PATIENT PORTAL USE AND ITS ASSOCIATION WITH CLINICAL OUTCOMES IN PATIENTS WITH TYPE 2 DIABETES

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Background: The rapid growth of type 2 diabetes mellitus (T2DM) in the United States presents significant challenges. Patient portals are promising tools that address the increasing number of individuals with T2DM and engage these people in the process of managing their chronic condition. **Objectives:** The purposes of this study were: 1) to describe the portal usage pattern by individuals with T2DM over the two-year study period; 2) to identify whether sociodemographic, socioeconomic, and clinical characteristics differ between portal users and non-users; and 3) to longitudinally examine the effect of portal use on glycemic control in patients with T2DM. **Methods:** This two-year retrospective, observational cohort study utilized data from the ambulatory electronic health records (EHR) of the University of Pittsburgh Medical Center (UPMC) Physician Services and its ancillary patient portal. The study included adults seen in an outpatient setting of UPMC between January 2015 and December 2016. We applied descriptive statistics to describe sample characteristics and portal usage patterns. Logistic regression was used to examine factors associated with portal use. A propensity score matching (PSM) technique was conducted to equate the portal user and non-user groups, and mixed modeling was performed to examine the effect of portal use on hemoglobin A1c (HbA1c) over time. **Results:** Nearly one-third of the individuals (n=12,615, 32.9%, 95% CI: [32.3%,33.3%]) with T2DM used the portals. An increased portal usage was observed before and after a physician visit, and on weekdays compared to weekends ($p<0.001$). In general, we found associations of age, race, income, and the number of chronic conditions with portal usage, and several other predictors modified these effects ($ps<0.05$). After PSM, both groups showed a non-linear decline of HbA1c over time ($p<.001$), and the portal users (n=4,924) demonstrated a greater decrease and better maintenance than the non-users (n=4,924, $p<.001$). **Conclusions:** Our findings highlight the promising effect of a patient portal on clinical glycemic control in persons with T2DM. Disparities in patient portals need to be addressed to bridge the existing gaps in diabetes outcomes. Future study should explore mechanisms through which the portal contributes to better clinical outcomes to guide evidence-based portal design and implementation.

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Preface

During my journey to the Ph.D. degree, I have received profound support from many people. I would like to acknowledge those who encouraged me with love and understanding.

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1.0 PROPOSAL

1.1 SPECIFIC AIMS

Diabetes affected 30.2 million U.S. adults in 2017 (Centers for Disease Control and Prevention, 2017a) and the prevalence of diabetes is expected to increase to nearly 55 million by 2030 (Rowley, Bezold, Arikan, Byrne, & Krohe, 2017). Type 2 diabetes mellitus (T2DM) is the most common form of diabetes, accounting for 90% to 95% of all cases (Centers for Disease Control and Prevention, 2017b). To optimally manage their T2DM, patients need to be equipped with knowledge, skills, and ability to consistently perform self-care activities, including adopting a healthy eating plan, performing regular physical activity, and taking medication (Powers et al., 2017). Moreover, effective diabetes care requires integrated efforts by patients and healthcare providers, characterized by greater coordination, communication over time and between visits, tailored services to each patient's needs and preferences, and shared patient-provider responsibility (Singer et al., 2011). The current healthcare system, however, does not meet all of the needs of persons with chronic conditions (Priester, Kane, & Totten, 2005).

Emerging technologies are transforming healthcare delivery and creating opportunities to manage chronic conditions for a larger population. Since the passing of the Health Information Technology for Economic and Clinical Health Act in 2009, healthcare organizations have widely adopted health information technology, such as patient portals, to meet patient needs. Patient portals, also referred to as tethered personal health records (PHR), are a secure online website providing patients access to their own health information. This technology is becoming increasingly popular in healthcare systems. By 2015, nearly 70% of the U.S. hospitals had

provided patients access to view, download, and transmit their health information online (Office of the National Coordinator for Health Information Technology, 2015). Patient portals hold the potential to improve patient-provider communication and engage patients and families in healthcare, which can lead to improved clinical outcomes, especially for management of chronic diseases such as diabetes, hypertension, and cancer (Sorondo, Allen, Fathima, & Bayleran, 2016).

Researchers focusing on persons with diabetes have investigated the effects of patient portal use on glycemic control and found inconsistent findings. Using a randomized controlled trial (RCT) design, Ralston et al. examined the impact of using an online portal for diabetes management on changes in HbA1c among individuals with uncontrolled glycemic control. Compared to the usual care group, the intervention group had a greater reduction in HbA1c at 12 months (Ralston et al., 2009). Four other RCTs did not find an improved HbA1c at the end of the study compared to the usual care group (Grant et al., 2008; McCarrier et al., 2009; Tang et al., 2013; Vugt et al., 2016). In addition to these RCTs, three observational studies examined the association of portal use with HbA1c. Tenforde et al. found a significantly lower HbA1c among portal users than non-users (Tenforde, Nowacki, Jain, & Hickner, 2011). Harris et al. demonstrated that frequent use of electronic messaging was associated with HbA1c < 7% (relative risk [RR] = 1.36, 95% CI:1.16–1.58) (Harris, Haneuse, Martin, & Ralston, 2009). A more recent study observed that persons with uncontrolled blood glucose (i.e., HbA1c ≥ 7%) at baseline were more likely to achieve HbA1c < 7% at follow-up if they used the secure messaging for two years (odds ratio [OR] = 1.24, 95% CI:1.14–1.34) and more (OR = 1.28, 95% CI:1.12–1.45) (Shimada, Allison, Rosen, Feng, & Houston, 2016); however, this study examined only certain features within the portal and did not investigate the overall effect of the patient portal.

In recent years, patient portals have received greater attention and gained rapid acceptance by patients and providers; yet few current studies have described the usage pattern of the portal by

persons with T2DM. Moreover, our review of the literature revealed that no studies have longitudinally examined the association between patient portal use and HbA1c. In an effort to address these issues, we propose a study using data from the ambulatory electronic health records (EHR) of the University of Pittsburgh Medical Center (UPMC) physician services to describe portal use by individuals (N=38,399) with T2DM between January 2015 and December 2016. Additionally, we examined whether the portal use was associated with HbA1c outcome over time. Hence, the **Primary Specific Aims** were:

Aim 1: To describe the pattern of portal use by individuals with T2DM during the period of January 2015 to December 2016

1a: To describe the portal features used by individuals and how frequently each feature was used (i.e., the number of users and the total volume)

1b: To describe the frequency of portal use during weekdays as compared to on weekends and in relation to clinic visits

Aim 2: To identify predictors (e.g., age, gender, race, education, income, insurance type, number of chronic conditions) of portal use (use vs. non-use)

The **Exploratory Aim** is:

Aim 3: To longitudinally examine the association of portal use with HbA1c among individuals with uncontrolled glycemic control (HbA1c > 7%)

1.2 BACKGROUND AND SIGNIFICANCE

1.2.1 Background

1.2.1.1 Diabetes prevalence, complications and economic burden in the United States (U.S.)

A 2017 CDC report revealed that approximately 30.3 million people of all ages, or 9.4% of the U.S. population, have diabetes (Centers for Disease Control and Prevention, 2017a). The prevalence is projected to increase by 54% to more than 54.9 million Americans by 2030 (Rowley et al., 2017). Among all diabetes cases, nearly 90% to 95% are T2DM (Centers for Disease Control and Prevention, 2017b). Optimal glycemic control effectively minimizes the complications; however, nearly half of patients did not achieve their glycemic control as measured by hemoglobin A1c (HbA1c) at less than 7% (Carls, Huynh, Tuttle, Yee, & Edelman, 2017; Menon & Ahluwalia, 2015). Poorly controlled T2DM increases the risk for developing serious macro- or microvascular complications, including heart disease, visual impairment, renal disease, and lower-extremity amputation (Fowler, 2008; Gerstein & Werstuck, 2013). These complications have led to significant economic consequences. More than 20% of healthcare spending is for the care of individuals with diabetes (Centers for Disease Control and Prevention, 2016). The medical and societal costs related to diabetes is projected to increase from $408 billion in 2015 to over $622 billion by 2030 (Rowley et al., 2017). In summary, T2DM is a growing problem facing U.S. healthcare systems, and it is critical to identify strategies to better manage the increasingly large proportion of the population with diabetes.

1.2.1.2 Management of type 2 diabetes

Diabetes management is burdensome, requiring affected patients to acquire the knowledge,

skills, and ability to consistently perform self-care activities (e.g., healthy eating, regular physical activity, adherent medication taking), attend regular clinic visits, and manage other comorbid conditions (American Diabetes Association, 2017; Powers et al., 2017). Moreover, effective diabetes care requires integrated efforts by patients and healthcare providers, characterized by greater coordination, communication over time and between visits, tailored services to each patient's needs and preferences, and a shared patient-provider responsibility (Singer et al., 2011). The current healthcare system, however, is structured to diagnose and treat acute medical conditions rather than chronic conditions. Thus, it limits the system's ability to fully meet the needs of persons with chronic conditions (Anderson, 2010). Considering the growing prevalence and the extensive demands on the current healthcare system to manage such a complex chronic disease, it is imperative to identify innovative approaches to address these challenges.

1.2.1.3 Patient portals and their functionality

The emerging technologies are transforming healthcare delivery and creating opportunities to manage chronic conditions for a larger proportion of the population. Healthcare organizations have commonly adopted electronic health record (EHR) systems and incorporated a patient portal as an essential component in their system. Patient portals are often tethered to an institution's electronic health record. The functionalities offered by each patient portal vary across systems. Most portals allow patients to view lab results, schedule appointments, request medication refills, receive visit summaries, and electronically communicate with healthcare providers. More advanced portals enable individuals with multiple chronic conditions to record their symptoms and test results (such as blood glucose or blood pressure readings) that can be seen by providers (Office of the National Coordinator for Health Information Technology, 2013). More recently, patients are able to access their patient portal information from their tablets or smartphones. With this instant

access to health record data, patients may become more engaged with their health conditions and proactive about questions and concerns related to their diseases.

1.2.1.4 Regulation and Meaningful Use

Several Centers for Medicare and Medicaid Services (CMS) programs promote the use of patient portals. The Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009 launched the EHR use incentive program, often referred to as "Meaningful Use," wherein those physicians and healthcare systems that meet the criteria for the three stages of Meaningful Use would receive financial incentives. Stage 2 of the Meaningful Use incentive program requires patients to 1) view online, download, and transmit information about a hospital admission and 2) communicate electronically using secure messaging on relevant health information (Healthcare Information and Management Systems Society, 2014). Eligible professionals must provide 50% of patients with access to an electronic copy of their health information, and 5% of their patients must view, transmit, or download their health information. Additionally, providers must implement notifications for follow-up appointments and identify clinically relevant health information to more than 10% of their patients with two or more appointments in the preceding two years (Centers for Medicare and Medicaid Services, 2014).

In the current era of the Medicare Access and CHIP Reauthorization Act (MACRA), healthcare systems place greater emphasis on patient engagement and quality of care. Under one of the two MACRA reimbursement tracks, the Merit-based Incentive Payment System (MIPS), physicians are rated based on their performance categories: advancing care information (ACI), quality, improvement activities, and cost. Each of the performance categories is considered dependent heavily on features provided in patient portal technology, such as receiving reminders of services due and secure messaging with providers (Rodocker, 2016).

1.2.1.5 Patient portal adoption by healthcare providers and patients

These CMS payment incentive programs have been successful in boosting the adoption rate. Healthcare organizations are committed to increasing the number of patients who use the portal and developing a comprehensive approach to having patients registered and supporting their use of the portal. The percentage of hospitals that have provided patients with the capability to view, download, and transmit their health information online has risen exponentially from 10% in 2013 to 69% in 2015 (Office of the National Coordinator for Health Information Technology, 2015). A recently conducted survey with 1,756 healthcare leaders revealed that 90% of healthcare organizations offer portal access to patients (Medical Group Management Association, 2018). Physicians have made similar progress in expanding their capability for supporting portal use with their patients. For example, 64% of physicians exchanged secure messages with their patients, 63% provided access to patients to view medical record, 41% permitted patients to download their health record, and 19% electronically transmitted their health record to a third party (The Office of the National Coordinator for Health Information Technology, 2015).

As more healthcare providers offer these services, patients have a growing interest in registering for patient portals to perform routine medical-related tasks and interact with providers. Patient enrollment in some well-established health systems is high. Kaiser Permanente, an institution that has used portals for over a decade, reported that over 70% of eligible adult members registered to use its patient portal since the third quarter of 2015 (T. Garrido, Raymond, & Wheatley, 2016). It is estimated that the percentage of people who will adopt a PHR is expected to exceed 75% by 2020 (Ford, Hesse, & Huerta, 2016).

1.2.1.6 Conceptual framework

The proposed study is based on the Chronic Care Model (CCM), which represents a comprehensive model of care to meet the needs of the growing numbers of people with chronic disease in a primary care setting (E. Wagner, 1998). The 2015 position statement by the American Diabetes Association has recommended that diabetes care should be concentrated on the components of CCM to ensure productive patient-provider interactions between informed patients and a prepared care team (American Diabetes Association, 2015). This model of care posits four main components that facilitate the productive interactions: 1) self-management support, 2) delivery system design, 3) decision support, and 4) clinical information system within community and health systems. A systematic review of 16 studies from 1999 to 2011 using CCM-based interventions demonstrated positive clinical outcomes for managing diabetes in primary care settings (Stellefson, Dipnarine, & Stopka, 2013).

The CCM model was further modified by Gee et al. in 2015, which offered insight into the role of health information technology (e.g., mobile health, patient portals) in self-management support for people with chronic conditions (Gee, Greenwood, Paterniti, Ward, & Miller, 2015). Gee et al. conducted a review of 95 papers on technology and chronic disease self-management support. The results strengthened the contribution of eHealth tools to the CCM and suggested that patient outcomes could be further enhanced by adding eHealth education and a complete feedback loop (Gee et al., 2015).

1.2.1.7 Literature review of patient portals for diabetes management

Patient portals enable continuous patient-centered care and are intended to improve patient-provider communication, engage patients and families in healthcare, and result in improved clinical outcomes, especially for management of chronic diseases such as diabetes (Sorondo et al.,

2016). Patient portals have been considered to potentially fill the unmet needs related to chronic disease management and improve chronic care by facilitating continuous patient education and ongoing communication regarding symptoms, medication and side effects (Umejei & Wiafe, 2010). Many patients' needs could potentially be met more quickly and at a lower cost through patient portals.

Earlier randomized controlled trials (RCT) were conducted to examine the impact of patient portals on blood glucose control among individuals with T2DM revealing inconsistent results. A 12-month study by Tang et al. evaluated the online disease management system developed by the Palo Alto Medical Foundation for individuals with uncontrolled diabetes (i.e., A1c $\geqslant$ 7.5%). The researchers found a significantly reduced A1c in the intervention group (n = 193) compared to the usual care group (n = 189) at 6 months (-1.32% vs. -0.66%, $p < 0.001$), but not at 12 months (-1.14 vs. -0.95%, $p = 0.133$) (Tang et al., 2013). Another RCT (N = 83) conducted by Ralston et al. at the University of Washington General Internal Medicine Clinic demonstrated a greater decrease in glycated hemoglobin (GHb) in the intervention group than the usual care group at 12 months (change -0.9% vs. 0.2%, $p = 0.01$) (Ralston et al., 2009). However, two RCTs failed to observe significant changes in HbA1c over time or an overall difference between groups. Grant et al. included 244 persons with diabetes from the Partners HealthCare system and assigned them to one of the two study arms containing different PHR content. No significant difference was observed in HbA1c between the study arms after a 1-year follow-up (Grant et al., 2008). A more recent study conducted at the VU University Medical Center in the Netherlands used the PHR e-Vita for persons with T2DM (N = 132) in a primary care setting. The 2-group 6-month study aimed to test the effect of a personal health record including a self-management support program with and without coaching on diabetes-related outcomes, including diabetes self-care, diabetes-related distress, emotional wellbeing, and health status (e.g., HbA1c).

The results demonstrated a minimum impact of utilizing a PHR including self-management support on diabetes-related outcomes (Vugt et al., 2016).

Three observational studies examined the association of portal use with HbA1c. Two of the three studies investigated a certain single feature (e.g., secure messaging, online medication refill) within the portal. Shimada et al. conducted a retrospective study of veterans with diabetes registered for the MyHealth*e*Vet patient portal. The individuals with uncontrolled glycemia (i.e., HbA1c $\geq$ 7%) at baseline tended to achieve glycemic control (i.e., HbA1c < 7%) after two (OR = 1.24, 95% CI: 1.14–1.34) or more years of secure messaging use (OR = 1.28, 95% CI: 1.12–1.45); however, the online medication refill feature was not associated with glycemic control (Shimada et al., 2016). A cross-sectional study focusing only on the secure messaging feature revealed that frequent use of secure messaging (over 12 threads) was associated with controlled blood glucose (RR = 1.36, 95% CI: 1.16–1.58) among Group Health Cooperative patients (Harris et al., 2009). Finally, a study that examined the overall effect of the PHR on 10,746 adults at the Cleveland Clinic demonstrated that an incremental increase in portal use was associated with a minimum decrease in HbA1c (0.02%, $p < 0.01$) (Tenforde et al., 2011).

There are major gaps in the literature on patient portals for diabetes management. First, most of the existing studies used cross-sectional study design, thus limiting their ability to identify or relate events to certain exposure and establish the sequence of events (Caruana, Roman, Hernández-Sánchez, & Solli, 2015). Few studies have longitudinally examined the association between patient portal use and HbA1c. Second, the small sample sizes in most of the studies make them difficult to infer conclusions about the non-linear associations (i.e., quadratic or cubic changes over time) and to detect interactions among predictors, while relatively larger sample sizes enable more complicated statistic models that capture and convey richer information. Last, in recent years, patient portals have received greater attention and gained rapid acceptance by patients

and providers, especially after the launch of the Meaningful Use incentive program; yet, the majority of studies were conducted earlier, and few current studies have described the usage pattern of the patient portal in patients with T2DM. The proposed study addresses these gaps.

1.2.2 Significance and Innovations

1.2.2.1 Significance

The Institute of Medicine (IOM) called for a redesign of the healthcare delivery system toward continuous, coordinated care, and a leveraging of information technology, especially for chronic conditions that require frequent monitoring and ongoing support (Institute of Medicine, 2001). The use of patient portals could address these demands for ongoing care for chronic illnesses such as diabetes, but the evidence is limited as to how to use this technology to improve diabetes-related outcomes. It is important, therefore, to understand which persons use the portal, how they use it, and whether this usage will affect the clinical outcomes for persons with diabetes. Thus, the proposed study is significant because the findings could do the following:

- Provide a timely and detailed description of the actual use of patient portal features offered as part of an EHR by an integrated healthcare organization
- Reveal disparities in access to the patient portal between patient groups to further identify strategies for reducing disparities and, consequently, improving diabetes outcomes;
- Apply to other patient populations using patient portals as an innovative and promising approach to support chronic disease management; and
- Expand knowledge about the effectiveness of our healthcare system to support disease management pertaining to the broader domain of using technology as a tool in chronic disease management.

1.2.2.2 Innovation

The proposed study is innovative because it does the following:

- Leverages the existing EHR data to provide evidence on the use of information technology for chronic conditions, specifically the use of patient portals to manage diabetes management; and
- Applies the propensity score matching to mimic certain characteristics of randomized controlled trials and then longitudinally examines the association between portal use and HbA1c using available repeated measures data.

1.3 RESEARCH DESIGN AND METHODS

1.3.1 Study design

This study was a two-year retrospective, observational cohort study. The data being used were from the ambulatory electronic health records of UPMC Physician Services and its ancillary source of the patient portal.

MyUPMC, previously called UPMC HealthTrak, is the name of the patient portal system, which is linked to the EpicCare (MyChart product) EHR system. This web-based portal has been available to UPMC patients since 2007. The service, which is free to all patients18 years of age or older, is also available for mobile devices using the MyChart application. Patients can perform a wide variety of actions through the portal: accessing portions of their EHRs by linking them to their medical history and test results; renewing prescriptions; managing appointments; viewing

billing statements and making payments; and manually uploading blood pressure or glucose readings. By 2014, nearly 240,000 patients had registered an account with MyUPMC.

1.3.2 Sample

UPMC is a non-profit, integrated health system located in Western Pennsylvania containing more than 30 academic, community, and specialty hospitals and over 600 doctors' offices and outpatient sites. For this study, the cohort of individuals with DM was determined by the presence of the International Classification of Diseases, Ninth Revision (ICD-9) diagnosis codes of 250.* and the International Classification of Diseases, 10th Revision (ICD-10) diagnosis codes of E11.* between January 2015 and December 2016. To accurately identify individuals with DM in the UPMC dataset, two or more indicators, as suggested from a previous study, need to be applied (Zgibor et al., 2007). Therefore, we included in this study only patients who had any HbA1c assessments and were prescribed with diabetes medications during the study period. Patients who potentially had type 1 diabetes (T1DM) were excluded as indicated by the following either 1) having only ICD-9 codes for T1DM (250.x1 or 250.x3) with no ICD-9 codes for T2DM diagnosis, or 2) being younger than 40 years old and taking only insulin (Lo-Ciganic, Zgibor, Ruppert, Arena, & Stone, 2011). Furthermore, patients were removed if they were 1) new to the portal as determined by having no record of portal activities before 2015, 2) newly diagnosed with T2DM during the study period based on patients' problem list, and 3) had only one specialty care visit over the study period, since these patients may not be ongoing consumers of the UPMC health system. To longitudinally examine the association between portal use and HbA1c in individuals with uncontrolled blood glucose, we only included patients who had two or more HbA1c assessments with their initial HbA1c value equal to or greater than 7%.

1.3.3 Measures

Patient portal use Information captured regarding portal access included the date of access and the type of activities performed within the portal. The type of activities performed by users was grouped into six categories: view lab results, view medical summary, electronic messaging, manage appointment, update and share medical information, and renew prescriptions. For each category, we counted the number of users who have used that feature for 1-9 times, 10-19 times, more than 20 times during the 2-year study period. Also, we calculated the frequency of the overall portal use as well as the frequency of use for each type of activity over time. To address Aim 2 and Aim 3, we analyzed the portal use as a binary variable (any use vs. non-use).

Sociodemographic and socioeconomic characteristics Sociodemographic factors extracted from the EHR were age (years), gender (male or female), race (white, black, or other), and type of insurance (government programs, commercial, self-insured, or other). We linked the following neighborhood-level socioeconomic ratio variables from the US Census Bureau's 2011-2015 American Community Survey (five-year estimates)(US Census Bureau, 2015) to each patient via their five-digit zip code: income (the median household income in the past 12 months in 2015 inflation-adjusted dollars); educational attainment (the percentage of residents who have attained a bachelor's degree or higher); and urbanization (the percentage of urban residents in a specific zip code).

Clinical characteristics Glycemic control was measured using HbA1c, an indicator of long-term glycemic control that reflects mean glycemia over the previous 8 to 12 weeks. The repeatedly measured HbA1c and the date of measurements over the two-year study period were extracted from laboratory test data. We identified the initial HbA1c date and value and the frequency of HbA1c tests for each patient. For two or more HbA1c tests performed less than two

weeks apart, we kept only the first measurement of HbA1c in our analysis because 1) HbA1c is an indicator of average glucose in the past two or three months and 2) the HbA1c values measured within a short time span were close or identical.

The number of chronic conditions was determined from the encountered diagnosis for each patient. We used the Chronic Condition Indicator (CCI), found in the Clinical Classification System (CCS) developed as part of the Healthcare Cost and Utilization Project (HCUP) sponsored by the Agency for Healthcare Research and Quality (AHRQ) (Agency for Healthcare Research and Quality, 2016), to determine whether an ICD code represents a chronic condition or non-chronic one. We then calculated a new continuous-type ratio variable–the number of chronic conditions–by adding up the number of distinct chronic conditions in addition to diabetes for each patient during the study period.

Medication information was retrieved from the medication prescriptions. Insulin use and oral agents for T2DM were identified using the therapeutic classes according to the American Hospital Formulary Services (AHFS) Pharmacologic-Therapeutic Classification System (American Society of Health-System Pharmacists, 2016). The number of distinct diabetes medications prescribed to each patient was calculated. Insulin use was a binary variable (yes/no) representing whether or not the patient was prescribed insulin.

Patient weight and height were measured at each clinical visit. To determine a patient's body mass index (BMI), we used the mode of all height assessments and the median weight of each patient. The BMI was calculated as (weight in pounds*703) / (height in inches)2.

Healthcare utilization The date of outpatient visits and the specialty (e.g., internal medicine, cardiology, endocrinology) of visits were retrieved. Two types of visits were used in this study and included visits to an endocrinologist (yes/no) and visits to a primary care physician (PCP, the frequency of visits during the study period). Additionally, the documented telephone

contacts of patients with healthcare providers over the 2-year period were received, and the number of telephone contacts was then calculated for each patient.

Most of these variables, which were related to sociodemographic and socioeconomic characteristics (e.g., age, gender, race, education, household income) and clinical characteristics (e.g., number of chronic conditions, number of distinct diabetes medications, insulin use), served as descriptors or predictors. For Aim 3, we matched portal users and non-users on variables (e.g., BMI, insulin use, visit an endocrinologist) that were significantly associated with the HbA1c outcome.

1.3.4 Statistical analysis plan

Statistical analyses were conducted using R Statistical Software (R version 3.5.1 and R Studio 1.1.456) for Mac.

1.3.4.1 Sample size justification

This study used existing data from the electronic health record over the two-year period; thus, the sample size was fixed (N = 38,399) after applying the cohort selection criteria. When describing the pattern of portal use by individuals with T2DM in terms of the portal features used and how frequently each feature was used (i.e., the number of users and the total volume of accesses) and the frequency of portal use in relation to clinic visits (Aim 1), proportions and means were estimated with margins of error (in terms of the half-width of two-sided confidence interval) of .005 (conservatively assuming a base proportion 0.50) and 0.009σ (where σ is the population standard deviation of the particular continuous type variable of interest), respectively, with 95% confidence.

When examining patient predictors of portal use (Aim 2) with a total sample of 38,399, of which 12,615 (32.9%) were expected to be portal users, unadjusted odds ratios (ORs) for portal use as small as 1.043 for continuous type predictors (that are linear in the logit and follow a normal distribution) could be detected with 90% power at an adjusted, testwise significance level of 0.01 for two-sided hypothesis testing. Adjusted ORs for portal use as small as 1.053 for the continuous type predictors could be derived given the obtained R-Square of 0.34 due to the multiple regression of the independent variable on the other independent variables in the logistic regression. When considering categorical type predictors, such as race and sex, small detectable effect sizes in terms of the OR were again expected. For example, for patient's sex, where 19,140 (49.8%) were expected to be female, unadjusted ORs for portal use as small as 1.087 (1.108 for the adjusted ORs) could be detected with 90% power at a significance level of 0.01 for two-sided hypothesis testing, while for patient's race, where most (n=32,706, 85.2%) were expected to be white, unadjusted ORs for portal use as small as 1.124 (1.155 for the adjusted ORs) could be detected with 90% power a significance level of 0.01 for two-sided hypothesis testing.

Exploratory Aim. This specific aim is purely exploratory; however, in a previous study a small effect size (in terms of the standardized mean difference, d = 0.214) was observed in HbA1c between portal users (7.0 ± 1.3, n = 4,036) and non-users (7.3 ± 1.5, n = 6,710) (Tenforde et al., 2011). With this small effect size in mind and with 12,615 portal users and 25,784 portal non-users, we would have >> 99.9 power to detect an effect as small as 0.214 at a significance level of 0.05 for two-sided hypothesis testing. For the reduced sample size of the propensity-score matched portal-users (n=4,924) and non-users (n=4,924), we would also achieve >>99.9 power at a significance level of 0.05.

1.3.4.2 Preliminary analysis procedures

We assessed for data accuracy, univariate and bivariate data distributions, univariate and multivariate outliers, amount and pattern of missing data, and the underlying statistical assumptions given the planned analysis strategies. A validation process was performed before the data analysis. We checked the accuracy of the outcome variable HbA1c by displaying the frequency of all values to identify problematic entries (e.g., >14.0, @13, 8.3/8.7, coded as -2), and also implausible values (i.e., HbA1c < 3.5%, HbA1c > 20%, to be recoded as -3). Both problematic entries and implausible values were treated as missing values in the analysis. A similar approach was applied to weight data. Patient weight was repeatedly assessed in every clinic visit. Values that fell within the acceptable range (i.e., weight > 50 lbs. and weight < 1000 lbs.), but were likely erroneous when compared to the patient's other weight measures, were identified by calculating within-patient z scores for that individual. An absolute z score greater than 3.29 was identified as a problematic entry (recoded as -2). We displayed the frequency of BMI values, and further examined the presence of clinically implausible BMI values (i.e., BMI < 15 kg/m^2 or BMI > 100 kg/m^2).

After identifying missing values, we screened for possible patterns in these missing values to determine whether or not data were missing at random. Little's test was performed to assess whether data were missing completely at random (MCAR). Listwise deletion was used if data were MCAR and the amount of missing data were not affecting the precision when estimating parameters and statistical power when testing hypotheses. If data appear to be not missing at random (NMAR), we explored the sensitivity of the results, assuming different patterns of data missingness.

Univariate and multivariate outliers were assessed based on the variables' levels of measurement. For nominally scaled categorical variables (e.g., gender, race), the frequency

distribution was displayed. For ratio variables, we examined the shapes of data distributions via histograms, checked the tails of the distribution, and inspected boxplots for extreme values. Also, we calculated z scores on that continuous type variable, with absolute values of z scores greater than |3.29| indicating univariate outliers. Multivariate outliers were identified by examining a bivariate scatterplot between each pair of variables and computing a Mahalanobis distance for the set of variables of interest.

The underlying the statistical assumptions (i.e., linearity between variables/linearity of logit of all continuous type independent variables with the logit of the probability of being a portal user, independence of observations, homoscedasticity of error variance, normality of residuals, absence of multicollinearity) for statistical modeling were assessed. To check the normality of raw data distribution, histograms were used to graphically display the distribution of the variables. We mainly focused on graphical methods (i.e., histogram or pie chart) rather than inferential statistics given the large sample size we had in our study. Appropriate data transformations (e.g., log base 10 or square root) were considered when data deviate from normality. Bivariate scatterplots were used to examine the independence of cases by plotting the key variables of interest versus the subject's identification number. Linearity between any pair of variables was assessed by displaying the bivariate scatterplot. Any multicollinearity issues were revealed by bivariate correlations and variance inflation factors (VIF). A Levene test and bivariate scatterplots were examined for homoscedasticity.

1.3.4.3 Data analysis procedures

Data analysis plan for Aim 1. The descriptive statistics (e.g., line chart) of the overall portal use, as well as the use of each feature (e.g., secure messaging, lab results, appointment management) over time were reported (Aim 1a). To describe the portal use around an office visit

for Aim 1b, we created a two-week window before and after a physician visit. We selected the first visit for each patient as an example and illustrated the number of users within the four-week window. The number of users for each day within the window was also delineated in relation to visits. Comparison of portal usage between weekdays (5 days) and weekends (2 days * 2.5) was performed using the Wilcoxon signed-rank test for the two-related samples. Tables and graphs (e.g., line chart) were displayed as appropriate.

Data analysis plan for Aim 2. Binary logistic regression was used to investigate the association between patient characteristics and the use of patient portal (use vs. non-use). Patient characteristics examined included age, gender, race, education, income, urbanization, type of health insurance, number of chronic conditions, insulin use and number of diabetes medications for T2DM, initial HbA1c, the frequency of HbA1c tests, and the total number of outpatient visits and telephone contacts over the study period. All two-way interactions between the predictor variables were assessed. Outliers were detected by Pearson residuals or deviance residuals through index plots. Further checking for influential cases was performed by calculating the Cook's distance. Unadjusted and adjusted odds ratios with their corresponding 95% confidence intervals (CI) were reported. We used the likelihood ratio test to examine whether our model was significantly better than the intercept-only model. The Hosmer–Lemeshow test was used to assess the model goodness of fit.

For model evaluation, we split our dataset into two parts, using the dataset containing 75% of the sample for model training and the remaining 25% of the sample for model testing. The backward elimination procedure was used to remove non-significant variables ($p \geqslant 0.5$) and to generate a parsimonious model. The evaluation of the model was performed in the testing dataset by calculating the model sensitivity and specificity. Furthermore, we determined the percentage of cases that were accurately classified based on the fitted model in the testing dataset with respect

to the observed classification. We plotted a receiver operating characteristic (ROC) curve to identify the optimal threshold value, and we determined the percentage of the area under the ROC curve (AUC) to indicate the model discrimination.

Data analysis plan for Aim 3. For Aim 3, we investigated the changes in HbA1c over time between portal user group and non-user group. Patients with uncontrolled glycemic control were included as determined by the initial HbA1c value great than 7%. To perform longitudinal data analysis, we further limited our cohort to patients with two or more HbA1c assessments.

The propensity score matching technique was applied to balance the differences in demographic and clinical covariates between patient portal users and non-users. This approach allows an unbiased estimation of the treatment effect in the context of observational studies (Rosenbaum & Rubin, 1983). The propensity score for each patient was generated using a logistic regression model, including all covariates (age, gender, race, health insurance type, household income, educational level, urbanization of a zip code, BMI, number of HbA1c tests, initial HbA1c value, number of distinct glucose-lowering medications, insulin use, and visits to an endocrinologist) that were associated with the outcome HbA1c as identified in the literature. One-to-one nearest-neighbor matching without replacement was used (Austin, 2011a). Evaluation of the balance of each confounding variable between portal user and non-user group was performed by determining the standardized absolute means difference (SMD) with a caliper of 0.2 (Austin, 2009, 2011b).

Linear mixed-effect modeling or random coefficient modeling was used to investigate the changes in HbA1c over time between portal users and non-users. We included time and portal use group as fixed effects and treated the intercepts for the subject and by-subject random slope for the effect of HbA1c as random effects. Time was treated as a continuous variable indicating the days since the study started. Both linear and non-linear functions of time were considered. We first

examined the interaction between group and time, if there was a significant interaction effect on the outcome, the interaction was included in the model; otherwise, we excluded it and investigated only the main effects of group and time on HbA1c values. We controlled for the covariates that were not balanced after the propensity score matching between the two groups. For fitting the model, the variance-covariance structure of the repeated assessments was determined such as variance components, compound symmetry or unstructured covariance. The dependent variable HbA1c was measured repeatedly at unequal intervals, thus we considered covariance structures that allow for unequal spacing (e.g., spatial covariance structure) and assessed using standard information criteria (e.g., AIC, BIC). The restricted maximum likelihood method (REML) was used for model fitting and parameter estimation. A likelihood ratio test was used to compare nested models; a significant test means that the more complex model has a better fit than the simpler model. Estimated regression coefficients with confidence intervals, standard error, values of test statistics, and p-values were reported.

1.4 POTENTIAL LIMITATIONS OF THE PROPOSED PROCEDURES AND ALTERNATIVE APPROCHES

Using secondary EHR data within healthcare systems presents a large number of challenges and limitations. These data are commonly collected from a variety of practitioners from different service specialties and geographic locations, which commonly result in erroneous data that are incomplete (reduced data frequency), inaccurate (out-of-range values or based on different units of measurement), and inconsistent (mismatch between hospital units or within the same unit).

In clinical trials, data tend to be collected at fixed time intervals during the study period; whereas data for studies using EHRs are captured when patients are seen or when tests are performed. For example, the primary outcome HbA1c is not assessed at regular intervals, and the frequency of HbA1c measurements is expected to vary across patients. The standards of medical care in diabetes, as suggested by the American Diabetes Association, are that HbA1c testing should be performed regularly for all patients with diabetes; for patients who meet treatment goals, HbA1c testing needs to be obtained at least twice a year, but quarterly HbA1c testing is recommended for patients who do not meet glycemic goals (American Diabetes Association, 2017). However, these decisions are sometimes subject to the patient's and physician's preference.

Ideally, EHRs capture and integrate data on all aspects of care over time; in reality, existing data in one EHR system rarely contains information generated from visits to other clinical or non-clinical settings or lab results done during those visits. Patients may seek care from other physicians using paper records or different EHR platforms that are not linked; as a result, patients' data included in our study may not be complete. Moreover, data on some patients are not available for the entire study period due to 1) the variability when clinics or physicians transitioned into EHR documentation–recent adoption in EHR may result in a lack of historical data, or 2) patients who leave the system making it difficult or impossible to observe their status.

Additionally, the point-of-care (POC) HbA1c testing results are less accessible and not included in our data analysis. The POC HbA1c testing is sometimes performed during a patient encounter as a supplement clinical laboratory test. By doing this, providers can receive immediate results that minimize the delay in diabetes treatment, and reduce the need for additional office visits to implement clinical decisions. However, these results were not captured electronically in the EHRs.

Using EHR data, some variables included in the statistical model may not accurately reflect the variables we want to include. For example, we calculated the years since the first diabetes diagnosis as noted in the patient's problem lists, which may not reflect the true diabetes onset date. According to an article by the American Health Information Management Association (AHIMA), the problem list should support documentation of the patient's historical information and identify the time of occurrence and resolution of the condition (AHIMA Work Group, 2011). However, the date of diabetes diagnosis information may not be accurate or updated timely in the EHRs.

The absence of certain data fields in the EHR limits the variables we studied and the number of explanatory factors we considered. Medication adherence can greatly affect glycemic control outcomes; yet, the longitudinal medication record in the EHR often fails to provide information regarding patient adherence to medication-taking. This occurs because institutions commonly track medications that are prescribed, they do not monitor whether prescriptions were filled or medications were taken by the patients.

Finally, we are cautious that our sample may be biased. We included only patients who had at least one visit to UPMC physician services or clinics from 2015 to 2016, which may not be representative of those with no visits during the two-year study period. Usually, the most health-conscious people visit their providers more often than less health-conscious peers in the community.

1.5 RESEARCH PARTICIPANT RISK AND PROTECTION

The proposed study used existing data from the ambulatory electronic health records and the UPMC patient portal; no screening, recruitment, or follow-up of human subjects occurred.

Data were requested through the Center for Assistance in Research using eRecords (CARe). An honest broker work for CARe assisted with the de-identification of protected health information by removing the patient's name, address, and other identifiers. The study protocol was submitted to the University of Pittsburgh Institutional Review Board (IRB) for an exempt review, and IRB approval (#PRO16120082) was received on December 19, 2016, before obtaining the data.

As an analysis using de-identified existing data, the subjects received no direct benefit from the proposed study. Instead, the findings and knowledge gained provided an understanding of portal usage pattern by patients with T2DM, patients' characteristics associated with portal use, and the impact of portal use on glycemic control.

2.0 MANUSCRIPT 1: PATIENT PORTAL USE IN DIABETES MANAGEMENT: LITERATURE REVIEW

2.1 ABSTRACT

Background: Health information technology tools (e.g., patient portals) have the potential to promote engagement, improve patient-provider communication, and enhance clinical outcomes in the management of chronic disorders such as diabetes mellitus (DM). **Objectives**: The aim of this study was to report the findings of a literature review of studies reporting patient portal use by individuals with type 1 or type 2 DM (T2DM). We examined the association of the patient portal use with DM-related outcomes and identified opportunities for further improvement in DM management. **Methods**: An electronic literature search was conducted using PubMed and PsycINFO databases. The keywords used were "patient portal*," "web portal," "personal health record," and "diabetes." Inclusion criteria included (1) published in the past 10 years, (2) used English language, (3) restricted to age ≥18 years, and (4) available in full text. **Results:** This review included 6 randomized controlled trials, 16 observational, 4 qualitative, and 4 mixed-methods studies. The results of these studies revealed that 29% to 46% of patients with DM have registered for a portal account, with 27% to 76% of these patients actually using the portal at least once during the study period. Portal use was associated with the following factors: personal traits (e.g., sociodemographics, clinical characteristics, health literacy), technology (e.g., functionality, usability), and provider engagement. Inconsistent findings were observed regarding the association of patient portal use with DM-related clinical and psychological outcomes. **Conclusions**: Barriers to use of the patient portal were identified among patients and providers. Future investigations into

strategies that engage both physicians and patients in the use of a patient portal to improve patient outcomes are needed.

2.2 INTRODUCTION

DM is a significant public health problem that is associated with many debilitating health conditions. Prevalence data indicate that approximately one of every ten adults in the United States has DM with predictions that the number will triple by 2050 (Centers for Disease Control and Prevention, 2010). The economic burden of DM and its complications to the U.S. healthcare system is enormous. One in four healthcare dollars is spent for the care of people with DM (American Diabetes Association, 2018). Thus, the steady increase in the prevalence of DM and the substantial associated costs make this one of the most pressing public health concerns in the U.S.

Effective DM management requires continuous collaboration between individuals and their providers (Singer et al., 2011), yet the infrastructure of current health delivery systems does not fully support the needs of patients with chronic conditions (Anderson, 2010). A call has been sounded to redesign the care delivery systems in order to improve chronic disorder care (Institute of Medicine, 2001). The Chronic Care Model (CCM) was developed in 1998 to reorganize care delivery to improve functional and clinical outcomes for people with chronic disorders (E. H. Wagner et al., 2001). A primary focus of the CCM is on creating productive interactions between informed patients and a prepared care team (E. H. Wagner et al., 2001). To achieve this, patients need to have the knowledge and skills to make informed decisions, and care teams need to be able to provide relevant patient information, resources, and decision support at the point of encounter. Health information technologies, such as patient portals, can facilitate these activities within healthcare systems.

Patient portals, often referred to as tethered personal health records (PHR), provide online platforms for patients access to their health information from a health organization's electronic health record (EHR). Patient portals were widely adopted by healthcare organizations in the late 1990s, and gained greater attention when the Medicare and Medicaid incentive programs for Electronic Health Record (a.k.a. "Meaningful Use") implementation was initiated in 2011 (Irizarry, DeVito Dabbs, & Curran, 2015). Today, the PHR adoption rate by consumers is rapidly increasing. It is estimated that the percentage of people who will have a PHR is expected to exceed 75% by 2020 (Ford et al., 2016). Patients can perform a variety of medical-related tasks within the portal. For example, most portals permit patients to view laboratory results, receive visit summaries, manage appointments, and electronically communicate with healthcare providers. More advanced portals enable individuals to record their symptoms and test results, such as blood glucose or blood pressure readings, data that can be viewed for decision-making and changes in therapy by providers (Office of the National Coordinator for Health Information Technology, 2013). Healthcare organizations have commonly adopted patient portals as an essential strategy to provide patient-centered care and engage patients for the purpose of improving clinical outcomes.

2.2.1 Purpose

Given the continuous increase in the prevalence of DM and the increasing development of patient portal applications, a review of the literature on the current use of patient portals in supporting patients with DM can be informative. In this review, we identified studies that used qualitative or quantitative methods to describe the state of science in the use of patient portals for diabetes management. Specifically, we evaluated the use of patient portals by patients with DM, including the portal functionalities, predictors of portal use, and the effects of portal use on diabetes-related outcomes. These findings provide opportunities for further approaches to improve

DM management through the use of a patient portal.

2.3 METHODS

2.3.1 Search Strategies

Electronic literature searches were conducted through PubMed and PsycINFO databases. Keywords included "patient portal*," "web portal," "personal health record," and "diabetes." Additional articles were searched by identifying similar articles in PubMed and manually reviewing the bibliography of published papers in relevant articles. The literature search was limited to publications in the English language and peer-reviewed articles, but no restrictions as to the country in which the study was conducted were imposed.

2.3.2 Inclusion and exclusion criteria

Articles selected were based on the following inclusion criteria: (1) published in the past 10 years (2007-2017), (2) used the English language, (3) study participants were adults (i.e., age ≥18 years), and (4) available in full text. Studies using both quantitative and qualitative methods were included in this review. The focus of the selected articles was a patient population of adults with either type 1 diabetes mellitus (T1DM) or T2DM. Studies were excluded if the portal was designed for parents of children with diabetes.

2.3.3 Data extraction

The initial search from PubMed and PsycINFO retrieved 128 articles after filtering out 11 articles that did not meet the inclusion criteria. We removed 8 duplicates, which reduced the number to 120 articles for review of the title and abstract. The assessment of these 120 articles resulted in a further removal of 74 articles, including 63 that were not relevant, five articles that focused on children, and six articles that applied mobile apps for diabetes management. Thus, a review of full text was conducted on 46 articles based on the aforementioned inclusion criteria, and 17 were excluded because of the use of stand-alone Web portals that were not connected to any healthcare organizations; also two review papers were excluded. We later added three additional articles by searching the bibliography of previously published literature reviews. Therefore, a total of 30 articles were included in our study (see Figure 1), including six randomized controlled trials (RCTs), 16 observational studies, four qualitative studies, and four mixed-methods studies. RCTs and observational studies were summarized based on the following categories: authors and country, study aims and design, sample size and retention, intervention (only for experimental studies), PHR features, measures, and findings. Studies that used qualitative methods or mixed methods were summarized based on study aims, study design, sample, PHR features, measures or questions, and findings (see Tables 1 and 2; Appendix 1).

2.3.4 Quality Assessment

The quality of the reviewed studies that used quantitative methods was assessed using the evidence grading system developed by the American Diabetes Association. An evidence grade of A, B, C, or E was assigned depending on the quality of the evidence. A grade A evidence was considered optimal because it is derived from large, well-designed clinical trials or meta-analyses;

it is estimated to have the best chance to improve outcomes when applying the treatment to the appropriate population. Grade B ratings indicated supporting evidence from well-conducted cohort studies or case-control studies. Grade C ratings indicate supporting evidence from poorly controlled or uncontrolled studies. A separate category E was applied to papers reporting expert opinions or clinical experience when there was no evidence from clinical trials.

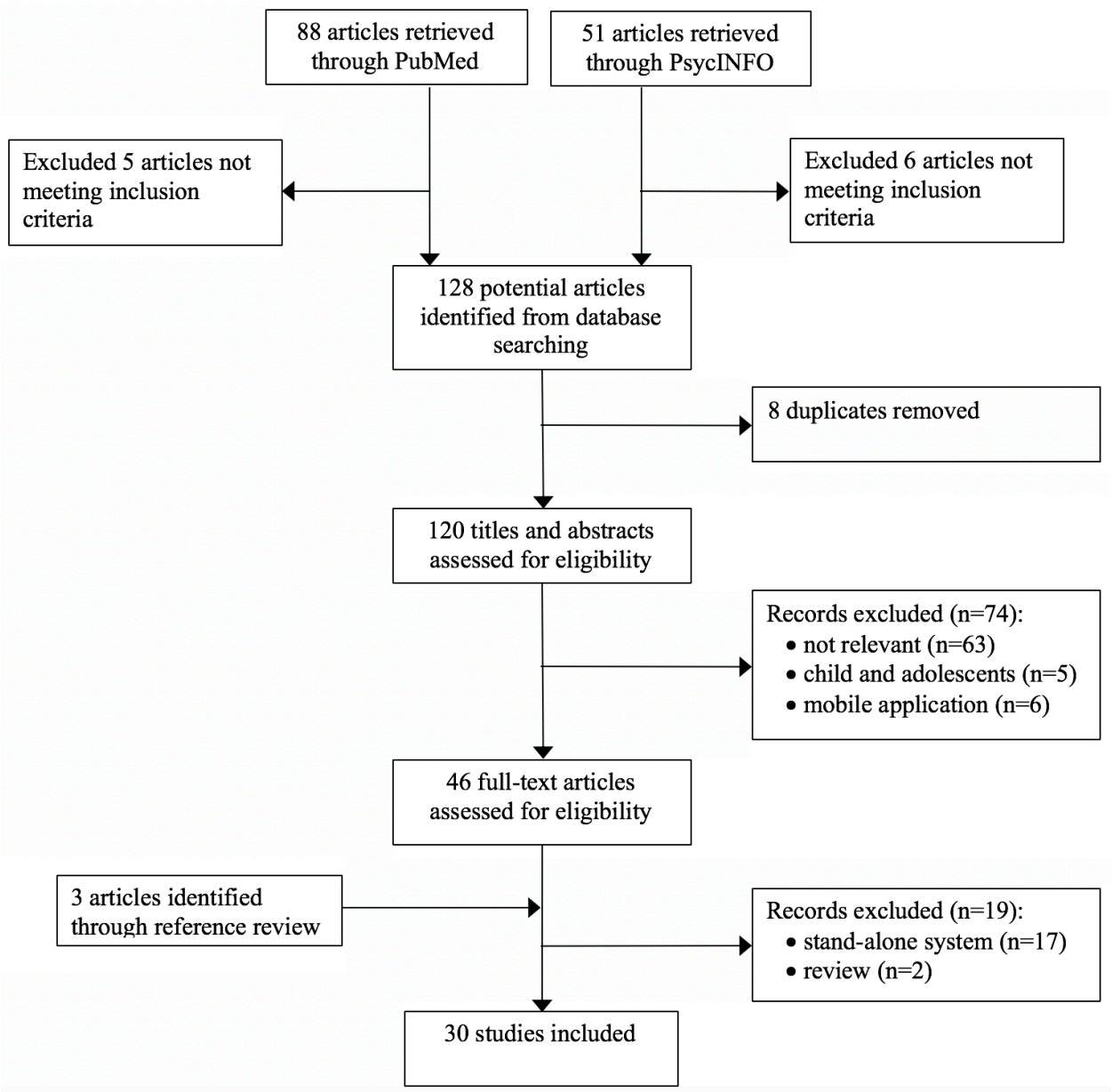


Figure 1. Flow Diagram for Paper Selection Process

2.4 RESULTS

2.4.1 Description of included studies

We reviewed 30 studies focusing on 13 different portals from three countries—10 from the United States, two from the Netherlands, and one from Canada. Of these 13 portals, five were designed for patients with diabetes and functioned as a component in Web-based diabetes management programs. These five DM-specific patient portals were from the Palo Alto Medical Foundation, VA Boston Healthcare System, University of Washington General Internal Medicine Clinic, the VU University Medical Center, and the Diamuraal of the Netherlands. Almost half of the included studies (n=13) focused on patients with T2DM, one on patients with T1DM, six included both types, and ten did not specify.

Of all the studies included, six were RCTs (Fonda, McMahon, Gomes, Hickson, & Conlin, 2009; Grant et al., 2008; McCarrier et al., 2009; Ralston et al., 2009; Tang et al., 2013; Vugt et al., 2016) (Table 1). These studies examined the effect of a DM-specific patient portal on diabetes-related outcomes. The sample sizes for the RCTs ranged from 77 to 415, with the number of subjects in two studies being less than 100 (McCarrier et al., 2009; Ralston et al., 2009) and in one study more than 400 (Tang et al., 2013). The study duration in the five RCTs was 12 months (Fonda et al., 2009; Grant et al., 2008; McCarrier et al., 2009; Ralston et al., 2009; Tang et al., 2013), with the duration of the remaining RCTs being 6 months (Vugt et al., 2016). Of six RCTs, five reported a retention rate range of 50.4% to 89.2% and employed an intention-to-treat approach to handle protocol deviations (Grant et al., 2008; McCarrier et al., 2009; Ralston et al., 2009; Tang et al., 2013; Vugt et al., 2016). These six RCTs studied an array of diabetes-related outcomes, including glycated hemoglobin (HbA1c) or glycohemoglobin (GHb), systolic blood pressure (SBP) and diastolic blood pressure (DBP), body mass index (BMI reported as kg/m^2), total

cholesterol, and low-density lipoprotein (LDL). The psychological outcomes that were examined included diabetes-related distress and diabetes-related self-efficacy.

Table 1. Randomized Controlled Trials Examining Patient Portal for Diabetes Management

Authors and Country	Study aims, design, and level of evidence	Sample and retention	Patient portal features	Intervention	Outcomes (portal related)	Findings
van Vugt et al (2016), Netherlands	2-group study, 6-month randomized controlled trial (RCT) to study the uptake and effects of e-Vita with a self-management support program (SSP) and personalized coaching for Ps with type 2 diabetes mellitus (T2DM) Evidence: Grade A	N=132; males: 59.1%; white: 91%; age: 67.9 (SD 10.4) years; body mass index (BMI): 30.2 (SD 5.2); glycated hemoglobin (HbA1c): 6.6%; retention: Coaching group (CG): 43.9%; noncoaching group (NCG):59.1%	e-Vita (diabetes mellitus [DM]-specific) by VU University Medical Center allows patients (Ps) to access diabetes education; access data from electronic medical records (EMRs) of primary care physicians (PCPs); receive messages from providers; receive SSP	CG (n=66): Personal health record (PHR)+SSP+ coaching NCG (n=66): PHR+SSP	HbA1C, BMI, systolic blood pressure (SBP), diastolic blood pressure (DBP), cholesterol, diabetes self-care, diabetes-related distress, and PHR and SSP use	Intention-to-treat (ITT) was applied. PHRs were assessed by 128 Ps, of which 59 Ps never returned to the PHR. The use declined over time. The SSP was used by 5 Ps in the CG and 1 patient in the NCG group, 3 of whom asked a coach for feedback. Ps recently diagnosed actively used the SSP; no differences were observed on outcome measures between baseline (BSL) and 6 months for the 2 groups.
Tang et al (2013), United States	2-group study, 12-month RCT to evaluate a Web-based disease management system by Ps with uncontrolled T2DM Evidence: Grade A	N=415; Intervention (Int) vs Control (Con): males: 58.9% vs 61%; white: 60% vs 58%; age: 54 (SD 10.7) vs 53.5 (SD 10.2) years; weight: 215.3 (SD 49.4) vs 218.4 (SD 51.3) pounds; HbA1c: 9.24 (SD 1.59) vs 9.28 (SD 1.74); Retention: 87%	Web-based diabetes management system (DM specific) by Palo Alto Medical Foundation allows Ps to monitor glucose remotely; view summary report; document nutrition and exercise; record insulin; communicate with the health team; receive advice; personalized education	Int (n=202): access to Web-based disease management system for diabetes; Con (n=213): usual care	HbA1c, BP, low-density lipoprotein (LDL), healthcare utilization, diabetes knowledge, diabetes treatment satisfaction, and depression screening	ITT was applied. Int had reduced HbA1c at 6 months (−1.32% Int vs −0.66 Con, *P*<.001), but not at 12 months. The Int had better LDL control at 12 months (*P*=.001), but no difference for BP, or weight. Ps in the Int had a lower distress score (*P*<.001), better knowledge of glucose testing (*P*=.004), better understanding of diabetes (*P*<.001), greater treatment satisfaction (*P*<.001). No differences were noted in the depression screening or health care utilization.
Fonda et al (2009), United States	2-group study, 12-month RCT to examine changes in Problem Areas in Diabetes (PAID), and its association with use of an internet-based diabetes care management (IBCM) program;	N=104; males: 99%; white: 76.7%; age: 60.9 (SD 10.3) years; HbA1c: 9.9 (SD 0.9%); Retention not reported	IBCM (DM specific) by VA Boston Healthcare System allows Ps to transmit BP and glucose data from devices; view BP and glucose data; message care managers; access diabetes education	Int (n=52): access to the IBCM program; Con (n=52): usual care	Diabetes distress (PAID), and pattern of usage	The decline in PAID score was significant for sustained users of the portal but not for nonusers in the Int group. Sustained users (n=27) had lower PAID scores at baseline.

	Evidence: Grade A					
McCarrier et al (2009), United States	2-group study, 12-month RCT to test whether a diabetes case management program can improve glycemic control and self-efficacy in adults with T1DM; Evidence: Grade A	N=77; males: 67.5%; white: 96.1%; age: 37.3 [8.09] years; HbA1c: 8%; Retention: 83%	Web-based program (DM specific) by University of Washington (UW) General Internal Medicine Clinic allows Ps to view EHR data; upload glucose readings; enter medication, nutrition, and exercise; create action plans; access education	Int (n=41): usual care+Web-based case management pro gram; Con (n=36): usual care	HbA1c, diabetes-related self-efficacy, and usage	ITT was applied. A nonsignificant decrease in HbA1c in the Int compared with the Con group (−0.48%, 95% CI −1.22 to 0.27) between groups. The Int group had an increase in self-efficacy compared with the Con group (95% CI 0.01-0.59, P=.04). The log-in rate was 61%, and averaged 3.3 log-ins per patient. Emails were sent by 44% users, with a mean of 5.0 messages.
Ralston et al (2009), United States	2-group study, 12-month RCT to test Web-based care management of glycemic control using a shared EMR in Ps with T2MD; Evidence: Grade A	N=83; Int vs Con: females: 47.6% vs 51.2%; white: 89.7% vs 73% (P=.06); age: 57 vs 57.6 Glycohemoglobin (GHb): 8.2% vs 7.9%; Retention: 89.2%	Web-based diabetes support program (DM specific) by UW General Internal Medicine Clinic allows Ps to access EHR data; communicate with providers; send glucose readings; enter exercise, diet, and medication data; access education	Int (n=42): usual care+Web-based case management program; Con (n=41): usual care	GHb, total cholesterol, SBP, DBP, health care utilization, and usage	ITT was applied. More change in GHb among the Int group compared with the Con group at 12 months (change −0.7%, P=.01). SBP, DBP, total cholesterol levels, and use of in-person health care services did not differ between groups. EHR was accessed 76%, 69% emailed, and 33% entered data. Number of page views was not associated with GHb improvement.
Grant et al (2008), United States	2-group study, 12-month RCT to evaluate the impact of a PHR for T2DM; Evidence: Grade A	N=244; Int vs Con: females: 43% vs 56% (P=.04); white: 93% vs 84% (P=.04); age: 58.8 vs 53.3 years (P<.001); HbA1c: 7.3% vs 7.4%; Retention: 50.4%	Patient Gateway by Partners Health care system allows Ps to update registration information; send messages; confirm appointments; request prescription refills; access DM modules	Int (n=126): access to a DM-specific PHR (ie, review mediations, and access decision support and care plans); Con (n=118): non-DM-specific PHR	HbA1c, BP, and LDL	ITT was applied. More Ps in the Int group had DM treatment adjusted compared with the Con group (53% vs 15%; P<.001). There was no difference in HbA1c between groups (Int vs Con: 7.1% vs 7.2%) after 1 year. BP and LDL showed similar patterns at BSL and follow-up between groups.

There were 16 observational studies identified (Bredfeldt, Compton-Phillips, & Snyder, 2011; Cho et al., 2010; Harris et al., 2009; Lyles et al., 2013; Roelofsen et al., 2014; Ronda, Dijkhorst-Oei, Gorter, Beulens, & Rutten, 2013; Ronda, Dijkhorst-Oei, & Rutten, 2014, 2015, Sarkar et al., 2010, 2011, 2014; Shimada et al., 2016; Sieverink, Kelders, Braakman-Jansen, & Van Gemert-Pijnen, 2014; Tenforde et al., 2011; Wald et al., 2009; Weppner et al., 2010), which

included three retrospective cohort studies (Sarkar et al., 2014; Shimada et al., 2016; Weppner et al., 2010) and 13 cross-sectional studies (Appendix 1). The sample sizes of these studies were variable; seven studies had more than 10,000 participants (Harris et al., 2009; Lyles et al., 2013; Sarkar et al., 2010, 2011, 2014; Shimada et al., 2016; Tenforde et al., 2011), and five studies had less than 1000 (Bredfeldt et al., 2011; Cho et al., 2010; Ronda et al., 2015; Sieverink, Kelders, et al., 2014; Wald et al., 2009). The data obtained only from the EHR were examined in 7 studies (Bredfeldt et al., 2011; Harris et al., 2009; Sarkar et al., 2014; Shimada et al., 2016; Sieverink, Kelders, et al., 2014; Tenforde et al., 2011; Weppner et al., 2010), and nine studies combined data collected from the EHR and patient surveys (Cho et al., 2010; Lyles et al., 2013; Roelofsen et al., 2014; Ronda et al., 2013, 2014, 2015, Sarkar et al., 2010, 2011; Wald et al., 2009). The association between patient portal use and diabetes-related outcomes was investigated in five studies; one of the studies examined the overall portal use (Tenforde et al., 2011), whereas the other four studies investigated only certain features within the portal, such as secure messaging (Bredfeldt et al., 2011; Harris et al., 2009; Shimada et al., 2016) or medication refills (Sarkar et al., 2014; Shimada et al., 2016). The remaining 11 studies examined the usage of the patient portal and factors associated with portal use (Cho et al., 2010; Lyles et al., 2013; Roelofsen et al., 2014; Ronda et al., 2013, 2014, 2015, Sarkar et al., 2010, 2011; Sieverink, Kelders, et al., 2014; Wald et al., 2009; Weppner et al., 2010).

Qualitative methods were used in four studies (Hess et al., 2007; Sieverink, Braakman-Jansen, et al., 2014; Urowitz et al., 2012; Zickmund et al., 2008), and four additional studies used mixed methods to address the benefits and barriers of using patient portals (Bryce et al., 2008; Mayberry, Kripalani, Rothman, & Osborn, 2011; Osborn, Mayberry, Wallston, Johnson, & Elasy, 2013; Wade-Vuturo, Mayberry, & Osborn, 2013) (Table 2). Focus group was used in six studies (Bryce et al., 2008; Hess et al., 2007; Mayberry et al., 2011; Osborn et al., 2013; Wade-Vuturo et

al., 2013; Zickmund et al., 2008), of which four also used patient surveys (Bryce et al., 2008; Mayberry et al., 2011; Osborn et al., 2013; Wade-Vuturo et al., 2013). The sample sizes in the six studies using focus groups ranged from 39 to 75 (Bryce et al., 2008; Hess et al., 2007; Mayberry et al., 2011; Osborn et al., 2013; Wade-Vuturo et al., 2013; Zickmund et al., 2008). In one study, semistructured interviews with 11 primary care nurses were conducted (Sieverink, Braakman-Jansen, et al., 2014). Another study conducted telephone interviews with 17 patients and collected qualitative data using open-ended questionnaires from 64 providers (Urowitz et al., 2012).

Table 2. Qualitative or Mixed Methods Studies on Patient Portal for Diabetes Management

Authors and Country	Study aim	Study design	Sample	Portal features	Measures or Questions	Findings
Sieverink et al (2014), Netherlands	To explore factors associated with diffusion of a personal health record (PHR) for patients with type 2 diabetes mellitus (T2DM) in primary health care workers	Semistructured interview with primary care nurses: qualitative	N=11	e-Vita (diabetes mellitus [DM]-specific) by the Diabetes Center in Zwolle allows patients (Ps) to access diabetes education; access EMR data; receive messages from providers	1. What are the reasons for using a PHR? 2. What training do you receive? 3. How to embed PHR in your daily routine? 4. What are the barriers and facilitators for embedding PHR in daily routine? 5. What are your expectations?	Practice nurses indicated barriers for using a PHR: lack of integration with work routines, time constraints, and experience usability problems.
Osborn et al (2013), United States	To understand Ps with T2DM who use MyHealthAtVanderbilt (MHAV) and reasons for use and nonuse, how users are using a portal to manage medications, and explore ideas for functionality improvement	Focus groups and medical chart review: mixed methods	N=75; females: 67%; white: 63%; age: 56.9 (SD 8.8) years	MHAV by Vanderbilt University Medical Center (VUMC) allows Ps to access EHR data; message providers; manage appointments; assess risks; access education	1. Do you use MHAV or not? How and why? 2. What could be added to MHAV to help manage medications? 3. What do you think about an email reminder to refill or dose reminders?	Users were more likely to be white, have higher incomes, and be privately insured. Reasons for nonuse: unaware of the portal (n=3), no access to a computer (n=3), and helped by a family member (n=1). Users used the portal to request prescription refills and view medication list, and Ps were enthusiastic about the idea of adding refill reminder functionality, alerting providers to fill or refill nonadherence, and providing side effects and interactions.

Wade-Vuturo, et al (2013), United States	To explore how Ps with T2DM use and benefit from secure messaging within a patient portal	Focus group and patient survey: mixed methods	N=54; females: 65%; white: 76%; age: 57.1 (SD 8.4) years; body mass index (BMI): 34.4 (10.2); HbA1c: 7.0 (SD 1.4)	MHAV by VUMC allows Ps features same as above	HbA1c, self-reported frequency of use, benefits and barriers to use messaging	Greater use of messaging to schedule an appointment was associated with patients' glycemic control (r=−.29, P=.04). Benefits of messaging: improved patient satisfaction, enhanced efficiency and quality of face-to-face visits, and access to care. Barriers to use messaging: negative experiences with messaging. Ps' assumptions about providers' opinion and instruction.
Urowitz et al (2012), Canada	To evaluate the experience of Ps with T1DM or T2DM and providers using a Web-based diabetes management portal	Telephone interview and open-ended questionnaire: qualitative	Ps (n=17); females: 53%; providers (n=64)	Patient portal by the Waterloo Wellington Local Health Integration Network allows Ps to access DM education; access EHR data	Telephone interview with Ps and open-ended questionnaires with providers	17 Ps were interviewed. Facilitators of disease management: increase awareness of their disease, access to educational information, and promote behavior change. Barriers to portal use: poor usability, not useful, challenges with physician engagement, and lack of understanding. Recommendations for portal improvements: more Web-based tutorial about the portal content, improve usability.
Mayberry et al (2011), United States	To examine the role of health literacy, numeracy, and computer literacy on usage of a patient Web portal (PWP) in Ps with T2DM	Focus group and patient survey: mixed methods	N=75; females: 68%; white: 47%; age: 56.9 (SD 8.8) years	MHAV by VUMC allows Ps features same as above	Health literacy, numeracy, computer literacy, self-report usage of PWP and health information technology (HIT)	Lower health literacy was associated with less use of a compute for searching diabetes medications or treatments, but not usage of a PWP. Numeracy and computer literacy were not associated with PWP use. Family members' support facilitated Ps usage of both PWP.

Bryce et al (2008), United States	To rate the potential or actual usefulness of 15 features of a Web-based portal for diabetes management	Focus group and patient survey: mixed methods	Preportal group (n=21) vs Portal-user group (n=18): nonwhite: 33% vs 22%; age: 53 (SD 13) vs 55 (SD 11)	HealthTrak by University of Pittsburgh Medical Center (UPMC) allows Ps to access EMR data; schedule appointments; message providers; access education; logbooks	The study asked how the portal affected management of diabetes, Ps' experiences in using the portal and communicating with physicians	Features rated most favorably were: calculator to estimate blood glucose control (74%), appointment reminder (74%), email to health team (74%), personal tracking logs (69%), and scheduling (69%). More patients from the preportal group than the portal-users group favored personal logs (*P*=.02) and opportunities to form interest groups (*P*=.03).
Zickmund et al (2008), United States	To examine the impact of the provider-patient relationship on interest in using the patient portal	Focus group: qualitative	N=39; white: 72%; males: 52%; age: 54 (SD 12)	HealthTrak by UPMC allows Ps features same as above	Topics included the relationships with providers, and feedback on the patient portal	Interest in the portal was linked to dissatisfaction with provider responsiveness, unable to obtain medical information, and logistical problems. Disinterest in the portal was linked to satisfaction with the provider communication, difficulty in using the portal, and fear of losing connections with providers. No patient identified email communication through the portal was helpful
Hess et al (2007),United States [	To assess the impact of HealthTrak on patient-provider communication during September 2004-January 2007	Focus groups: qualitative	N=39; males: 51%; white: 72%; age: 54 (SD 12) years	HealthTrak by UPMC allows Ps to features same as above	Discussion around living with diabetes, desired information about diabetes, current sources of information about diabetes, doctor-patient communication, and reaction to the portal	The number of patient visits or telephone calls received did not change, but the number of HealthTrak messages increased. Participants felt that the system enhanced communication. Having access to laboratory tests was preferred. The became frustrated when test results were not released, or messages not answered by providers.

2.4.2 Features provided in patient portals

Features offered in patient portals varied across systems. Most portals allowed patients to access a component of the EHR data (e.g., visit summary, medical history, physical examination

results, lab results), receive general health education, request prescription refills, and communicate with healthcare providers. In the DM-specific portals, patients were able to perform more activities such as wirelessly uploading their blood glucose readings assessed via home-monitoring devices (Fonda et al., 2009; McCarrier et al., 2009; Ralston et al., 2009; Ronda et al., 2015; Tang et al., 2013). The education provided in these DM-specific portals was specifically related to patients' conditions and prescribed medications (Fonda et al., 2009; Grant et al., 2008; McCarrier et al., 2009; Ralston et al., 2009; Tang et al., 2013). A few portals also enabled patients to enter lifestyle data such as diet and exercise (McCarrier et al., 2009; Ralston et al., 2009; Shimada et al., 2016; Tang et al., 2013). In four RCTs, the interventions included access to the portal and assigned case managers (nurses, dietitians, or pharmacists) to assist patients in using the Web-based portal, responding to messages, reviewing blood glucose values and food intake, and adjusting medications as appropriate (Fonda et al., 2009; McCarrier et al., 2009; Ralston et al., 2009; Tang et al., 2013).

2.4.3 Patient usage of the portal

The percentage of patients with diabetes who registered for a portal account ranged from 29% to 46% (Harris et al., 2009; Roelofsen et al., 2014; Sarkar et al., 2010; Sieverink, Braakman-Jansen, et al., 2014). Among patients with portal accounts, 27% to 76% actually logged on to the portal at least once (Fonda et al., 2009; Roelofsen et al., 2014; Ronda et al., 2014; Sarkar et al., 2010, 2011; Sieverink, Kelders, et al., 2014). However, 50% (3/6) of these studies indicated a response rate of less than 50% (Roelofsen et al., 2014; Ronda et al., 2014; Sieverink, Kelders, et al., 2014)). In two studies, an initial high log-in frequency was observed that declined over time (Sieverink, Kelders, et al., 2014; Vugt et al., 2016).

Patients logged on to portals for various tasks. Of all the included studies, one study identified viewing laboratory results as the most frequently used feature, followed by requests for medication refills, sending and reading messages, and making appointments (Sarkar et al., 2011). Another study reported similar findings, with checking which laboratory tests were ordered by providers being the most frequent activity, followed by reading messages from providers and reviewing laboratory results (Tenforde et al., 2011).

2.4.4 Patient characteristics of portal users and nonusers

Significant differences between portal users and nonusers have been identified. Portal users were more likely to be younger (Ronda et al., 2013, 2014; Sarkar et al., 2011; Shimada et al., 2016; Tenforde et al., 2011; Weppner et al., 2010), white (Osborn et al., 2013; Sarkar et al., 2011; Shimada et al., 2016; Tenforde et al., 2011), and male (Ronda et al., 2013; Shimada et al., 2016; Weppner et al., 2010) with higher incomes (Osborn et al., 2013; Tenforde et al., 2011; Weppner et al., 2010) and greater educational attainment (Ronda et al., 2013, 2014; Sarkar et al., 2011; Tenforde et al., 2011). Other factors reported to be associated with portal use were higher health literacy (Sarkar et al., 2011) and higher morbidity (Weppner et al., 2010). Ronda et al found that insulin use, T1DM, longer duration of diabetes, polypharmacy, and treatment by an internist were associated with using the portal (Ronda et al., 2013, 2014, 2015)

2.4.5 Impact of patient portals on glycemic control

The impact of DM-specific patient portals on glycemic control was investigated in five RCTs. Of these, four targeted patients with T2DM and yielded inconsistent results. Tang et al randomized 415 patients to either the usual care group or the intervention group. The results

demonstrated reductions in HbA1c in the intervention group, where patients had access to a Web-based diabetes management system, compared with that of the usual care group (−1.32% vs −0.66%, P<.001) at 6 months, but the difference between groups was no longer significant at 12 months (−1.14 vs −0.95%, P=.13) (Tang et al., 2013). Ralston et al observed that the intervention group (n=42) in which patients were introduced to the Web-based diabetes support program had a greater decline in GHb than the usual care group (n=41) at 12 months (difference in mean change between groups=−0.7%, P=.01) (Ralston et al., 2009). Another two RCTs provided patients with access to portals in both groups. The only difference between groups in the study conducted by Grant et al. was the content of the module that was diabetes related in the intervention group but not the control group (Grant et al., 2008). In the study by Vugt et al, patients in the intervention group, but not in the control group, were able to request feedback from a health coach (Vugt et al., 2016). Both these studies failed to observe changes in HbA1c over time in either group (Grant et al., 2008; Vugt et al., 2016). The study by McCarrier et al., which examined 77 patients with T1DM, did not find a significant decrease in the average HbA1c in the intervention group with a Web-based management program when compared with the usual care group over 12 months (McCarrier et al., 2009).

There were three observational studies that used data from EHR as well as an audit of portal registration and usage to examine the association of portal use with glycemic control. Of these three studies, two studies focused on single features (i.e., secure messaging, Web-based medication refill). The 5-year retrospective cohort study conducted by Shimada et al. in 111,686 veterans demonstrated that patients with HbA1c ≥7%at baseline tended to achieve HbA1c <7% with 2 (odds ratio [OR] 1.24, 95% CI 1.14 to 1.34) or more (OR 1.28, 95% CI 1.12 to 1.45) years of messaging use. Use of Web-based medication refills was not associated with changes in glycemic control (Shimada et al., 2016). An earlier study of 15,427 patients that examined the messaging feature

revealed that frequent use of messaging (i.e., ≥12 threads) was associated with HbA1c less than 7% (relative risk [RR] 1.36, 95% CI 1.16 to 1.58) (Harris et al., 2009). Another study of 10,746 adults, which investigated the association between overall portal use and diabetes quality measures, observed a minimum decrease in HbA1c was associated with an increase in portal use (0.02%, P<.01) (Tenforde et al., 2011).

2.4.6 Impact of patient portals on other diabetes-related outcomes

In addition to glycemic control, researchers also explored other diabetes-related physiological outcomes. The RCT by Tang et al. found that patients who had Web-based access to the diabetes management system had better control of LDL, but not BP or weight, when compared with patients in the usual care group at 12 months (P=.001) (Tang et al., 2013). A significant decline in LDL and BP was observed in two retrospective cohort studies that examined single features in the portal (Sarkar et al., 2014; Shimada et al., 2016). Sarkar et al. focused on individuals with diabetes who were prescribed statins. They observed that for patients with poor adherence to a statin medication at baseline (n=3887), those who requested all their medication refills on the Web during the 5-year study period had a 2.1 mg/dL decrease in LDL compared with nonusers (95%CI −4.4 to 0.18). This decrease in LDL can be explained by the improved statin adherence (Sarkar et al., 2014). Shimada et al. demonstrated that both secure messaging use and Web-based medication refill requests were associated with lower LDL at follow-up. Patients with uncontrolled BP at baseline tended to achieve better control at follow-up, if they used the Web-based medication refill function for two (OR 1.07, 95% CI 1.01 to 1.13) or more years (OR 1.08, 95% CI 1.02 to 1.14) (Shimada et al., 2016). Significant associations between portal use and improved physiological measures were reported by two other cross-sectional studies (Harris et al., 2009; Tenforde et al., 2011). Tenforde et al. reported that portal users (n=4036), compared with

nonusers (n=6170), had a small difference in SBP (by 1.13 mm Hg, P<.01) and DBP (by 0.54 mm Hg, P<.01) (Tenforde et al., 2011). In the Harris et al. study of 15,427 patients, a small but significant association was observed between secure messaging use and LDL <100 mg/dL (P<.001) (Harris et al., 2009). Other studies did not find a difference in total cholesterol (Ralston et al., 2009; Vugt et al., 2016), LDL (Grant et al., 2008; Ralston et al., 2009; Tenforde et al., 2011), BP (Grant et al., 2008; Harris et al., 2009; Ralston et al., 2009; Tang et al., 2013; Vugt et al., 2016), or BMI (Vugt et al., 2016)between groups.

Several studies also assessed changes in psychological measures, including diabetes-related distress and self-efficacy for managing diabetes. Data on diabetes-related distress as measured by the Problem Areas in Diabetes (PAID) questionnaire were reported in four studies. Of these studies, one study using an RCT design found a lower distress score in the intervention group (n=202) compared with the usual care group (n=213, 0.6, SD 0.8, vs 1.0, SD 1.0, P<.001) at 12 months (Tang et al., 2013). Self-efficacy between groups was assessed in two studies. In an RCT by McCarrier et al. (n=77 patients with T1DM), the intervention group had a significant increase in diabetes-related self-efficacy compared with the control group (P=.04) (McCarrier et al., 2009). The study from the Netherlands analyzed data from 1390 respondents and found a significantly higher self-efficacy score for portal users (i.e., patients with at least 1 log-in, 79.5, SD 15.8) than nonusers (i.e., patients without a log-in, 72.7, SD 17.8) among patients with T2DM (n=1262, P<.001) but not T1DM (n=128) (Ronda et al., 2013).

2.4.7 Qualitative studies reporting benefits and barriers to using patient portals

There were eight studies that evaluated patient portals by applying qualitative methods—six used focus groups, one used face-to-face interviews, and one used telephone interviews. Qualitative responses revealed that patients favored features that allowed them to view summaries,

request prescription refills, receive reminders for medical appointments, access laboratory results, and communicate with providers (Bryce et al., 2008; Hess et al., 2007; Osborn et al., 2013). Patients stated that benefits of using the portal included more awareness of their disease, increased access to care outside of office visits, enhanced communication and satisfaction, and promotion of behavior change (Hess et al., 2007; Urowitz et al., 2012; Wade-Vuturo et al., 2013).

Patients who never used the portal provided the following reasons for not requesting a log-in: unawareness of the existence of the portal, no use of computers, family members as delegates, slow response from physicians or nurses, and poor usability of the portal (Hess et al., 2007; Osborn et al., 2013; Urowitz et al., 2012). Mayberry et al. highlighted the role of family members in supporting patients' access to and use of the portal, especially for those with limited health literacy, numeracy, or computer literacy. Family members taught the patient how to use each function in the portal, and some acted as delegates for patients by managing their health conditions (Mayberry et al., 2011). Several studies also identified that physician engagement in using the portal remains challenging. Providers with negative attitudes toward the portal listed lack of integration with work routine, minimal knowledge about the portal, limited time, and usability problems as reasons for not using the portal (Sieverink, Braakman-Jansen, et al., 2014; Urowitz et al., 2012).

2.5 DISCUSSION

2.5.1 Principal findings

This literature review reported on the current evidence on EHR portal use in the clinical management of patients with diabetes. The 13 patient portals that were represented in the 30 studies showed wide variability in features examined and provided across portals, evaluated diabetes

outcomes, and whether the technology resources were applied in combination with a disease management program for diabetes. These variabilities increased the difficulty of performing a meta-analysis and generating any conclusions about the effectiveness of patient portals for diabetes management. In our review of the RCTs, we found inconsistent findings regarding the effect of the portal use on diabetes outcomes. Observational correlational studies also yielded mixed findings regarding the association between portal use and diabetes outcomes. However, we were able to identify that the patient portal, which leverages strong patient-centered principles (e.g., DM education, tailored feedback on patient's DM-related health data), performed better in improving patient outcomes. The DM-specific portals enabled patients to receive personalized education, send blood glucose readings, and obtain individualized feedback from the health team.

Although we observed more favorable outcomes associated with using the DM-specific portals, the effect sizes in the studies reviewed were small. This may be due to several challenges associated with the use of patient portals. The design of the majority of the patient portals currently available was not patient-centered, meaning that features provided do not align with patient expectations, and in many cases were not evidence based. For a self-management intervention to be effective, appropriate theories of engagement and implementation should be in place to support the evidence-based intervention. For example, to ensure the effective application of a system, the system needs to provide a complete feedback loop, which consists of multiple components that include monitoring and transmission of patient status, data interpretation in comparison with personalized goals, adjustment of treatment regimen based on patient status, timely communication with individualized recommendations, and repetitiveness of this cycle (Jimison et al., 2008). However, from the studies reviewed, current patient portals often provided only one of these functions or a subset of them, which may contribute to the less robust favorable results. To significantly improve diabetes management, patient portals need to do more than provide

convenient services such as requesting medication refills or reviewing laboratory results. They should also integrate more evidence-based strategies, such as patient education, to enhance patient engagement.

The current state of low engagement by patients in portal use may interfere with the ability to achieve meaningful clinical benefits. Initial high log-in rates followed by a rapid decline in portal use suggest that multifaceted barriers prevented patients from engaging in the long-term use of patient portals. These barriers are technology-related (e.g., functionality, usability), patient-related (e.g., access to the internet or a computer, low health literacy, perceived usefulness, sociodemographic and clinical characteristics), and provider-related (e.g., provider engagement).

A recently published review indicated that endorsement from providers was one of the most influential factors that contributed to patients' accepting the portal and using it as a tool for diabetes self-management (Irizarry et al., 2015). However, healthcare providers commonly expressed concerns toward using a patient portal such as a disruption of their workflow and time constraints. These challenges may limit physicians' adoption and engagement of portal use and lead to minimal improvement in patient outcomes (Miller, Latulipe, Melius, Quandt, & Arcury, 2016). Future research needs to focus on addressing these barriers to promote more physician involvement in using the portal.

2.5.2 Limitations

There were several noted limitations of this review. First, our findings lacked sufficient quality evidence; the results of this review are not well-supported by level A evidence, with the majority of studies graded as the B or C level. It is no longer feasible to randomly assign patients to either portal use or nonuse group as individuals have the right to access their health information, but studies could consider examining different designs or additional features, given the necessary

health information included in the portal. Second, this literature review only included studies explicitly concerned with patient portals and diabetes, studies evaluating patient portals for multiple chronic disease management that may include diabetes were not included. Finally, only one person was involved in the selection of the studies for inclusion in our review. Future studies should consider using a multiple-rater approach for study evaluation and data extraction.

2.5.3 Conclusions

In conclusion, this review identified several opportunities that could potentially improve diabetes outcomes through a patient portal. Because the majority of the studies examined the overall effect of patient portals, future investigations should consider investigating single features to understand the contribution of each component and understand which component is more influential than others in helping patients manage their diabetes. Moreover, a conceptual framework is needed to standardize an approach to guide the design and evaluation of patient portals. Specifically, functionalities need to be specified to provide guidance on system requirements for patient portal developers. Moreover, a set of evaluation metrics needs to be developed for the evaluation of patient portals to enable them to be compared and ranked. To further improve diabetes outcomes, continued investigation of strategies that could potentially enhance the implementation of the patient portal (e.g., portal design, implementation strategy) may enable the patient portal to reach its fullest potential in supporting diabetes management and increasing patient engagement. At the same time, physicians' perceptions of portal use need to be assessed, and potential barriers need to be addressed to foster physicians' engagement in patient portals.

3.0 MANUSCRIPT 2: USE OF A PATIENT PORTAL FOR ENGAGING PATIENTS WITH TYPE 2 DIABETES: PATTERNS AND PREDICTIONS

3.1 ABSTRACT

Objective: Patient portals empower patients by providing access to their health information and by facilitating communication with care providers. This study aimed to understand the usage patterns of a patient portal offered as part of an electronic health record (EHR) and to examine predictors of portal use among patients with type 2 diabetes (T2DM). **Methods**: A 2-year retrospective cohort study including patients who visited an outpatient setting of UPMC. Demographic and clinical data on 38,399 patients from the outpatient EHR were analyzed. Descriptive statistics were used to present portal usage patterns. Binary logistic regression was employed to examine predictors and two-way interactions associated with portal use. **Results**: Almost one-third of patients with T2DM (n=12,615; 32.9%, 95% CI: [32.38%, 33.32%]) had used the portal for an average of 2.5±1.9 years prior to the study. Portal use was higher on weekdays than weekends ($p<0.001$). An increase in portal use was observed in response to email reminders. A nonlinear relationship between age and portal use was observed, depending on several other predictors ($ps<0.05$). Patients living in more rural areas with low income, were less likely to use the portal ($p=0.021$), this finding also applied to non-whites with low income ($p<0.001$). More chronic conditions and a high HbA1c value were associated with patient portal use. **Conclusions**: Patient engagement in portal use can be facilitated through a proactive approach by healthcare providers. Additional research is needed to reduce disparities in portal use and to evaluate the effectiveness of portal use on diabetes outcomes.

3.2 INTRODUCTION

The prevalence of type 2 diabetes (T2DM) has doubled in the past two decades (Selvin, Parrinello, Sacks, & Coresh, 2014), and the rate continues to rise at a significant rate (Rowley et al., 2017). Diabetes management remains challenging due to the growing number of adults with diabetes and the increasing complexity of self-management required by continuous adjustments in treatment. Engaging patients in self-management of their disease is essential to achieve adherence to treatment regimens that align with patient needs and preferences (Haas et al., 2012). Driven by the increasing use of health information technology, diabetes management greatly relies on facilitating patient access to health information and enhancing clinical decision support for more comprehensive and individualized care delivery during a clinical visit.

Healthcare organizations frequently adopt patient portals to support patient access to health information with the goal of engaging patients in their care and self-management. A recent poll of 1,756 healthcare leaders revealed that 90% of healthcare organizations offer a patient portal to patients (Medical Group Management Association, 2018). This particular type of personal health record (PHR) connects to a health organization's electronic health record (EHR) system and provides patients with access to medical information including visit summary, medical history, medications, and lab results. Some advanced portals allow interactive functionalities such as scheduling appointments and facilitating communication with physicians. Patients are becoming increasingly interested in using these portals. It is anticipated that 75% of U.S. adults will adopt a patient portal by 2020 (Ford et al., 2016).

Three earlier observational studies described patient portal use by patients with diabetes and noted that 27.8% - 37.6% of the patients used a portal (Sarkar et al., 2011; Tenforde et al., 2011; Weppner et al., 2010). One study reported the following activities and proportion of patients

who performed them in their use of the portal: 53% viewed lab results, 28% requested medication refills and 15% scheduled appointments (Sarkar et al., 2011). All studies examined portal usage before 2009 when the Meaningful Use (MU) incentive program was enacted. The MU program provided physicians with monetary incentives for allowing patients to access their health information and communicating with patients on health issues. To date, few recent studies that have examined the usage of an EHR based patient portal following implementation of this incentive program.

With the increasing attention on patient portals and the expectation to improve patient outcomes, it is critical to understand when patients use the portal, which patients use the portal, and what features patients use when accessing the portal. The aims of this study were to: 1) describe the usage pattern of the patient portal in patients with T2DM over time, including what features the patients accessed and when patients used the portal (i.e., weekdays vs. weekend, proximity to a face-to-face clinic visit), and 2) examine the associations of patient demographics (e.g., age, gender, race) and clinical characteristics (e.g., number of chronic conditions, initial HbA1c value, insulin use, number of primary care physician visits) with portal use.

3.3 METHODS

3.3.1 Study Design

This study employed a 2-year retrospective, longitudinal cohort design using existing data from the ambulatory EHR of University of Pittsburgh Medical Center (UPMC) Physician Services (Epic Systems, Verona, WI). The study was approved by the University of Pittsburgh Institutional

Review Board (IRB), and an honest broker system was used to obtain the de-identified protected health information.

3.3.2 Setting and Patient Selection

UPMC has over 600 doctors' offices and outpatient sites throughout western Pennsylvania. The cohort of patients with T2DM was identified using the International Classification of Diseases, Ninth Revision (ICD-9) diagnosis codes of 250.* and the International Classification of Diseases, 10th Revision (ICD-10) diagnosis codes of E11.* Patients were included if they were prescribed diabetes medications and had HbA1c results posted during the study period. Our use of two or more indicators have previously demonstrated accuracy to determine whether or not patients have diabetes (Zgibor et al., 2007). Potential patients with type 1 diabetes were removed from the analysis as indicated by having only ICD-9 code for type 1 diabetes without ICD-9 code for type 2 diabetes, or age being younger than 40 years who were prescribed only insulin (Lo-Ciganic et al., 2011). Patients were further excluded if they 1) were newly diagnosed with T2DM, 2) had only one specialty care visit, and 3) were new to the portal during the study period. As a result, a total of 38,399 patients were included in the study. Figure 2 presents the cohort selection process for this study.

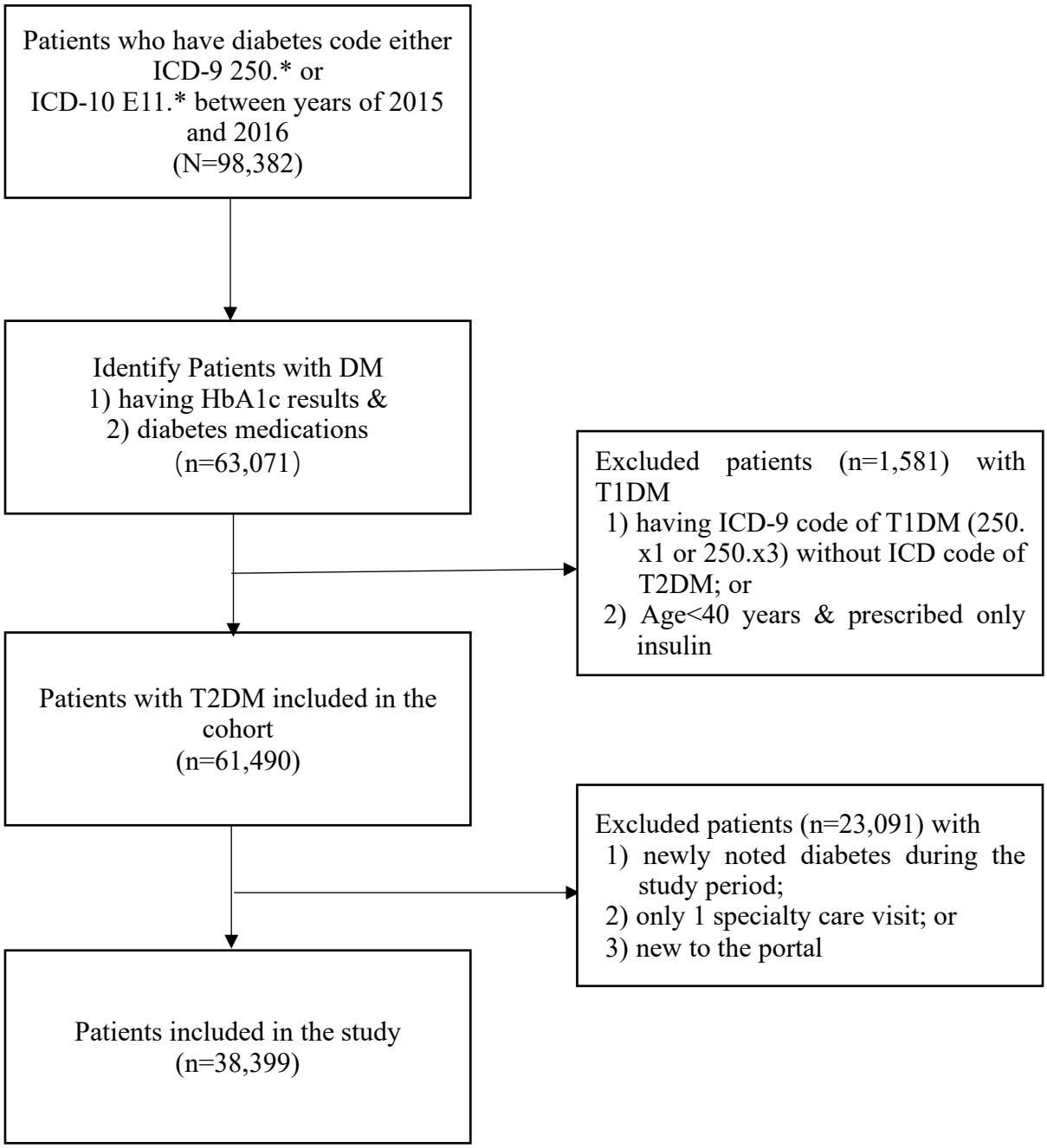


Figure 2. Cohort Selection Diagram

3.3.3 Measures

3.3.3.1 Demographic and Socioeconomic Characteristics

Patient demographic data extracted from the EHR included age, gender, race, primary health insurance, and zip code. We linked neighborhood summary statistics from the U.S. Census Bureau's 2011-2015 American Community Survey (5-year estimate) to each patient via their 5-digit zip code (US Census Bureau, 2015). The patient socioeconomic characteristics that were estimated from U.S. Census data included educational attainment, urbanization, and median household income for the particular zip code. Education attainment was a continuous variable defined as the proportion of residents who had obtained a bachelor's degree or higher in a specific zip code. Urbanization was measured as the proportion of residents within an urbanized area in a specific zip code.

3.3.3.2 Clinical Characteristics

Table 3 summarizes the data retrieved from the EHR and the variables to be considered as predictor variables in the modeling. The laboratory test results contained the date of the HbA1c test and the value of HbA1c result. We calculated the total number of HbA1c tests that were performed for each patient over the study period and included the first reported HbA1c value for each patient in the analysis.

Patient-prescribed medications were retrieved from the medication prescriptions. Insulin use and the glucose-lowering medications for T2DM were identified using the therapeutic classes according to the American Hospital Formulary Services (AHFS) Pharmacologic-Therapeutic Classification System (American Society of Health-System Pharmacists, 2016). The number of different diabetes medications prescribed to each patient was determined. Insulin use was a binary variable (yes/no) representing whether or not the patient was prescribed insulin.

Table 3. Variables Represented in the Electronic Health Record and in the Model

Data category	Representation in EHR	Represented in model as
Administration	Age, gender, race, primary health insurance	Age, gender, race, health insurance (Medicare, Medicaid, Commercial, Self-insured, Other)
Laboratory results	Date of HbA1c test and result	Initial HbA1c result, total # of HbA1c tests
Medication orders	Name and date of prescribed medications	Insulin use (yes/no), total # of distinct diabetes medications
Visits	Type of visit and visit date	Total # of PCP visits
Encounter diagnosis	ICD diagnosis code	Total # of distinct chronic conditions
Telephone contact	Contact date	Total # of telephone contacts

Patient comorbidities were calculated using the chronic disease indicator that was found in the Clinical Classification System (CCS) developed as part of the Healthcare Cost and Utilization Project (HCUP) sponsored by the Agency for Healthcare Research and Quality (AHRQ) (Agency for Healthcare Research and Quality, 2016). The CCS determines whether an ICD code represents a chronic or non-chronic condition. The total number of comorbidities for each patient was calculated by summing the distinct clinical problems of each patient.

Healthcare utilization data obtained included primary care physician (PCP) visits and telephone contacts. We calculated the total number of visits to a PCP office and the total number of telephone contacts with healthcare providers during the 2-year study period for each patient.

3.3.4 Statistical Analysis

Analyses were performed in R Statistical Software (R version 3.5.1 and R Studio 1.1.456). Using summary statistics, we characterized patients regarding their demographic and clinical characteristics overall and by portal use (yes/no). Medians and interquartile ranges (IQR) were reported for the continuous variables with skewed distributions, and frequencies and percentages were reported for categorical variables. Comparisons of patient characteristics between portal users and non-users were performed using either Mann-Whitney *U*-tests or Chi-square tests of independence as appropriate.

The portal features that the patient used were categorized into six major types: manage appointments, view medical summaries, update and share medical information, renew medication prescriptions, view lab results, and access messages. To describe patient portal usage around a clinic visit, we used each patient's first visit as an example and created two-week windows before and after the day of visit. For each day within the window, we indicated whether or not the patient used the portal. A line chart was plotted to describe the number of users of each day within the window. Furthermore, we calculated the total number of access events to each portal feature category Monday through Sunday to describe the usage patterns by the day of the week. Comparison of the average daily portal usage between weekdays and weekends was performed using the Wilcoxon signed-rank test for two-related samples. A line chart was used to present the portal usage by the day of the week.

Binary logistic regression was used to investigate the association between patient characteristics and the probability of the use of the patient portal (use vs. non-use). Test statistics, including p-values, adjusted odds ratios (OR), and their corresponding 95% confidence intervals (CI) for each predictor variable were reported. Missing data on certain zip codes were found in the

three variables linked from the U.S. Census Bureau including education attainment (n = 115), urbanization (n = 112), and household income (n = 192). Also, a small number of patients (n = 24) had missing values on initial HbA1c due to either problematic entries or implausible values (i.e., HbA1c < 3.5%, HbA1c > 20%). The percentage of patients with missing data (n = 216) was less than 1% of the total sample. A comparison of patient demographics between those with missing and without missing was performed, and showed that patients with missing resided in areas with a slightly lower percentage of people with bachelor or higher degree (median 17.9%) as compared to those with complete data (median 24.8%); however, the small difference may not have practical meanings. Thus, listwise deletion was applied to remove cases with missing values. Due to the relatively small number of cases in certain categories of race and insurance, we collapsed race categories "Black" and "Other (Asian, American Indian, Alaska Native, Other Pacific Islander, and not specified)" into "Other". Insurance categories "Medicaid", "Self-insured", and "Other (Auto, VA Health Care, and Worker Compensation)" were grouped together as "Other". Predictor variables with a p-value of less than 0.20 in the bivariate analyses were included in the binary logistic regression analysis with multiple explanatory covariates. The linearity assumption of continuous independent variables with the logit of the probability of portal use was checked using the Box-Tidwell test; the results showed that age and education were non-linearly related with the logit of the probability of portal use. We further categorized age and education into four categories and re-ran the model and plotted the log odds ratios for each category against the mid-point values of each category to determine the appropriate scaling of age and education as age squared and log base 10 (education + 1) in the multivariable model because they demonstrated the smallest Akaike information criterion (AIC) when compared to other forms of transformation. Two-way interactions between the predictor variables were also assessed. We performed mean centering of

the age variable in the model due to its high multicollinearity with insurance. The Cook's distance was calculated, and no potential influential data point was identified.

We split our dataset into two parts, using the dataset containing 75% of the sample for model training and the remaining 25% of the sample for model testing. Using the training dataset, a manual backward elimination procedure was used to remove non-significant variables ($p < 0.05$) to generate a parsimonious model. The Hosmer-Lemeshow (H-L) test were applied to assess the model fit. Using the model obtained from the training dataset, we evaluate evaluation was performed in the testing dataset by calculating the model sensitivity and specificity. A receiver operating characteristic (ROC) curve was plotted to identify the optimal threshold value, and the percentage of the area under the ROC curve (AUC) was determined to indicate the model discrimination; a percentage of 70% or higher is considered high discrimination between portal users and non-users (Rice & Harris, 2005).

3.4 RESULTS

The sample (N= 38,399) was primarily white (85.2%) with a mean age of 63.49 (SD 11.89) years. Slightly over half of the patients (54.10%) were insured by Medicare. The neighborhood-estimated variables linked from the Census Bureau showed that patients resided in areas, where on average 28.69% (SD 14.15%) had at least a bachelor's degree, and 80% (SD 30.29%) were urbanized areas, with a median household income of $51,054 (SD $16,595). The mean number of HbA1c tests that patients had performed was 2.93 (SD 1.38) with an average initial HbA1c (%) value of 7.63 (SD 1.67). Additionally, our sample of patients with T2DM had on average 7.31 (SD 3.77) chronic conditions, were prescribed on average 1.78 (SD 1.0) distinct diabetes medications, and 37.3% were prescribed insulin. The average number of telephone contacts documented with

healthcare providers was 14.2 (SD 15.3) with an average 7.67 (SD 6.40) primary care physician visits during the 2-year study period.

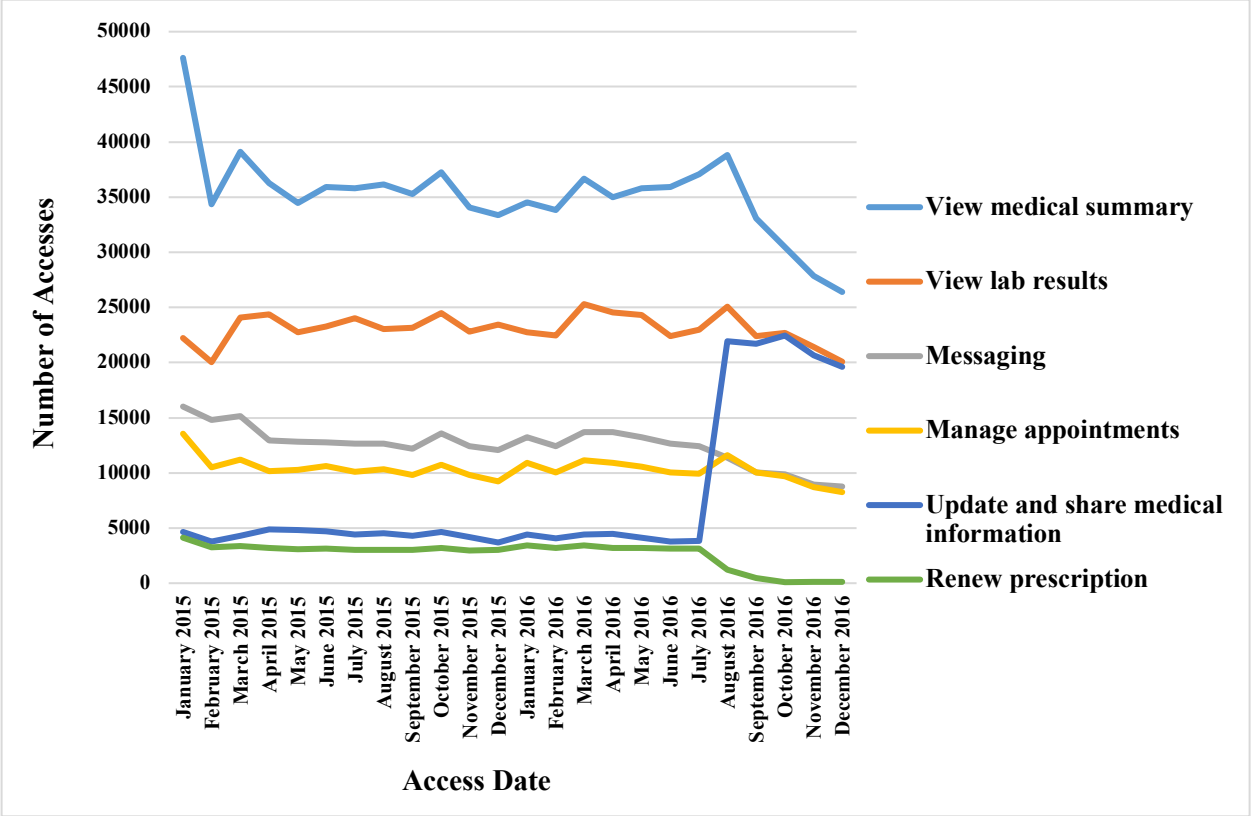
3.4.1 Patient Portal Usage

Nearly one-third (n = 12,615, 32.9%, 95% CI: [32.38, 33.32]) of the sample used the portal for a median of 31 days with interquartile range (IQR) of 44 days between January 2015 and December 2016. Among the 12,615 portal users, patients with T2DM had used the portal for an average of 2.48 years (SD 1.91) prior to the beginning of the study. Table 4 presents detailed information on the number of users for each portal feature category by the frequency of access (i.e., 1~9 times, 10-19 times, and ≥ 20 times). The most frequent feature accessed by these portal users was viewing medical summaries (38.4%), followed by viewing lab results (25.2%), using secure messaging (13.7%), managing appointments (11.3%), updating and sharing medical information (8.6%), and renewing medication prescriptions (2.9%).

Table 4. Description of portal features accessed by portal users with T2DM (n=12,615) from 2015 to 2016

Category	Activity description	# users (%)	# users (%) accessed 1~9 times	# users (%) accessed 10-19 times	# users (%) accessed ≥ 20 times
View lab results	Lab tests ordered Lab results Results component graphing	12,359 (98.0%)	1,906 (15.1%)	2,150 (17.0%)	8,303 (65.8%)
View medical summary	Allergies Medications Immunizations Health snapshot Health maintenance Problem list My conditions Visit summary Histories Encounter details	12,265 (97.2%)	1,391 (11.0%)	1,596 (12.7%)	9,278 (73.5%)
Electronic messaging	Messaging	12,170 (96.5%)	3,990 (31.6%)	2,923 (23.2%)	5,257 (41.7%)
Manage appointment	Appointment review Appointment details Appointment schedule Appointment auto-schedule Appointment confirmation Appointment cancel	11,681 (92.6%)	4,921 (39.0%)	2,807 (22.3%)	3,953 (31.3%)
Update and share medical information	Update medications Update allergies Patient-initiate questionnaires Patient entered flowsheet Flowsheet reports list Flowsheet report details History questionnaire Questionnaire	11,341 (89.9%)	5184 (41.1%)	2,931 (23.2%)	3,226 (25.6%)
Renew prescription	Medication renewal request	9,351 (74.1%)	7,325 (58.1%)	1,402 (11.1%)	624 (4.9%)

Figure 3. Portal Access Between January 2015 and December 2016 by Feature Category



Overall, the usage of each portal feature remained relatively stable from January 2015 to July 2016 (Figure 3). Noticeable changes in portal usage occurred on August 2016 due to a system upgrade; numerous functionalities had been modified with that release, which could have changed their login to the portal. We observed that the patient usage patterns differed by the day of the week. Patients tended to access the portal on weekdays rather than during weekends (median (IQR): 28.00 (37) vs. 17.50 (25), $p < 0.001$). More frequent access occurred at the beginning of the week and toward the end of the week, except for the messaging feature where a consistent high usage was observed from Monday through Friday (Figure 4). Moreover, we noted that patients were more likely to use the portal prior and after a clinic visit (Figure 5), and a reminder email before an office visit facilitated portal access of patients.

Figure 4. Number of Portal Accesses by Feature and Day of the Week

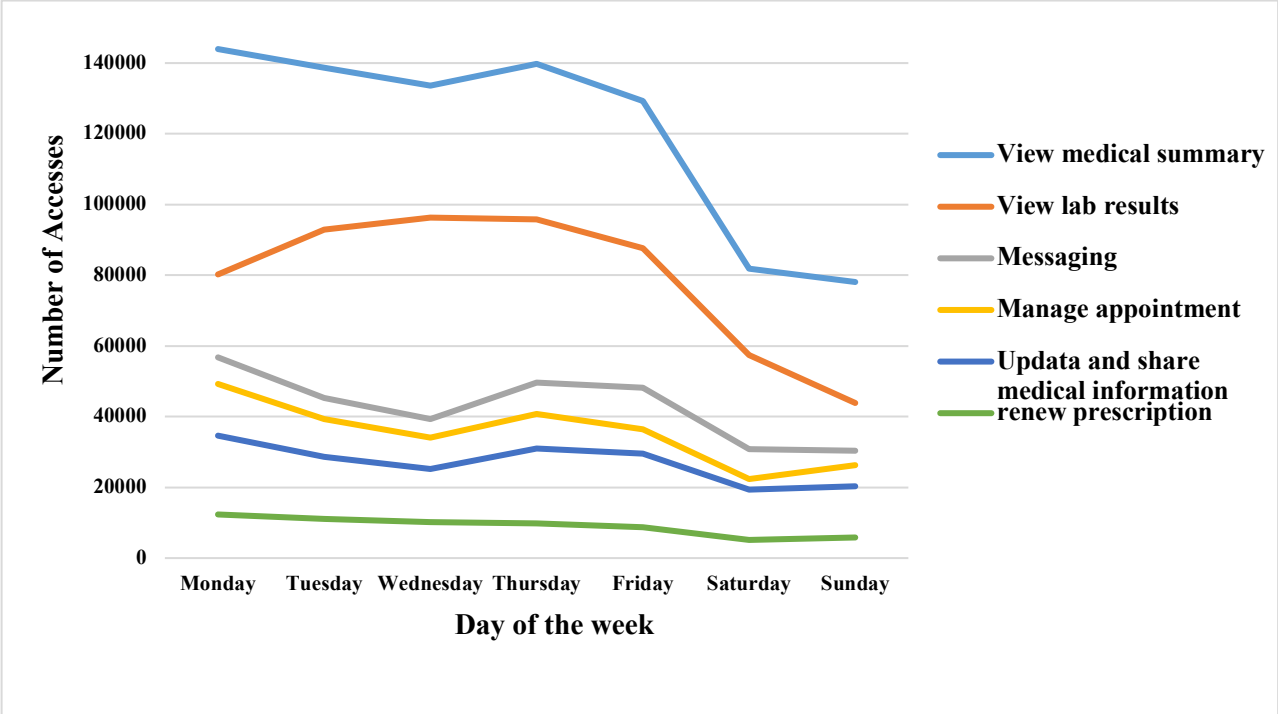
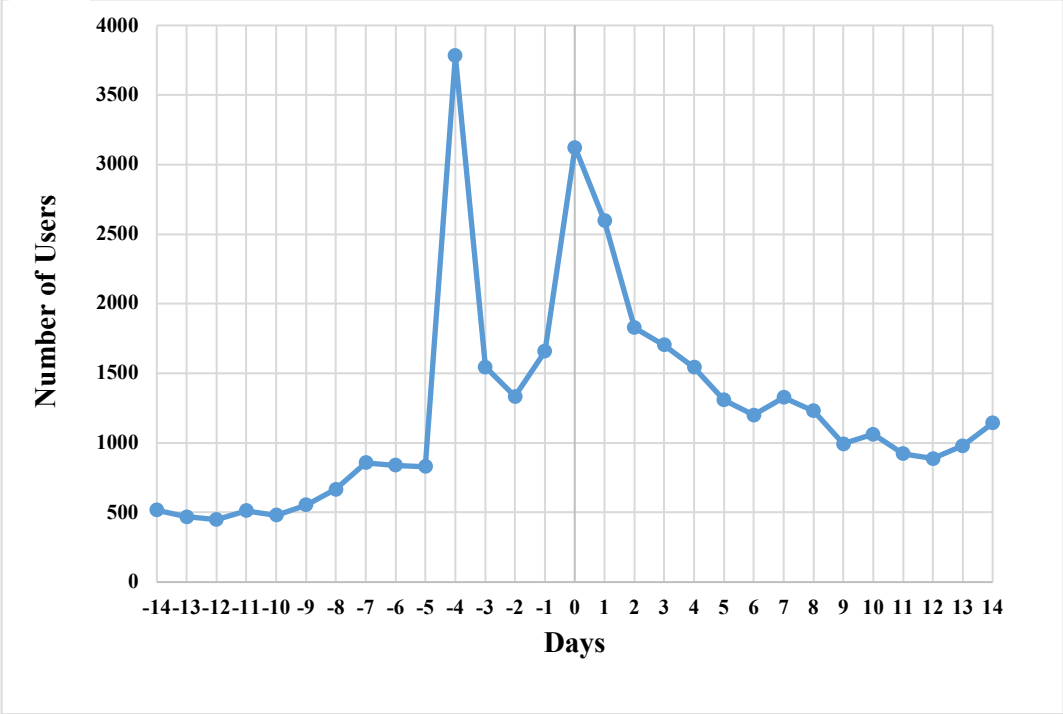


Figure 5. Daily Number of Portal Users Two Weeks Before and After the First Clinical Visit in the Two-year Period



3.4.2 Portal Users versus Non-users

Table 5 summarizes the patient demographic and clinical characteristics of the overall sample and the results for the bivariate analysis of variables between portal users and non-users. Compared to non-users, portal users tended to be younger ($p < 0.001$); be male ($p = 0.001$); resized in zip codes that have higher median household income ($p < 0.001$), higher education level ($p < 0.001$), and higher percent of urbanization ($p < 0.001$); were prescribed more distinct glucose-lowering drugs ($p < 0.001$); and had a greater number of chronic conditions ($p = 0.001$). Also, we noted a significantly greater number of HbA1c tests performed ($p < 0.001$) and a lower median initial HbA1c value ($p < 0.001$) among portal users than non-users. Regarding healthcare utilization, portal users were less likely to use alternative forms of care delivery methods such as telephoning ($p < 0.001$) or visiting a primary care physician ($p < 0.001$) during the study period. No difference in insulin use was observed between portal users and non-users ($p = 0.114$).

Table 5. Characteristics of Study Patients with T2DM and by Portal Use Groups

Demographics	Overall (n=38,399) Median (IQR)/ n (%)	Portal user (n=12,615) Median (IQR)/ n (%)	Portal non-user (n=25,784) Median (IQR)/ n (%)	p-value
Age, years	64.00 (16)	62.00 (14)	66.00 (17)	<0.001
Gender				0.001
Female	19,140 (49.9%)	6,129 (48.6%)	13,011 (50.5%)	
Male	19,259 (50.1%)	6,486 (51.4%)	12,773 (49.5%)	
Race				<0.001
White	32,706 (85.2%)	11,339 (89.9%)	21,367 (82.9%)	
Black	4,895 (12.7%)	935 (7.4%)	3,960 (15.4%)	
Other	798 (2.1%)	341 (2.7%)	457 (1.8%)	
Household income, Median	$48750 ($16,227)	$52,128 ($19,852)	$47,216 ($14,235)	<0.001
Bachelor's degree and above, %	24.80 (19.3)	28.80 (21.2)	23.20 (17.5)	<0.001
Urbanization, %	95.64 (30.9)	96.73 (23.6)	94.73 (33.1)	<0.001
Insurance type				<0.001
Medicare	20,772 (54.10%)	5,542 (43.93%)	15,230 (59.07%)	
Commercial	13,773(35.87%)	6,119 (48.51%)	7,654 (29.69%)	
Medicaid	2,671 (7.00%)	548 (4.34%)	2,123 (8.23%)	
Self-insured	1,048 (2.73%)	345 (2.73%)	703 (2.73%)	
Other	135 (0.35%)	61 (0.05%)	74 (0.03%)	
# of distinct glucose-lowering drugs	1.00 (1)	2.00 (1)	1.00 (1)	<0.001
Insulin use				0.114
Yes	14,324 (37.3%)	4,635 (36.7%)	9,689 (37.6%)	
No	24,075 (62.7%)	7,980 (63.3%)	16,095 (62.4%)	
Initial HbA1c value	7.10 (1.70)	7.10 (1.60)	7.10 (1.70)	<0.001
# of HbA1c tests	3.00 (2)	3.00 (2)	3.00 (2)	<0.001
# of chronic conditions	6.00 (4)	7.00 (4)	6.00 (4)	0.001
# of telephone contacts	9.00 (14)	9.00 (13)	10.00 (14)	<0.001
# of primary care physician visits	7.00 (6)	6.00 (5)	7.00 (6)	<0.001

Note. Comparisons between groups were conducted using Mann-Whitney U test or Chi-Square test of independence where appropriate.

Results of binary logistic regression analysis including multiple explanatory variables and significant two-way interactions are presented in Table 6. In general, the effects of age, race,

income, and the number of chronic conditions on portal usage were modified by several other predictors. A non-linear relation between age and portal usage was found to be dependent on eight other predictors in the model including one's race, household income education attainment, number of telephone contacts, initial HbA1c value, use of insulin, and the number of prescribed glucose-lowering drugs (*ps* < 0.05). Those who were white (linear OR = 0.98859, 95% CI: [0.97939, 0.99788]), had a higher education (linear: OR = 1.00753, 95% CI: [1.00183, 1.01327]), and a lower initial HbA1c (linear: OR = 0.99801, 95% CI: [0.99622, 0.99981]) were more likely to be a portal user particularly among older people. Females were more likely to use the portal compared to males among patients younger than 65 years, and males were more likely to be portal users among those older than 65years (linear: OR = 1.03900, 95% CI: [1.03316, 1.04487], quadratic: OR = 1.00075, 95% CI: [1.00043, 1.00107]).

Table 6. Binary Logistic Regression for Predictors of Patient Portal Use

Characteristic	*p*-value	Adjusted Odds Ratio (OR)	95% CI for OR	
			Lower limit	Upper limit
Main effects				
Age (centered)	< 0.001***	0.93865	0.91700	0.96080
Age^2 (centered)	< 0.001***	0.99655	0.99606	0.99705
Gender				
Female	Reference			
Male	< 0.001***	0.87918	0.82105	0.94144
Race				
White	Reference			
Non-White	< 0.001***	0.23060	0.15899	0.33446
Household income	< 0.001***	1.00005	1.00003	1.00007
Education, $\log_{10}$[Education+1]	< 0.001***	1.96705	1.62987	2.37399
Urbanization	0.196	1.00481	0.99753	1.01215
Insurance				
Medicare	Reference			
Commercial	< 0.001***	1.29292	1.19383	1.40023
Other	< 0.001***	0.66744	0.57291	0.77757
# of distinct glucose-lowering medications	0.135	0.96989	0.93174	1.00959
Insulin use				

Non-use	Reference			
Use	0.927	1.00643	0.87784	1.15386
Initial HbA1c value	< 0.001***	0.85054	0.77732	0.93065
# of chronic conditions	0.763	1.00582	0.96862	1.04445
# of telephone contacts	< 0.001***	0.85054	0.77732	0.93065
# of HbA1c tests	0.786	0.98990	0.92012	1.06497
# of PCP visits	< 0.001***	0.98849	0.98326	0.99375
Interaction effects				
Age × Gender				
Age × Female	Reference			
Age × Male	< 0.001***	1.03900	1.03316	1.04487
Age × Race				
Age × White	Reference			
Age × Non-white	0.016	0.98859	0.97939	0.99788
Age × Insurance				
Age × Medicare	Reference			
Age × Commercial	< 0.001***	0.97849	0.97080	0.98624
Age × Other	0.118	1.01238	0.99687	1.02813
Age × Education	0.009**	1.00753	1.00183	1.01327
Age × # of telephone contacts	0.033*	1.00021	1.00002	1.00041
Age × Initial HbA1c value	0.030*	0.99801	0.99622	0.99981
Age × Insulin use				
Age × Insulin non-use	Reference			
Age × Insulin use	0.049*	0.99382	0.98770	0.99997
Age × # of distinct glucose-lowering medications	0.395	1.00135	0.99824	1.00447
Age^2 × Gender				
Age^2 × Female	Reference			
Age^2 × Male	< 0.001***	1.00075	1.00043	1.00107
Age^2 × Insurance				
Age^2 × Medicare	Reference			
Age^2 × Commercial	< 0.001***	1.00117	1.00074	1.00160
Age^2 × Other	< 0.001***	1.00251	1.00192	1.00310
Age^2 × # of telephone contacts	< 0.001***	1.00003	1.00001	1.00004
Age^2 × # of distinct glucose-lowering medications	0.036*	1.00018	1.00001	1.00034
Race × Insurance				
Race × Medicare	Reference			
Race × Commercial	0.043*	1.25582	1.00765	1.56512
Race × Other	0.015*	0.68782	0.50803	0.93123
Race × Income				
White × Income	Reference			
Non-White × Income	< 0.001***	1.00001	1.00001	1.00002
Race × # of HbA1c tests				

White × # of HbA1c tests	Reference			
Non-White × # of HbA1c tests	0.007**	1.09895	1.02642	1.17660
Urbanization × Household Income	0.021*	0.9999999	0.9999998	1.0000000
Urbanization × Initial HbA1c	0.030*	1.00071	1.00007	1.00136
Education × Household Income	0.003 **	0.999994	0.999990	0.999998
Household Income × # of HbA1c tests	0.002 **	1.000002	1.000001	1.000003
Household Income × Initial HbA1c value	0.021*	0.999999	0.999998	1.000000
# of telephone contacts × # of chronic conditions	0.042*	1.00033	1.00001	1.00064
Initial HbA1c value × # of chronic conditions	0.014*	1.00606	1.00120	1.01094
Insulin use × # of glucose-lowering medications				
Insulin non-use × # of glucose-lowering medications	Reference			
Insulin use × # of glucose-lowering medications	0.038*	1.06549	1.00353	1.13128

Household income appeared to be an important predictor of portal use. Patients with a higher income who had performed more HbA1c tests (OR = 1.000002, 95% CI: [1.000001, 1.000003]) or had a low initial HbA1c value (OR = 0.999999, 95% CI: [0.999998, 1.000000]) were more likely to use the portal. Importantly, we found that patients with a low household income living in a rural area were less likely to use the portal, except for those with a high household income (OR = 0.9999999, 95% CI: [0.9999998, 1.00000]). The association of household income and portal usage also depended on one's race. Both whites and non-whites with higher incomes had a higher probability of being a portal user. Whites with incomes less than $110,000 were more likely to use the portal than non-whites and non-whites were more likely to use the portal when their household income was over $110,000 (OR = 1.00001, 95% CI: [1.00001, 1.00002]).

Patients who had a greater number of chronic conditions with a high initial HbA1c value (OR = 1.00606, 95% CI: [1.00120, 1.01094]) or with fewer telephone contacts (OR = 1.00033, 95% CI: [1.00001, 1.00064]) tended to use the portal. The number of PCP visits was also found to be independently associated with portal use after controlling for other predictor variables in the model. Portal users tended to have fewer PCP visits (OR = 0.988, 95% CI: [0.983, 0.993]). Lastly, we found that portal users had a smaller number of telephone contacts in the middle and older age groups (> 40 years old), but not in the young adult group (< 40 years old) (linear: OR = 1.00021, 95% CI: [1.00002, 1.00041]; quadratic: OR = 1.00003, 95% CI: [1.00001, 1.00004]).

The H-L test yielded a significant result ($\chi^2 = 11.081$, $p = 0.197$), showing the model fit the training data very well. Additionally, model performance was evaluated on the testing dataset. A sensitivity of 76.7% and a specificity of 51.0% were yielded with a threshold value set at 0.4. The percentage of the area under the curve was 71.1%, indicating high discrimination between the portal users and non-users.

3.5 DISCUSSION

Our study examined the actual use of patient portal functions offered as part of an EHR by a large healthcare organization. One-third (32.9%) of the patients with T2DM had accessed the portal between January 2015 and December 2016. This number is slightly higher than what has been reported recently by the Office of the National Coordinator for Health Information Technology (ONC), where it was reported that 28% of patients viewed the online medical record at least once within the past year (Patel & Johnson, 2018). Among portal users, we observed a sustained use of the portal over the two-year study period, and 70% of patients logged in to view

medical summary information more than 20 times, suggesting that patients with T2DM engaged in using the portal and that the portal was convenient for reviewing medical information.

We identified times when patients were more likely to use the portal. Patients were more likely to use the portal on weekdays than on weekends. This weekly usage pattern was consistent with internet usage by the day of the week, where Monday has the highest usage rates and weekends have the lowest rates (Mozilla, n.d.). Additionally, although the portal is available 24/7, patients tended to interact with the portal as a reaction to an email about updates in the portal. An upcoming visit facilitated patients' logging into the portal to confirm their appointment and complete health history forms; after a visit, patients logged into the portal to check lab results. These observed usage patterns suggest that healthcare providers could take advantage of the usage pattern to proactively engage patients in performing self-care activities. For example, a reminder email of prescription renewal sent to patients may help facilitate timely medication refill and improve medication adherence.

Our results expand upon prior research showing that portal use was related to certain demographic characteristics, including being white, having attained a higher level of education, higher household income, and having commercial health insurance (Jhamb et al., 2015; Perzynski et al., 2017; Tenforde et al., 2011). We found a parabolic association between age and portal use. Patients in young and middle-aged groups demonstrated an increase in portal use as they aged. While in older adults, increased age was associated with being less likely to use the portal. This finding can be explained by the gradually developed health issues among young and middle-aged adults that may require greater use of healthcare services. Older adults aged 65 or older, when compared to people in their 50s and early 60s, were less likely to use the computer for communication about their health issues or were not comfortable with technology (Malani, 2018).

Additionally, a consistent finding was that differences exist in access to and use of personal health information between residents of rural and urban areas. Patients who live in a rural area, where access to the internet might be limited, are less likely to use the portal compared to patients who live in an urban area (Greenberg, Haney, Blake, Moser, & Hesse, 2018). Our study expands on this result that portal use was not a concern for rural dwellers with a relatively high household income. Moreover, we observed that portal users, despite having greater number of chronic conditions, had a smaller number of PCP visits and telephone contacts, which may indicate that the portal can assist with addressing some questions patients have about their health and may replace the need for a physician or clinic visit or phone conversation.

Although we found sustained use of the portal in our sample of patients with T2DM who used the portal, two-thirds of the patients with T2DM have not yet adopted the patient portal. There persists a digital divide in access to and use of such technology. This disparity in the use of patient portal and emerging health information technology may negatively affect the existing health disparities in diabetes outcomes. Strategies need to be identified to reduce these discrepancies. Patient education and development of skills in using technology are important since patients may not be aware of the portal or not perceive the value of portal use (Osborn et al., 2013; Ronda et al., 2014). Strategies and avenues are needed to help patients understand the benefits of using the patient portal. Finally, smartphone ownership has almost become universal (Pew Research Center, 2018). In the United States, low-income adults in particular, are increasingly accessing the internet only via mobile devices (Horrigan, Rainie, & Page, 2015). As consumers make a shift away from traditional desktop computers to more mobile options, patient portals need to be available in a more convenient form to allow easy and quick access.

Our study has several strengths and limitations. It assesses the real-world use of a patient portal as part of a large healthcare organization serving patients with T2DM. Sufficient data were

available to reveal detailed usage patterns, and linear and non-linear associations between patient characteristics and portal use were examined with two-way interactions. Several limitations also need to be acknowledged. Our results are based on an analysis of data from a single healthcare organization, which may not generalize to other medical centers that offer patient portals with different functionalities, or on a different platform. Additionally, the large sample of the study provided sufficient power to detect small differences in patient characteristics between portal users and non-users; however, these small odds ratios observed may lack practical relevance and were unlikely to be clinically meaningful. Last, the neighborhood-estimated variables from the U.S. Census were linked via each patient's zip code that may span a wide range of areas and cover a significant variation in socioeconomic status.

In conclusion, portal users in our sample of patients with T2DM demonstrated continued usage of the portal over time; email reminders significantly facilitated patient access to the portal. Healthcare providers may consider proactive approaches to reach patients through the portal and engage them in managing their chronic conditions. Ultimately, the impact of patient portals will rely on the portal's ability to reach across populations and have an impact on self-care and outcomes. Discrepancies in technology use could lead to a healthcare divide if issues remain unaddressed. Future research needs to examine the barriers to portal use in underserved populations with T2DM and engage patients who have not adopted the portal but could benefit the most from using it. Future research also needs to evaluate the effect of portal use on diabetes outcomes.

4.0 MANUSCRIPT 3: A LONGITUDINAL EXAMINATION OF PATIENT PORTAL USE ON GLYCEMIC CONTROL AMONG PATIENTS WITH TYPE 2 DIABETES

4.1 ABSTRACT

Background: Optimal glycemic management reduces complications and promotes quality of life in patients with type 2 diabetes mellitus (T2DM), yet achieving this goal remains a challenge. Activating patients and enhancing care delivery using a patient-centered approach are essential for improving glycemic control. Patient portals hold the potential to address these challenges and provide ongoing care for the growing population with diabetes. **Objective:** Prior research has demonstrated inconsistent results on the association between patient portal use and glycemic control. Also, these studies are limited by their cross-sectional design. Our study longitudinally examined changes of HbA1c over time between users and non-users of a patient portal in individuals with uncontrolled T2DM. **Methods:** This study employed a retrospective cohort design using existing data over a 2-year period from an electronic health record (EHR) and its ancillary patient portal. Patients with T2DM who visited an outpatient setting of the University of Pittsburgh Medical Center (UPMC) from January 2015 to December 2016 were included if they had 1) initial HbA1c value greater than 7%, and 2) two or more HbA1c assessments during the study period. Propensity score matching (PSM) technique was used to balance the portal user and non-user group on demographic and clinical covariates. Linear mixed-effects modeling was employed to investigate the impact of the portal on patient HbA1c over time. **Results:** The patient cohort (N=15,528) was 85.9% white and 52.5% female. On average, patients were 62.8±11.7 years of age with a BMI of 34.2±7.2 kg/m^2 and an initial HbA1c of 8.5±1.5%. Before PSM, patients who

used the portal were more likely to be younger, white, have higher education and income, commercially insured and live in an urbanized area (all p<.001). Moreover, portal users tended to have a higher BMI (p<.001), a lower initial HbA1c (p<.001), more frequent HbA1c assessments (p=.001), a greater number of medications for diabetes (p<.001), and visit an endocrinologist (p<.001). After PSM, both portal user (n=4,924) and non-user (n=4,924) groups were balanced on these demographic and clinical characteristics except for health insurance. Linear mixed-effects regression modeling showed a nonlinear decrease for HbA1c in both groups over time. A significant interaction was observed, with a greater decline and less rise of HbA1c in the portal users than the non-users. **Conclusions:** These findings support patient portals as promising tools for improving clinical outcomes in patients with T2DM. Healthcare providers need to consider strategies to encourage patients to adopt and use the portal for managing their chronic conditions. Future research is needed to examine the mechanisms through which portal use contributes to better outcomes.

4.2 INTRODUCTION

Type 2 diabetes (T2DM) is a significant public health concern that affects 30.2 million adults in 2015 in the United States (US) (Centers for Disease Control and Prevention, 2017a). Optimal glycemic management effectively minimizes the complications and improves quality of life (Khaw et al., 2001; Stratton et al., 2000); however, nearly 50% of patients do not achieve desired levels of glycemic control as measured by hemoglobin A1c (HbA1c) of <7% (Carls et al., 2017; Menon & Ahluwalia, 2015).

Diabetes imposes a substantial financial burden on the US healthcare system; in 2017, every 1 in 4 healthcare dollars were spent on caring for individuals with diabetes (American

Diabetes Association, 2018). At the same time, the demand for providing ongoing health care for the increasing number of people with diabetes is one of the most significant challenges in the coming decades. Innovative approaches that enable continuous care for this rapidly increasing population are greatly needed.

The Chronic Care Model (CCM) provides an evidence-based framework that enhances care delivery by modifying essential components of the healthcare system to support patient-centered care for chronic disease (E. Wagner, 1998). The key elements of the CCM include health systems, decision support, clinical information system, patient self-management support, community resources, and delivery system design (Improving Chronic Illness Care (ICIC), 2015). The American Diabetes Association emphasized that diabetes care needs to be consistent with the elements of the CCM to ensure productive interactions between a prepared practice team and an informed patient (American Diabetes Association, 2015). The CCM has been widely used to improve the management of diabetes, and it has been shown to be an effective framework for increasing the quality of diabetes care (Coleman, Austin, Brach, & Wagner, 2009; Si, Bailie, & Weeramanthri, 2008; Stellefson et al., 2013). Information technologies, such as patient portals, provides an enhanced use of the CCM to facilitate improved delivery of chronic care management (Siminerio, 2010).

Patient portals represent a component of electronic health records (EHRs) that provide direct access to health information and provider communication outside of the office visit. Healthcare organizations often adopt portals as a strategy to more effectively engage patients and deliver patient-centered care. Patients also expressed growing interest in portal use as demonstrated by increasing numbers of patients who register for these programs (Patel & Johnson, 2018). A recent study revealed that approximately one-third of patients with T2DM had adopted the portal, which is slightly higher than what is observed in the general population. The advantages

associated with using this technology include increased awareness of health conditions, facilitated communication and access to care between visits, and promotion of behavioral change (Sun et al., 2018). The increasing attractiveness of patient portals among individuals with diabetes and the potential capability of these portals to support and facilitate diabetes self-management necessitates an examination of portal effectiveness.

Prior interventional studies have found inconsistent results regarding the effect of patient portals on glycemic control (Grant et al., 2008; Ralston et al., 2009; Tang et al., 2013; Vugt et al., 2016). The portals used in these studies functioned as part of established diabetes management programs, and few studies examined the effect of a portal on diabetes-related outcomes in a real-world setting. Several observational studies demonstrating efficacy of real-world portals offered as part of the integrated health system are limited by their cross-sectional design (Harris et al., 2009; Shimada et al., 2016; Tenforde et al., 2011). There are currently no longitudinal studies that examine changes of HbA1c over time between portal users and non-users in patients with diabetes.

4.3 METHODS

4.3.1 Design

This study was a 2-year retrospective cohort study using data from the EHR of the University of Pittsburgh Medical Center (UPMC) Physician Services. The University of Pittsburgh Institutional Review Board (IRB) approved the study

4.3.2 Setting and Sample

The study cohort included 38,399 patients with T2DM who were seen in outpatient settings of the UPMC from January 2015 to December 2016. The selection process for this cohort was detailed in the previous study. Briefly, this cohort was derived from ongoing consumers of healthcare from UPMC who had a date of noted diabetes on the EHR problem list before the study began (January 1, 2015). Patients were excluded if they were new to the portal during the study period. Because this study focused only on patients with uncontrolled diabetes based on HbA1c values ≥ 7%, those with initial HbA1c values < 7% during the 2-year study period were excluded. To longitudinally examine the association of portal use and HbA1c, only data from patients with two or more HbA1c assessments were included for analysis. Therefore, 18,508 patients were eligible for this study, whether or not they use the portal.

UPMC patient portal, also known as MyUPMC, has been available for patients since 2007. This web-based portal enables patients to access part of their health information from the EHR, including a medical summary (e.g., immunizations, medications), laboratory results, and after visit summaries. Individuals can also manage appointments, renew prescriptions, pay bills, and securely communicate with their healthcare providers through the portal.

4.3.3 Measures

Patients' demographic data, including age, gender, race (white, non-white), primary health insurance (Medicare, Commercial, Other), and 5-digit zip code, were collected from the EHR. Using the patient's zip code, we estimated neighborhood variables from the U.S. Census Bureau's 2011-2015 American Community Survey (5-year estimate), including median household income, educational attainment (percentage of residents who had bachelor's degree and above), and

urbanization (percentage of residents within an urbanized area within the zip code) (US Census Bureau, 2015).

Outpatient visit data of each patient were collected, from which we identified whether or not the patient visited an endocrinologist within the 2-year period. The height and weight of each patient were recorded repeatedly at each clinic visit. The mode value of the height measures and the median value of weight were used to calculate the body mass index (BMI, kg/m^2) using the formula (weight in pounds*703) / $(\text{height in inches})^2$.

Medication data obtained included the generic name of the medication and the date of prescription. The American Hospital Formulary Services (AHFS) Pharmacologic-Therapeutic Classification System was utilized to identify anti-diabetic agents and all types of insulin (American Society of Health-System Pharmacists, 2016). The total number of distinct glucose-lowering medications over the 2-year period was calculated. Insulin use was treated as a binary yes/no variable indicating whether or not the patient used insulin.

HbA1c was measured when the tests were performed during the 2-year period and reflects the mean glycemia over the previous 8 to 12 weeks. The date of HbA1c assessments and the test result values were extracted directly from laboratory test results in the EHR. Time was treated as a continuous variable indicating the number of days elapsed between the date of the HbA1c assessment and the first day of the study period (i.e., January 1, 2015). When two or more HbA1c tests were performed less than two weeks apart, only the first measurement of HbA1c was kept in our analysis because 1) HbA1c is an indicator of average glucose in the past 8 to 12 weeks and 2) the HbA1c values measured within a short time span in our study were often close or identical.

4.3.4 Statistical Analysis

Statistical analyses were performed using R statistical packages (R version 3.5.1 and R Studio 1.1.456). We assessed differences between portal users and non-users using the Mann-Whitney U-test for continuous variables with skewed distributions and the Chi-square test of independence for categorical variables, with two-sided statistical testing and the level of statistical significance set at 0.05.

We applied propensity score matching (PSM), a statistical matching approach that mimics randomized controlled trials and attempts to estimate treatment effects for causal inference (Rosenbaum & Rubin, 1983). PSM aims to balance the measured covariates across the treatment and the comparison groups. This approach is useful when estimating a treatment's effect on an outcome using observational data and when randomization of patients to treatment groups is not possible or ethical (M. M. Garrido et al., 2014). In our study, we used this approach to remove bias associated with the differences in the observed patient characteristics between portal user group and the non-user group. We calculated propensity scores using a binary logistic regression model and a robust selection of independent variables to estimate the probability of patient portal use. The variables considered when estimating the propensity scores were factors associated with glycemic control, including demographic and socioeconomic factors (age, gender, race, health insurance type, and neighborhood household income, educational level, and urbanization based on the patient's zip code) and clinical characteristics (BMI, number of HbA1c tests, initial HbA1c value, number of distinct glucose-lowering medications, insulin use, and any visit a UPMC endocrinologist). The nearest neighbor one-to-one matching approach was used (Austin, 2011a). Patients who were portal non-users were matched to those portal users on the logit of the propensity

score. A caliper of width equal to 0.2 of the pooled standard deviation of the logit of the propensity score was used that eliminated 99% of the bias due to the measured confounders (Austin, 2011b).

We compared the change in HbA1c over time between the propensity-matched groups of portal users and non-users by fitting a linear mixed-effects model in the R package using lme4 for mixed models. We treated portal groups (portal users vs. non-users), time (linear and quadratic), and the interaction between group and time as the fixed effects. To account for variability in the patient-specific changes in HbA1c over time, random effects for intercepts and slope for each patient were included in the model. We removed the random quadratic effect of time for subject due to the convergence issue when being included in the model. To reduce the multicollinearity and different scaling issues among variables, time was standardized by subtracting the mean and then divided by the standard deviation (SD) ([time-mean]/SD). Non-significant effects were eliminated to achieve parsimonious models. Health insurance was included as a covariate due to the unadjusted difference between portal users and non-users after matching. A visual inspection of the residual plots did not reveal deviations from homoscedasticity and normality.

4.4 RESULTS

The final cohort consisted of 15,528 patients with initial HbA1c > 7%; 5198 (33.5%) of whom used the portal and 10,330 (66.5%) who did not. The majority of patients were white (85.9%), male (52.5%), and used public insurance (51.6% Medicare), with a mean age of 62.8 (SD 11.7) years and BMI of 34.2 kg/m^2 (SD 7.2 kg/m^2). The neighborhood-estimated variables linked to each patient via their zip code demonstrated an average median household income of $51,106 (SD $16,478) and on average 28.6% (SD 14.1%) had a bachelor's degree or higher; and 79.2% (SD 30.5%) represented an urban population. On average, patients were prescribed 2.1 (SD 1.1)

distinct anti-diabetic medications and had received 3.4 (SD 1.2) HbA1c assessments during the 2-year study period with initial HbA1c of 8.5% (SD 1.5%).

The propensity score-matched cohort included 9848 patients: 4924 portal users and 4924 non-users (Table 7). Before matching, portal users varied from non-users on a number of characteristics. Patients who used the portal were more likely to be younger ($p < 0.001$), white ($p < 0.001$), commercially insured ($p < 0.001$), and resided in zip codes having greater education attainment ($p < 0.001$), having higher median incomes ($p < 0.001$), and being more urban ($p <0.001$). Additionally, portal users overall had a higher on average median BMI ($p < 0.001$) and had more frequent HbA1c assessments ($p = 0.001$) with a lower mean initial HbA1c ($p < 0.001$), and had visited a UPMC endocrinologist ($p < 0.001$). After propensity score matching, patient characteristics in both groups were similar except for the type of health insurance ($p < 0.001$). Portal users tended to be insured with commercial products more than non-users.

Table 7. Comparison of Demographic and Socio-economic Neighborhood Characteristics of Portal Users and Non-users Before and After Matching

	Unmatched Cohort			Matched Cohort		
	Portal user (n=5,198) Mean ± SD/ n(%)	Portal non-user (n=10,330) Mean ± SD/ n(%)	P Value	Portal user (n=4,924) Mean ± SD/ n(%)	Portal non-user (n=4,924) Mean ± SD/ n(%)	P Value
Age, years	60.15 ± 10.90	64.06 ± 11.91	<.001	60.53 ± 10.75	60.54 ± 12.01	.762
Gender			.057			.505
Female	2413 (46.4)	4962 (48.0)		2284 (46.4)	2251 (45.7)	
Male	2785 (53.6)	5368 (52.0)		2640 (53.6)	2673 (54.3)	
Race			<.001			.336
White	4675 (89.9)	8658 (83.8)		4404 (89.4)	4433 (90.0)	
Non-white	523 (10.1)	1672 (16.2)		520 (10.6)	491 (10.0)	
Insurance			<.001			<.001
Medicare	2127 (40.9)	5891 (57.0)		2057 (41.8)	2331 (47.3)	
Commercial	2655 (51.1)	3272 (31.7)		2475 (50.3)	1945 (39.5)	
Other[a]	416 (8.0)	1167 (11.3)		392 (8.0)	648 (13.2)	
Education[b]	31.93 ± 14.93	26.89 ± 13.36	<.001	31.04 ± 14.35	30.81 ± 14.51	.291
Household income,[b] median	55,329 ± 18,167	$48,981 ± $15,136	<.001	$54,145 ($17,034)	$53,713 ($17,130)	.103
Urbanization[b]	82.22 ± 27.69	77.66 ± 31.65	<.001	81.61 ± 28.19	81.40 ± 27.98	.320
BMI (kg/m^2), median	34.84 ± 7.10	33.89 ±7.19	<.001	34.74 ± 7.06	34.84 ± 7.45	.863
# of HbA1c tests	3.42 ± 1.20	3.35 ± 1.20	.001	3.33 ± 1.15	3.40 ± 1.24	.080
Initial HbA1c value	8.32 ± 1.38	8.53 ± 1.59	<.001	8.34 ± 1.40	8.34 ± 1.39	.894
# of distinct DM medications	2.16 ± 1.12	2.04 ± 1.08	<.001	2.13 ± 1.11	2.14 ± 1.14	.833
Insulin use			.214			.952
Yes	2385 (45.9)	4631 (44.8)		2232 (45.3)	2235 (45.4)	
No	2813 (54.1)	5699 (55.2)		2692 (54.7)	2689 (54.6)	
Any visit to an endocrinologist			<.001			.962
Yes	1264 (24.3)	1959 (19.0)		1136 (23.1)	1138 (23.1)	
No	3934 (75.7)	8371 (81.0)		3788 (76.9)	3786 (76.9)	

Note. BMI, body mass index; DM, diabetes mellitus.

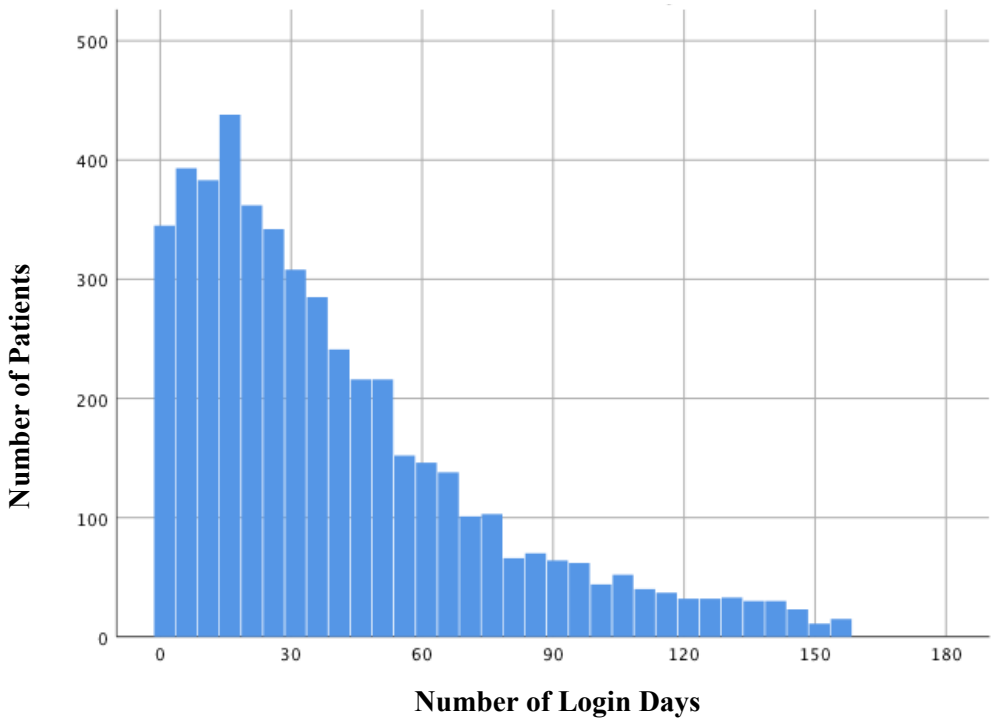


Figure 6. Histogram of Number of Login Days for Portal Users

In the propensity score matched cohort, patients (n=4,924) with HbA1c > 7% in the portal user group showed a median usage of 32 login days with an interquartile range of 44 days during the 2-year study period (Figure 6). When examining the frequency of access to each portal feature, viewing the medical summary was used most frequently accounting for 38.3% of all portal access events, and followed by viewing laboratory results (24.6%), secure messaging (14.1%), managing appointments (11.3%), updating and sharing medical information (8.8%), and renewing medication prescriptions (3.0%) (Figure 7).

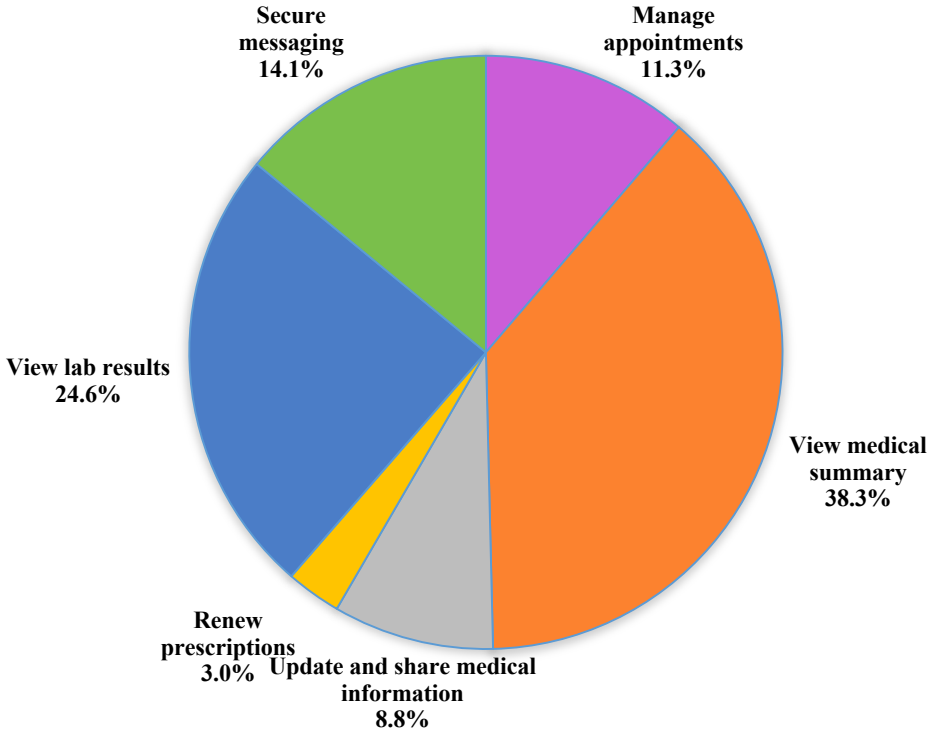


Figure 7. Percentage of Accesses for Each Portal Feature

An examination of patient portal use on glycemic control in the propensity score-matched group demonstrated significant group-by-time interaction ($p < 0.001$), group effect ($p = 0.009$), and linear and nonlinear time effect (all $p < 0.001$) on HbA1c (Table 8). Both groups showed a non-linear decline of HbA1c over time, with a greater decline in portal users compared to the non-users. A slight rise was observed in both groups, with an earlier and larger increase observed among portal non-users (Figure 8).

Table 8. Final Linear Mixed-effect Model for HbA1c in the Propensity-matched Cohort

Fixed effects	Estimate	Standard error (SE)	P values
Portal use	-0.063	0.025	.010**
Time, standardized days	-0.035	0.008	<.001***
Portal use*Time	-0.068	0.012	<.001***
Time^2	0.067	0.006	<.001***
Health insurance			
Medicare	Reference		
Commercial	0.240	0.026	<.001***
Other	0.688	0.042	<.001***

Note. Time was measured by subtracting the first day of the study from the HbA1c assessment date.

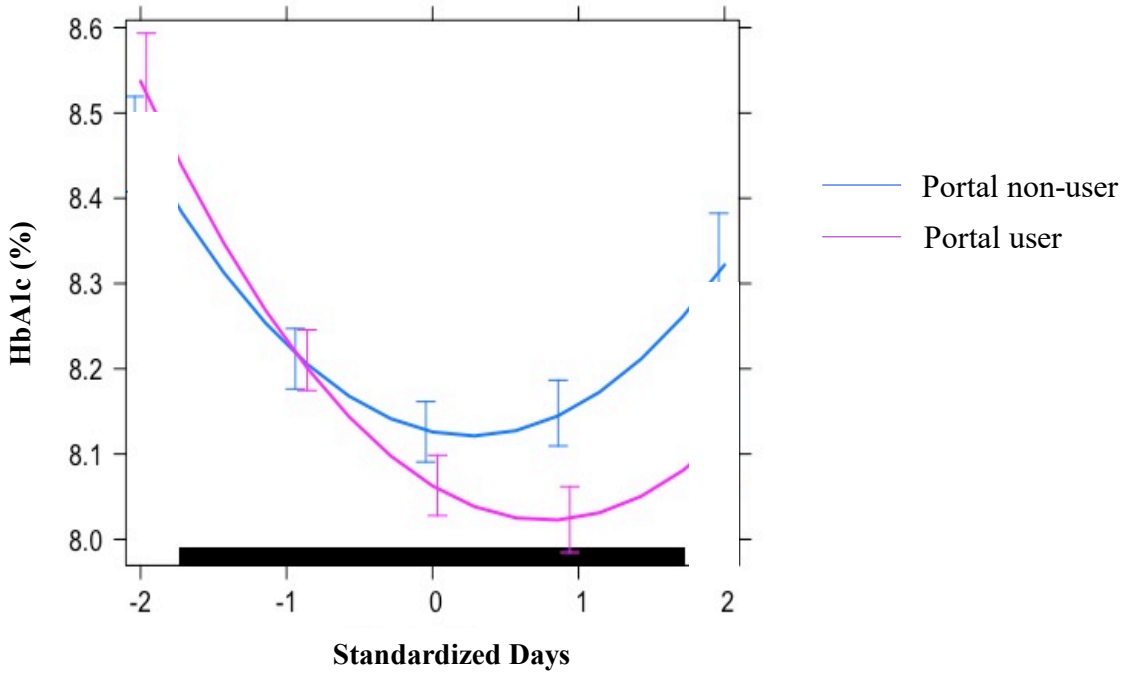


Figure 8. Predicted HbA1c Over Time (Standardized Days) by Portal Use Groups

Legend: The x-axis standardized days is the z scores calculated based on the mean and the standard deviation of time measured in days; a standardized day of 0 equals to the mean days of HbA1c assessments (253.3 days) from the first day of the study. The standardized days of -2, -1, 1, 2 represent how many standard deviations (SD 146.5 days) below (negative values) or above (positive values) the mean days.

4.5 DISCUSSION

This study extends results from previous cross-sectional investigations of patient portal use by longitudinally examining changes in glycemic control over time in patients with T2DM who do and do not engage in this technology. Our results from applying linear mixed-effects modeling revealed that patients who used the portal had a greater decrease of HbA1c over time, and this decrease was better maintained among portal users compared to the non-users over the 2-year study period.

There are several possible explanations for the greater decline in HbA1c that we observed among portal users. First, patients with diabetes in one study reported the benefits of using patient portals, including engaging them in self-care through tracking their disease and improving awareness of their health status (Urowitz et al., 2012). Such patient engagement with chronic illness self-care is an important strategy that leads to positive health outcomes (Greene & Hibbard, 2012). Second, patients who registered and logged onto the portal tended to have a higher level of engagement with managing their diabetes than those who did not use the portal. These individuals may have been more proactive in seeking healthcare services and were more likely to learn about their health conditions through other forms of media in addition to the portal. Finally, patient portal use of an online refill function may result in enhanced medication adherence among patients with diabetes, as a previous study has demonstrated (Sarkar et al., 2014).

Prior studies using cross-sectional data from EHRs examined certain features (i.e., secure messaging, refill prescription) within the portal and its association with glycemic control. An earlier study of 15,427 patients found that 12 or more threads of message exchange between patients and providers over a period of 14 months were associated with better glycemic control (HbA1c < 7%, relative risk [RR] 1.36, 95% CI: 1.16–1.58) (Harris et al., 2009). A study by

Shimada et al. demonstrated that patients with two or more years of secure messaging use, but not online medication refill use, were more likely to achieve glycemic control three years later at follow up (Shimada et al., 2016). Only one study examined the association of the overall portal use with diabetes specific measures, including HbA1c. The results demonstrated a slight decrease in HbA1c (0.02%, $p < 0.01$) associated with a 10-day increase of portal use (Tenforde et al., 2011). These studies support the use of patient portals for improving clinical outcomes in patients with diabetes.

Although we observed statistically significant HbA1c change over time, the clinical significance needs to be evaluated given the sufficient power of detecting differences due to the very large sample. According to Khaw et al., a 0.1% decrease of mean HbA1c could prevent 12% of the excess death, and a 0.2% decrease of HbA1c lowered the all-cause mortality by 10% (Khaw et al., 2001). Thus, our results are meaningful in practice, although greater improvements are desirable.

Despite the number of studies demonstrating efficacy of portal use on A1c in patient populations with diabetes, major disparities in using this information technology exist. These include unawareness of portals or their efficacy, lack of access due to educational issues or socioeconomic status, or lack of buy-in on the part of physicians who may see this as a source of non-reimbursable care fee for service settings (Sun et al., 2018). It will be important to address existing barriers to portal use among both patients and providers in the future. Interventions targeting increased awareness of, access to, and physician involvement in using these tools have potential to not only improve care delivery but also guiding patients to take better care of their own health.

Several strengths of this study need to be recognized. We examined the patient portal use over time in a real-world setting offered by an integrated health system. Our study was the first

longitudinal investigation of the effect of a patient portal on glycemic outcomes in a large sample of patients with T2DM. The use of a propensity score matching approach allowed us to infer causal inference through balancing patient socio-demographics (e.g., age, gender, race, education) and clinical characteristics (e.g., the number of HbA1c assessments, any visit to an endocrinologist).

This study also has several limitations. Distinct from randomized controlled trials, where the intervention and the control group are balanced on both the observed and unobserved/latent variables through randomization, PSM allows matching only on observed variables associated with the outcome as identified from theory or literature. This may interfere with the ability to obtain balance on other unobserved/latent variables (M. M. Garrido et al., 2014). In addition, baseline HbA1c values before entering the study were not collected; instead, a patient's initial HbA1c value during the 2-year period was used as the baseline blood glucose level to balance portal users and non-users. Other limitations were associated with the inaccuracies and incomplete EHR data. Diabetes diagnosis dates that appeared on the problem list underestimated the duration of patient diabetes when compared to other studies using data from similar sources. Some patients performed point-of-care HbA1c testing during a clinic visit; however, the results of those assessments were not available in the outpatient EHR. Moreover, we were unable to track patient data if they visited another healthcare system that is not comparable to the current EHR system. Lastly, it is important to note that we were unable to track in the EHR behavior change and self-efficacy for managing diabetes, or whether or not the patients took their medications or filled or refilled the prescription. These limitations are similar to those of many other studies using EHR data.

These findings highlight the significance of patient portals as a promising technology for engaging patients and enhancing clinical outcomes in patients with diabetes who are seeking to optimize their glycemic control. Future research is needed to reveal the underlying mediating

mechanisms that may contribute to the improved glycemic control as well as other outcomes. Some portal features may be more important than others in assisting patients to manage their conditions; these features need to be identified to provide an evidence-based portal design and implementation. Clinicians and researchers need to identify strategies to ensure the sustained use of the portal and encourage those who have not begun using the portal to sign up for access and use of the portal.

Appendix A TABLES OF OBSERVATIONAL STUDIES EXAMINING PATIENT PORTALS FOR DIABETES MANAGEMENT

Observational Studies Examining Patient Portals for Diabetes Management

Authors and country	Study aims, design, and level of evidence	Sample	Portal features	Outcomes (portal-related)	Results
Shimada et al (2016), US	5-year retrospective cohort study to examine the association of secure messaging (SM) use and Web-based prescription refills use with physiological measures among Patients (Ps) with type 2 diabetes mellitus (T2DM) Evidence: Grade B	N=111,686; user 45.2%; females: 3.6%; white: 68.9%; age 62.1 (SD 9.6) years	My Health*e*Vet by Department of Veterans' Affairs allows Ps to: 1) enter data for diet, activity, and vital signs 2) set goals 3) access data from electronic health record (EHR) 4) communicate with providers 5) request prescription refills	HbA1c, low-density lipoprotein (LDL), blood pressure (BP), SM use, and prescription refill use	34.1% of the sample used refill and 15.8% used SM. Users were younger (P<.001), and more likely to be female (P<.001). Ps with uncontrolled glucose were more likely to achieve glycemic control after ≥2 year of SM use. Ps with uncontrolled BP were more likely to achieve BP control after ≥2 years of refill use. No association of refill use with glycemic control were noted. Both features were associated with lower LDL at follow-up.
Ronda et al (2015), Netherlands	Survey study of Ps with diabetes mellitus (DM) to understand their experiences with a web portal Evidence: Grade C	N=632; T2DM: 81.8%; males: 63.1%; white: 92.8%; age 59.7 (SD 13.2) years; HbA1c: 7.2%	Digitaal Logboek (diabetes mellitus [DM]-specific) by Diamuraal allows Ps to: 1) access data from EHR 2) review medication list 3) receive diabetes education 4) view examinations and a visit summary 4) upload glucose remotely 5) message providers	login frequency, perceived usefulness, and diabetes knowledge	Insulin use (odds ratio [OR] 2.07), frequently experiencing hyperglycemic episodes (OR 1.30), and better diabetes knowledge (OR 1.02) increases the odds of being a persistent user (≥2 times). Early quitters (n=219) felt items were not applicable to their situation. Ps prefer a reminder function and including medication information and side-effects.
Ronda et al (2014), Netherlands	Survey study of Ps with DM on their opinions and the barriers to requesting a login and to using a portal Evidence: Grade C	N=1,390; T2DM: 77.5%; regular use (n=632) vs. nonuser (n=758); males: 62.7% vs. 56.5%; Caucasian: 93.6% vs. 89.3%; age:	Digitaal Logboek (DM-specific) by Diamuraal allows patients to: same as above	self-reported usage, reasons for requesting or not requesting a login, how they heard of the portal, frequency and duration of	14% were nonusers among Ps with type 1 diabetes mellitus (T1DM) compared to 69.2% among Ps with T2DM. The main reason for not using was unawareness (72.4%). Younger age, higher education, being treated by an internist, insulin use, polypharmacy, better diabetes knowledge, and

		60.2 vs. 68.1 years; HbA1c: 7.1% vs. 6.8%		portal use, who helped add data to the portal	more hyperglycemic episodes were associated with portal use. Nonusers perceived specific portal content as less useful.
Roelofsen et al (2014), Netherlands	Cross-sectional study to explore the differences in Ps with T2DM who were interested and uninterested in the portal Evidence: Grade C	N=1,378; Interested (n=974) vs uninterested (n=404); males: 56.6% vs. 48.5%; age: 62.3 (SD 9.7) vs. 68.4 (SD 9.7) years; body mass index (BMI): 29.8 (SD 5.0) vs. 30.2 (SD 5.5)	e-Vita (DM-specific) by the Diabetes Center in Zwolle allows Ps to: 1) receive messages 2) review checkup results 3) set goals and actions 4) monitor metabolic values 5) receive education	Usage	Of the 974 Ps who interested in the portal, 405 (41.6%) were registered for it, and 110 (27.2%) actually logged on to the portal. Interest Ps were more likely to be male, younger, higher educated, and have shorter T2DM duration.
Sarkar et al (2014), US	Observation cohort study to determine the statin adherence before and after using the refill function in the portal between 2006 and 2010 Evidence: Grade B	N= 17,760 males: 54%; white: 58%; age: 62.7 (SD 11) years	Web-based portal kp.org by Kaiser Permanente Northern California (KPNC) allows Ps to: 1) request medication refills 2) view medical history and office visit summary 3) view laboratory results 4) schedule appointments 5) message providers	Statin adherence, LDL, use of refill function	49% (n=8,705) of the cohort used the refill. LDL decreased by 3.1 mg/dL among exclusive users (i.e. request all statin refills on the Web) than nonusers. Nonadherence declined by 6% (95% confidence interval [CI]: 4%–7%) among exclusive users, without changes among occasional users (request refills on the Web as least once). No differences were identified between occasional users and non-users. The improvement in LDL was partially mediated by improved adherence.
Sieverink et al (2014), Netherlands	Descriptive study to understand the usage pattern of the first 6 weeks using the personal health record (PHR) by patients with T2DM Evidence: Grade C	N=568	e-Vita (DM-specific) by the Diabetes Center in Zwolle allows Ps to: same as above	Number of logins, time and day of the action, actions taken, information reviewed, and goals added	28% of all registered users (n=161) visited e-Vita at least once in the first 6 weeks, the number declined over the weeks. 93% of users ended their session the first time they visited the education session.

Lyles CR, et al (2013), U	Survey design to examine the association between patient-provider communication or trust ratings and 1) being a registered user and 2) use of SM Evidence: Grade C	N=14,102; males: 51%; white: 33%; age ⩾ 60 years: 50%	Web-based portal by KPNC allows Ps to: same as above	Portal use in the 2 years during or following survey completion (2006–2007), secure message use, communication, trust	36% of the user used messaging. Increased trust was associated with being a registered user among white, Latino, and older Ps, as well as SM use among white Ps. Better communication ratings were related to being a registered user.
Ronda et al (2013), Netherlands	Survey study design to examine the differences of Ps with and without a login by DM type Evidence: Grade C	N=1,390; T1DM: 9.2%; males: 59.4%; age: 63.9 (SD 12.2) years; response rate: 67%	Digitaal Logboek (DM-specific) by Diamuraal allows patients to: 1) access data from EHR 2) receive general diabetes education 3) view all examinations and diabetes visits 4) upload glucose level remotely 5) contact with care provider	Diabetes treatment satisfaction, diabetes-specific distress, general well-being, diabetes management self-efficacy, and diabetes knowledge	Among 128 Ps with T1DM, those with a login (89.8%) were younger, had better diabetes knowledge, and treated by an internist. In 1,262 Ps with T2MD, fewer Ps had a log-in (41.0%), and having a login was associated with younger age, male, higher education, treatment by an internist, longer diabetes duration, and polypharmacy (all *P*<.001). Ps with a login perceived more diabetes-related distress, more hyper- and hypo- glycemic episodes, more self-efficacy, and better diabetes knowledge.
Tenforde et al (2011), US	Retrospective audit of PHR use during July 2008–June 2009 to measure the association between PHR use and diabetes quality measures Evidence: Grade C	N=10,746; user vs nonuser; females: 46% vs. 50% (*P*<.01); white: 84% vs. 66% (*P*<.01); age: 59 (SD 10) vs. 62 (SD 10) years (*P*<.01) Income: 53,000 vs. 47,500 (*P*<.01)	MyChart by Cleveland Clinic allows Ps to: 1) access data from electronic medical record (EMR) 2) view glucometer readings 3) access diabetes education 4) receive reminders for diabetes-related tests 5) communicate with providers	HbA1C, LDL, BP, BMI, ACEi/ARB use and/or microalbumin testing, pneumococcal vaccination, foot and dilated eye examination, and smoking status, PHR use	Compared to non-users (n=6,710), PHR users (n=4,036) were younger, had higher income and education, tend to be Caucasian. PHR users had lower HbA1c (by 0.29%), SBP (by 1.13 mmHg), and DBP (by 0.54 mmHg) (all *P*<.01). An incremental increase in PHR use days by 10 was associated with greater odds of having decreased HbA1c values (0.02%, *P*<.01).

Bredfeldt et al (2011), US	Retrospective study to determine whether interaction with physician between office visits provide better care during January 2007–December 2008 Evidence: Grade C	N=174 primary care physician (PCPs); Ps panels that are white or mixed race vs. black or Hispanic: age: 57.8 (SD 2.3) vs. 57.9 (SD 2.5) years; Income: $90,359 vs. $60,499	MyChart by Kaiser Permanente, Mid-Atlantic States allows Ps to: 1) access laboratory and pharmacy information 2) schedule appointments 3) communicate with physicians	Diabetes Recognition Program (DRP) score, use of messaging and number of phone calls	Physicians (n=116) whose Ps were white or mixed race tend to use more messaging and phone with their Ps between visits. No association between such contacts and DRP scores was noted. Physicians (n=58) with black or Hispanic Ps had higher DRP scores associated with the messaging (*P*<.01).
Sarkar et al (2011), US	Survey method to examine Ps use patterns of the kp.org by patients with DM during January–December 2006 Evidence: Grade C	N=14,102; females: 49%; non-white: 78%; age: 50-59 33%; HbA1c: 7.59%;	kp.org by KPNC allows Ps to: 1) view lab results 2) communicate with providers 3) request medication refills 4) schedule appointment	Proportion of Ps who activated accounts, logged on, and use of health-services functions	40% of the 14,102 Ps requested a password for the portal. Of these, 4311 (76%) activated the accounts, and 69% logged on; 53% viewed laboratory results, 38% requested medication refills, 37% sent messages, and 15% made appointments. African-Americans and Latinos had higher odds of never logging on (OR 2.6; OR 2.3) compared to non-Hispanic Caucasians, as did those without an educational degree (OR 2.3).
Cho et al (2010), US	Cross-sectional survey to measure veterans' access to and use of the Internet, and their interest in using the portal for T2DM Evidence: Grade C	N=201; males: 97%; white: 60%; age: 58.9 (SD 10.4); HbA1c: 9.6%	My Health*e*Vet by Department of Veteran Affairs Medical Center allows Ps to: 1) access EHR data 2) enter medications, glucose and BP readings 3) request prescription refills 4) access provider notes 5) receive reminders 6) message providers	Awareness and current use of the Web portal, and interest in using it to manage diabetes	41% are very interested in using MHV to track blood glucose readings at home. A third did not have access to internet at home. Factors associated with being very interested were: having internet access at home (*P*<.001), "a lot/some" trust in the Internet as a source of health information (*P*=.002), younger age (*P*=.03), and some college (*P*=.04).

Sarkar et al (2010), US	Survey study design to investigate use of an internet-based patient portal among adults with DM during January–December 2006 Evidence: Grade C	N=14,102; females: 49%; non-white: 78%; age: 50-59 33%; HbA1c: 7.59%	Patient portal by KPNC allows Ps to: same as above	Health literacy, use of each feature in the portal	40% (n=5,671) registered, 76% (n=4,311) logged in. The pages visited were view laboratory results, request medication refills, send messages to providers, and make appointments. People with limited health literacy had higher odds of never signing on to the portal (OR 1.7, 95% CI 1.4–1.9).
Weppner et al (2010), US	Retrospective cohort study to describe use of a web-based shared medical record (SMR, MyGroupHealth) by older patients with DM during August 2003–August 2007 Evidence: Grade B	N=6,185; females: 50.9%; age: 75.2 (SD 6.7) years	MyGroupHealth by Group Health Cooperative allows Ps to: 1) view EHR data 2) request medication refills 3) make appointments 4) communicate with providers	Initial use, subsequent use, PCP's use of the communicatio n feature	32.2% (n=1,990) used the SMR. Portal use was associated with younger age, male, and higher socioeconomic status, overall morbidity, and PCP's use. SMR use was more likely within 3 months of an increase in morbidity (hazard ratio 1.61, 95% CI 1.28–2.01) and within 1 month of changing to a PCP with higher SM use (hazard ratio 3.02, 95% CI 1.66–5.51).
Harris et al (2009), US	Cross-sectional analysis to test the association of electronic messaging with care quality for DM or outpatient utilization between January 2004–March 2005 Evidence: Grade C	N=15,427	MyGroupHealth by Group Health Cooperative allows Ps to: same as above	HbA1c, BP, LDL, outpatient visits, use of electronic messaging	34% (n=5,274) registered the portal, and 19% of Ps (n=2,924) used electronic messaging. Frequent use of electronic messaging (i.e.≥12 threads) was associated with A1C<7% (RR 1.36, 95% CI 1.16–1.58), a higher rate of outpatient visits (RR 1.39, 95% CI 1.26–1.53), but not BP. Small but significant association was observed between secure messaging and LDL<100 mg/dl.
Wald et al (2009), US	Survey design to examine patient journal use and patient experience using the diabetes journal by Ps with T2DM during 2005–2007 Evidence: Grade C	N=126; males: 58%; white: 93%; age: 59.4 years; HbA1c<7.0%: 60%; response rate: 67%	Patient Gateway by Partners Health care allows Ps to: 1) access data from EHR 3) enter concerns and requests about glucose, cholesterol, and BP control 4) request for referrals or education 5) change medication and allergy list	Use of the electronic journal, journal experience	A diabetes care plan took 5–9 minutes to complete by the patient. 61% reported they talked with their provider about their journal information and it helped Ps feel more prepared for their visit (60%) and provide more information to provider (53%).

Appendix B IRB APPROVAL LETTER

University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu

Memorandum

To: Ran Sun, MSN, RN
From: IRB Office
Date: 12/19/2016
IRB#: PRO16120082
Subject: Supporting Diabetes Management with a Patient Portal

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The above-referenced protocol has been reviewed by the University of Pittsburgh Institutional Review Board. Based on the information provided to the IRB, this project includes no involvement of human subjects, according to the federal regulations [§45 CFR 46.102(f)]. That is, the investigator conducting research will not obtain information about research subjects via an interaction with them, nor will the investigator obtain identifiable private information. Should that situation change, the investigator must notify the IRB immediately.

Given this determination, you may now begin your project.

Please note the following information:

- If any modifications are made to this project, use the "**Send Comments to IRB Staff**" process from the project workspace to request a review to ensure it continues to meet the determination.
- Upon completion of your project, be sure to finalize the project by submitting a "**Study Completed**" report from the project workspace.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

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