women who are not overweight (Centers for Disease Control and

Prevention, 2011a). The prevalence of hyperlipidemia for obese adults (BMI >30) is

20% for men and 25% for women (Brown, 2010).

Randomized controlled clinical trials, cross-sectional studies, longitudinal studies

of concurrent weight and LDL increases, and prospective epidemiological studies have

consistently linked increased BMI to increased incidence of hyperlipidemia (Natarajan,

2004; National Heart Blood and Lung Institute, 2010; Williams, 2007; Wong, 2009).

These studies support the hypothesis that weight gain (increased BMI) acutely increases

the risk of hyperlipidemia (Morris, 2010). Further evidence regarding the important link

between BMI and hyperlipidemia comes from guidelines published by the Third National

Cholesterol Education Program, part of the CDC's initiative to increase awareness of

health risks associated with hyperlipidemia. The Guidelines contain specific

recommendations for control and prevention of hyperlipidemia via weight loss and/or weight control (Centers for Disease Control and Prevention, 2011a).

<div align="center">Behavioral Measures of Adherence</div>

Medication Possession Ratios

Research reveals that individuals taking self-administered medications on average take less than half of the prescribed doses (Haynes, 2005). According to the Healthcare Compliance Packaging Council, an estimated 125,000 U.S. deaths per year can be attributed to the result of taking medications improperly, and healthcare costs are negatively impacted by treatments and hospitalizations associated with non-adherence to prescribed medications (Magee, 2005). The American Medical Association reports that non-adherence to medications is an issue that can be expected to grow in significance along with coincident increases in the prevalence of chronic diseases (American Medical Association, 2005). Further, according to the World Health Organization (WHO), medication adherence among patients in developed countries suffering chronic diseases averages only 50% (World Health Organization, 2003). Clearly adherence to medication is a very concerning and challenging issue on a global scale, and there is a great need to develop strategies to improve levels of taking medications as prescribed.

The issue of adherence is a highly complex phenomenon and has numerous components and factors that may contribute to an individual's ability or willingness to adhere to taking medications as prescribed. The direct question of adherence to medications was not addressed in this analysis. However, medication possession ratios were calculated among participants included in the sample who were prescribed medications for diabetes, hypertension or hyperlipidemia as a strategy to gauge behaviors

associated with high or low use of the KP.Org PHR that could influence physiological measures of metabolic control, including HbA1c, BP and LDL.

Outcomes: Physiological Measures of Metabolic Control

Hemoglobin A1c (HbA1c)

Although diabetes cannot be cured, controlled clinical trials have provided evidence that improved glycemic control can reduce the risk of long-term complications and potentially delay or eliminate many of the consequences associated with diabetes (American Diabetes Association, 2008). Thus, promoting glycemic control has become the ADA's primary goal in establishing standards for medical care for the treatment and management of diabetes. Glycosylated hemoglobin, HbA1c, is a measure of the average plasma glucose concentration over prolonged periods of time, and is the gold standard used to evaluate glycemic control among diabetic patients. In the normal 120-day lifespan of red blood cells, glucose molecules react with hemoglobin, forming glycated hemoglobin. In individuals with poorly controlled diabetes, the quantities of glycated hemoglobin are much higher than in non-diabetic people. Once a hemoglobin molecule is glycated, it remains that way. A buildup of glycated hemoglobin within the red cell, therefore, reflects the average level of glucose to which the cell has been exposed during its life cycle. Measuring glycated hemoglobin assesses the effectiveness of therapy by monitoring long-term serum glucose regulation. The HbA1c level is proportional to average blood glucose concentration over the previous four weeks to three months. For optimal diabetic control, the American Diabetes Association recommends the target HbA1c at a level no greater than 7% for most people (American Diabetes Association,

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2008). For the purpose of this analysis, movement toward the target level of HbA1c of 7% or reducing overall HbA1c measures was considered an improvement in clinical outcome. The specific HbA1c laboratory values were compared to determine whether the change was statistically significant.

Blood Pressure (BP)

Blood pressure below 120 /80 millimeters of mercury (mmHg) is considered optimal for adults (United States Department of Health and Human Services, 2010). Currently, the American Diabetes Association recommends a blood pressure goal of <130/80 mmHg for individuals with diabetes (American Diabetes Association, 2008). The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure also recommends a blood pressure goal of <130/80 mmHg for patients with diabetes (Centers for Disease Control and Prevention, 2011b). For the purpose of this analysis, a decrease in BP (systolic) was considered improvement in this clinical outcome.

Low Density Lipoprotein (LDL)

The role of LDL in the body is to transport cholesterol and triglycerides from the liver to the peripheral tissues. An elevated plasma concentration of LDL is associated with increased risk of cardiovascular disease and complication. An established body of evidence points to reducing LDL cholesterol as one of the most effective ways to prevent and treat cardiovascular disease, regardless of an individual's risk (Cobain, 2007). On average, each 1% reduction in LDL cholesterol is matched by a 1% reduction in the

likelihood of a major cardiovascular event. Thus, even small reductions in population LDL could prevent many cardiovascular-related deaths and could substantially reduce associated risks of developing comorbid diseases (Upadhyay, 2010).

The gold standard for measuring LDL cholesterol is via a blood serum lipid laboratory panel. Recent guidelines suggest that serum lipids should be evaluated at a minimum every six months, and for very high risk patients, more frequently (United States Department of Health and Human Services, 2010). Currently, there is disagreement among the experts regarding the ideal goal for appropriate LDL levels. The recommended LDL goal for patients with comorbid hyperlipidemia and coronary heart disease (CHD) is < 100 mg/dl, which is considered an achievable goal (National Heart Blood and Lung Institute, 2010). However, this goal has not been shown to reduce CHD or associated risk (Laaksonen, 2008). Lowering LDL to < 70 mg/dl has been shown to reduce CHD risk, but may not achievable in the average patient. Thus, additional research to support optimal LDL control levels is ongoing. For the purpose of this analysis, a decrease in magnitude of LDL was considered improvement in this clinical outcome.

The State of Health in Georgia

The state of Georgia has the 9th fastest growing population of individuals age 60 years and older in the United States (Greene, 2007). Age is a known risk factor for the development of diabetes, hyperlipidemia and hypertension, and the prevalence of these chronic diseases in Georgia appears to be well above the national average.

Table 8. Diabetes, Hypertension and Hyperlipidemia: Prevalence in the U.S. and GA

Demographics by Disease: United States and State of Georgia (2008)

Diagnosis	National Prevalence %	Georgia Prevalence %
Diabetes	7.8 adult population	10.4 adult population
Hypertension	31.3	62.0
Hyperlipidemia	41.6 female: 34.2 male	64.0 total population

Overweight and obesity affect 60.4% of the population in Georgia, a factor known to exacerbate many comorbidities (Penn, 2009). Risk factors for overweight, obesity, and associated comorbidities include low socioeconomic status and minority group membership (Glass, 2007). Both low socioeconomic status and minority group membership are prevalent in Atlanta metropolitan area, the primary service area for Kaiser Permanente Georgia. The information in this Review of Literature was intended to provide a framework and rationale for the selection of KPGA as a source of data as well as support regarding the clinical value and significance of each of the selected variables of interest. It was anticipated that analysis of these variables within the context of KP.Org use would provide meaningful knowledge regarding the current and potential use of this tool in working toward improved health outcomes.

CHAPTER 3

METHODS

The purpose of this study was to examine patterns of use of an electronic personal

health record (PHR) among adults diagnosed with selected chronic diseases including

diabetes, hypertension and hyperlipidemia, to evaluate changes in intermediate

behavioral measures of adherence, medication possession ratios, and to examine

physiological measures of metabolic control for the respective diseases (HbA1c, BP, and

LDL). This chapter includes a description of Kaiser Permanente's KP.Org and associated

data and is followed by the research plan utilizing data from Kaiser Permanente Georgia

KP.Org to answer the research questions.

Kaiser Permanente Georgia (KPGA)

KPGA is a federally-qualified group and network model HMO that provides

comprehensive medical services to approximately 275,000 residents in the Atlanta

metropolitan area. KPGA members gain access to 6,800 doctors, 40 hospitals, and

hundreds of pharmacies. Kaiser Permanente Georgia is unique in that within the region,

Kaiser contracts with hospitals but does not own or operate their own hospital facilities.

KPGA has a specialized team of hospitalists who are Kaiser Providers, and they are

directly responsible for entering information into the EHR.

KPGA provides services throughout a 28-county area in the Atlanta metropolitan area. Numerous outpatient KPGA clinics are owned, operated and fully staffed by KPGA. These clinics support the KPGA community benefit program, which provides services for health education, community partnerships, subsidized health coverage for low-income families, and collaborations with local clinics, health departments, and nonprofit organizations. This study included data from all service facilities within the Atlanta metropolitan area, including owned and operated outpatient clinics and inpatient hospitalist-staffed facilities.

Structure of KP.Org Data

Data collected by Kaiser Permanente EHR and KP.Org are stored in individual database tables for the purpose of generating meaningful information that is both accessible and manageable. This allows certain tables to have a 'one-to-many' relationship with other tables. Data used to populate the Kaiser Permanente EHR and KP.Org are derived from several different tables that are linked via a unique identification health record number. This is commonly referred to as a relational database.

Data populate the electronic medical record in near real-time primarily through an automated process, although there are some exceptions. For example, pharmacy, patient problem lists and medications are input into the EHR and KP.Org electronically. Information populates the tables when a user selects items from a pre-developed comprehensive list. Medication names, dosages, instructions, dispersement count, and other specific details can be selected from a list and automatically added to several tables

connected to a particular patient identifier within the EHR. In other words, the names of

medications and other prescribing details are not manually typed into the system, but are

selected from a pre-established list in conjunction with the established prescribing

protocols of Kaiser Permanente.

Kaiser Permanente utilizes a national central pharmacy repository. Therefore,

names of medicines, prescribing parameters, contraindications, cost, available dosages

and quantities, etc., are consistent across the entire network. This system serves to

simplify the complex processes associated with prescribing medications, while providing

critically important information for providers at the point of care related to medication

safety. For instance, providers can view all the medications a particular patient is

prescribed at any given time and can make adjustments to dosages. Adjustments are

updated throughout the entire database in real time. Likewise, patient problem lists are

algorithmically derived based on a series of patient-specific criteria and automatically

populate the EHR. Manually entered data, for example patient vital signs, are input into

the EHR using a data entry process by a provider (nurse, physician, nurse practitioner, or

other qualified provider).

Laboratory values represent a unique set of data and are capable of being

electronically inserted into the EHR via an electronic system, but must be verified first to

prevent highly sensitive or upsetting information from being viewed by a patient without

a provider's explanation, or possibly counseling, in person. An example of information

that would be considered highly sensitive might be test results that demonstrate values

that fall outside a range considered appropriate or normal, confirmatory lab values for

HIV or a sexually transmitted infection, biopsy results that support the diagnosis of

cancer, or other life threatening conditions. This additional verification step is a built-in precautionary measure for the safety and well-being of patients and is an effective strategy to ensure the highest regard for the protection of personal health information.

Likewise, the use of the secure messaging system within KP.Org has a two-tiered security feature. Patients can send secure messages to their KP providers directly through KP.Org. Provider responses generate an automatic message to the email address provided by the patient, notifying the patient that there is a message waiting to be reviewed in the KP.Org system. To read the message, the patient must logon to the KP.Org secure site and access the information through that portal.

Study Methodology

Adult members of KPGA diagnosed with selected chronic diseases (diabetes, hypertension and hyperlipidemia) were included in the sample to examine patterns of use of KP.Org, to evaluate changes in intermediate behavioral measures of adherence, and to compare physiological measures of metabolic control among users of the KP.Org system. This portion of the chapter is organized into the following sections: Design, Setting, Sample, Data Collection, Data Preparation, Statistical Analysis, and Data Management and Protection of Data.

Design

This was a retrospective cohort study using secondary administrative data. Exposure was defined as the first point of logon to KP.Org in calendar year 2008. The cohort was comprised of adult enrollees of Kaiser Permanente Georgia (age 21 or older)

who were diagnosed with one or more specific chronic condition (diabetes, hypertension, hyperlipidemia) who logged on to the KP.Org system at least one time during calendar year 2008, and who were members of KP.Org at least 6 months prior to and 14 months following initial KP.Org logon. Each individual in the cohort served as his/her own control within the analysis.

This study was developed because information regarding the potential relationship between use of electronic PHRs, intermediate behavioral outcomes and physiological parameters that demonstrate improvement in health outcomes was needed to support use of these electronic tools as an effective strategy to support individuals in managing their health. Diabetes, hypertension and hyperlipidemia were selected as the inclusion criteria for the records used in the analysis because they are common chronic conditions identified algorithmically as priority health needs of the Atlanta metropolitan area and are believed most likely to benefit from use of the KP.Org system.

A retrospective cohort design was selected because it is the most appropriate design, by definition, to address the research questions based on the available data. The study is retrospective because it examines patterns of behavior and change over time from a specific event that has already occurred and is being examined after the fact. The retrospective cohort design is also reasonably inexpensive and can reveal meaningful information about a sample (Polit & Beck, 2004).

Inclusion in the cohort required membership in the KPGA healthcare delivery system with baseline data available along the study variables at a time point at least 6 months prior to initial logon to KP.Org, and at least one time point in the ensuing 14 months following initial logon during calendar year 2008. Data were collected along the

study variables between baseline time period and up to 14 months following KP.Org

logon. Data were examined to assess frequency of use, change in intermediate behavioral

outcomes and change in physiological clinical outcomes over time.

Within the KPGA system, protocols have been established for the management of

these selected chronic conditions that include regular prescribing of medications that

support effective management of diabetes, hyperlipidemia and hypertension, regularly

scheduled visits with KPGA providers for ongoing health assessments (usually at 6

month intervals), and regularly scheduled laboratory evaluations to monitor levels of

medication and effectiveness of management via specific lab values. Within the KPGA

protocol, laboratory assessments are scheduled at three month intervals, but orders for

laboratory work remain effective for 45-60 days post visit with provider. For this reason,

the time intervals for inclusion in the analysis include 6 months prior to the initial KP.Org

logon and up to 14 months following initial KP.Org logon, for potential capture of

information associated with laboratory outcome variables for the purpose of assessing

change over time in association with use of the KP.Org system.

Setting

For this study, data from the KPGA database that electronically captures

transactions within the KP.Org system for its members was utilized. The KP.Org system

is a service available to all Kaiser Permanente members. Members can visit the Kp.Org

website to activate and access their personal health records free of charge from any

location that provides computer access. Activation and access to KP.Org includes a

series of secure password functions for the purpose of protecting personal health

information and KPGA member confidentiality in accordance with the laws and

protocols of HIPAA, the Joint Commission, and KAISER Permanente. Among adult

registered users of KP.Org in calendar year 2008 (N = 57,021), there were 621,653

recorded logons, and 5,453, 144 functions performed within logon sessions.

Sample

The cohort for this study is comprised of adult enrollees of Kaiser Permanents

Georgia (KPGA) age 21 or older, who utilized KP.Org electronic PHR at least once

during calendar year 2008 and who have been diagnosed with one or more selected

chronic condition (diabetes, hyperlipidemia or hypertension). Each individual in the

cohort served as his/her own control within the analysis. Estimated numbers of

participants included in the present analysis are based on the data provided in the table

below depicting estimations for calendar year 2008 provided by the Centers for Disease

Control, Atlanta, Georgia comparing national prevalence percentages with prevalence

percentages for the state of Georgia for hypertension, hyperlipidemia and diabetes (CDC,

2008).

Table 9. National and State Level Prevalence (Percent) of Diabetes, Hypertension and
Hyperlipidemia in the U.S. and State of Georgia (2008)

Prevalence (Percent) of Diabetes, Hypertension and Hyperlipidemia in the United States and Georgia, 2008		
Disease	**National Prevalence %**	**Georgia Prevalence %**
Hypertension	31.3	62.0
Hyperlipidemia	Female 41.6 Male 34.2	Total population 64.0
Diabetes	Total population (adult) 7.8	Total population (adult) 10.4

It is apparent from these data that the selected chronic diseases occur at

significantly higher rates in the state of Georgia compared with the national prevalence.

Estimations of inclusion data for the present analysis were calculated using a percentage

rounded down to the nearest tenth for each of the three selected chronic illnesses. Among

the total KPGA users of KP.Org (n = 57,021), there were 22%, (n = 12,551) unique

individuals that met all inclusion criteria for this study. Data were examined and outliers

and missing data were excluded (n = 3047). Of the individuals meeting criteria for

inclusion76% (n = 9,504) were included in the analysis.

Data Collection

KP.Org functions examined in this study included KP/Org logon patterns,

intermediate behavioral measures of adherence, and outcome measures of metabolic

control. KP.Org logon patterns were examined using frequencies and categorical

descriptions of the types of functions selected for use within the KP.Org system. The

number of logon events per member was calculated, and the types of transactions and

patterns of transactions were examined and described.

Functions in the analysis included the most frequently utilized functions identified

by the FREQ Procedure of overall transaction type for calendar year 2008 and are

displayed in Table 10. Excluding the Logon function, which serves as the initial point of

contact, the six most frequently used functions during 2008 were included in the analysis.

Table 10. Available Functions of Use Within KP.Org (2008-2010)

Transaction Type	Individuals (N)	Number of Transactions	Percent use among available functions within KP.Org
Account Reenable	172	172	0.02
Account Sign up for Proxy Use	3281	3291	0.33
Allergies	5487	7776	0.55
Benefit Details	1598	2341	0.16
Claims	191	1606	0.02
*Encounter Details	19341	96019	1.94
Get PCP	1983	5274	1.99
Health Maintenance	13694	28965	1.38
Immunizations	5830	9030	0.59
Insurance	2129	3651	0.21
*Lab Results	49216	1067300	4.95
Lab Tests	53307	1336225	5.36
*Logon	57021	621653	5.73
*Medical Advice Request	28611	192719	2.88
*Medication	13481	43125	1.35
*Messaging	38337	835265	3.85

*Functions included in the analysis for this study

Intermediate measures of adherence were examined by calculating ratios of medication possession. Change in adherence was measured by calculating ratios at 6 months prior to and up to 14 months following initial Kp.Org logon, using the first login that occurred during calendar year 2008 as the initial point of contact. Medication possession ratios were calculated by taking the total days of supply of medications dispensed, divided by the total number of days between the first and last prescription

refill for each medication prescribed for an individual with a known diagnosis of diabetes, hypertension or hyperlipidemia.

Clinical outcome measures of metabolic control included measures of hemoglobin A1c (HbA1c), low density lipoproteins (LDL), and blood pressure (BP). These three clinical outcome measures represent the gold standard in clinical evaluations of diabetes (HbA1c), hyperlipidemia (LDL), and hypertension (BP) (Corbett, 2008). Outcome measures were collected for each participant from the LAB-SERV database (HbA1c and LDL) and from the VITAL_SIGNS database (BP). Measures were taken at points in time 6 months prior to and up to 14 months following initial KP.Org logon, using the first logon that occurred during calendar year 2008 as the initial point of contact.

Data Preparation

A sub-sample of 500 randomly selected unique participants was selected for the purpose of coding and modeling preparation. Syntax was developed in Statistical Analysis Software (SAS) version 9.2. All code was tested for accuracy and preliminary results were analyzed for the purpose of determining correlations and models for use in the analysis of the larger data set. Errors in programming were addressed and corrected prior to analyzing the larger data set. A set of programs to link and clean existing data was completed and a code book was developed as a template for the final analysis.

Univariate descriptive statistics (measures of central tendency [mean, median, mode], and dispersion [standard deviations, quartiles, max, min] for continuous variables, and frequency counts and percentages for categorical variables were computed for all study variables. Statistics, histograms and box plots were examined for accuracy of input

through the assessment of plausible means, standard deviations, and univariate outliers. The initial descriptive analyses served to identify outliers, missing values, inconsistencies in the data, or other issues that could potentially skew the data and findings. Descriptive analyses and percentiles were used to categorize continuous variables. Logons were defined using univariate analyses to establish quartiles ranging from lowest to highest frequency of use of KP.Org. The use of quartiles was advantageous within this data set because it provided the ability to eliminate outliers and define cut-off points based on the data rather than arbitrarily assigning a value.

Statistical Analysis

Initial logon to KP.Org served as the median point. The cohort was assessed for a period of 6 months prior to initial KP.Org logon to establish baseline information. The cohort was then followed forward in time from initial KP.Org logon for a period of 14 months to assess post-exposure outcomes of adherence and metabolic control measures. Frequency of logon to KP.org (interval level of measurement where N was one or greater for inclusion) was measured utilizing a frequency tabulation from the KPGA Transaction database.

Patterns of KP.Org use were evaluated by examining frequency counts and the ordering of use of each selected function including the following: Encounter Details, Lab Results, Medical Advice Request, Medication and Messaging. Intermediate behavioral outcomes (medication possession ratios) were calculated by taking the total days of supply of medications dispensed, divided by the total number of days between the first and last prescription refill for each medication prescribed.

Changes in clinical outcome measures (HbA1c, LDL, and BP) were assessed over time. Baseline data were collected at the point in time 6 months prior to initial logon to KP.Org during calendar year 2008 for each participant. Each participant record was followed forward in time for a period of up to 14 months following initial logon to KP.Org. Data during the 14 month time period were recorded and analyzed along each variable of interest (patterns and frequency of use within the KP.Org system, behavioral measures of adherence, and physiological measures of metabolic control).

The covariates age, SES (using Geostrata code quartiles), gender, and % African American were included in the analyses. The covariates were examined to see if these variables explained differences between patterns of use, measures of adherence (medication possession ratios), and physiologic measures of metabolic control (HbA1c, BP, LDL). Analyses were stratified by comorbidity (diabetes, hypertension and hyperlipidemia).

Correlation analyses were performed to determine whether the variables displayed associations, and to quantify existing relationships between two or more variables, including the strength and direction of the relationship. Covariate analysis were performed to control for collinearity between variables at the .89 level (O'Rourke, 2005). Variables falling below the .89 level of correlation were maintained in the model. Variables that correlated greater than .89 were excluded from the model (O'Rourke, 2007, p. 391).

Mediation analysis was performed to evaluate whether medication possession ratio served as a mediator between frequency of Logon to KP.Org and the primary outcomes of change in HbA1c, BP or LDL (Barron, 1986; MacKinnon, 2007). For all models used

in mediation analysis, the main independent variable was a dichotomous indicator of logon frequency equal to zero for the bottom (lowest) quartile of KP.Org logon frequency, and 1 for all other quartiles of KP.Org logon.

First, each mediation variable (medication possession ratio for specific diagnosis of diabetes, hypertension or hyperlipidemia) was regressed on the independent variable logon to KP.Org set as a dichotomous variable (Model 1). Next, each dependent variable (primary outcome measure of change in HbA1c, BP or LDL) was regressed on the mediator variable (medication possession ratio) with the independent variable (logon to KP.Org) on the outcome (Model 2). Finally, each dependent variable (primary outcome measure) was regressed on the independent variable (Logon to KP.) to determine the total effect (Model 3).

The indirect effect, or mediated effect, of the independent variable (Logon to KP.Org) on the outcome variable (change in HbA1c, BP or LDL) via the mediator (mediation possession ratio) was calculated as a product of the coefficient for the mediator (Model 2) and the coefficient for the independent variable (Model 1) for each of the three outcomes (Hba1c, BP and LDL). The statistical significance of the indirect effect was calculated using the Sobel test (Fritz, 2007). To complete the mediation analysis, the proportion mediated was reported as the indirect effect divided by the total effect (the sum of the direct and indirect effects). All mediation models were run without adjustments for covariates, and then repeated with adjustments for age, gender, percent African American and Geostrata quartiles (a proxy measure of SES). Final calculations of the total effect, direct effect, indirect effect and proportion mediated were performed.

Logistic and multiple regression analyses were conducted without adjustments for covariates, and were repeated with adjustments for age, gender, percent African American and Geostrata quartiles (a proxy measure of SES) using the primary independent variable logon to KP.Org and primary outcome measures of HbA1c, BP and LDL. Additional logistic and regression analyses were performed using secondary independent variables of specific functions of use within KP.Org (Secure Messaging, Medical Advice, Lab Results, Medication and Encounter Details) and primary outcome measures of HbA1c, BP and LDL to determine associations and relationships among these variables. Each variable was examined in the model and evaluated for significance of change over time. Significance was set at the alpha level of .05.

Data Management and Protection of Data

The primary analysis for the purpose of testing the study hypothesis was conducted at the University of Alabama. KPGA enrollees included in the analysis were coded with a unique study identifier provided by KPGA research scientists working to extract the data for analysis. The unique identifier was not linkable back to the patient's health record except in a database stored in a password protected folder on the KPGA secured network. Information included laboratory test dates, dates of diagnosis of major chronic illnesses (hypertension, hyperlipidemia, diabetes), frequencies and event event patterns of logon sessions, use of secure messaging functions (absent details of the correspondence). Medical service event dates were necessary to sequence events for a period of 14 months following initial KP.Org logon in calendar year 2008. PHI was not disclosed.

This was a data only study where the use of PHI to link datasets with the KPGA secured network presented no more than a minimal risk to the individual participants. Computerized data were retrieved from KPGA's HealthConnect® databases (including KP.Org transactions) and stored on KPGA's password protected network server in datasets to which only authorized KPGA Research Department staff had access.

Prior to obtaining access to the data, IRB approval was obtained by Kaiser Permanente Georgia and by the University of Alabama at Birmingham. The required Data Use Agreement between the investigator and Kaiser Permanente Georgia was executed and filed. Data were stored on KPGA approved, encrypted servers and maintained behind the KPGA firewall and security systems. Access to data was via secure link to specific server files containing the approved data per Data Use Agreement authorized by KPGA. Access, analysis and storage of data was closely supervised by the KPGA Senior Research Scientist, Douglas Roblin, PhD., and by Dissertation Committee Member Thomas K. Houston, II., MD, MPH, who provided mentorship and guidance throughout this analysis. Any printouts with patient identifiers were stored in a locked file cabinet at the KPGA Research Department or shredded. Any retained printouts or computerized datasets were stored for a period consistent with HIPAA guidelines and then destroyed.

CHAPTER 4

FINDINGS

This chapter presents a description of the sample and findings from the data analysis. Preliminary findings from a randomly selected sub-set of the data are discussed first, including decisions regarding variable parameters, outliers, missing data, and programming and coding for analysis. The next section provides a description of the sample including age, gender, % African American, diagnosis and Geostrata code (a proxy of socioeconomic status). Sample characteristics are further described according to the number of comorbid conditions of diabetes, hypertension or hyperlipidemia, and use of KP.Org functions for the selected variables of interest. Findings from the analysis of data relevant to the specific research questions including statistical models and significance are provided in the remaining sections.

Preliminary Analysis and Coding

A random sub-sample (N = 500) of unique participants were drawn from the study population (n = 9504) for the purpose of programming and coding data and developing tables and models for analysis. Data were received from KPGA in SAS 9.2 format including five tables linked by unique study identifiers in a one-to-many relationship.

Table 11. KPGA Datasets, Observations and Variables

Dataset Name	Number of Observations/Records	Number of Variables
Sample1_Cohort	500	12
Sample1_Cohort_BP	3314	10
Sample1_Cohort_Lab	1260	9
Sample1_Cohort_Rx	5319	9
Sample1_Transactions	43, 980	5

Cleaning and Coding Data

Sub-sample data were examined and comparisons were performed using SAS 9.2 Proc Contents. A sample printout was used to compare the number of observations and the number of variables for each dataset. All variables and data were validated to ensure the sample was matched variable by variable to the total data set. Frequency tabulations (Proc_Freq) and Means (Proc_Means) were used to examine all variables. Values that were clearly data entry errors or unrealistic (i.e., BMI in excess of 3800, height of five inches, HbA1c of 350) were excluded. Variables with multiple labels were examined for clinical relevance and interpretability. For example, LDL values were labeled as calculated, direct or fasting LDL. Calculated LDL, the standard clinical measure, was retained. Fasting and direct LDL were excluded based on the sparse number of available records and the lack of interpretable information provided by these measures.

After correcting for errors, it was determined that the variable BMI was available for fewer than 20% participants in the sample. Data values for height and weight from

which BMI might have been calculated were also missing in excess. Therefore, the variable BMI (a potential covariate) was excluded from analysis.

Geostrata Code (GC)

The Geostrata code served a proxy measure of SES in the analysis. The Geostrata code, a numeric value from 1-4, was developed as a representation of quartiles of the SES index within a given neighborhood based on zip code and census tract data (Roblin, 2011). The first quartile (1) represents the lowest range of SES, areas that are the most economically deprived. The second quartile (2) represents the lower-middle range of SES. The third quartile (3) represents the higher middle range of SES; and the fourth quartile (4) represents the highest SES from among the zip codes, census tract and patient level reported data included in the analysis. All SES data included in this report are representative calculations of the Geostrata code quartiles.

Percent African American

A preliminary review of demographics from KPGA sample data revealed that variables of race and ethnicity were captured for only 40% of members in the existing data set for this analysis. Therefore, data generated from census tract and block information was used to indicate the percent of African Americans within a given geographic block matched with Geostrata codes. This variable was developed and validated by researchers at KPGA (Roblin, 2010) as a strategy to overcome the issue of missing data on member race, as race is not a required field in the KPGA database, but is optional. The variable % African American is intended to provide an estimate of the

percent of African Americans living within a given neighborhood included in the KPGA

service area, but is not a direct measure of race. The value of this variable can range from

0 to 1. Research shows that this measure is a reliable proxy of KPGA membership in the

region for which the sample was selected for use in this study (Roblin, 2011).

Study Sample

Table 15 displays a description of the total study sample by diagnosis. Each

individual included in the sample had a confirmed diagnosis of diabetes, hypertension or

hyperlipidemia (or any combination of the three), verified by date of initial diagnosis

within the KPGA record at least 6 months prior to initial logon to KP.Org that occurred

during calendar year 2008.

Table 12. Participant- Level and Location- Based Demographics for the Sample Stratified
by Diagnosis of Diabetes, Hypertension and Hyperlipidemia

Total N = 9504	Diabetes N = 1183		Hypertention N = 7471		Hyperlipidemia N = 5381	
Participant-level Demographics						
Age (mean, SD)	51.99	13.17	51.53	12.55	54.05	11.60
Gender (female , %)	1063	56.45	4282	57.31	2692	50.03
BMI (mean, SD)	33.72	7.72	31.94	7.30	30.69	6.58
Location –based Demographics						
*GC Quartile 1, Lowest (N, %)	533	28.31	1946	26.05	1257	23.36
*GC Quartile 2 (N, %)	484	25.70	1937	25.93	1331	24.74
*GC Quartile 3 (N, %)	462	25.54	18.36	24.58	1342	24.94
*GC Quartile 4, Highest (N, %)	404	21.46	1752	23.45	1451	26.97
**African- Americans (%, SD)	28.0	31.0	30.0	32.0	26.0	30.0

*The Geostrata code (GC Quartile) served a proxy measure of SES within the analysis.

Among the sample, 20% had a confirmed diagnosis of diabetes, 79% had confirmed diagnosis of hypertension, and 57% had a confirmed diagnosis of hyperlipidemia. Of these, 57% were diagnosed with one of the three conditions of diabetes, hypertension or hyperlipidemia, 30% were diagnosed with two, and 12% were diagnosed with all three. Individuals meeting criteria for inclusion in more than one group at the start of data collection were included in analyses for each group for which they met full inclusion criteria. Thus, individuals are included in more than one group of analyses based on diagnosis.

Table 13. Participant- Level and Location- Based Demographics for the Sample Stratified by Number of Selected Comorbid Diagnoses (Limited to Diabetes, Hypertension and Hyperlipidemia)

	One Diagnosis N = 5448		Two Diagnoses N = 2881		Three Diagnoses N = 1175	
Participant-level Demographics						
Age (mean, SD)	47.32	11.77	54.82	11.86	56.74	11.20
Gender (female,%)	3214	59.00	1534	53.30	585	49.80
BMI (mean, SD)	30.75	7.13	31.53	6.86	34.43	7.38
Location –based Demographics						
[*]GC Quartile 1, Lowest (N, %)	1325	24.32	745	25.86	307	26.13
[*]GC Quartile 2 (N, %)	1411	25.90	701	24.33	313	26.64
[*]GC Quartile 3 (N, %)	1364	25.04	700	24.30	292	24.85
[*]GC Quartile 4, Highest (N, %)	1348	24.74	735	25.51	263	22.38
[**]African- Americans (%, SD)	28.0	31.0	28.0	31.0	31.0	33.0

[*] The *Geostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

[**]*Percent of African-Americans* is a variable generated from census tract and block information to indicate the percent of African Americans within a given geographic block matched with Geostrata codes.

After correcting issues of outliers, missing values and multiple variable labels, new variables were defined for use in the analysis. These included laboratory values for HbA1c and LDL, blood pressure measures, and counts of disease-specific laboratory tests (including change and improvement), medication-possession ratios, number of selected comorbid conditions, and KP.Org usage.

Bivariate Correlations among Study Variables

Associations among the explanatory variables were assessed by calculating correlation tests for each variable. Two sets of variables were problematic. The variables Encounter Details and Appointment Details within KP.Org were correlated at (0.89), and Lab Tests and Lab Results at (0.97). Further examination revealed that these functions are linked within the KP.Org system. Lab Results can be viewed only by first accessing the Lab Tests page, and Encounter Details could be accessed directly or alternatively by first viewing the Appointment Details page. Thus, the destination variables Lab Results and Encounter Details were retained, and the variables providing links to these pages were excluded.

Results of the bivariate correlations between study variables stratified by diagnosis (diabetes, hypertension, hyperlipidemia) are presented in Tables 14a -16b, and include the demographic explanatory variables of age, gender, percent African American, and Geostrata code (a proxy measure of SES) by quartile in Tables 14a, 15a, and 16a. The variables of use within KP.Org including Secure Messaging, Medical Advice, Lab Results, Medication and Encounter Details are included in Tables 14b, 15b, and 16b.

Bivariate Correlations of Study Variables among Individuals Diagnosed with Diabetes

Among diabetics, female gender was also negatively associated with Geostrata Quartile 2 (r = -.091, *p* <.05), but positively correlated with Geostrata Quartile 4, the highest quartile of SES (r=.073, *p* < .05). The variable % African American was positively associated with Geostrata Quartile 2 (r = .315 *p* <.0001) and Geostrata Quartile 3 (r =.057, *p* <.05), but was negatively associated with Geostrata Quartile 4 (r = -0.55, *p* <.05). The variable % African American was also negatively associated with use of Secure Messaging, Medical Advice and Lab Results within the KP.Org system, each at the *p* <.05 level.

Bivariate Correlations of Study Variables among Individuals Diagnosed with Hypertension

Among individuals diagnosed with hypertension, female gender was positively associated with age (r = .056, *p* <.0001) and with use of the Secure Messaging function within KP.Org (r = .032, *p* < 05). Female gender was negatively associated with % African American (r = -.103, *p* <.0001), Geostrata Quartile 2 (r = -.056, *p* <.0001), and use of the Encounter Details function within KP.Org (r = -.053, *p* <.0001). Age was negatively associated with % African American (r = -.080, *p* <.0001), Geostrata Quartile 2 (r = -.056, *p*<.0001) and Geostrata Quartile 3 (r = -.042, *p* < .05). Age was positively associated with use of the Lab Results (r = .036, *p* <.05) and Encounter Details (r = .075, *p* <.0001). The variable % African American was positively associated with Geostrata Quartile 2 (r = .305, *p* <.0001) and with Geostrata Quartile 3 (r =.075, *p* <.0001), but was negatively associated with Geostrata Quartile 4 (r = -.039, *p* <.05).

Among hypertensives, % African American was negatively associated with use of Secure Messaging (r = -.066, *p* <.0001), Medical Advice (r = -.062, *p* <.0001) and Lab Results (r = -.049, *p* <.05). Geostrata Quartile 2 was also negatively associated with use of Secure Messaging (r = -.027, *p* <.05), Medical Advice (r = -.027, *p* <.05), and Lab Results (r = -.036, *p* <.05). Geostrata Quartile 4 was positively associated with use of the Medication function (r = .044, *p* <.05).

Bivariate Correlations of Study Variables among Individuals Diagnosed with Hyperlpidemia

Among those diagnosed with hyperlipidemia, age was negatively associated with female gender (r = - .082, *p* <.0001), % African American (r = - .059, *p* <.05) and use of the Secure Messaging (r = -.037, *p* <.05). Gender was negatively associated with % African American (r = -.111, *p* <.0001), Geostrata Quartile 2 (r = -.062, *p* <.05) and use of Encounter Details (r = -.039, *p* <.05). The variable % African American was again positively correlated with Geostrata Quartiles 2 and 3, and negatively associated with Geostrata Quartile 4 (*p* <.0001). Geostrata Quartile 3 was positively associated with use of Lab Results (r = .037, *p* <.05) and Encounter Details (r = .045, *p* <.05). Among individuals with hyperlipidemia, being in Geostrata Quartile 4 was negatively associated with use of Encounter Details (r = -.049, *p* <.05).

Table 14a. Bivariate Correlations among Study Variables Stratified by Diagnosis of Diabetes (a).

Pearson Correlation Coefficients and *p*-values Diabetes (N = 2125)

		Age	Female	% AA	Q2GC	Q3GC	Q4GC
Age	r	1.00					
Female	r	.035	1.00				
	p	.215					
% African	r	-.75	-.108	1.00			
American	p	*.007	**<.0001				
Q2GC	r	-.052	-.091	.315	1.00		
	p	.062	*.0012	**<.0001			
Q3GC	r	-.040	-.030	.057	-.374	1.00	
	p	.153	.276	*.042	**<.0001		
Q4GC	r	-.100	.073	-.055	-.360	-.33	1.00
	p	.722	*.009	*.049	**<.0001	**<.0001	
Secure	r	-.036	-.014	-.090	-.075	.017	-.338
Messaging	p	.203	.622	*.0014	*.007	.543	**<.0001
Medical	r	-.013	-.0004	-.104	-.079	.0127	.018
Advice	p	.627	.989	*.0002	*.004	.654	.511
Lab Results	r	.024	.023	-.078	-.078	-.019	.010
	p	.392	.412	*.005	*.005	.490	.704
Medication	r	.011	.020	-.043	-.037	-.0022	.044
	p	.692	.462	.128	.180	.936	.112
Encounter	r	.007	-.027	-.021	-.023	.015	.001
Details	p	.782	.339	.443	.411	.580	.961

*p < .05   **p < .0001   (SES is represented by Geostrata Code [GC] quartiles)

Table 14b. Bivariate Correlations among Study Variables Stratified by Diagnosis of Diabetes (b).

Pearson Correlation Coefficients and *p*-values Diabetes (N = 2125)

		Secure Messaging	Medical Advice	Lab Results	Medication	Encounter Details
Secure Messaging	r	1.00				
Medical	r	.782	1.00			
Advice	p	**<.0001				
Lab Results	r	.506	.284	1.00		
	p	**<.0001	**<.0001			
Medication	r	.403	.294	.185	1.00	
	p	**<.0001	**<.0001	**<.0001		
Encounter	r	.260	.182	.435	.271	1.00
Details	p	**<.0001	**<.0001	**<.0001	**<.0001	

*p < .05   **p < .0001   (SES is represented by Geostrata Code [GC] quartiles)

Table 15a. Bivariate Correlations among Study Variables Stratified by Diagnosis of Hypertension (a).

Pearson Correlation Coefficients and *p*-values Hypertension (N = 6152)

		Age	Female	% AA	Q2GC	Q3GC	Q4GC
Age	r	1.00					
Female	r	.056	1.00				
	p	**<.0001					
% African	r	-.080	-.103	1.00			
American	p	**<.0001	**<.0001				
Q2 GC	r	-.056	-.065	.305	1.00		
	p	**<.0001	**<.0001	**<.0001			
Q3 GC	r	-.042	-.011	.075	-.352	1.00	
	p	*.0009	.357	**<.0001	**<.0001		
Q4 GC	r	.009	-.0009	-.039	-.340	-.339	1.00
	p	.455	.939	*.001	**<.0001	**<.0001	
Secure	r	-.003	-.032	-.066	-.027	-.012	-.008
Messaging	p	.801	*.010	**<.0001	*.031	.334	.488
Medical	r	.007	-.022	-.062	-.027	-.009	-.016
Advice	p	.545	.081	**<.0001	*.033	.436	.900
Lab	r	.036	.016	-.049	-.036	-.009	-.010
Results	p	*.004	.201	*<.0001	*.004	.464	.390
Medication	r	-.007	.017	-.010	-.014	-.014	.044
	p	.568	.173	.410	.249	.260	*.0005
Encounter	r	.0751	-.053	.010	.005	.015	.0006
Details	p	**<.0001	**<.0001	.396	.691	.213	.960

*$p < .05$ **$p < .0001$ (SES is represented by Geostrata Code [GC] quartiles)

Table 15b. Bivariate Correlations among Study Variables Stratified by Diagnosis of Hypertension (b).

Pearson Correlation Coefficients and *p*-values Hypertension (N =6152)

		Secure Messaging	Medical Advice	Lab Results	Medication	Encounter Details
Secure Messaging	r	1.00				
Medical	r	.804	1.00			
Advice	p	**<.0001				
Lab Results	r	.436	.332	1.00		
	p	**<.0001	**<.0001			
Medication	r	.264	.208	.104	1.00	
	p	**<.0001	**<.0001	**<.0001		
Encounter	r	.293	.198	.287	.238	1.00
Details	p	**<.0001	**<.0001	**<.0001	**<.0001	

*$p < .05$ **$p < .0001$ (SES is represented by Geostrata Code [GC] quartiles)

Table 16a. Bivariate Correlations among Study Variables Stratified by Diagnosis of Hyperlipidemia (a).

Pearson Correlation Coefficients and *p*-values Hyperlipidemia (N=2579)

		Age	Female	% AA	Q2GC	Q3GC	Q4GC
Age	r	1.00					
Female	r	-.082	1.00				
	p	**<.0001					
% African	r	-.059	-.111	1.00			
American	p	*.002	**<.0001				
Q2GC	r	-.014	-.062	.306	1.00		
	p	.460	*.001	**<.0001			
Q3GC	r	-.021	-.015	.119	-.296	1.00	
	p	.280	.446	**<.0001	**<.0001		
Q4GC	r	-.028	.020	-.040	-.300	-.332	1.00
	p	.146	.292	*.038	**<.0001	**<.0001	
Secure	r	-.037	.015	-.039	-.045	.027	-.006
Messaging	p	*.057	.422	*.047	*.019	.168	.738
Medical	r	-.012	.005	-.041	-.046	.015	.002
Advice	p	.515	.766	*.033	*.017	.425	.902
Lab Results	r	-.022	.014	-.003	-.055	.037	-.007
	p	.261	.468	.857	*.005	*.055	.707
Medication	r	-.009	.036	-.022	-.022	-.005	.033
	p	.631	.065	.264	.255	.770	.086
Encounter	r	-.015	-.039	.031	-.005	.045	-.049
Details	p	.430	*.042	.105	.778	*.020	*.012

*$p < .05$ **$p < .0001$ (SES is represented by Geostrata Code [GC] quartiles)

Table 16b. Bivariate Correlations among Study Variables Stratified by Diagnosis of Hyperlipidemia (b).

Pearson Correlation Coefficients and *p*-values Hyperlipidemia (N = 2579)

		Secure Messaging	Medical Advice	Lab Results	Medication	Encounter Details
Secure Messaging	r	1.00				
Medical	r	.788	1.00			
Advice	p	**<.0001				
Lab Results	r	.480	.341	1.00		
	p	**<.0001	**<.0001			
Medication	r	.272	.200	.195	1.00	
	p	**<.0001	**<.0001	**<.0001		
Encounter	r	.344	.263	.380	.358	1.00
Details	p	**<.0001	**<.0001	**<.0001	**<.0001	

*$p < .05$ **$p < .0001$ (SES is represented by Geostrata Code [GC] quartiles)

Research Questions

Among adult enrollees of Kaiser Permanente Georgia (age 21 or older) who were
diagnosed with one or more specific chronic disease (diabetes, hypertension,
hyperlipidemia) who logged on to the KP.Org system at least one time during calendar
year 2008, and who were members of KPGA at least six months prior to and 14 months
following initial KP.Org logon:

Research Question 1

What were the frequencies of use of the following functions within Kp.Org?

        a. Logon to KP.Org
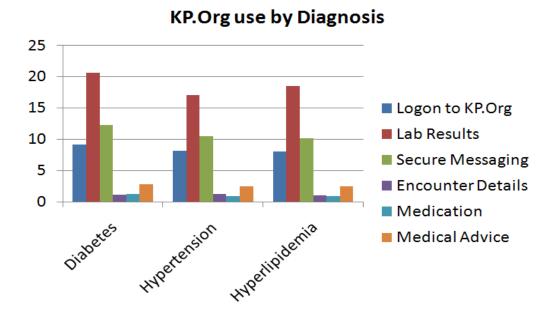
        b. Encounter Details

        c. Lab Results

        d. Medical Advice

        e. Medication

        f. Secure Messaging

Frequency of Logon to the KP.Org system and five selected functions within
KP.Org were examined for the total sample and for the sample stratified by number of
comorbid diagnoses, limited to the diagnoses included in the analysis (diabetes,
hypertension or hyperlipidemia). The mean frequencies of use of KP.Org functions
including Logon, Encounter Details, Lab Results, Medical Advice, Medication and
Secure messaging are presented Table 17 and in Figure 5.

Table 17. Mean Frequency of Use of KP.Org Functions for the Total Sample and the Sample Stratified by Number of Comorbid Diagnoses (Limited to Diabetes, Hypertension or Hyperlipidemia)

KP.Org Function	Total Sample (N = 9504)		One Diagnosis (N = 5448)		Two Diagnoses (N =2881)		Three Diagnoses (N = 1175)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Logon	8.04	12.17	7.80	12.22	7.95	11.97	9.37	12.34
Encounter Details	1.25	3.69	1.31	3.86	1.23	3.60	1.01	3.04
Lab Results	16.97	24.05	15.14	22.02	18.47	24.18	21.81	30.86
Medical Advice	2.48	5.49	2.47	5.54	2.33	5.11	2.91	6.06
Medication	0.88	2.97	0.79	2.89	0.90	2.90	1.22	3.41
Secure Messaging	10.35	24.61	10.12	25.04	10.01	23.61	12.23	24.95

Figure 5. Mean Frequency of use of KP.Org Functions among Members Diagnosed with Diabetes, Hypertension or Hyperlipidemia

Measures of Use of KP.Org

Measures of use of the KP.Org system were calculated using univariate analysis to determine quartiles. In examining the data, high-end users were found to utilize the KP.Org system significantly more frequently than others. Therefore, the sample was separated into quartiles, with Quartile 1 (lowest use) as the referent for all analyses. Quartile 4 represents the most frequent users. Table 16 shows the calculation of quartiles used to define usage of KP.Org stratified by diagnosis.

Table 18. Univariate Analysis for Logon to KP.Org Stratified by Diagnosis of Diabetes, Hypertension and Hyperlipidemia (N = 9504)

Diagnosis	Mean	SD	Quartile 1 (Lowest use)	Quartile 2	Quartile 3	Quartile 4 (Highest use)
*Diabetes (N= 1883)	9.20	12.33	2.0	5.0	11.0	143.0
*Hypertension (N= 7471)	8.16	12.40	2.0	4.0	9.0	231.0
*Hyperlipidemia (N = 5381)	7.99	11.76	2.0	4.0	10.0	231.0

*Some individuals have more than one diagnosis and were included in each group for which they met all inclusion criteria.

Intermediate Measures of Adherence: Medication Possession Ratios

Intermediate measures of adherence were used to evaluate whether use of KP.Org was associated with behavioral measures (medication possession ratios) that could influence outcome measures of metabolic control. Diagnosis-specific medication possession ratios were calculated by taking the total days of supply of medications

dispensed between the first and last prescription for each disease, divided by the total number of days between the first and last prescription refill for each medication prescribed. The calculated ratio was reported as a number between zero and one, where one represents 100% medication adherence based on prescribed medications and dates of refills. For example, an individual fills a prescription for a 30 day supply of hypertension control medication. If this individual does not fill another prescription for this prescribed medication for 40 days, the medication possession ratio is calculated by taking 30 /40 = 0.75 or a medication possession ratio 75%.

In some circumstances, diet and exercise may be an effective strategy for improving overall health status and for reducing elevated HbA1c, BP and/or LDL. Individuals not prescribed medications for control or maintenance of diabetes, hypertension or hyperlipidemia were excluded from this portion of the analysis. Table 19 provides a description of the medication possession ratios stratified by diagnosis. Overall, participants had medication possession ratios of 73% or greater, which is better than the national estimate of medication adherence of 50% or less (World Health Organization, 2003). Individuals taking medication for hypertension were nearly 7% more adherent to filling prescriptions on time than individuals taking medicines for diabetes or elevated cholesterol.

Table 19. Medication Possession Ratio by Diagnosis of Diabetes, Hypertension or Hyperlipidemia

Diagnosis	N	Medication Possession Ratio	SD	Minimum	Maximum
Diabetes	1213	0.74	0.23	0.05	1.00
Hypertension	3318	0.80	0.21	0.05	1.00
Hyperlipidemia	2278	0.73	0.22	0.06	1.00

Research Question 2

Among adult enrollees of Kaiser Permanente Georgia (age 21 or older) who were diagnosed with one or more specific chronic condition (diabetes, hypertension, hyperlipidemia) who logged on to the KP.Org system at least one time during calendar year 2008, and who were members of KP.Org at least 6 months prior to and 14 months following initial KP.Org logon: Was there an association between frequency of use and intermediate behavioral measures of adherence (medication possession ratios)?

In the following tables, regression analyses (unadjusted) were performed using medication possession ratio as the dependent variable. The independent variable in this model is Frequency of Logon to KP.Org by quartile, with lowest use (Quartile 1) as the reference group. Table 20 presents the findings for the regression analysis stratified by Diabetes (n = 1213). Table 21 presents the findings of the regression analysis stratified by Hypertension (n = 3818). Table 22 presents the finding for the regression analysis stratified by hyperlipidemia (n =2278).

Table 20. Unadjusted Medication Possession Ratios by Frequency Quartile of Logon to KP.Org Stratified by Diabetes (N = 1213)

Unadjusted Medication Possession Ratios for Diabetes (N = 1213)				
Frequency of Logon to KP.Org by Quartile	**Parameter Estimate**	**Standard Error**	**Confidence Interval**	***p*-value**
*Quartile 2 Use of KP.Org	0.04382	0.01720	1.01015-1.08061	0.0110
*Quartile 3 Use of KP.Org	0.04927	0.01803	1.01402-1.08829	0.0064
*Quartile 4 Use of KP.Org	0.08753	0.01852	1.05256-1.13182	<.0001

*Quartile 1 Use of KP.Org (lowest use) is the constant referent group for use of KP.Org

Table 21. Unadjusted Medication Possession Ratios by Frequency Quartile of Logon to KP.Org Stratified by Hypertension (N = 3818)

Medication Possession Ratios for Hypertension (N = 3818)				
Frequency of Logon to KP.Org by Quartile	**Parameter Estimate**	**Standard Error**	**Confidence Interval**	**p-value**
*Quartile 2 Use of KP.Org	-.00602	.00882	0.97686-1.01133	.4949
*Quartile 3 Use of KP.Org	.01231	.00962	0.99347-1.03165	.2011
*Quartile 4 Use of KP.Org	.02453	.00918	1.00655-1.04343	.0076

*Quartile 1 Use of KP.Org (lowest use) is the constant referent group for use of KP.

Table 22. Unadjusted Medication Possession Ratios by Frequency Quartile of Logon to KP.Org Stratified by Hyperlipidemia (N =2278)

Medication Possession Ratios for Hyperlipidemia (N = 2278)				
Frequency of Logon to KP.Org by Quartile	**Parameter Estimate**	**Standard Error**	**Confidence Interval**	**p-value**
*Quartile 2 Use of KP.Org	.03844	.01394	1.01117-1.06797	.0059
*Quartile 3 Use of Kp.Org	.04109	.01254	1.01664-1.06787	.0011
*Quartile 4 Use of KP.Org	.04797	.01286	1.02302-1.07591	.0002

*Quartile 1 Use of KP.Org (lowest use) is the constant referent group for use of KP.

Physiologic Measures of Metabolic Control

Metabolic control measures of HbA1c, BP and LDL were captured at baseline (up to 6 months prior to initial logon to KP.Org) and subsequently extending up to 14 months following initial logon to KP.Org. Inclusion in this portion of the analysis required at least two valid laboratory measures from unique occasions within the data

collection period. In clinical practice, lower values for the selected measures of

metabolic control (Hba1c, BP and LDL) are generally desirable. According to study

hypotheses, lab values among frequent users of KP.Org were expected to improve

(numbers should decrease over time). Calculation of change for laboratory values was

calculated as first lab value minus last lab value, to reflect improvement as a positive

number for all metabolic control outcome variables in the analysis (HbA1c, BP, and

LDL). The findings of these calculations are summarized Table 23.

Table 23. Summary Statistics of Metabolic Control Measures for Diabetes (HbA1c),
Hypertension (Systolic BP) and Hyperlipidemia (LDL), and Overall Improvement (Mean
and Standard Deviation)

Metabolic Control Measures Stratified by Diagnosis	Improved		Unchanged		Worsened		Improvement	
	N	%	N	%	N	%	Mean	(SD)
HbA1c (N = 1525)	788	51.67	289	18.95	448	29.38	0.567	1.477
Systolic BP (N = 6918)	3540	51.17	756	10.93	2622	37.90	3.694	17.58
LDL (N = 4243)	1574	37.10	1670	39.36	999	23.54	7.680	26.91

Analysis revealed that among participants utilizing KP.Org diagnosed with

diabetes, 52% showed improvement in HbA1c measures (mean = .567, SD 1.477), while

19% remained unchanged over time, and 29% showed a decrease (worsening) of

metabolic control. Among eligible participants diagnosed with hypertension, 51%

showed an improvement in systolic blood pressure (mean = 3.694, SD 17.58), while 11%

remained unchanged, and 38% showed an increase in systolic blood pressure, indicative

of worsening control of hypertension. Of eligible participants diagnosed with

hyperlipidemia, 37% showed improvement in measures of LDL (mean = 7.68, SD 26.91),

while 39% showed no change, and 23% revealed less effective metabolic control of LDL.

Only individuals with a confirmed diagnosis of the chronic disease and the

requisite minimum of two laboratory values from unique encounters for the specific

outcome associated with that disease were included in the analysis for each group.

Individuals with appropriate diagnoses and laboratory data for more than one diagnosis

were included in each group for which they met full inclusion criteria.

Table 24. Physiologic Outcome Laboratory Values for HbA1c, BP and LDL (Pre and
Post) and Associated Change (Calculated as Pre Minus Post)

	HbA1c (N = 2157)			Systolic BP (N = 8805)			LDL (N = 6205)		
	Lab Value (Pre)	Lab Value (Post)	Δ	Lab Value (Pre)	Lab Value (Post)	Δ	Lab Value (Pre)	Lab Value (Post)	Δ
Mean	7.554	7.147	.407	127.66	124.63	3.035	124.0	118.71	5.295
SD	1.990	1.619	1.402	17.487	15.93	17.089	38.74	36.65	26.53
Min.	5.20	5.20	-6.5	80.00	76.00	-104.0	37.00	37.0	-157.0
Max	17.70	15.80	10.0	280.00	240.00	128.0	350.0	331.0	278.0

Research Question 3

Among adult enrollees of Kaiser Permanente Georgia (age 21 or older) who were

diagnosed with one or more specific chronic condition (diabetes, hypertension,

hyperlipidemia) who logged on to the KP.Org system at least one time during calendar

year 2008, and who were members of KP.Org at least 6 months prior to and 14 months

following initial KP.Org logon: Was there an association between frequency of use and improvement in physiologic measures of metabolic control (HbA1c, LDL, BP)?

Outcome measures were set as a binary variable (improve versus not improve) and logistic regression was used to explore the relationship between frequency of KP.Org use and the outcome variables. The results are depicted in Table 25.

Table 25. Logistic Regression: Frequency Quartiles of KP.Org Use and Unadjusted Primary Outcome Measures of Metabolic Control, (Improved Versus Not Improved) for Diabetes (HbA1c), Hypertension (BP) and Hyperlipidemia (LDL)

	Odds Ratio	95% Confidence Interval	*p*-Value
Diabetes: HbA1c Improved (N = 1525)			
*Quartile 2 Use of KP.Org	3.093	2.349 – 4.072	<.0001
*Quartile 3 Use of KP.Org	3.421	2.558 – 4.575	<.0001
*Quartile 4 Use of KP.Org	3.062	2.279 – 4.113	<.0001
Hypertension: Systolic BP Improved (N = 6918)			
*Quartile 2 Use of KP.Org	1.601	1.413 – 1.813	<.0001
*Quartile 3 Use of KP.Org	1.591	1.386 – 1.825	<.0001
*Quartile 4 Use of KP.Org	1.413	1.238 – 1.613	<.0001
Hyperlipidemia: LDL Improved (N = 4243)			
*Quartile 2 Use of KP.Org	5.565	4.587 – 6.750	<.0001
*Quartile 3 Use of KP.Org	6.821	5.683 – 8.188	<.0001
*Quartile 4 Use of KP.Org	7.948	6.558 – 9.633	<.0001

*Quartile 1 (lowest use) is the constant reference group for use of KP.Org

Research Question 4
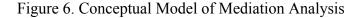
Among adult enrollees of Kaiser Permanente Georgia (age 21 or older) who were diagnosed with one or more specific chronic condition (diabetes, hypertension, hyperlipidemia) who logged on to the KP.Org system at least one time during calendar year 2008, and who were members of KP.Org at least 6 months prior to and 14 months following initial KP.Org logon, was there an association between frequency of use, intermediate behavioral measures of adherence (medication possession ratios) and physiologic measures of metabolic control (HbA1c, Systolic BP, LDL)?

A mediation analysis was performed to evaluate whether medication possession ratios served as a mediator between frequency of Logon to KP.Org and the primary outcomes of change in HbA1c, BP or LDL. For all models used in mediation analysis, the main independent variable was a dichotomous indicator of logon frequency equal to 0 for the bottom quartile and 1 for all other quartiles. First, each mediator variable (medication possession ratio by specific diagnosis) was regressed on the independent variable (Model 1). Next, each dependent variable (primary outcome measures of change in HbA1c, BP or LDL) was regressed on the mediator variable (MPR) with the independent variable (Model 2) to estimate the direct effect of the independent variable on the outcome. Finally, each dependent variable (primary outcome measure) was regressed on the independent variable (Logon to Kp.Org by quartiles) to establish the total effect (Model 3).

The indirect effect, or mediated effect, of the independent variable on the outcome via the mediator was calculated as product of the coefficient for the mediator (Model 2) and the coefficient for the independent variable (Model 1) for each of the three disease

states. The statistical significance of the indirect effect was calculated using the Sobel test

(Fritz, 2007). To complete the mediation analysis, the proportion mediated was reported

as the indirect effect divided by the total effect, the sum of the direct and indirect effects.

All mediation models were run without adjustment for covariates and then repeated with

adjustments age, gender, percent African American, and Geostrata quartiles (a proxy

measure of SES). Final calculations of total effect, direct effect, indirect effect and

proportion mediated were performed.

A conceptual model of mediation analysis is depicted in Figure 6, which shows the

independent variable (use of KP.Org), the mediator variable medication possession ratio

(MPR) and the dependent variable (change in primary outcome measure). In the

conceptual model, change in LDL is provided as an example for better understanding of

the model. Results of the mediation analysis are displayed in Table 26.

Figure 6. Conceptual Model of Mediation Analysis
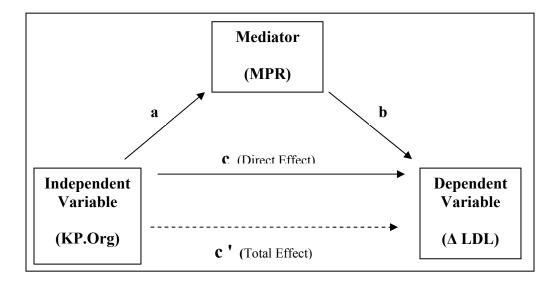
Figure 6 visually depicts the components of a mediation analysis. The coefficient of regressing the mediator (medication possession ratio) on the independent variable (KP.Org use) is represented by 'a'. When the dependent variable (change in LDL) is regressed on the mediator and the independent variable together, 'b' is the coefficient of the mediator and 'c', the direct effect , is the coefficient of the independent variable. When the dependent variable (change in LDL) is regressed on the independent variable (KP.Org use) without adjustment for the mediator (MPR), the model coefficient, c ' , is the total effect. The mediated, or indirect, effect is the product of 'a' and 'b' or (ab). The proportion of the total effect mediated is calculated by (ab/c') (Barron, 1986; MacKinnon, 2007; Richman, 2011).

Table 26. Results of Mediation Analysis (Unadjusted and Adjusted) for the Association of KP.Org Use and Physiologic Outcomes of HbA1c, BP and LDL Potentially Mediated through Medication Possession Ratios

	*Total Effect (c')	p-value	*Direct Effect (c)	p-value	*Indirect Effect (ab)	*Sobel p-value	*Proportion Mediated (ab/c')
Unadjusted							
HbA1c	.321	.004	.2939	.008	.0283	.057	.088
BP	-.055	.94	-.123	.863	.068	.142	***
LDL	10.996	<.0001	10.50	<.0001	.500	.009	.045
**Adjusted							
HbA1c	.340	.002	.315	.005	.025	.057	.074
BP	-.020	.98	-.076	.915	.056	.232	***
LDL	10.823	<.0001	10.22	<.0001	.607	.004	.056

*Mediation analysis is calculated as follows:

*Total Effect (c') is the Direct Effect plus the Indirect Effect.

*Direct Effect (c) is the result of the dependent variable (outcome measure of HbA1c, BP or LDL) regressed on the mediator variable (medication possession ratio) and the independent variable (KP.Org frequency of use, set as a dichotomous indicator of "0" for the bottom quartile of use (lowest use frequency) and "1" for all other quartiles of frequency of use).

*Indirect Effect (ab) is the product of the coefficient for the regression of the mediator (medication possession ratio) on the independent variable (KP.Org frequency of use, set a dichotomous indicator), and the coefficient of the regression of the dependent variable (primary outcome measure of HbA1c, BP or LDL) and the mediator (medication possession ratio).

* Proportion Mediated (ab/c') is the Indirect Effect divided by the Total Effect.

**Adjusted for age, gender, percent African American, and SES quartiles

*** Due to numerical instability and non-significance of the total and indirect effects for the BP mediation analysis, the proportion mediated could not be meaningfully estimated.

Research Question 5

Among adult enrollees of Kaiser Permanente Georgia (age 21 or older) who were diagnosed with one or more specific chronic condition (diabetes, hypertension, hyperlipidemia) who logged on to the KP.Org system at least one time during calendar year 2008, and who were members of KP.Org at least 6 months prior to and 14 months following initial KP.Org logon: Did the covariates of age, gender, % African American, Geostrata code by quartile (a proxy measure of SES), explain differences between frequency of use and physiologic measures of metabolic control (HbA1c, Systolic BP and LDL)?

Covariate variables of age, gender, % African American, and Geostrata Quartile (a proxy measure of SES) were first examined individually with outcome variables of HbA1c, BP and LDL set as binary outcomes (improved versus not improved) to determine associations among covariates and the primary outcome measures. Analyses were repeated for each covariate with outcome measures of HbA1c, BP and LDL set as continuous outcomes (change over time) to examine whether differences in associations were revealed. The findings of these analyses are presented in Tables 27-32.

Table 27. Associations of Covariate Variables with HbA1c set as a Binary Outcome Measure (Improved versus Not Improved)

[***]Associations of Covariate Variables and HbA1c (Improved versus Not Improved)			
Variable	Unadjusted Odds Ratio	95% Confidence Interval	*p*-Value
Age	1.004	0.996-1.012	0.3408
Gender (female)	1.153	0.943-1.410	0.1657
[**]% African American	1.134	0.833-1.543	0.4244
[*]GS Quartile 2	1.067	0.799-1.425	0.6610
[*]GS Quartile 3	0.843	0.628-1.131	0.2536
[*]GS Quartile 4	1.054	0.782-1.419	0.7311

[*] The G*eostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

[**]*Percent of African-Americans* is a variable generated from census tract and block information to indicate the percent of African Americans within a given geographic block matched with Geostrata codes

[***] Each variable represents an individual simple logistic regression model

Table 28. Associations of Covariate Variables with Systolic Blood Pressure set as a Binary Outcome Measure (Improved versus Not Improved)

*** Associations of Covariate Variables and Systolic BP (Improved versus Not Improved)			
Variable	Unadjusted Odds Ratio	95% Confidence Interval	p-Value
Age	1.001	0.997-1.004	0.6901
Gender (female)	1.034	0.940-1.137	0.4951
**% African American	0.908	0.784-1.051	0.1951
*GS Quartile 2	0.926	0.810-1.059	0.2630
*GS Quartile 3	0.980	0.856-1.121	0.7657
*GS Quartile 4	0.930	0.812-1.065	0.2960

* The *Geostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

**Percent of African-Americans* is a variable generated from census tract and block information to indicate the percent of African Americans within a given geographic block matched with Geostrata codes

***Each variable represents an individual simple logistic regression model

Table 29. Associations of Covariate Variables with LDL set as a Binary Outcome Measure (Improved versus Not Improved)

*** Associations of Covariate Variables and LDL (Improved versus Not Improved)			
Variable	Unadjusted Odds Ratio	95% Confidence Interval	p-Value
Age	1.007	1.002-1.013	0.0079
Gender (female)	1.007	0.889-1.140	0.9179
% African American	0.670	0.541-0.829	0.0002
*GS Quartile 2	0.947	0.793-1.132	0.5517
*GS Quartile 3	0.958	0.806-1.138	0.6233
*Gs Quartile 4	1.102	0.929-1.308	0.2644

* The *Geostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

**Percent of African-Americans* is a variable generated from census tract and block information to indicate the percent of African Americans within a given geographic block matched with Geostrata codes

***Each variable represents an individual simple logistic regression model

Table 30. Associations of Covariate Variables with HbA1c set as a Continuous Outcome Measure (Change Over Time)

[***]Associations of Covariate Variables and HbA1c (Change Over Time)				
Variable	Parameter Estimate	Standard Error	95% Confidence Interval	*p*-Value
Age	-0.00919	0.00329	-0.01563- ̄0.00274	0.0053
Gender (female)	0.10062	0.08244	-0.06096-0.26620	0.2225
% African American	0.15672	0.12611	-0.09045-0.40389	0.2142
[*]GS Quartile 2	0.02268	0.11854	-0.20965-0.25501	0.8483
[*]GS Quartile 3	-0.13166	0.12039	-0.36762-0.10430	0.2743
[*]GS Quartile 4	-0.00844	0.12188	-0.27432-0.23044	0.9448

[*] The G*eostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

[**]*Percent of African-Americans* is a variable generated from census tract and block information to indicate the percent of African Americans within a given geographic block matched with Geostrata codes

[***] Each variable represents an individual simple regression model

Table 31. Associations of Covariate Variables with Systolic Blood Pressure set as a Continuous Outcome Measure (Change Over Time)

[***]Associations of Covariate Variables and Systolic BP (Change Over Time)				
Variable	Parameter Estimate	Standard Error	95% Confidence Interval	*p*-Value
Age	0.00451	0.01716	-0.02912-0.03814	0.7928
Gender (female)	0.95209	0.43979	0.09010-1.81407	0.0304
% African American	-2.22006	0.67457	-3.54221- ̄0.89790	0.0010
[*]GS Quartile 2	-0.26201	0.61814	-1.47356-0.94954	0.6717
[*]GS Quartile 3	-0.35218	0.61045	-1.54866-0.84430	0.5697
[*]GS Quartile 4	-0.92768	0.62571	-2.15407-0.29871	0.1382

[*] The G*eostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

[**]*Percent of African-Americans* is a variable generated from census tract and block information to indicate the percent of African Americans within a given geographic block matched with Geostrata codes

[***] Each variable represents an individual simple regression model

Table 32. Associations of Covariate Variables with LDL set as a Continuous Outcome Measure (Change Over Time)

[***]Associations of Covariate Variables and LDL (Change Over Time)				
Variable	**Parameter Estimate**	**Standard Error**	**95% Confidence Interval**	***p*-Value**
Age	-0.05543	0.04091	-0.13561-0.02475	0.1755
Gender (female)	-1.02384	0.93678	-2.85592-0.81224	0.2745
% African American	-4.26117	1.56063	-7.32000-¯1.20233	0.0064
[*]GS Quartile 2	-0.66535	1.33167	-3.27542-1.94472	0.6174
[*]GS Quartile 3	-1.16073	1.28893	-3.68703-1.36557	0.3679
[*]GS Quartile 4	1.24664	1.29311	-1.28785-3.78113	0.3351

[*] The G*eostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

[**]*Percent of African-Americans* is a variable generated from census tract and block information to indicate the percent of African Americans within a given geographic block matched with Geostrata codes

[***] Each variable represents an individual simple regression model

Full models were examined using two strategies. First, outcome variables were set as binary variables (improved versus not improved). Logistic regression was used when the outcome variable was set as a binary variable. Next, outcome variables were set as continuous variables (change over time). Change was calculated as pre- minus post- laboratory value. Regression analysis was performed when the continuous outcome variable was in the model.

Table 33. Unadjusted and Adjusted Logistic Regression for HbA1c Set as a Dichotomous Outcome Measure (Improved versus Not Improved)

Dependent Variable: HbA1c Improved (N = 1525)						
	Unadjusted			**Adjusted**		
Explanatory Variables	**Odds Ratio**	**95% CI**	***p*-value**	**Odds Ratio**	**95% CI**	***p*-value**
Quartile 2	3.09	2.34-4.07	<.0001	3.07	2.33-4.06	<.0001
Quartile 3	3.42	2.55-4.57	<.0001	3.47	2.59-4.65	<.0001
Quartile 4	3.06	2.27-4.11	<.0001	3.06	2.27-4.13	<.0001
Age				.99	.99-1.00	.8426
Gender (female)				1.17	.94-1.44	.1418
*GC Quartile 2				1.00	.71-1.39	.9962
*GC Quartile 3				.80	.58-1.10	.1832
*GC Quartile 4				.97	.71-1.34	.8904
**% African American				1.199	.84-1.70	.3162

* The G*eostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

**Percent of African-Americans* is a variable generated from census tract and block information to indicate the percent of African Americans within a given geographic block matched with Geostrata codes.

Table 34. Unadjusted and Adjusted Logistic Regression for Systolic BP Set as a Dichotomous Outcome Measure (Improved versus Not Improved)

Dependent Variable: Systolic BP Improved (N = 6918)						
	Unadjusted			**Adjusted**		
Explanatory Variables	**Odds Ratio**	**95% CI**	***p*-value**	**Odds Ratio**	**95% CI**	***p*-value**
Quartile 2	1.60	1.41-1.81	<.0001	1.60	1.41-1.82	<.0001
Quartile 3	1.59	1.38-1.82	<.0001	1.59	1.39-1.88	<.0001
Quartile 4	1.41	1.23-1.61	<.0001	1.41	1.23-1.61	<.0001
Age				1.00	.99-1.00	.9905
Gender (female)				1.04	.94-1.15	.3773
[*]GC Quartile 2				.96	.83-1.11	.6087
[*]GC Quartile 3				1.00	.87-1.15	.9437
[*]GC Quartile 4				.94	.81-1.08	.3960
[**]% African American				.92	.785-1.08	.3359

[*] The G*eostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

[**]*Percent of African-Americans* is a variable generated from census tract and block information to indicate the percent of African Americans within a given geographic block matched with Geostrata codes.

Table 35. Unadjusted and Adjusted Logistic Regression for LDL Set as a Dichotomous
Outcome Measure (Improved versus Not Improved)

	Dependent Variable: LDL Improved (N = 4243)					
	Unadjusted			**Adjusted**		
Explanatory Variables	**Odds Ratio**	**95% CI**	***p*-value**	**Odds Ratio**	**95% CI**	***p*-value**
Quartile 2	5.56	4.58-6.75	<.0001	5.51	4.54-6.69	<.0001
Quartile 3	6.82	5.68-8.18	<.0001	6.77	5.64-8.14	<.0001
Quartile 4	7.94	6.55-9.63	<.0001	7.84	6.46-9.50	<.0001
Age				1.00	.99-1.00	.4955
Female				.98	.85-1.13	.8612
*GC Quartile 2				1.14	.92-1.42	.2078
*GC Quartile 3				1.10	.90-1.34	.3303
*GC Quartile 4				1.20	.99-1.46	.0617
**%African American				.757	.58-.98	.0349

* The *Geostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

**Percent of African-Americans* is a variable generated from census tract and block
information to indicate the percent of African Americans within a given geographic block
matched with Geostrata codes.

The regression analyses were also performed for the primary outcome measures
of physiologic metabolic control set as continuous variables (change over time). Change
was calculated as a positive number (pre minus post). Thus, a positive parameter
estimate was indicative of a change of the outcome measure in the direction of clinical
improvement (a lower number) over time. Conversely, a negative parameter estimate
indicated a change of the outcome measure in the direction of clinical decline (a higher
number).

Table 36. Unadjusted and Adjusted Regression for HbA1c Set as a Continuous Measure (Change) Calculated as Pre minus Post HbA1c

Dependent Variable: HbA1c Change (N = 1525)

Explanatory Variables	Unadjusted				Adjusted			
	ß	SE	95% CI	*p*-value	ß	SE	95% CI	*p*-value
Quartile 2	.307	.107	.096-.518	.004	.334	.108	.122-.546	.0021
Quartile 3	.356	.011	.334-.378	.001	.386	.113	.164-.608	.0007
Quartile 4	.428	.116	.201-.656	.0002	.466	.116	.238-.695	<.0001
Age					-.011	.003	-.017-.004	.0009
Female					.111	.082	-.049-.273	.1755
*GC Quartile 2					-.077	.129	-.332-.176	.5480
*GC Quartile 3					-.193	.124	-.436-.050	.1206
*GC Quartile 4					-.076	.124	-.319-.166	.5374
**% African American					.211	.138	-.059-.483	.1265

* The G*eostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

**Percent of African-Americans* is a variable generated from census tract and block information to indicate the percent of African Americans within a given geographic block matched with Geostrata codes.

Table 37. Unadjusted and Adjusted Regression for Systolic BP Set as a Continuous Measure (Change) Calculated as Pre minus Post BP

	Dependent Variable:		**Systolic BP Change (N = 6918)**					
	Unadjusted				**Adjusted**			
Explanatory Variables	**ß**	**SE**	**95% CI**	***p-value***	**ß**	**SE**	**95% CI**	***p-value***
Quartile 2	1.02	.569	-.092-2.14	.072	1.097	.569	-.019-2.21	.0542
Quartile 3	1.67	.629	.438-2.90	.007	1.740	.629	.050-2.97	.0057
Quartile 4	.734	.607	-.455-1.92	.226	.699	.608	-.492-1.89	.2501
Age					-.001	.017	-.349-.032	.9442
Female					.890	.443	.021-1.75	.0446
*GC Quartile 2					.769	.677	-.559-2.09	.2567
*GC Quartile 3					.355	.647	-.914-1.62	.5833
*GC Quartile 4					-.429	.640	-1.68-.825	.5020
**% African American					-2.48	.744	-3.94-1.02	.0009

* The *Geostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

**Percent of African-Americans* is a variable generated from census tract and block information to indicate the percent of African Americans within a given geographic block matched with Geostrata codes.

Table 38. Unadjusted and Adjusted Regression for LDL Set as a Continuous Measure
(Change) Calculated as Pre minus Post LDL

	Dependent Variable LDL Change (N = 4243)							
	Unadjusted				**Adjusted**			
Explanatory Variables	**ß**	**SE**	**95% CI**	***p-value***	**ß**	**SE**	**95% CI**	***p-value***
Quartile 2	8.22	1.37	5.52-10.92	<.0001	8.28	1.38	5.57-10.98	<.0001
Quartile 3	8.51	1.27	6.01-11.02	<.0001	8.54	1.28	6.03-11.05	<.0001
Quartile 4	11.7	1.33	9.15-14.40	<.0001	11.69	1.34	9.06-14.32	<.0001
Age					-.094	.040	-.174-.014	.020
Female					-1.49	.093	-1.68-1.31	.109
*GC Quartile 2					.796	1.43	-2.02-3.61	.579
*GC Quartile 3					-.198	1.33	-2.81-2.41	.881
*GC Quartile 4					1.74	1.30	-.814-4.30	.181
**% African American					-3.70	1.70	-7.04-.362	.029

* The G*eostrata code* (GC Quartile) served a proxy measure of SES within the analysis.

**Percent of African-Americans* is a variable generated from census tract and block
information to indicate the percent of African Americans within a given geographic block
matched with Geostrata codes.

Individual functions of use within KP.Org (Secure Messaging, Medical Advice,

Lab Results, Medication, and Encounter Details) were also modeled with primary

outcome variables (HbA1c, BP and LDL) stratified by diagnosis. Logistic regression was

performed when the outcome variable was set as a binary measure (improved versus not

improved). Findings of logistic regression analyses (unadjusted and adjusted) are

presented in Tables 39-41. Because of multicollinearity, functions of use within KP.Org

were each analyzed as individual regression models. The findings are displayed in a

single table for each outcome measure (HbA1c, BP, LDL) and for each of the KP.Org

functions, but measures of use within KP.Org were not included in the same model for

the analyses.

Table 39. Unadjusted and Adjusted Logistic Regression for HbA1c Set as a Binary
Outcome Measure (Improved versus Not Improved) and Use of Individual Functions
within KP.Org

Dependent Variable: HbA1c Improved (N = 1525)

Functions of Use within KP.Org**	Unadjusted			Adjusted*		
	Odds Ratio	95% CI	*p*-value	Odds Ratio	95% CI	*p*-value
Secure Messaging	1.01	1.004-1.015	.0003	.010	1.005-1.016	.0002
Medical Advice	1.04	1.018-1.065	.0005	1.043	1.019-1.067	.0003
Lab Results	1.01	1.011-1.022	<.0001	1.017	1.011-1.022	<.0001
Medication	1.04	1.005-1.082	.0246	1.042	1.005-1.081	.0256
Encounter Details	1.07	1.025-1.123	.0027	1.074	1.026-1.124	.0023

*Adjusted for age, gender, % African American and Geostrata code by quartile

** Each Use Function within KP.Org represents a separate model of analysis

Table 40. Unadjusted and Adjusted Logistic Regression for Systolic BP Set as a Binary Outcome Measure (Improved versus Not Improved) and Use of Individual Functions within KP.Org

Dependent Variable: Systolic BP Improved (N = 6918)

Functions of Use within KP.Org**	Unadjusted			Adjusted*		
	Odds Ratio	95% CI	*p*-value	Odds Ratio	95% CI	*p*-value
Secure Messaging	1.00	.999-1.00	.599	1.000	.998-1.003	.6332
Medical Advice	1.00	.995-1.01	.435	1.003	.994-1.012	.4718
Lab Results	1.00	1.000-1.00	.022	1.002	1.000-1.004	.0272
Medication	1.02	1.002-1.03	.025	1.021	1.003-1.040	.0243
Encounter Details	1.01	.998-1.02	.086	1.012	.999-1.026	.0735

[*]Adjusted for age, gender, % African American and Geostrata code by quartile

** Each Use Function within KP.Org represents a separate model of analysis

Table 41. Unadjusted and Adjusted Logistic Regression for LDL Set as a Binary
Outcome Measure (Improved versus Not Improved) and Use of Individual Functions
within KP.Org

Dependent Variable: LDL Improved (N = 4243)

Functions of Use within KP.Org**	Unadjusted			Adjusted*		
	Odds Ratio	95% CI	*p*-value	Odds Ratio	95% CI	*p*-value
Secure Messaging	1.02	1.01-1.02	<.0001	1.02	1.01-1.02	<.0001
Medical Advice	1.10	1.08-1.12	<.0001	1.10	1.08-1.12	<.0001
Lab Results	1.02	1.02-1.03	<.0001	1.02	1.02-1.03	<.0001
Medication	1.16	1.11-1.22	<.0001	1.16	1.11-1.21	<.0001
Encounter Details	1.15	1.11-1.19	<.0001	1.15	1.11-1.19	<.0001

*Adjusted for age, gender, % African American and Geostrata code by quartile

** Each Use Function within KP.Org represents a separate model of analysis

Individual functions of use within KP.Org (Secure Messaging, Medical Advice,

Lab Results, Medication, and Encounter Details) were also modeled with primary

outcome variables (Hba1c, BP and LDL) stratified by diagnosis using regression

analysis. In these models, the outcome variable was set as a continuous measure (change

over time), which was calculated using the formula 'pre minus post' laboratory measures.

Findings for regression analyses (unadjusted and adjusted) are presented in Tables 42-44,

Because of multicollinearity, functions of use within KP.Org were each analyzed as

individual regression models. The findings are displayed in a single table for each

outcome measure (HbA1c, BP, LDL) and for each of the KP.Org functions, but measures

of use within KP.Org were not included in the same model for the analysis.

Table 42. Unadjusted and Adjusted Regression for HbA1c Set as a Continuous Measure (Change) Calculated as Pre minus Post HbA1c and Use of Individual Functions within KP.Org

	Dependent Variable: HbA1c Change (N = 1525)							
	Unadjusted				**Adjusted***			
Functions of Use within KP.Org**	**ß**	**SE**	**95% CI**	***p-value***	**ß**	**SE**	**95% CI**	***p-value***
Secure Messaging	.005	.002	.001-.008	.004	.006	.002	.001-.009	.0027
Medical Advice	.013	.008	-.002-.029	.106	.015	.008	-.001-.031	.075
Lab Results	.005	.002	.002-.008	.0003	.006	.002	.002-.008	.0001
Medication	.032	.013	.006-.057	0.015	.033	0.013	.007-.059	.011
Encounter Details	.045	.016	.014-.076	.004	.047	.015	.016--.078	.0026

*Adjusted for age, gender, % African American and Geostrata code by quartile

** Each Use Function within KP.Org represents a separate model of analysis

Table 43. Unadjusted and Adjusted Regression for Systolic BP Set as a Continuous Measure (Change) Calculated as Pre minus Post Systolic BP and Use of Individual Functions within KP.Org

Dependent Variable: Systolic BP Change (N = 6918)

Functions of Use within KP.Org**	Unadjusted				Adjusted*			
	ß	SE	95% CI	*p-*value	ß	SE	95% CI	*p-*value
Secure Messaging	.002	.009	-.016-.019	.850	.001	.009	-.017-.019	.912
Medical Advice	.009	.041	-.071-.089	.823	.005	.041	-.075-.086	.895
Lab Results	-.0003	.009	-.018-.017	.973	-.001	.009	-.019-.016	.907
Medication	.086	.075	-.060-.234	.249	.089	.075	-.058-.236	.239
Encounter Details	.107	.060	-.014-.226	.074	.117	.061	-.001-.236	.052

*Adjusted for age, gender, % African American and Geostrata code by quartile

** Each Use Function within KP.Org represents a separate model of analysis

Table 44. Unadjusted and Adjusted Regression for LDL Set as a Continuous Measure (Change) Calculated as Pre minus Post LDL and Use of Individual Functions within KP.Org

Dependent Variable: LDL Change (N = 4243)

Functions of Use within KP.Org **	Unadjusted				Adjusted			
	ß	SE	95% CI	*p*-value	ß	SE	95% CI	*p*-value
Secure Messaging	.089	.025	.039-.139	.0004	.086	.025	.037-.138	.0006
Medical Advice	.347	.118	.112-.579	.003	.334	.118	.105-.563	.0048
Lab Results	.070	.021	.028-.113	.0012	.070	.021	.023-.116	.0013
Medication	1.37	.235	.913-1.83	<.0001	1.36	.235	.899-1.82	<.0001
Encounter Details	.659	.198	.269-1.04	.0009	.673	.199	.283-1.06	.0007

*Adjusted for age, gender, % African American and Geostrata code by quartile

** Each Use Function within KP.Org represents a separate model of analysis.

Summary of Research Findings

The data analysis of 9,504 participants who were adult enrollees of Kaiser Permanente Georgia (age 21 or older), diagnosed with one or more specific chronic condition (diabetes, hypertension, hyperlipidemia) who logged on to the KP.Org system at least one time during calendar year 2008, and were members of KP.Org at least 6 months prior to and 14 months following initial KP.Org logon yielded the following results:

1. Among participants who met inclusion criteria, more were diagnosed with hypertension than with diabetes or hyperlipidemia. Hyperlipidemia was the smallest of the three groups. Individuals diagnosed with hyperlipidemia tended to be older, non African American, and male. More women than men were diagnosed with diabetes and/or hypertension, and women were younger.

2. Older age was associated with higher SES (Geostrata Quartile) and better medication possession ratios. Older women had the highest calculated medication possession ratios. There was a consistent association between higher socioeconomic status (GC Quartile) and increased medication possession ratios.

3. Medication possession ratio played a considerable, if modest, role in partially mediating the relationship between KP.org usage and change in the physiologic outcomes of HbA1c and LDL. However, there was no evidence of mediation for change in BP.

4. The most frequently used functions within KP.Org included Lab Results and Secure Messaging. The minimal use of the Medications function (which includes medication refill options) was an unexpected finding.

5. Unadjusted finding revealed a consistent relationship between KP.Org usage and improvement in primary physiological outcomes of HbA1c, BP and LDL. However, the relationship was not always linear regarding highest quartile of use and highest probability of improvement.

6. The relationship between KP.Org usage and physiologic outcome improvement held when adjusted for covariates of age, gender, % African American and

Geostrata quartiles (SES). The combination of strong associations between usage of KP.Org and outcomes but lack of linearity suggests a complex relationship.

7. Individuals in the hyperlipidemia group showed the greatest associations with KP.Org usage and the greatest improvement in physiologic outcome measures.

8. There were fewer significant associations for BP than for HbA1c or LDL, despite the larger number of individuals diagnosed with hypertension, possibly because blood pressure is a highly variable outcome measure.

9. Geostrata quartile (SES) was not generally significant in the models.

10. In this study, use of KP.Org was an appropriate predictor of improvement in physiological outcome measures of HbA1c, BP and LDL for individuals included in the sample who were diagnosed with diabetes, hypertension or hyperlipidemia.

CHAPTER 5

DISCUSSION

In this study, the use of the KP.Org online PHR was examined to see if frequency of use of this technological tool was associated with intermediate level behavioral measures (medication possession ratios), and/or outcome measures of metabolic control for diabetes (HbA1c), hypertension (BP) or hyperlipidemia (LDL). The sample included 9504 adult enrollees of Kaiser Permanente Georgia who were diagnosed with one or more specific chronic condition (diabetes, hypertension or hyperlipidemia), and who were members of KPGA at least 6 months prior to and 14 months following initial logon to KP.Org during calendar year 2008. This chapter presents a discussion of the findings of the study. Conclusions, implications, limitations and recommendations for future research are included.

Research Question1a: Frequency of Logon to KP.Org

Frequency of Logon to KP.Org and use of five selected functions within the KP.Org system were examined. Among the total sample, the mean logon to KP.Org was 8.04 during the data collection period. Stratified by diagnosis, the mean logon to KP.Org among individuals diagnosed with diabetes was 8.89 times, those with hypertension 9.35 times, and those with hyperlipidemia 9.50 times. Individuals with hyperlipidemia (N = 5381) were the most frequent users of the system.

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Frequency of use was also examined by number of diagnoses of the specific

diseases included in the analysis (diabetes, hypertension and/or hyperlipidemia). The

mean frequency of logon to KP.Org among members diagnosed with one condition was

(7.80). The mean frequency of logon to KP.Org increased to (7.95) among members with

two conditions, and to (9.37) among members with all three conditions. This finding

suggests that greater health need may increase the likelihood of utilizing electronic tools,

such as the KP.Org PHR, as a strategy for managing multiple chronic conditions.

Research Question 1b: Use of Encounter Details within KP.Org

The Encounter Details function was developed to provide users with a summary

of a completed in-person encounter (face to face visit) with a KP provider. An encounter

could be a visit to a clinic for laboratory testing, an in-patient hospital admission, or an

outpatient clinic appointment. Encounter types are not specified in the database, so it is

not possible to discern what type of encounter occurred based on the available data.

It is interesting to note that as the number of comorbid conditions increased

(limited to diabetes, hypertension and hyperlipidemia), use of Encounter Details function

within KP.Org decreased. This was the only function within the analysis that

demonstrated this type of downward trend. It is possible that individuals using the

KP.Org system did not perceive a benefit to reviewing Encounter Details in the online

format. A standard protocol within the KP healthcare network is the provision of a

written summary detailing each clinical encounter is provided to each patient on each

visit. As part of KP Quality Improvement Initiatives, providers are encouraged to review

these details with each patient prior to the conclusion of an appointment (Oldenburg,

2009). Thus, it may be that the Encounter Details function was perceived as redundant, particularly among patients who might see their provider in person frequently as a strategy for managing complex comorbid conditions.

Research Question 1c: Use of Lab Results within KP.Org

Lab Results was the most frequently used function within the KP.Org system among individuals diagnosed with diabetes and hyperlipidemia, (but not for those diagnosed with hypertension), regardless of whether individuals had one, two or all three of the diagnoses included in the analysis. This finding is congruent with those of Seto and colleagues (2007) who implemented a comprehensive survey to assess patient preferences in electronic PHRs and found that as many as 60% of participants reported that they would look up laboratory and test reports if this was available to them via an electronic PHR.

Both HbA1c and LDL test results are available to patients within the KP.Org system via the Lab Results function. Blood pressure, on the other hand, is not a laboratory result, but is part of a collection of vital sign measures captured at each appointment with a KP.Org provider. Although blood pressure measures can be viewed in the KP.Org system via the Encounter Details, blood pressure is a measure readily available to patients at the time of each appointment. Further, many patients check their own blood pressure regularly and therefore may choose not to go online to look for information they may already have.

A new function within the KP.Org system (Health Maintenance) became available at the end of calendar year 2008 that allows participants to enter their vital signs

and trend them over time. Patients can generate graphs and visual diagrams to assist them in monitoring their blood pressure. The Health Maintenance function can also be used for many other diagnoses and includes the ability to track diet, exercise, weight, smoking, etc., and provides step-by-step guidance in developing individually tailored health maintenance goals. Unfortunately, this function was not available at the onset of the data collection period and was not included in this analysis. Future studies to examine the frequency and patterns of use of the Health Maintenance function may provide valuable insights into the effects of this type of comprehensive and interactive health promotion tool within an electronic PHR.

Research Question 1d: Frequency of use of Medical Advice within KP.Org

The Medical Advice page provides users with information on a variety of health-related topics including tools for weight loss, diet and nutrition, exercise, medication management, and disease specific information written in layman's terms for optimal patient comprehension. The Medical Advice page includes a search engine to help members navigate to KP- recommended web-sites from which materials and information can be printed. This was the third most frequently used function in the KP.Org system in the total sample, and for all members stratified by disease and number of comorbid conditions. This finding is congruent with the work of Allen, and colleagues (2008) and Cummings and Turner (2009) who have reported increasing trends among adults using electronic tools such as the Internet to seek out health information on a variety of topics, and preferences for websites that have legitimate and meaningful information for health related issues.

Research Question 1e: Frequency of use of Medication within KP.Org

An unexpected finding was that the Medications function within KP.Org, which includes a convenient option for ordering medication refills with the click of a button, was the least frequently used function in the analysis. This is contrary to findings reported in the literature indicating high desirability of patients to have online medication refills available within an electronic PHR (Roblin, 2008). Among users of the Medication function in this analysis, individuals diagnosed with all three conditions viewed the Medications page more frequently than others.

One explanation for low use of this function might be that options for selected medication refills were new to the KP.Org system at the start of data collection. An alternative explanation could be the telephone prescription refill system that has been available to KPGA members for several years. The telephone system calls out to patients with friendly reminders when prescription are nearing expected refill. The system also provides patients with the opportunity to refill prescriptions at the time of the reminder call, simply by confirming information already available in the pharmacy database. The system can be accessed from any telephone, uses voice recognition or telephone key-pad information entry, and prescriptions can be refilled the same day. The added convenience of refilling prescriptions at the time a reminder call is received, without having to logon to a computer, may simply be more appealing for many KPGA members.

Research Question 1f: Frequency of use of Secure Messaging within KP.Org

Among all users regardless of diagnosis or number of comorbid conditions, Secure Messaging was the second most frequently used function within KP.Org. This

finding is highly consistent with the findings of Schiamanna and colleagues (2007) and

Delbanco (2008), who have reported consistent increasing trends in patients' willingness

and desire to communicate electronically with their primary care providers. Investigators

from Kaiser Permanente, California examined the use of secure messaging within the KP

Health Connect© system and found that more than 700,000 secure messages were being

exchanged between patients and providers on a monthly basis with highly favorable

responses (Scott, 2011). This report is particularly encouraging, as it reveals new

patterns of use of electronic communication strategies between patients and providers,

suggesting a shift away from the "high desirability but low usage" phenomenon discussed

by Williams (2008) and noted by Houston and colleagues (2004).

Although the findings from the current analysis provide evidence that the use of

secure messaging within KP.Org was frequently used, the specific tasks associated with

use of secure messaging were not available. Studies conducted by Taylor (2004) and

Couchman (2005) found that electronic communication initiated by patients was highly

correlated with specific tasks perceived by patients to be advantageous, such as requests

for prescription refills, inquiring about specific non-urgent health issues, obtaining

laboratory results or making and cancelling appointments. The structure of KP.Org

provides options for completing these kinds of tasks outside of the use of the Secure

Messaging function. For example, patients can review their laboratory results by

utilizing the Lab Results function within KP.Org. While it is not necessary to use Secure

Messaging within KP.Org to request access to Lab Results, users of the system can (and

may) use the system in that manner. Further research regarding the specific types of

communications being exchanged between patients and providers may provide better

understanding of how Secure Messaging is currently being used and may guide processes for improving the efficiency and effectiveness of this communication strategy for managing health.

Research Question 2: Frequency of use of KP.Org and Medication Possession Ratios

Not all individuals diagnosed with diabetes, hypertension or hyperlipidemia are prescribed medication for the management of these chronic conditions. In many cases, modification in diet and exercise may be the preferred first line of treatment. This analysis included only individuals who are prescribed medications and who had data for at least one medication refill event. Individuals who stopped taking prescribed medications or were removed from prescription medications during the data collection period would influence the analysis by producing lower medication possession ratios, which did not occur to a significant degree.

There was a consistent dose-response relationship between frequency of use of KP.Org and improved medication possession ratios, with the exception of Quartile 2 in the hypertensive group. All associations between frequency of use and medication possession ratios were significant, except for Quartile 2 and 3 of use frequency in the hypertensive group. Individuals diagnosed with hypertension overall had the weakest associations of medication possession ratios.

One possible explanation for the relationship between frequency of use and improved medication possession ratios could be that individuals using the KP.Org system may already be more engaged in managing their health, which likely includes paying more attention to appropriate medication management. However, it is important to note

that the Medication function within KP.Org, which provides medication refill opportunities, was not likely the mechanism by which individuals with high medication possession ratios refilled their prescriptions, as evidenced by the low frequency of use for that function among all logon events included in the analysis, regardless of diagnosis. This finding is inconsistent with the work of Couchman and colleagues (2005) who found that 83% of patients reported they would most use an electronic communication strategy such an electronic PHR for the purposes of obtaining prescription refills. It may be that the prescription refill phone system is simply a more convenient mechanism for refilling prescriptions. Regardless of the mechanism by which patients are filling their prescriptions, it is noteworthy that high frequency users of KP.Org have significantly better medication possession ratios.

There was a consistent association of higher Geostrata quartile (higher SES) and increased medication possession ratios. Stated another way, individuals from lower Geostrata quartiles had decreased medication possession ratios. The literature provides several potential explanations for this trend. Egede (2003) hypothesized that socioeconomically vulnerable patients may be more fatalistic about their disease trajectory and may be less motivated to treat their disease aggressively, including taking medications as prescribed. Natarjan (2004) found that patients with low socioeconomic status often struggle with the costs of medicines which may lead to decreased medication adherence. Recent work by Kershawn (2010) revealed that the socioeconomic characteristics of a neighborhood can affect health status and may influence medication adherence. According to Kirchhoff (2008), disparities in the availability, affordability, timely use and effectiveness of healthcare services individually impact those with low

socioeconomic status greatest, who may not be able to access healthcare services or afford medications. Unfortunately, this analysis reveals a similar trend regarding the association between lower socioeconomic status and lower medication possession ratios. Although the specific factors influencing this finding were outside the scope of this analysis, it appears that the issues may be highly complex and numerous, and certainly worthy of additional research.

Research Question 3: Frequency of Use of KP.Org and Primary Outcome Measures of Metabolic Control (Hba1c, BP, LDL)

Logistic regression analysis for frequency of use of KP.Org and primary physiologic outcome measures were significant at the *p* < .0001 level for all measures. The odds ratios and confidence intervals reveal that the strongest associations were between use of KP.Org and improvement in physiologic outcomes among individuals diagnosed with hyperlipidemia. It is important to note that some individuals had more than one diagnosis and were included in more than one group for analysis. It is likely that an individual's behaviors within one group based on diagnosis was consistent with that individual's behavior in all groups for which he/she met inclusion criteria for the analysis.

Among individuals diagnosed with diabetes, 52% showed improvement in their HbA1c, 19% were unchanged, and 29% worsened. Among individuals with hypertension, 51% showed improvement, 11% remained unchanged, and 38% worsened. Among individuals diagnosed with hyperlipidemia, 37% improved, 39% remained unchanged, and 24% worsened. A non-change in lab values over time should be interpreted cautiously. This could represent HbA1c, BP and/or LDL that was already

well-controlled, or metabolic control that was poor to begin with and remained unchanged.

Patterns of outcome measures and use of KP.Org were similar among individuals diagnosed with diabetes and those diagnosed with hyperlipidemia, but were more variable among individuals in the hypertensive group. This is logical, because blood pressure is a highly variable measure, as noted in the findings between and within participants diagnosed with hypertension.

There are a number of possible explanations for the differences in trends noted in the analyses of hypertensives. Reports published by the U.S. Department of Health and Human Services (2010) in conjunction with establishing the Healthy People 2020 initiatives, suggest that various factors may influence an individual's average BP, including age, gender, exercise, emotional reactions, sleep, digestion and time of day. The National Institute on Aging (2005) reports that as adults age, systolic pressure tends to rise and diastolic tends to fall, largely because of reduced flexibility in the arteries over time. Findings of studies conducted with the support of the American Heart Association (2010) reveal differences between left and right arm BP measurements that tend to be random and average to nearly zero if enough measurements are taken. In a comprehensive evaluation using data from the Framingham Heart Study, Lloyd-Jones (2005) found that there is often a large variation in blood pressure measures from person to person and from moment to moment, and that the average of any given population may have a questionable correlation with its general health.

Details regarding specific methods for taking blood pressure among those included in the present analysis were not available. The blood pressures used in this

analysis were basic measures from clinic visits without use of specifically calibrated equipment or consistently administered protocols. BP measures were also entered manually into the database by numerous individuals seeing patients at various locations and are therefore prone to additional variation and potential human error. Thus, it may be that because of the 'noisy' nature of blood pressure measures, blood pressure alone may not be the most effective mechanism for evaluating improvement in hypertensive outcomes. Further consideration of measures used in combination with blood pressure to evaluate physiologic outcomes of hypertension management may be useful.

In contrast, HbA1c and LDL are much more stable measures and are derived from laboratory testing using blood samples. According to KPGA protocols, HbA1c laboratory testing is generally scheduled once every three months, and LDL testing once every six months. Compared with blood pressure which is measured and immediately available for patients during each clinical appointment, there is a time delay for obtaining results of HbA1c and LDL. This may help to explain why individuals having these tests performed were more motivated to use the KP.Org system in general and to view Lab Results within KP.Org.

Research Question 4: Frequency of use of KP.Org, Medication Possession Ratios and Primary Outcome Measures (Hba1c, BP. LDL)

Findings from the mediation analysis suggest that medication possession ratio plays an important, if modest, role in partially mediating the relationship between KP.Org usage and change in the physiologic outcomes of HbA1c and LDL but that there is no evidence of mediation for change in BP. The standard test for the statistical significance of a mediating effect is the Sobel test for the indirect effect. While Fritz and MacKinnon

(2007) note that this is not the most powerful test, especially for smaller sample sizes, their analysis shows that for sample sizes larger than 500 its performance is comparable to more complicated methods. For HbA1c, the Sobel test had a *p*-value of 0.057 with and without adjustment, very close to the significance threshold of 0.05, while the Sobel *p* for LDL was less than 0.01 with and without adjustment. The direct effect of KP.Org usage on physiologic outcomes was statistically significant for both HbA1c and LDL in both unadjusted and adjusted analyses indicating that any mediation is only partial, with 8.9% of the effect mediated for HbA1c and 4.6% for LDL.

In contrast, there was no evidence of mediation for BP. All *p*-values were greater than 0.05 and failed to reach statistically significant thresholds. Given the highly variable nature of BP measurements, this is not altogether surprising. Because overall use of KP.org is not specific to medication, there is the potential that in future work a stronger mediating relationship may be uncovered between a more medication-specific usage measure and medication possession ratios.

Research Question 5: Did the Covariates of age, gender, % African American and Geostrata Code (by quartile) explain differences between frequency of use and Primary outcome measures of HbA1c, BP, LDL?

The unadjusted logistic regression analyses for the primary outcome measures of metabolic control set as a binary measure (improved versus not improved) revealed statistically significant relationships among the upper three quartiles compared with the lowest quartile (*p* <.0001), for all three diagnoses. These results remain consistent when adjusted for age, gender, Geostrata quartile (SES) and % African American. The covariate % African American in the adjusted logistic regression model for LDL was the only variable that had significant explanatory value (OR .757, CI .584 - .980; *p* < .05).

This suggests that being African American is associated with a lower probability of improvement in measures of LDL. The level of significance for Geostrata quartile 4 (highest SES) was 0.061 (less than 0.1) for improvement of LDL. However, it did not reach the standard threshold of significance of $p < .05$.

The regression analyses were also performed for the primary outcome measures of physiologic metabolic control set as continuous variables (change over time). Change was calculated as a positive number (pre minus post). Thus, a positive parameter estimate was indicative of a change of the outcome measure in the direction of clinical improvement (a lower number) over time. Conversely, a negative parameter estimate indicated a change of the outcome measure in the direction of clinical decline (a higher number).

The regression analyses for change in HbA1c revealed a statistically significant relationship between the upper three Quartiles of frequency of use among individuals diagnosed with diabetes at the ($p < .05$) level for three quartiles. In the adjusted regression model for HbA1c change, age was the only covariate with explanatory value. For each year of increased age, the change in HbA1c is expected to decrease by .011. The other covariates in the full model were not significant.

The regression analysis for change in BP was statistically significant for frequency of use Quartiles 2 and 3 in both the adjusted and unadjusted models, but not significant for Quartile 4 frequency of use. This may mean that the most frequent users of KP.Org already had well controlled BP measures. These results could also be the effect of the challenges associated with the BP measures in general and high levels of variability in using BP as the sole indicator of improvement in hypertension control.

Being female was associated with increased likelihood of improved BP. However, being African American was negatively associated with change in BP such that African American BP measures were an average of 2.5 mmHg greater than non-African Americans.

There was a positive significant association ($p < .0001$) for the three upper quartiles of frequency of use of KP.Org and improved change in LDL, unadjusted and adjusted. In the adjusted model, age was negatively associated with change in outcome. For each year of increased age, the likelihood of improvement of LDL decreased by .09. Being African American was again negatively associated with improvement in physiologic outcome. Individuals included in the % African American variable for the outcome measue LDL had an average of 3.74 points higher than individuals included in the analysis who were not included in the % African American category.

Conceptual Model

The proposed model, a variation of Donabedian's Triad, was an appropriate model for examining the relationships between and among the study variables. Kp.Org was depicted as the structural component of the model and served as the initial point of patient engagement with the electronic PHR. Frequency of use of selected functions within KP.Org (including logon to the system) were examined as process measures and served as the independent variable in the analysis. In the proposed model, medication possession ratios provided an intermediate –level measure of adherence. Using mediation analysis, medication possession ratios were shown to partially mediate the relationship between use of KP.Org and outcome measures of metabolic control (HbA1c,

BP and LDL). The proposed model, with the addition of the intermediate behavioral measures (medication possession ratios) reveals a new and important step in better understanding the relationship among the study variables. This study supports the proposed relationships depicted in the conceptual model including the KP.Org PHR system (structure), frequency of use of selected functions within KP.Org (process), medication possession ratios (intermediate behavioral measures) and physiologic measures of metabolic control (outcomes).

Hypotheses

Hypothesis 1: Among adult users (age 21 or older) of KP.Org who were diagnosed with one or more selected chronic disease (diabetes, hypertension, hyperlipidemia), who logged on to KP.Org at least one time during calendar year 2008, increased use of KP.Org (greater than one use) will be associated with improved intermediate patient-centered process measures of adherence (medication possession ratios) from the time 6 months prior to the first KP.Org logon in calendar year 2008 up to the time 14 months following initial KP.Org logon.

Hypothesis 1 was supported among participants diagnosed with diabetes and those diagnosed with hyperlipidemia. Hypothesis 1 was not supported among individuals diagnosed with hypertension. In general, individuals with the highest frequency of logon to KP.Org were shown to have higher medication possession ratios.

Hypothesis 2: Among adult users (age 21 or older) of KP.Org who were diagnosed with one or more selected chronic disease (diabetes, hypertension,

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hyperlipidemia), who logged on to KP.Org at least one time during calendar year 2008, increased use of KP.Org (greater than one use) will be associated with improved physiologic metabolic control measures including: (a) HbA1c, (b) LDL (c) BP from the time 6 months prior to the first KP.Org logon in calendar year 2008 up to the time 14 months following initial KP.Org logon.

Hypothesis 2 was supported. Increased use of KP.Org was consistently and significantly associated with improved physiologic outcomes for diabetes, hypertension and hyperlipidemia. The highest levels of significance were among the highest users of KP.Org (Quartile 4) for all three groups. Individuals with use of KP.Org in Quartile 2 and Quartile 3 diagnosed with both diabetes and hyperlipidemia also showed significant associations of improvement in physiologic outcome measures of HbA1c and LDL. However, among individuals diagnosed with hypertension, only individuals in Quartile 4 (highest use) revealed significant improvement in BP.

Conclusions

The findings from this study reveal significant associations between frequency of use of the KP.Org system and improvement in physiological outcome measures among individuals diagnosed with diabetes, hypertension and hyperlipidemia. Based on the study findings, the following inferences were identified:

1. Increased frequency of use of KP.Org was associated with improvement in physiological outcome measures of HbA1c, BP and LDL among individuals included in this analysis diagnosed with diabetes, hypertension and hyperlipidemia.

2. The associations were consistently strongest among individuals diagnosed with hyperlipidemia and diabetes and were more variable among individuals diagnosed with hypertension.

3. Medication possession ratios were a significant indicator of improved physiologic outcome measures for individuals diagnosed with diabetes and hyperlipidemia, but not among individuals in this analysis diagnosed with hypertension.

4. Older women diagnosed with hyperlipidemia and individuals in the highest Geostrata quartile (highest SES) had the highest medication possession ratios.

5. Individuals in the lowest Geostrata quartile (lowest SES) used the KP.Org system less frequently, had poorer medication possession ratios and revealed less improvement in physiological outcome measures of HbA1c, BP and LDL. However, in general, the Geostrata quartile did not produce significant explanatory findings when entered into the full models.

6. Older age was associated with increased use of KP.Org among individuals diagnosed with hyperlipidemia, but younger age was associated with increased use of KP.Org among individuals diagnosed with diabetes, perhaps due to age of initial diagnosis of these two disease processes.

7. There was a significant age effect for change in HbA1c and LDL, but not for BP. Older age was associated with less improvement in HbA1c and LDL.

8. Individuals with hyperlipidemia revealed the greatest improvement in physiologic measures of metabolic control in this analysis.

9. Inclusion in the % African American measure was negatively associated with change in BP and LDL but was not significant for HbA1c.

10. Among the functions of use within KP.Org, viewing Lab Results and using the Secure Messaging functions were the most frequently used options.

11. Among individuals diagnosed with diabetes, use of Secure Messaging, Medical Advice, Medication, and Encounter Details within KP.Org were each significancly associated at the $p < .05$ level with improvement in HbA1c.

12. Among individuals diagnosed with diabetes, use of the Lab Results function within KP.Org was significantly associated with improvement in HbA1c at the $p < .0001$ level in the unadjusted model and in the model adjusted for age, gender, % African American and Geostrata quartile.

13. Among individuals diagnosed with hypertension, use of the Lab Results and Medication functions were significantly associated with improvement in blood pressure when blood pressure was set as a binary outcome variable.

14. Among individuals diagnosed with hyperlipidemia, use of Secure Messaging, Medical Advice, Lab Results, Medication and Encounter Details within KP.Org were all significantly associated with improvement in outcome measures of LDL at the $p < .0001$ level, in both the unadjusted and adjusted models, when LDL was set as a binary outcome variable.

15. Among individuals diagnosed with diabetes, significant associations were revealed at the $p < .05$ level between use of Secure Messaging, Lab Results, Medication and Encounter Details and change in HbA1c, in the unadjusted modeland in the model adjusted for age, gender, % African American, and

Geostrata quartile. In this model, Medical Advice did not reach the standard level of significance, but was .075, when the outcome variable HbA1c was set as a continuous variable (change over time).

16. Among individuals diagnosed with hypertension, use of the Encounter Details function within KP.Org was the only function that reached the level of significance ($p = 0.52$) in association with change in blood pressure.

17. Among individuals diagnosed with hyperlipidemia, there associations between use functions of Secure messaging, Medical Advice, Lab Results, Medication and Encountrer Details within KP.Org were significantly associated (at the level of p $<.05$) with change in outcome measures of LDL in the unadjusted model and in the model adjusted for age, gender, % African American, and Geostrata quartile.

Limitations

There were several limitations for this study. They are as follows:

1.   This study was a secondary analysis of existing data from Kaiser Permanente, Georgia KP.Org. Consequently, the ability to measure and analyze the data was based on the information that was already available in the dataset.

2. Secondary data cannot be modified or altered after the fact. The data in this study were already defined, and in some cases, data were limited. In this analysis, data regarding socioeconomic status and race/ethnicity were limited such that alternative variables Geostrata codes (in distributed quartiles) and % African American were necessary for the analysis.

3. Only de-identified data were available for inclusion in the study. Information that might have added meaning to the findings, such as comorbid conditions (in addition to diabetes, hypertension or hyperlipidemia), zip codes, years of education, marital status and income were not available for inclusion.

4. Participants with incomplete data or data ranges outside the clinical scope considered appropriate for life (such as LDL > 600, HbA1c of 200) were excluded from the entire analysis, as verification of appropriate values within the de-identified dataset was not possible.

5. It cannot be assumed that data are without error. However, those individuals entering data into the EHR were trained to a minimal level of proficiency and tested regarding their ability to understand and appropriately use the system for data entry.

6. People who engaged with the system and took extra time to utilize KP.Org related to their healthcare may already have been better at self-managing their health in general.

7. Frequency of use of KP.Org functions provided information that an individual went to a particular page within the KP.Org logon session. It is not possible to know what the individual did (or did not do) with the information displayed via access to those functions.

8. There are additional physical and psychosocial factors that could have influenced the outcomes that were not assessed in this study.

9. The use of alternate variable % African American as a proxy measure for race was not a direct measure of race and cannot be interpreted as such.

10. Illness severity, while not examined in this study, may have played an important role in individual's frequency of use of KP.Org.

Future Implications

This study provides meaningful information regarding the associations between use of an electronic PHR and selected physiologic outcome measures of HbA1c, BP and LDL, and provides new insights into the potential applications of electronic PHRs for improved management of selected chronic diseases such as diabetes, hypertension and hyperlipidemia.

Findings from this study are specific to individuals with chronic conditions in the south east United States. Although the information developed from this analysis is meaningful, continued research regarding the specific use functions within the PHR system might be helpful for guiding policy and developing strategies to further engage patients in the management of their chronic illnesses. For example, individuals in this study utilized the lab results and secure messaging functions within KP.Org with the highest frequencies. It would be helpful to know whether patients believe the use of these functions within KP.Org contributed to their improved physiological outcome measures. Knowledge about patient perceived benefits could be used to refine electronic PHR systems to better meet specific needs and expectations of patients and might contribute to more widespread acceptance and use of these types of tools. In keeping with a patient-centered focus in healthcare policy development at the national level, gathering patient feedback and input regarding use of electronic PHRs for the management of their health could be helpful in meeting the goals set forth in Healthy

People 2020, and in working toward a more streamlined healthcare delivery system using technology (Office of the National Coordinator of Health Information Technology, 2010; United States Department of Health and Human Services, 2010).

Tailored electronic PHRs might increase the use of these tools and potentially increase patient engagement in managing their health overall. For example, if functions within the PHR were tailored to specific disease processes, such as chronic obstructive pulmonary disease or congestive heart failure, or to certain behaviors such as smoking cessation, use of these electronic tools could become more personally relevant for users.

For more than a decade, online marketing and retail sales companies have utilized electronic tools that capture patterns of use and make recommendations to customers. For example, a shopper looking at an online clothing catalogue for an outfit may automatically be directed to items that other shoppers with similar shopping patterns have purchased. It might be a highly effective strategy to utilize this type pattern profiling for health-related issues. For instance, an individual with diabetes reviewing an HbA1c lab result might receive a prompt to take a brief risk assessment for hypertension or hyperlipidemia, as these diseases have been shown to cluster together (Natarajan, 2004) Another strategy might be to encourage the diabetic individual to check out the latest news in diabetes research (with a link attached) or to look at healthy diabetic recipes (link provided). One can quickly see that the potential uses of electronic PHRs could extend far beyond their current applications and become more highly interactive and engaging for individuals. When electronic systems can actually anticipate potential needs for users based on previous patterns of use, the potential for a more customized personal experience might be realized.

The increasing trend of secure messaging between patients and providers discussed by (Scott, 2011) and supported in the finding of this study, suggest that this type of communication is growing in popularity. However, the potential exists for this communication strategy to become overwhelming for providers if trends such as those revealed by (Terry, 2008) continue. Details regarding the specific uses of the secure messaging might provide further insight into how patients are currently engaging with providers. Information about whether secure messaging within KP.Org was used to accomplish tasks that could have been completed via other mechanisms or functions within the system might help developers to refine systems to become more efficient for both patients and providers. Perhaps future systems could better-capture specific patterns of use (or non-use) of specific functions within individual logon sessions. This could lead to more pervasive acceptance of electronic PHRs that are more patient-centered, streamlined, cost-effective and efficient. Functions that are not used might be eliminated or streamlined as a cost-reduction strategy.
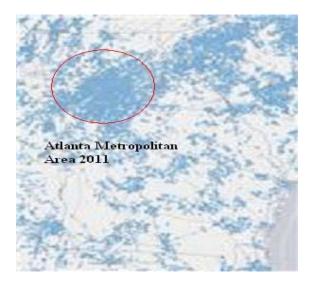
It would be interesting to compare use of the KP.Org system among users from different regions. Participants in this study represented the Atlanta Metropolitan area, a region that has a high level of internet connectivity and wireless capabilities. Figure 7 provides a snapshot of broadband availability in the United States. Figure 8 provides a closer look at the Atlanta metropolitan area and broadband connectivity (National Telecommunications & Information Administration, 2011).

Figure 7. United States Broadband Availability, 2011

There is a striking difference in the availability of broadband in the east and southeast United States (noted by the dark patches on the map) compared with the western half of the country (with the exception of upper northwest corner of the mapped area). Additional research from other regions that are less "wired" might produce different results. Research that includes information about level of education, literacy and technological awareness and skill might provide opportunities for addressing the 'digital divide' that exists due to unbalanced access to technological tools such as electronic PHRs (Chang, 2004).

Figure 8. Broadband Mapping for Atlanta Metropolitan Area, 2011

It is unfortunate that information on BMI in the present study was limited such that the variable could not be included in the analysis. BMI has been shown to have a strong association with diabetes, (citation), hypertension (citation) and hyperlipidemia (citation). Future research including BMI as a predictor or explanatory variable might be highly informative in examining chronic disease and use of electronic PHRs.

Future research that includes comorbid conditions not limited to diabetes, hypertension and hyperlipidemia and use of electronic PHRs could inform the development of more patient-centered electronic health tools for chronic disease management. Inclusion of variables to assess severity of illness might further contribute to understanding variances in patient levels of engagement regarding use of electronic PHRs.   It is unclear whether individuals in the present study who had the greatest severity of illness were among high or low users of KP.Org. Information regarding severity of illness might also provide an opportunity to better understand variances in

ranges of improvement. In the present study, improvement among individuals stratified by diagnosis included all individuals with that diagnosis, and did not distinguish between a multi-point improvement (large improvement) or a fraction of a point improvement (slight improvement). The addition of levels of change or inclusion of specific cut-off values might enable more elegant analyses that could potentially enhance the findings. The inclusion of multi-morbidities could be used as a covariate to adjust for level of illness burden or illness severity. It is possible that individuals who were extremely ill did not have the motivation, energy or opportunity to access online tools such as KP.Org. It is also possible that individuals who were healthier did not feel the need or desire to use an online tool such as KP.Org. Future research to address these types of questions might enhance our understanding of these issues.

This study provides a solid foundation for additional evaluation of PHR use. Recommendations for additional research include the ability to follow patients over a longer time period with multiple measurements of the outcome variable. This would provide information regarding patterns of use over time and potential associations. It would also provide the ability to detect distinctions and nuances in the relationships among the variables. Potentially, multiple data collection points would provide opportunities to develop prediction models that might reveal curvilinear relationships and not just linear associations. Information generated from multiple observations might enhance overall understanding of variability in PHR use and associated outcomes.

Implications for Nursing Research

Nurses, particularly nurse informaticists, are positioned to conduct meaningful research regarding the use of electronic tools for improved management of patient health in a variety of ways. Electronic tools in all healthcare settings are on the rise, and there is a great need to understand the implications of these tools and how they will influence nursing practice and the role of the professional nurse. There are myriad opportunities for nurse researchers to contribute to the development of nursing knowledge in examining the associations between electronic tools and the delivery of nursing care to patients. Research to support the role of the professional nurse in guiding policies for the improvement in the quality and safety of patient care using technological tools is unlimited.

Implications for Nursing Practice

This study provides support for the use of electronic PHRs in the improvement of selected physiological outcomes associated with diabetes, hypertension and hyperlipidemia. Nurses provide patient education and can teach patients about the value of using electronic tools to become more engaged with the healthcare system and with their providers. According to survey results reported by Nursing Times (2009), professional nurses ranked very high in public trust. Among the 1700 survey participants, 95% reported that they trust nurses 'a great deal' or 'quite a lot'(Payne, 2009). This high level of public trust places the professional nurse in an ideal position to guide patients toward becoming more engaged in managing their health and may provide opportunities for nurses to educate patients about the effective use of technological tools such as the electronic PHR to support their self-management efforts.

Implications for Nursing Education

The increasing availability of courses for nurses in nursing informatics and the inclusion of informatics curricula in advanced nursing practice programs is encouraging. As leaders in the delivery of healthcare, nurses must know how to interact with technologies in the practice of providing high quality, safe and effective patient care. Nurses should also understand the advantages and disadvantages of using technological tools and should understand the limitations of the technology itself. Technological tools cannot replace the expertise, critical judgment and caring components that are integral to the role of the professional nurse. However, the effective use of technological tools can enhance nursing care if used appropriately. Nursing education should include information and exposure to technologies that support nursing excellence, but should also include opportunities for dialogue regarding the limitations of technologies.

Summary

The use of technological tools to support increased patient engagement in managing chronic health conditions shows great promise as a strategy to improve the quality and delivery of healthcare services. This study makes a novel contribution to the current literature and provides evidence of significant associations between use of an electronic PHR (KP.Org), medication possession ratios, and improvement in scientifically derived outcome measures of metabolic control. Nurses are in an ideal position as leaders in the healthcare industry and as clinical experts to conduct research, guide policy development, teach patients and engage in professional collaborations in

working toward excellence in healthcare delivery with the added benefit of technological

tools to guide these processes.

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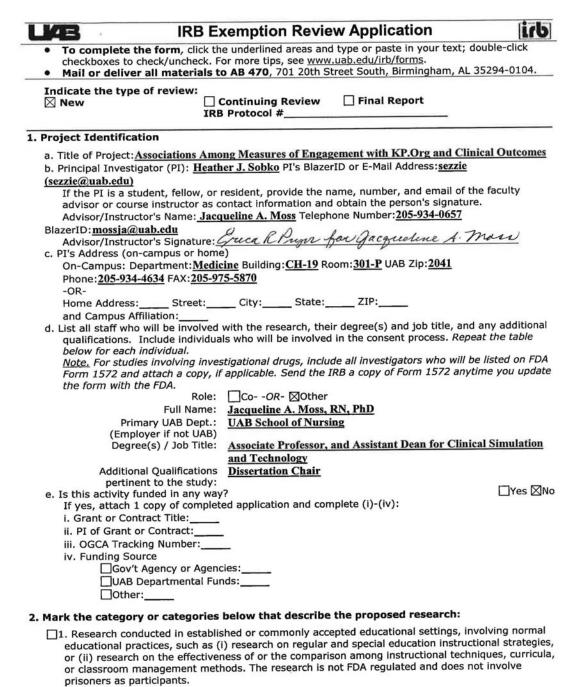
APPENDIX A

Institutional Review Board Protocol Oversight and Review Form

UAB SCHOOL OF NURSING

Institutional Review Board
Protocol Oversight Review Form

Date Submitted to IRB: 9/30/10

Title of Project: Associations Among Measures of Engagement with KP.Org ar

Name of PhD Student/Principal Investigator: Heather Sobko

Signature of PhD Student/Principal Investigator *Heather Sobko*

School: Nursing
Program: PhD in Nursing

Review Process:
- [✓] PhD Committee Chair sign off
- [ ] PhD Program Coordinator sign off

I have reviewed the proposed research and concluded that the following apply:
- The research is scientifically valid and is likely to answer the scientific question;
- The PhD student researcher and the study team are qualified and/or credentialed to conduct the procedures proposed;
- The PhD student researcher has identified sufficient resources in terms of experienced research personnel, facilities, and availability of medical or psychological services that may be necessary as a consequence of participation in the research to protect the research participants.

PhD Program Coordinator Review

Name of Review Official: Erica R. Pryor, RN, PhD

Title: PhD Program Coordinator
Signature: *Erica R Pryor*   Date: 8/27/2010

Administrative Review

Name of Review Official: Elizabeth Stullenbarger, RN, DSN

Title: Associate Dean for Academic Affairs
Signature: *Karen Kuneoes for Elizabeth Stullenbarger*   Date: 8/30/10

APPENDIX B

IRB Exemption Review Application

UAB   **IRB Exemption Review Application**   **irb**

- **To complete the form**, click the underlined areas and type or paste in your text; double-click checkboxes to check/uncheck. For more tips, see www.uab.edu/irb/forms.
- **Mail or deliver all materials to AB 470**, 701 20th Street South, Birmingham, AL 35294-0104.

Indicate the type of review:
☒ **New**   ☐ **Continuing Review**   ☐ **Final Report**
                IRB Protocol #_____

1. Project Identification

a. Title of Project:**Associations Among Measures of Engagement with KP.Org and Clinical Outcomes**
b. Principal Investigator (PI): **Heather J. Sobko** PI's BlazerID or E-Mail Address:**sezzie (sezzie@uab.edu)**
    If the PI is a student, fellow, or resident, provide the name, number, and email of the faculty advisor or course instructor as contact information and obtain the person's signature.
    Advisor/Instructor's Name: **Jacqueline A. Moss** Telephone Number:**205-934-0657**
BlazerID:**mossja@uab.edu**
    Advisor/Instructor's Signature: *Erica R Pryor for Jacqueline A. Moss*
c. PI's Address (on-campus or home)
    On-Campus: Department:**Medicine** Building:**CH-19** Room:**301-P** UAB Zip:**2041**
    Phone:**205-934-4634** FAX:**205-975-5870**
    -OR-
    Home Address:_____ Street:_____ City:_____ State:_____ ZIP:_____
    and Campus Affiliation:_____
d. List all staff who will be involved with the research, their degree(s) and job title, and any additional qualifications. Include individuals who will be involved in the consent process. *Repeat the table below for each individual.*
    Note. For studies involving investigational drugs, include all investigators who will be listed on FDA Form 1572 and attach a copy, if applicable. Send the IRB a copy of Form 1572 anytime you update the form with the FDA.

                 Role: ☐ Co- -OR- ☒ Other
           Full Name: **Jacqueline A. Moss, RN, PhD**
      Primary UAB Dept.: **UAB School of Nursing**
    (Employer if not UAB)
    Degree(s) / Job Title: **Associate Professor, and Assistant Dean for Clinical Simulation and Technology**
    Additional Qualifications **Dissertation Chair**
    pertinent to the study:
e. Is this activity funded in any way?   ☐Yes ☒No
    If yes, attach 1 copy of completed application and complete (i)-(iv):
    i. Grant or Contract Title:_____
    ii. PI of Grant or Contract:_____
    iii. OGCA Tracking Number:_____
    iv. Funding Source
          ☐Gov't Agency or Agencies:_____
          ☐UAB Departmental Funds:_____
          ☐Other:_____

2. Mark the category or categories below that describe the proposed research:

    ☐1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research is not FDA regulated and does not involve prisoners as participants.

☐2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Attach questionnaire(s) and/or surveys. If the research involves children as participants, the procedures are limited to educational tests and observation of public behavior where the investigators do not participate in the activities being observed. The research is not FDA regulated and does not involve prisoners as participants.

☐3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (2), if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. Attach to this application a copy of any questionnaire or survey to be used. The research is not FDA regulated and does not involve prisoners as participants.

☒4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. Attach a specimen release form if applicable. (_Specimens must be preexisting._) The research is not FDA regulated and does not involve prisoners as participants.

☐5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs;(iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. The protocol will be conducted pursuant to specific federal statutory authority; has no statutory requirement for IRB review; does not involve significant physical invasions or intrusions upon the privacy interests of the participant; has authorization or concurrent by the funding agency and does not involve prisoners as participants.

☐6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. The research does not involve prisoners as participants.

3. Briefly describe the proposed research: **This is a secondary analysis using data from calendar years 2007-2009. De-identified data from Kaiser Permanente Georgia (KPGA) will be examined and analyzed to discover if there are associations between use of the KPGA online personal health record system (KP.Org) and selected clinical outcomes. The dataset will include adult members of KPGA (age 21 or older) who have been diagnosed with diabetes, hypertension or hyperlipidemia and logged on to the KP.Org system at least one time during calendar year 2008. A sample data set will be provided to the principal investigator, who will use the sample data to develop programming for statistical analysis. After rigorous testing of the programming for statistical analysis, the program will be sent to KPGA where KPGA authorized research scientists will run the actual data through the statistical program. Information from the analysis will be provided to the principal investigator in aggregated form. All data will be deidentified and will NOT contain PHI. The principal investigator will evaluate the aggregated data analysis for development of findings and discussion as part of her dissertation project.**

4. Describe how subjects/data/specimens will be selected. If applicable, include the sex, race, and ethnicity of the subject population:**Adult members of KPGA (age 21 or older) who have a diagnosis of**

diabetes, hypertension or hyperlipidemia and who logged on to the KP.Org PHR system in calendar year 2008 will be included.

5. Does the research involve deception? ☐Yes ☒No

6. Describe why none of the research procedures would cause a subject either physical or psychological discomfort or be perceived as harassment above and beyond what the person would experience in daily life: **This is a secondary data analysis. The data contains no PHI. Data were collected between calendar year 2007-2009. The PI will develop statistical programming using a sample dataset. Actual data will remain on KPGA secure server at KPGA location.**

7. Describe the provisions to maintain confidentiality of data:**All data will be deidentified. Data will be provided to PI in aggregate form only.Computerized data will be stored on KPGA's password protected network server in password protected folders and datasets.**

8. Describe the provisions included in the research to protect the privacy interests of participants (e.g., others will not overhear your conversation with potential participants, individuals will not be publicly identified or embarrassed).:**The secondary data set used for this study contains only deidentified data in aggregate form.**

9. Will the research involve interacting with the subjects? ☐Yes ☒No
   If yes, describe the consent process and information to be presented to subjects, including:
   - That the activities involve research.
   - The procedures to be performed.
   - That participation is voluntary.
   - Name and contact information for the investigator.

10. Additional Information
   In the space below, provide any additional information that you believe may help the IRB review the proposed research, or enter "None." **None**

11. Findings? **(applicable for Continuing Review or Final Report only)**
   State both the positive and negative results received to date:**Not Applicable**

   Since the last IRB review, have any of the following occurred?

   a. Have participants experienced any harms (expected or unexpected)? ☐Yes ☐No
      If yes, attach Problem Summary Sheet, and briefly describe here the harms (serious and/or non-serious) experienced by participants:_____

   b. Have there been any unanticipated problems involving risks to participants or others?
      ☐Yes ☐No
      If yes, attach Problem Report, and briefly describe here the unanticipated problems involving risks to participants or others:_____

   c. Have you have any problems obtaining informed consent? ☐Yes ☐No ☒N/A
      If yes, briefly describe the problems here:_____

   d. Have any participants or others complained about the research? ☐Yes ☐No
      If yes, briefly describe the number and nature of the complaints:_____

   e. Have any participants withdrawn from the research? ☐Yes ☐No
      If yes, indicate the number of withdrawals and include the reason for each:_____

f. Have any obvious, study-related benefits occurred for participants? ☐Yes ☐No
   If yes, briefly describe the benefits here:____

g. Have the risks or potential benefits of this research changed? ☐Yes ☐No
   If yes, briefly describe the changes here:____

h. Has there been any published literature? ☐Yes ☐No
   If yes, attach a copy and summarize the published findings here:_____

Principal Investigator's Signature:_____Heather J Sobles_____ Date:**August 30, 2010**

APPENDIX C

Kaiser Permanente IRB Approval Form

KAISER PERMANENTE   Kaiser Foundation Health Plan of Georgia, Inc.

This is an official communication from the Kaiser Permanente Georgia Institutional Review Board

Date:	August 30, 2010
Principal Investigator(s):	Douglas Roblin, PhD
Project/Protocol Title:	Using Measures of Engagement with KP.Org as Predictors of Clinical Outcomes
Protocol Number:	GA-10DRobl-03
Next IRB Review Date:	July 15, 2011

Thank you for submitting the referenced study to the Kaiser Permanente Georgia Institutional Review Board. It was reviewed on August 27, 2010.

In compliance with federal regulations established by the Food and Drug Administration and the Office of Human Research Protections in the Department of Health and Human Services, a designated member of the Kaiser Permanente Institutional Review Board (FWA 00002344, IRB 00000406) has performed an **Expedited Review** of the following document(s):

- IRB Application dated 7/7/10
- Proposal
- Sobko Biosketch

The Board approved the referenced study and Kaiser Permanente's participation. In addition, the following determinations were approved:
- The requirement that informed consent be obtained from study participants whose data will be used in the referenced study was waived.
- The requirement that Privacy Rule authorization be obtained from study participants whose data will be used in the referenced study was waived.

The approval for GA-10DRobl-03 is for a twelve-month period and reviews will be conducted at eleven-month intervals.

Please be reminded of the following:

- **The next IRB review of GA-10DRobl-03 is July 15,2011** The IRB approval expires on August 26, 2011
- Any proposed changes to the protocol or other study-related materials prior to the annual review must be approved by the Institutional Review Board prior to implementation **unless** an emergent modification is necessary to eliminate apparent immediate hazards to one or more subjects. Such emergent modifications must be reported to the IRB as soon as possible but no later than five business days.
- Any safety reports, unanticipated serious adverse events associated with any patient participating in the above-mentioned study; as well as any violation of confidentiality or privacy must be reported to the IRB according to policy.

Please direct all questions regarding the review process to Yvette Benjamin, IRB Administrator, at (404) 504-5543 or yvette.benjamin@kp.org.

Center for Health Research/Southeast
11 Piedmont Center
3495 Piedmont RD NE, Suite 110
Atlanta, GA 30305

APPENDIX D

Authorization for Program Director to Sign for Committee Chair

Erica R Pryor
_____

To: Jacqueline Ann Moss
Subject: RE: Exempt IRB form (per IRB recommendation)

_____

From: Jacqueline Ann Moss
Sent: Tuesday, August 31, 2010 12:01 PM
To: Erica R Pryor
Cc: Relay-sezzie
Subject: RE: Exempt IRB form (per IRB recommendation)

Erica,
I give you permission to sign the IRB application for Heather Sobko in my absence.

Jacqueline Moss PhD, RN
Associate Professor
Assistant Dean for Clinical Simulation and Technology
School of Nursing
University of Alabama, Birmingham
NB 356
1530 3rd Ave South
Birmingham, AL 35294
205-934-0657
mossja@uab.edu

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APPENDIX E

Kaiser Permanente Data Use Agreement for Disclosure of a Limited
Data Set for Research Purposes

Data Use Agreement
for Disclosure of a Limited Data Set
For Research Purposes

This Data Use Agreement for Limited Data Set ("Agreement") is effective on the date of the last signature below by and between _____Kaiser Permanente Georgia_____ [1]("Covered Entity") and _____Heather J. Sobko, RN, PhDc_____ [2]("Recipient") (collectively "the Parties").

The Covered Entity is providing Recipient with a Limited Data Set of Protected Health Information ("PHI") as defined in 45 Code of Federal Regulations (CFR) §164 ("HIPAA"). In order to ensure that all PHI provided is handled in full compliance with the requirements of HIPAA, and to protect the interests of both Parties, the Parties hereby agree as follows:

1.   **DEFINITIONS.** Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in HIPAA.

1.1   **Limited Data Set,**[3] as defined in the Privacy Rule at 45 CFR Section 164.514(e), is PHI that can include specific identifiers and must exclude others considered to be PHI. A Limited Data Set may **include**: 1) dates (e.g., admission, discharge, and service dates, dates of birth and death); and 2) five-digit zip codes and state, county, city, and precinct, but not any other postal address information. A limited data set must **exclude** the following direct identifiers of an individual and his or her relatives, employer(s), and household members: name; postal address information (except town or city, state and zip code which are permitted); telephone numbers; fax numbers; electronic mail addresses; Social Security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; license plate numbers and other vehicle identifiers and serial numbers; device identifiers and serial numbers; URLs; Internet Protocol (IP) address numbers; biometric identifiers including finger and voice prints; and full-face photographic and any comparable images. In the event of any conflict between this description and the definition in the Standards for Privacy of Individually Identifiable Health Information (45 CFR, Parts 160 and 164, Subparts A and E) ("the Privacy Rule"), the Privacy Rule definition will govern.

1.2   Security Rule means the Standards for Security for the Protection of Electronic Protected Health Information, codified at 45 CFR parts 160 and 164, Subpart C, effective April 20, 2005.

1.3   The following terms shall also have the meanings given to them in the Privacy Rule: Covered Entity, Individual, Protected Health Information, and Required by Law.

2.   **USE OR DISCLOSURE.** Recipient agrees to use or disclose PHI only for the purposes of the following research project , except as required by law:

Project Title:	[4] Associations Among measures of Engagement with KP.Org and Clinical Outcomes
Disclosing Party IRB ID #:	[5]GA-10DRobl-03
Date of IRB Protocol	[67]July 15, 2010

[1] Disclosing Party
[2] Data Recipient
[3] An Exhibit A may be appended listing the classes of data elements being transmitted pursuant to IRB approval
[4] Study Title
[5] Internal IRB number utilized by Disclosing Party's IRB

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3. **RESTRICTIONS ON USE.**

    a) Recipient agrees that it will not use or further disclose PHI other than as permitted by this Agreement or as otherwise required by law.

    b) Recipient shall use appropriate safeguards to prevent any use or disclosure of PHI other than as specified in this agreement. To the extent that Recipient receives, creates, maintains or transmits Electronic PHI, Recipient shall use appropriate administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any Electronic PHI.

    c) Recipient shall not attempt to identify or contact the individuals to whom the PHI pertains.

    d) Recipient shall ensure that any agent or subcontractor to whom it provides PHI agrees in writing to the same terms set forth herein regarding the use and disclosure and security of PHI. Recipient shall terminate its agreement with any agent or subcontractor to whom it provides PHI if such agent of subcontractor fails to abide by any material term of such agreement.

    e) Recipient shall comply with applicable state and local security and privacy laws to the extent that they are more protective of the individual's privacy than the HIPAA Privacy Rule and Security Rule.

4. **REPORTING.** Recipient agrees to report to Covered Entity any use or disclosure of the PHI not provided for by this Agreement of which it becomes aware, or any Security Incident of which it becomes aware. Such reporting shall take place within 10 days of Recipient's becoming aware of the unauthorized use or disclosure.

5. **TERMINATION.**

    a) This Agreement shall be effective on the Effective Date set forth above and shall continue as long as Recipient retains the data, unless otherwise terminated by law.

    b) Recipient may terminate this Agreement by returning or destroying the PHI and providing written verification of this to the Covered Entity.

    c) Should the Covered Entity become aware of a pattern of activity or practice on the part of Recipient that constitutes a material breach of this Agreement, the Covered Entity shall have the right to summarily terminate this Agreement.

    d) This Agreement is valid only if the data set of PHI being provided meets the definition of a "Limited Data Set" as specified in HIPAA. Both Parties believe that the PHI does meet this definition. If, subsequent to implementation of this Agreement, either Party becomes aware that the PHI data set exceeds the definition of a Limited Data Set, this Agreement shall be terminated, and Recipient agrees to follow the Covered Entity's directions with respect to the return or destruction of the PHI. In this event, the Parties agree to make reasonable efforts to devise alternative means of providing the PHI to recipient in compliance with HIPAA.

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[6] Date of IRB approval that has authorized data to be shared

[7] In the event that an IRB modification results in any alteration to the PHI to be disclosed from the IRB approval noted above, the parties agree that any such data disclosure is also bound by the terms of this DUA and a modification or addendum to this DUA is not necessary.

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6. **MISCELLANEOUS**

a) Data Recipient agrees to mitigate, to the extent feasible and allowed by law, any harmful effect that is known or becomes known to Data Recipient that arises from a use or disclosure of the Limited Data Set by Data Recipient or its agents in violation of this Agreement, the Privacy Rule, or the Security Rule.

b) Within ten (10) business days of a written request by Data Provider, Data Recipient shall allow Data Provider to conduct a reasonable inspection of Data Recipient's facilities, systems, books, records, agreements, and policies and procedures relating to the use or disclosure of the Limited Data Set for the purpose of determining Data Recipient's compliance with this Agreement. Any failure of Data Provider to inspect or to detect or notify Data Recipient of an unsatisfactory practice does not constitute acceptance of the practice by Data Provider or a waiver of any remedy or right Data Provider has under the Agreement or applicable law.

c) When Data Provider reasonably concludes that an amendment to the Agreement is necessary to comply with applicable law, Data Provider shall notify Data Recipient in writing of the proposed modification(s) ("Legally-Required Modifications"). Data Provider shall request Data Recipients written approval in the form of an amendment to this agreement at the time of notification. Data Recipient shall have thirty (30) days to sign the amendment and return it to Data Provider. Data Recipient's rejection of a Legally Required Modification is grounds for termination of the Agreement by Data Provider on thirty (30) days written notice.

d) Responsibilities of Recipient. Recipient will comply with the requirements of 45 CFR Sections 164.524 (Access of Individuals to PHI), 164.526 (Amendment of PHI) and 164.528 (Accounting of Disclosures of PHI) as directed by Covered Entity.

e) Any ambiguity in this Agreement relating to the use and disclosure of the Limited Data Set by Recipient shall be resolved in favor of a meaning that further protects the privacy and security of the information.

10/25/10

Date

For Covered Entity

Robert L. Davis, MD, MPH
Director of Research
Printed Name & Title

10/26/2010

Date

Heather J Sobko

For Recipient

Heather J. Sobko, RN, PhDc
Doctoral Student/Clinical Research Coordinator
Printed Name & Title

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APPENDIX F

Exhibit A: To the Data Use Agreement for Research Study

EXHIBIT A
To the Data Use Agreement for Research
Study Title:
Associations Among Measures of Engagement with KP.Org and Clinical Outcomes

1. **Description of the Study:** The purpose of this study is to assess the association between the use of the Kaiser Permanente Georgia online personal health record (KP.Org), intermediate patient-centered process measures, and physiological control measures among a cohort of Kaiser Permanente Georgia enrollees diagnosed with one or more of these chronic conditions: a) diabetes (DM), b)hypertension (HTN) or c) hyperlipidemia (CHOL) who logged on to the KP.Org system at least one time during calendar year 2008.

Aim 1. Initial KP.Org logon in calendar year 2008 will serve as the initial measure of engagement with the system. Pre-exposure information will be assessed by examining the variables of interest at 6 months prior to initial KP.Org Logon. Records will be followed forward for a period of 14 months following KP.Org initial logon to describe patterns of use of the PHR and to evaluate change over time on variables including:
   A. Secure messaging patterns (communication exchanges between patients and providers)
   B. Frequency of logon to KP.Org
   C. Timing of logon to KP.Org after last clinical appointment(e.g., time from appointment to time of logon for the purpose of accessing visit-related information such as laboratory or test results, patient educational materials or viewing a summary of information from the clinical appointment)
   D. Patterns of use (combinations of transaction types and frequency of use of specific KP.Org feature such as scheduling appointments, requesting medication refills, or requesting medical advice)

AIM 2: Define and calculate intermediate patient-centered process measures (proximal dependent variables) including:
   A. Medication adherence (as measured by medication refill and medication possession ratios)
   B. Appointment attendance ratios (ratio of appointments scheduled and appointments kept)
   C. Laboratory test completion (ratio of laboratory tests recommended or scheduled and tests actually performed within recommended time frame)

AIM 3: Assess the cross sectional and longitudinal associations of KP.Org use and improvement of intermediate outcomes at pre-exposure and over time.

AIM 4: Assess the cross sectional and longitudinal relationship between KP.Org use and physiologic metabolic control measures at pre-exposure and over time including:
   A. Hemoglobin A1c measures (HbA1c)
      Optimal rage: < 7
   B. Low density lipoprotein (LDL) levels
      Optimal range: ≤ 100
   C. Blood pressure (BP)
      Optimal range: $\leq 130/80$

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Table 1: Study Variables		
Measures of Use	**Measures of Adherence and Compliance (proximal outcomes)**	**Physiologic Control Measures (distal outcomes)**
Secure messaging patterns	Medication possession ratio	Hemoglobin A1c (HbA1c)
Frequency of Logon	Appointment attendance ratio	Low density lipoprotein levels(LDL)
Time from appointment to KP.org logon	Laboratory test completion ratio	Blood Pressure (BP)
Use patterns of specific KP.org features		

<u>Inclusion Criteria/ Participant Records</u>: The cohort for this study shall consist of de-identified records of adult members of KPGA (age 21 or older) in the Atlanta metropolitan area who have been diagnosed by a healthcare provider with any of the following : a) diabetes, b) hypertension, c) hyperlipidemia, and who logged on to the KP.Org at least one time during calendar year 2008, and were members of KPGA for a period of at least 6 months prior to and 14 months following initial KP.Org initial logon.

General hypothesis: There will be a positive relationship, demonstrated by improvement in the proximal and distal dependent variables, associated with higher frequency of KP.Org use. Proximal patient-centered behavioral measures of adherence and distal physiologic measures of metabolic control will be included in the analysis.

Hypothesis 1: Among adult members of KPGA (age 21 or older) who have been diagnosed with one or more specific chronic condition (diabetes, hypertension, hyperlipidemia), and logged on to KP.Org at least one time during calendar year 2008, increased use of KP.org (greater than one occasion) will be associated with better intermediate patient-centered process measures of adherence including a) medication possession ratios, b) appointment attendance ratios, and c) laboratory test completion ratios measured from the time six months prior to the first KP.org logon up to the time 14 months following the initial KP.org logon.

Hypothesis 2: Among adult members of KPGA (age 21 or older) who have been diagnosed with diabetes, hypertension or hyperlipidemia and used the KP.org at least one time during calendar year 2008, increased use of KP.org (greater than one occasion) will be associated with better physiologic control measures including a) HbA1c, b) blood pressure, and, c) lipid measures from pre-exposure to KP.Org up to the time 14 months following the initial KP.org logon.

2. **Limited Data Set 1:** This is a secondary analysis using data from calendar years 2007-2009. De-identified data from Kaiser Permanente Georgia (KPGA) will be examined and analyzed to discover if there are associations between use of the KPGA online personal health record system (KP.Org) and selected clinical outcomes. The dataset will include adult members of KPGA (age 21 or older) who have been diagnosed with diabetes, hypertension or hyperlipidemia and logged on to the KP.Org system at least one time during calendar year 2008. A sample data set will be provided to the principal investigator, who will use the sample data to develop programming for statistical analysis. After rigorous testing of the programming for statistical analysis, the program will be sent to KPGA where KPGA authorized research scientists will run the actual data through the statistical program. Information from the analysis will be provided to the principal

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investigator in aggregated form. All data will be deidentified and will NOT contain PHI. The principal investigator will evaluate the aggregated data analysis for development of findings and discussion as part of her dissertation project.

The limited data set will consist of the following:
- StudyId (randomly generated patient identification number)
- Study Site
- Demographics: Patient sex, race, age group, geostrata score
- Medication Use: (including average daily Dose dispensed)
- Follow-up time (days from in-person visit to earliest logpon to KP.Org)
- Lab values: HbA1c values; Cholesterol panels (HDL/LDL/Trig/Total Chol prior to and during observation time (frequency and presence of abnormal values)
- Blood pressure measures: prior to and during observation time
- Diagnoses: diabetes, hypertension, hypercholesterolemia
- Appointment attendance ratios (number of attended appointments divided by number of scheduled appointments)
- Frequency and timing of Logons to KP.Org

Each patient record will be assigned a unique study ID. The linking code for the study ID will be securely stored at Kaiser Permanente Georgia and will not be disclosed with the limited data set.

Limited Data Set 2: A revised final dataset updated from above may also be sent.

3. **Permitted Uses:** Data Recipient may only use Protected Health Information for the Study as follows: Data recipient may use the Limited Data Set 1 described above to compile a final data set which will include data from all participating sites. No Protected Health Information will be included in the dataset. All manuscripts resulting from Kaiser Permanente Georgia data must be approved by the Kaiser Permanente Georgia study team (site investigator Douglas Roblin, PhD) prior to submission.

4. **Permitted Disclosures:** Data Recipient may only disclose the Limited Data Set 1 for the Study as follows: Data Recipient may only disclose the compiled data set described above to participating sites as necessary to conduct data analysis for the study described above.

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APPENDIX G

Kaiser Permanente Data Use Agreement Signature Page

IN WITNESS WHEREOF, the parties agree as follows:

Data Provider	Data Recipient
By:	By:
Name: Robert L. Davis, MD, MPH Kaiser Foundation Health Plan of Georgia, Inc. The Center for Health Research / Southeast	Name: Heather J. Sobko University of Alabama at Birmingham School of Nursing
Title: Director of Research	Title: Doctoral Candidate/ RN
Date:	Date: 10/20/2010

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