May 2020

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Recommended Citation

Holt, Jeana Marie, "The Impact of Pre-visit Contextual Data Collection on Patient Activation: Results from a Randomized Control Trial" (2020). *Theses and Dissertations*. 2383.
https://dc.uwm.edu/etd/2383

THE IMPACT OF PRE-VISIT CONTEXTUAL DATA COLLECTION ON PATIENT ACTIVATION: RESULTS FROM A RANDOMIZED CONTROL TRIAL

by

Jeana M. Holt

A Dissertation Submitted in
Partial Fulfillment of the
Requirements for the Degree of

Doctor of Philosophy
in Nursing

at
The University of Wisconsin-Milwaukee
May 2020

ABSTRACT

THE IMPACT OF PRE-VISIT CONTEXTUAL DATA COLLECTION ON PATIENT ACTIVATION: RESULTS FROM A RANDOMIZED CONTROL TRIAL

by

Jeana M. Holt

The University of Wisconsin-Milwaukee, 2020
Under the Supervision of Professor AkkeNeel Talsma, PhD, RN, FAAN

Background The majority of health indicators are outside of the healthcare system, and current electronic health records (EHR) do not capture those indicators. There is a compelling opportunity to test consumer informatics tools that integrate patient's life circumstances, goals, supports, risks, and care preferences into their EHR for point-of-care discussions.

Purpose To determine whether the use of a patient-generated contextual data (PCD) tool designed to enhance the capture and sharing of PCD influenced patient activation.

Design, Setting, and Participants A two-armed, non-blind, randomized control trial was conducted between May 2019, and October 2019 at two urban, academically affiliated primary care clinics. 301 patients were enrolled, randomized with stratification by race to study arms. Nearly equal percentages of control and intervention group participants (60.5% vs. 62.4%) and two-thirds of White vs one-third of Black participants completed both assessments (67% vs. 33%).

Main outcomes and Measures The main outcome was the pre-/post-visit change in Patient Activation Measure (PAM) score, evaluated using intention-to-treat principles. Analysis was also conducted to determine if patient factors mediated racial differences in baseline PAM scores.

Results Using intention-to-treat analysis, there were no significant differences in pre-/post-visit change in PAM scores by arm (p=.079). When allowing for an interaction between race and treatment arm, all interaction terms were not significant (p>0.05). Mediation analysis results indicate income (p=0.025) and difficulty paying monthly bills (p=0.04) when treated as continuous variables, mediated the relationship between race and baseline PAM score.

Conclusions and Relevance The findings indicate the PCD Tool did not affect patient activation. Socioeconomic status (SES) mediated baseline racial differences in the PAM score. These data indicate that further study of the relationships among SES and patient activation are needed. The findings also indicate that interventions targeting patient activation need to account for and be sensitive to patient's SES.

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ACKNOWLEDGEMENTS

First and foremost, I would like to thank my Major Professor, Dr. AkkeNeel Talsma, for her keen ability to guide my dissertation while offering strategic advice about my future research. I thank Dr. Bradley Crotty for his leadership and support during my post-doctoral and Ph.D. training, which allowed me to grow as a clinician-researcher. Thanks to Dr. Jeanne Erickson, whose work, passion, and encouragement assisted my growth as a writer. I thank Dr. Celeste Campos-Castillo for exposing me to research salient to my study. Thank you to Dr. Teresa S. Johnson, who has been an unfailing mentor since I began my post-secondary education.

A tremendous thanks to the clinical team at the UWM Community Nursing Centers. The nurse-led team exemplifies the meaning behind person-centered care. I am grateful for the years of learning with and from you.

I thank my family for their patience and support as I pursued a second doctoral degree. I know that they are thrilled that I achieved my goal.

Introduction

The impact of pre-visit contextual data collection on patient activation: Results from a randomized control trial

The dissertation, *The impact of pre-visit contextual data collection on patient activation: Results from a randomized control trial*, is nested in a larger study, *Avoiding Health Disparities When Collecting Patient Contextual Data for Clinical Care and Pragmatic Research*. To the larger study, I added a complementary and unique secondary outcome (i.e., patient activation), research questions, and study design during the preliminary phase of the project. I added corresponding variables (e.g., health literacy and self-reported mental, physical, and social health) to the larger study and linked the new variables to the complementary research questions.

The dissertation study was designed to determine whether completing a consumer informatics tool that systematically collected patient's values, goals, preferences, and challenges with health and healthcare would improve patient activation scores in primary care patients. The study's findings will address the gap in knowledge of how the standardized collection of patient contextual data for primary care use affects patient activation across populations.

Dissertation Chapters

Dissertation type – Manuscript option

Chapter 1. Introduction

Chapter 2. It is a relational study that reports patient and clinician adoption and the use of a PCD tool in a mid-western academic medical center. Logistic regression modeled the likelihood of adopting the PCD tool, accounting for multiple covariates of primary care patients. Analyzed data on clinician use of the technology was based on the number of patients for whom clinicians accessed the tool through the EHR on the visit day and up to three days before. It is formatted to meet the author guidelines of the target journal, *Journal of the American Medical Informatics Association* (JAMIA).

Chapter 3. It is the study protocol manuscript that describes the study design of the randomized control trial and dissertation. The manuscript adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (Calvert et al., 2018; Chan et al., 2013). It is formatted for the target journal, *Journal of Medical Internet Research* (JMIR).

Chapter 4. It is the main results paper that presents whether gathering pre-visit patient contextual data (PCD) using a consumer informatics tool improves patient-provider communication and patient activation.

Chapter 5. It is a mediation analysis that was conducted to examine if there were direct effects of race on the differences in baseline PAM scores or if they operated through socioeconomic factors, education, and/or health literacy.

Chapter 6. Conclusion

Background

The National Academy of Medicine (NAM), formally known as the Institute of Medicine (IOM), published the book *Crossing the Quality Chasm* to compelled nursing and medicine to address disparities in healthcare quality through innovation and improvements in healthcare delivery (NAM, 2001). They proposed that healthcare stakeholders develop policies and infrastructures that redesigned care processes, optimized health information technologies, and coordinated patient-centered care across the lifespan and healthcare setting. If the healthcare system fully implemented the strategies, the IOM suggested that individuals would interact with a healthcare system that was safe, effective, efficient, personalized, timely, and equitable.

The Last Mile

The ‘last mile’ in the telecommunication industry was a term coined to represent the struggle connecting new fiber optic cable to old copper wiring to deliver high-speed internet connectivity. Healthcare bloggers (Benayoya, 2017; Kaufman, n.d.) propose the ‘last mile’ in healthcare is connecting patient-generated data to their electronic health record (EHR). Over the last decade, many individuals have embraced smartphone applications and wearable activity trackers to monitor their health (NAM, 2015). EHR developers have simultaneously developed programs for patients to view their EHR data (i.e., patient portal). However patient-generated health data are often not linked to a patient's EHRs, excluding vital information the healthcare team could use to deliver patient-centered care (Dzau & Balatbat, 2018; Dzau et al., 2017; Estiri et al., 2018). Instead, EHR industry leaders such as Epic and Cerner cite privacy concerns relating to linking third-party applications to EHRs. They recently mounted a campaign to stop the Office of the National Coordination (ONC) of Health IT from passing interoperability requirements among EHRs and third-party applications proposed in the MyHealthEData and 21st Century Cures Act (Drees, 2020; Thompson, 2020). Their argument is puzzling, given the banking industry’s ability to manage risk, cybersecurity, and information security through structured, well-defined, and industry-endorsed policies (*FDIC: Financial Institution Letters (FILs) Addressing Information Technology Issues*, n.d.).

In addition to the ‘last mile’ in healthcare technology, the IOM recommended ‘last mile’ principles to creating a healthcare industry that was focused on patient-centered care. In a patient-centered healthcare delivery model, the patient must perceive the relationship he or she has with his or her healthcare team as equal, irrespective of differences in social, political, racial, or economic identities or where the person is on the health-illness continuum (Bourgois et al., 2017; Chinn, 2018; Chinn & Kramer, 2014). Furthermore, patients, as sentient humans, must have the ability to exert control of their healthcare decisions to the degree they choose (Higgins et al., 2017).

Primary care is the ideal healthcare setting to apply a patient-centered healthcare delivery model. An essential function of primary care is to facilitate an effective longitudinal partnership where the individual identifies and pursues health goals with the aid of the healthcare team, which is defined as a therapeutic alliance (Higgins et al., 2017). The therapeutic alliance fosters patient-provider communication (Rathert et al., 2017), patient activation (Higgins et al., 2017), and shared decision-making across a breadth of health conditions (Institute of Medicine (US) Committee on the Future of Primary Care, 2014). Primary care is further characterized by the place where patients have most of their healthcare needs to be resolved (Institute of Medicine (US) Committee on the Future of Primary Care, 2014).

Literature Review

Health Disparities

Despite healthcare systems endorsing the NAM's (2001) patient-centered care recommendations, disparities in healthcare quality, and outcomes persist. Disparities in health and healthcare refer to inequities in health and outcomes between populations (U.S. Department of Health and Human Services [DHHS], 2018). African Americans/Blacks (AA/Blacks) have the highest age-adjusted all-cause mortality rates per 100,000 persons of any single racial or ethnic group (Heron, 2018). This disparity persists for the top three leading causes of death, which are cardiovascular disease, malignant neoplasms, and cerebrovascular disease (Cunningham et al., 2017; Heron, 2018). Ethnic and racial minority populations may also be less active and effective in self-management of chronic diseases (Lubetkin et al., 2010). Differences in health outcomes affect all populations as lower health outcomes result in substantial economic losses and increases in healthcare expenditures (Ayanian & Williams, 2011). For example, increasing appropriate asthma medication use by 10% in AA/Blacks workers and dependents would save an estimated $1,600 per person with asthma annually in direct and indirect costs (Nerenz et al., 2011). Thus, the importance of research to generate new knowledge about effective interventions for disease prevention, health promotion, and delivering quality care treatment across populations (Ayanian & Williams, 2011; Bourgois et al., 2017; Cunningham et al., 2017).

Causes of Health Inequities

There are multifaceted and interconnected individual, healthcare provider, health care system, political, societal, environmental, and economic factors that contribute to the health (Ayanian & Williams, 2011; Bourgois et al., 2017; Chinn, 2018; Hall et al., 2015; NAM, 2001). Individual factors include various self-management behaviors from engaging in healthy lifestyle changes to following a medical plan of care (Orgera & Artiga, 2018). Although, risky health behaviors (e.g., alcohol and drug use) may reflect limited socioeconomic opportunities as low socioeconomic status (SES) is an independent predictor of health disparities (Canedo et al., 2018; Green, 2018; Kimmel et al., 2016).

Healthcare provider factors that influence health inequities include implicit biases that affect behavior (Chapman et al., 2013; Hall et al., 2015); diagnosis and clinical treatment decisions, and plans of care (FitzGerald & Hurst, 2017). Ineffective clinician and patient interactions influence patient satisfaction, patients’ likelihood to attend subsequent appointments, and adherence to medication regimens (Hall et al., 2015). Healthcare structures that impose productivity quotas on providers may also negatively impact patient-provider communication and patient activation (Lupton, 2013; Mitchell et al., 2019; Sheridan et al., 2015). Further, the sub-optimal design of electronic health records (EHRs) that excludes social and behavioral determinants of health creates an information gap between patients and clinicians, leading to potentially ineffectual plans of care.

The political, societal, and environmental factors that impact health include the complexities of healthcare financing, healthcare access, and accessibility to community resources (Canedo et al., 2018; Lurie et al., 2008). The current billing infrastructure also imposes limitations on appointment length, which makes it difficult for clinicians to elicit patients' health values, goals, and challenges (Singh Ospina et al., 2019). Therefore, healthcare providers must resolve their implicit biases and know the broad range of factors within and outside the healthcare system that affects a person's wellbeing and ability to self-manage their health (Orgera & Artiga, 2018).

Statement of the Problem

The U. S. Health Information Technology for Economic and Clinical Health (HITECH) ACT of 2009 drastically changed the way healthcare professionals practice. Congress appropriated over $35 billion to promote the development of EHRs to improve patient safety and quality (NAM, 2012). In an early review, the NAM (2012) concluded that EHRs' influence on patient safety was inconclusive. A more recent research report suggests EHRs may contribute to patient harm (Howe et al., 2018).

One reason for the unrealized goals of EHRs was the developers of the technology disregarded the end-users (i.e., healthcare clinicians and patients). The current EHR structure negates the collaborative work that occurs within and outside of the clinic visit and the critical information a clinician needs to co-design an effective plan of care. Expressly, a patient's social and economic factors, behavioral choices, and preferences, values, and goals of care, defined as patient contextual data (PCD). Without the inclusion of PCD, clinicians may fail to understand the essence of patients and derive a plan of care inclusive of the patient's values and life circumstances (Holt et al., 2019). Weiner and colleagues (2012) demonstrated that contextual errors (i.e., disregard of PCD in care planning) were more costly to the healthcare system than biomedical errors (guideline discordant care) ($30-biomedical vs. $231 contextual variant). Conversely, when providers incorporate PCD, into the care context, a patient's activation in their care increases (Greene et al., 2016). Researchers theoretically propose that as patient activation increases, health outcomes improve – across populations (Hibbard et al., 2008).

Recently, clinicians and policy influencers editorialize health information technology (HIT) must be redesigned to meet the needs of patients and clinicians (Dzau et al., 2017; Estiri et al., 2018; Mafi et al., 2018; Valdez et al., 2015). The proposed improvements to HIT must be designed to support patient activation in the self-management of care and to foster collaboration among patients and clinicians, including the incorporation of patient context and values (Estiri et al., 2018). The proposed collaborative work technologies theoretically will close the gap of health outcomes through improvements in patient-clinician communication, shared decision-making, and patient activation (Dzau et al., 2017; Valdez et al., 2015) although there is limited research to establish the theoretically proposed associations (Yamin et al., 2011).

In sum, patient preferences, social determinants of health (SDH), values, goals, and priorities of care are not systematically collected in traditional EHRs. Without this vital information, clinicians may derive plans of care irrespective of a patient’s life circumstances. In turn, patients are less likely to adhere to the plan of care that ignores their contextual complexities, leading to sub-par health outcomes and higher healthcare costs (Schwartz et al., 2012).

Disparities and Use of Health Information Technology

Researchers consistently document differences in adoption and use of HIT and health outcomes of marginalized groups (Anthony et al., 2018; Chang et al., 2018; Grossman et al., 2019; Highfield et al., 2014; Lyles et al., 2017). Healthy People 2020 identified the goal to “use health communication strategies and health information technology to improve population health outcomes and health care quality and to achieve health equity" (DHHS, 2018). Underscoring the goal is the need for more research to evaluate the consequences of health communication approaches and consumer informatics tools on health outcomes, disparities, and health care quality (DHHS, 2018). Of particular need is data to understand why Black Americans, who report poor communication with their provider (Yamin et al., 2011), are less likely to sign up for patient portals or use other consumer informatics tools (Spooner et al., 2017; Yamin et al., 2011).

Electronic Health Records

Developers configured EHRs to capture clinical transactions and record biological data, although there is wide variation in EHR interfaces and functionalities (Middleton et al., 2013). Often missing in EHRs configurations is an effective and efficient way for clinicians to document the myriad of factors that affect their patients' health (Cantor & Thorpe, 2018; Dzau & Balatbat, 2018; Dzau et al., 2017; Estiri et al., 2018). For example, administrators from one academic health system counted over 100 places in the EHR, where clinicians documented patients' SDH. The (World Health Organization [WHO]: Europe, 2003) defined the SDH as the circumstances in which individuals are born, grow, work, live, and age and the full composition of forces and systems influencing the conditions of daily life. Results from a recent literature review suggested that EHRs may interfere with developing and maintaining therapeutic and healing relationships between patients and providers (Rathert et al., 2017). To address the shortcomings of EHRs, clinicians and researchers recently began to suggest ways patients may directly contribute to their EHRs by providing structured and unstructured data about the factors that affect patients' health and capacity to engage in healthy behaviors (Estiri et al., 2018; Mafi et al., 2018). Researchers and policymakers hypothesized that patient contributions to the EHR may improve healthcare quality, patient-level outcomes, and reduce healthcare costs (Douglas et al., 2019;

Dzau & Balatbat, 2018; Dzau et al., 2017; Estiri et al., 2018; Grossman et al., 2019; Highfield et al., 2014; Mafi et al., 2018).

In sum, healthcare leaders and researchers suggest patient contributions to the EHRs, via consumer-designed technology, may mitigate some of the current shortcomings of the EHR infrastructure. Patients adding their contextual data may provide a complete picture of their health, resources, and priorities. Clinicians can incorporate this information into an individualized plan of care, which reflects their values, preferences, and life circumstances.

Eliciting and Integrating Patient Contextual Data

Obtaining PCD directly from patients and making them available to clinicians at the point of care may assuage the system-level barriers to provide patient-centered care. A time-motion study revealed the mean primary care visit length was less than 17 minutes (Young et al., 2018). In the shortened visit, clinicians only gather a partial picture of their patients' life circumstances and concerns. Patients often enter office visits with more concerns and views than elicited, let alone addressed, by busy medical professionals (C. A. Barry et al., 2000; M. J. Barry & Edgman-Levitan, 2012; Peltenburg et al., 2004). Estimates show that primary care physicians elicited agendas from patients in only 49% of visits (Singh Ospina et al., 2019). When physicians elicited the patient's visit agenda, they interrupted patients after a median of 11 seconds (Singh Ospina et al., 2019). Studies show that these unvoiced goals and concerns about care often relate to the patient's experience of illness (Lin et al., 2001), treatment, or psychosocial concerns (DeRouen et al., 2015; Keegan et al., 2012). Unvoiced agendas have a direct impact on individuals' ability to contribute to and follow through with the treatment plan (Kleinke & Classen, 2018; Kondryn et al., 2011).

Importantly, when clinicians do ask about the patient's needs, values, goals, and preferences relevant to planning care, they co-create care plans more reflective of a patient's circumstances — subsequently leading to improved health outcomes (Rathert et al., 2017, 2013). When clinicians employ interventions that focus on patient-centered care, patients experience improvements in quality, health, satisfaction, and reductions in both cost and healthcare disparities (Rathert et al., 2017, 2013). Weiner and colleagues (Weiner et al., 2013) showed that discussion of patient context resulted in 3.7 higher odds of a positive outcome in chronic conditions, including improved follow through with the treatment plan and keeping scheduled appointments, tests, or screenings. A diverse sample of adults with mental illness reported a relationship between feeling understood, respected, involved, engaged, and educated, and experiencing less uncertainty and distress associated with their disease (Hamovitch et al., 2018). A strong therapeutic alliance between primary care patients and their providers correlated with weight loss program attendance, emotional well-being, and the ability to complete activities of daily living (Sturgiss et al., 2016). Primary care patients with low SES and chronic conditions identified that when their primary care provider paid attention to their expressed desires, goals, and needs, patients felt empowered to self-manage their care (Sheridan et al., 2015). Taking this preliminary evidence into consideration, PCD used as part of the clinical exchange may drive the formation of care plans that are more congruent with patients' needs and values. Over time, healthcare systems may experience a reduction in health-related expenditures, and US populations may realize a reduction in healthcare disparities (Rathert et al., 2013).

Significance

Implementing NAM’s (2001) principles and the Patient Protection and Affordable Care Act’s (2010) provisions have led to healthcare organizations shifting to a care model that more fully values patients as active participants in their healthcare. Patient activation is the level of knowledge, ability, and confidence an individual has to self-manage care (Hibbard et al., 2004). Patient activation is further characterized by an individual’s “desire and capability to actively choose to participate in care in a way uniquely appropriate to them” (Higgins et al., 2017, p. 33). According to (Hibbard et al., 2005), an accurate measurement of a patient’s level of activation can provide insight into a patient’s self-care behaviors. Clinicians can then use the patient’s level of activation to determine strategies for supporting patients' self-management behaviors (Hibbard et al., 2005). Indeed, research findings indicate patients with higher activation are more adherent to treatment plans, lifestyle modifications, resulting in lower healthcare costs (Hibbard, 2008; Hibbard et al., 2013, 2017; Marshall et al., 2013).

Healthcare systems are beginning to understand that patients are vital in the healthcare process as they must follow through on the treatment plans and day-to-day lifestyle modifications needed to improve health (Ory et al., 2013). Without patient activation, the best clinicians and abundant healthcare resources may fail to achieve optimal health outcomes and low healthcare costs (Alvarez et al., 2016)

Prevalence

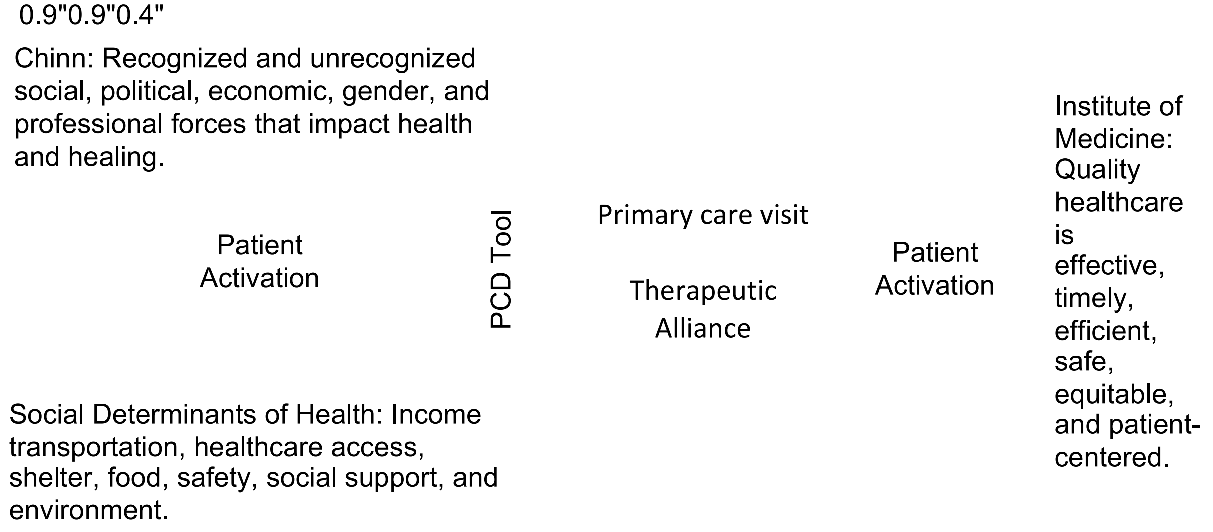
A majority of US adults engage in some level of self-management, as 60% of US adults report experiencing at least one chronic condition (CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), 2019). Management of the multiple morbidities associated with chronic conditions consumes 90% of US healthcare expenditures (*About Chronic Diseases* | *CDC*, 2019). Although widespread across populations, a disparity persists among those who have a chronic condition and how well it is managed. Disproportionately, AA/Blacks die at younger ages from cardiovascular disease, cancer, diabetes, and cerebrovascular events (Cunningham et al., 2017) than other populations. AA/Blacks between the ages of 18 and 64 are between 40% and 45% more likely to die from any cause than their non-Hispanic White counterparts (Cunningham et al., 2017; Heron, 2018). Improvements in chronic disease states are often measured using biological disease markers. Although organic makers are relevant measures of disease outcomes, the disease-focused approach ignores the complexity of factors that influence health (Crotty, 2018; Kotay et al., 2016; Weiner et al., 2013; White & Roosa, 2012). Indeed, population health studies establish that the physical environment, a person's health behaviors, and socioeconomic factors influence 80% of morbidity and mortality (University of Wisconsin Population Health Institute, 2014). It is, therefore, critical that researchers study PCD, which are factors about a person’s environment and behaviors that affect his or her health and well-being (Weiner & Schwartz, 2016). PCD also encompass the SDH, circumstances in which individuals are born, grow, work, live, and age and the full composition of forces and systems influencing the conditions of daily life (WHO, 2003), and further comprise patients' needs, values, goals, and preferences relevant to their care (Dzau & Balatbat, 2018; Dzau et al., 2017; Epstein & Street, 2011).

Theoretical Frameworks

There are two theoretical underpinnings of my proposed dissertation study. The first theoretical underpinning is from the Institute of Medicine’s (2001) six domains of healthcare quality framework, and the second is (Chinn, 2018) nursing theory of Emancipatory Knowing. The IOM describes healthcare quality as care that is effective, timely, efficient, safe, equitable, and patient-centered. I focus my research on improving patient-centeredness, which is providing care that is respectful of and responsive to individual patient preferences, needs, and values. Patient-centered care is a pillar of nursing practice (Lauver et al., 2002). (Figure 1 Conceptual Model).

Figure 1

Conceptual Model



Note. The model shows that social, political, economic, gender, and professional forces and social determinants of health affect patient activation. The dashed arrows depict the pathway to be tested in the study. Does completion of the PCD Tool and primary care visit affect patient activation? The ultimate goal of the intervention is the delivery of high-quality healthcare that is effective, timely, efficient, safe, equitable, and patient-centered.

Patient-centered care is increasingly central in areas of nursing research, practice, and health and social policy (M. J. Barry & Edgman-Levitan, 2012; Bolster & Manias, 2010; Dhaliwal, 2013; Institute of Medicine, 2001; Lauver et al., 2002; McCance et al., 2009; Valdez et al., 2015). Conceptually, patient-centered care is care that is receptive and tailored to the distinct needs of the person, based on the development of respectful and dignified therapeutic relationships (NAM, 2001). Patient-centered care is utilized to uphold that the person's desires, needs, and principles to guide care and decisions; thereby, improving the power imbalances inherent in the current healthcare system. Patient-centeredness seeks to advocate that all individuals are on a journey of health and healing. The *care* in patient-centered care must be discernible and received as caring by the recipient (Bolster & Manias, 2010; Lauver et al., 2002; Sharp et al., 2016).

In a patient-centered care delivery model, clinicians respect the person, but often, they do not recognize the discriminatory influences of health as part of the patient-centered care approach (Chinn, 2018). Chinn’s theory of Emancipatory Knowing upholds the importance of valuing the person and acknowledges there are recognized and unrecognized oppressive structures that restrain human potential. Emancipatory Knowing underpins scientific inquiry and influences the way nurses practice. The Emancipatory Knowing epistemology acknowledges that social, political, economic, gender injustices, and professional forces support inequalities that impact health and healing (Chinn, 2018). Emancipatory Knowing intends to uncover and resolve social, political, economic, and gender injustices while empowering people to seek and obtain their authentic well-being (Chinn, 2018).

The Emancipatory Knowing framework assists nurses in recognizing the sociological, economic, and political structures affecting individuals' wellness (Chinn, 2018). Through this lens, nurses understand well-established processes and structures that create and support health and social inequities (Chinn, 2018). The recognition occurs by reflecting on the following questions: What is wrong with this situation? Who benefits from the status quo? What are the barriers to resolving injustices? What changes are needed to achieve health equity? (Chinn & Kramer, 2014). Once nurses identify the roots of health and social injustices, Emancipatory Knowing evokes action to reduce or eliminate inequality and injustice (Chinn & Kramer, 2014). The action may occur in the form of a theory-linked research study that the researcher designs to deliberate linkages between the theory and independent outcomes (Chinn, 2018; Chinn & Kramer, 2014; Peart & MacKinnon, 2018).

Purpose

Effective use of consumer informatics technologies in primary health care may improve healthcare quality and outcomes (Dzau et al., 2017; López et al., 2011; Montague & Perchonok, 2012; Shields AE et al., 2007; Shipman & Sinsky, 2013; Valdez et al., 2015). Consumer informatics technologies that elicit and share patients’ contextual factors with the healthcare team may benefit patients and diminish health disparities (C. A. Barry et al., 2000; Dzau & Balatbat, 2018; Dzau et al., 2017; Montague & Perchonok, 2012; Nathan et al., 2016; Shields AE et al., 2007). PCD raises clinicians' awareness of the strengths and challenges their patients face.

In providing their contextual data, patients benefit through active reflection and identification of their health goals, values, priorities, and problems. According to the self-affirmation theory (Sherman & Cohen, 2006), when individuals reflect on and write about their values and goals, they affirm their overall competence and self-worth. The heightened sense of self-worth opens the individual to evaluate health information based on its importance for personal health (Sherman & Hartson, 2011). In a meta-analysis of 41 studies that evaluated the effects of manipulating self-affirmation on health outcomes, Epton and colleagues (2015) concluded that self-affirming interventions with health-promoting information had positive effects on message acceptance *d* = .17(*CI* = .03 to.31); intentions to change *d* = .14 (*CI* = .05 to .23); and subsequent improvements in healthy-related behaviors *d* = .32 (*CI* = .19 to .44). In a study evaluating emotional distress and physical symptoms among breast cancer survivors, the dose of self-affirming writing predicted the effects of reduced emotional distress and positive health outcomes (Creswell et al., 2007). Finally, in a meta-analysis of 13 randomized control trials of healthy participant samples, self-affirming writing interventions demonstrated a reduction in health care utilization with random effects estimation of 0.16 (0.02, 0.31) (Harris, 2006).

Incorporating PCD during the primary care visit may also enhance patient-provider communication (Bolster & Manias, 2010; Ha & Longnecker, 2010; Rathert et al., 2017) and patient activation (Deen et al., 2011; Schwartz et al., 2016; Weiner & Schwartz, 2016). When clinicians include PCD as part of the communication and shared decision-making processes, patients benefit by engaging in more effective self-management behaviors that lead to improvements in disease-specific outcomes and increases in quality of life (Rathert et al., 2017; Street et al., 2009). The purpose of this dissertation is to determine if systematically gathering pre-visit PCD using a consumer informatics tool affects patient activation after a primary care visit with an established provider.

Conceptual Definitions

In the section below, I list the definitions of the study's concepts. Following the conceptual definitions, I review the PAM (Hibbard et al., 2005), the secondary outcome measure I added to the larger study. Next, I present the study aims, hypotheses, methods, and analysis. Finally, I discuss the proposed dissertation chapters, manuscripts, and dissemination.

Therapeutic alliance. The therapeutic alliance is characterized by sustained personalized and supportive relationships among patients, providers, caregivers, and healthcare institutions. The therapeutic alliance includes the quality of “patient-provider clinical interaction, communication, empathy, or mutual understanding” (Higgins et al., 2017, p. 34).

Patient-centered care. In nursing practice, patient-centered care is the intentional integration of individual preferences when delivering care (Lauver et al., 2002). It promotes shared decision-making based on values, improved trust, and connectedness.

Patient-provider communication. Patient-provider communication is the continuous exchange of verbal or nonverbal information between healthcare clinicians and patients (Lor et al., 2016).

Patient-contextual data. Patient-contextual data (PCD) are factors about a person’s environment and behaviors that affect his or her health and well-being (Weiner & Schwartz, 2016). PCD encompass the SDHs, the circumstances in which individuals are born, grow, work, live, and age and the full composition of forces and systems influencing the conditions of daily life (WHO, 2003), and include an individual’s health preferences, goals, and challenges.

Patient activation. Patient activation is the level of knowledge, ability, and confidence an individual has to self-manage care (Hibbard et al., 2004). Patient engagement is “the desire and capability to actively choose to participate in care in a way uniquely appropriate to the individual” (Higgins et al., 2017, p. 33). Engaged patients collaborate with a healthcare provider or institution, to maximize outcomes or improve care experiences (Higgins et al., 2017).

Minority populations. Minority populations are groups of individuals who identify as Black or African American (AA), Asian, American Indian or Alaska Native, Native Hawaiian or other Pacific Islander race and/or ethnicity of Hispanic or Latino (Yamin et al., 2011).

Emancipatory Knowing. Emancipatory Knowing recognizes that social, political, economic, and professional forces construct inequalities that impact health and healing (Chinn, 2018).

Health literacy. “The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (Institute of Medicine (US) Committee on Health Literacy, 2004, p. 33).

Consumer information technology. Consumer-focused technological platforms designed to improve patient engagement in health and health care activities (Pradhan et al., 2019).

Health information technology (HIT) adoption. Acceptance and use of HIT is the activity of using a personalized profile on a HIT platform to improve health (Yamin et al., 2011).

Patient Activation Measure

A common measure of patient activation is the Patient Activation Measure (PAM) (Hibbard et al., 2005, 2004). The PAM measures patient activation to accurately provide insight into a patient's level of health knowledge, confidence, and skills to participate in self-care. The results assist the provider in devising specific approaches to support patients' self-management wherever they are on the continuum of activation (Hibbard et al., 2005). The original PAM was a 22-item tool designed to measure a person's activation in health and healthcare (Hibbard et al., 2004). The researchers demonstrate that being an active participant in one's care is linked to better health outcomes (Greene & Hibbard, 2012; Hibbard et al., 2015, 2009; Sacks et al., 2017). Further psychometric testing revealed a 13-item PAM questionnaire yielded a strong Rasch person reliability score (i.e., 0.85-real and 0.87 model), and Cronbach's alpha was acceptable at 0.87 (Hibbard et al., 2005) while decreasing the survey burden of the participants. Developers completed test-retest reliability in 30 patients who took the measure two weeks after the initial assessment using the standard error of measurement (SEM). Hibbard and colleagues (2004) reported an SEM of 1.96 with a 95% confidence interval for each person's measured activation.

Prior studies indicate the PAM valid in diverse populations, including Latinos, AA/Blacks, uninsured, and older adults with chronic conditions (Hibbard et al., 2008; Kenney, 2017). The authors purport the PAM measures constructs are broader than previously tested concepts of locus of control, self-efficacy, and readiness to change (Greene & Hibbard, 2012). The measure is not context-specific, nor does it assess a particular behavior (Greene et al., 2015). The directions for completion of the PAM ask participants to strongly disagree, disagree, agree, or strongly agree with each of the statements, or choose N/A if the statement does not apply to them. The constructs of health knowledge, skills, beliefs, and confidence comprise the survey's statements.

The PAM categorizes four levels of patient activation from least activated to most activated on a theoretical scale of 0-100. Level 1 is the lowest level of activation; it includes activation scores of 47 or lower. Hibbard and colleagues (2005) qualify Level 1 as staying the course under stress. Level 2 includes scores of 47.1 to 55.1. Hibbard and colleagues refer to this level as taking action. Level 3 includes scores of 55.2 to 67.0. Hibbard and colleagues define Level 3 as the confidence and knowledge to take action. Level 4 includes scores of 67.1 or above. At Level 4, an individual believes it is essential to take an active role in his or her health (Hibbard et al., 2005). A three- to four-point change in an individual's PAM score correlates with the differentiation in engaging or not engaging in certain behaviors (Hibbard et al., 2015).

According to a developing theory of patient and consumer activation (Hibbard & Mahoney, 2010), as people experience self-management accomplishments, successes can start a positive upward cycle, just like failure produces the opposite. Individuals on the lower levels of activation might benefit from the self-awareness of their role in their care processes and education about their chronic conditions at the appropriate health literacy level and mode of delivery. Interventions that encourage a patient to take small and realistic steps toward improving health, given the individual's level of activation, may start a positive cycle to increase activation. Therefore, interventions that aim to improve a person's level of activation should focus on improving self-efficacy and the individual's self-concept as a manager of their health (Hibbard & Mahoney, 2010).

Many chronic health conditions (e.g., diabetes, asthma, hypertension, and anxiety) require patients to engage in self-management behaviors. The behaviors include following medication administration regimens, embracing more healthful nutritional and physical activity habits, monitoring health indicators, and collaborating effectively with their healthcare team (Grady & Gough, 2014; Ray et al., 2017). Activated patients are more likely to work with a healthcare provider or institution, to optimize outcomes or report improved care experiences (Higgins et al., 2017). Consequently, assisting patients in their role as self-managers is a vital component in high-quality chronic disease care (Hibbard et al., 2005). When patients are activated in self-care, it may provide an economic benefit to the healthcare delivery systems (Stewart et al., 2000), the patients themselves, and, more generally, the United States (Greene & Hibbard, 2012).

Current healthcare policies acknowledge the importance of activated patients. Still, the policies lack incentives to encourage clinicians and researchers to study interventions that influence individuals to move from a passive to an active participant in their health (Greene & Hibbard, 2012). Patient activation research supports that patient activation is an amenable characteristic that can predict health outcomes and healthcare utilization (Hibbard et al., 2015) across populations (Hibbard et al., 2008). Patient activation is strongly related to a broad range of health-related outcomes including, participating in prevention activities (e.g., colon, cervical, and breast cancer screening), avoiding unhealthy behaviors (e.g., smoking tobacco products), maintaining clinical indicators (e.g., guideline-concordant systolic blood pressure (SBP), diastolic blood pressure (DBP), low-density lipoprotein (LDL), serum triglycerides (TRIG), and hemoglobin A1c), and utilizing healthcare resources appropriately (e.g., no emergency department (ED) visit in the prior 12 months), which suggests improving activation has great potential to advance or maintain individuals' health (Greene & Hibbard, 2012). Researchers conclude that patients are the greatest unused resource that, if used, would benefit not only the individual but the nation (Greene & Hibbard, 2012; Hibbard et al., 2015, 2009; Starfield, 2011; Ventres & Frankel, 2016).

Research Aims, Questions, and Hypotheses

The following are the study aims with corresponding research questions and hypotheses.

Aim 1: Determine whether changes in post-visit patient activation differ for patient-users and patient-non-users of a PCD tool (Figure 2).

Research question 1: Will changes in post-visit patient activation differ for users and non-users of a PCD tool?

H_0 Post-visit PAM scores will not differ between users and non-users of the PCD tool

H_a Post-visit PAM scores will differ between users and non-users of the PCD tool

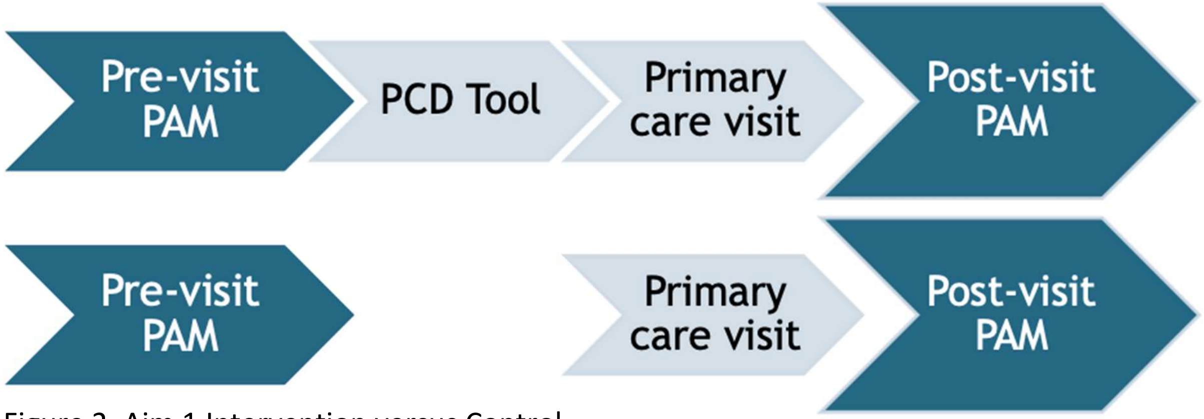


Figure 2. Aim 1 Intervention versus Control

Aim 2: Evaluate whether changes in post-visit patient activation differ for AA/Black and non-Hispanic White participants after using the PCD tool (Figure 3).

Research question 2: Will changes in post-visit patient activation, after using a PCD tool, differ for AA/Black and non-Hispanic White participants?

H_0 Changes in PAM scores will not differ for AA/Black and non-Hispanic White participants after using a PCD tool

H_a Changes in PAM scores will differ for AA/Black and non-Hispanic White participants after using a PCD tool

Figure 3. Aim 2 Intervention by Race

Aim 3: Identify mediators of patient activation in primary care patients (Figure 4).

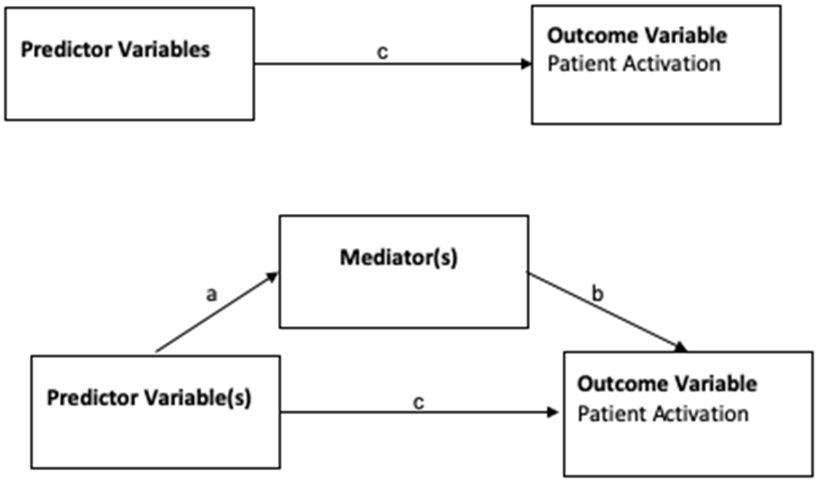
Research question 3: What patient characteristics and factors will be significant mediators of the baseline PAM score?

H_0. Baseline PAM will not differ by patient characteristics and factors

H_a: Baseline PAM will differ by patient characteristics and factors

Figure 4.

Aim 3 Patient characteristics and factors that mediate baseline patient activation



Aim 4. Assess the impact of facilitation on patient adoption of a PCD tool (Figure 5).

Research question 4: Does patient adoption of a consumer informatics tool increase with facilitated enrollment?

H_0 Rates of patient adoption will not increase with facilitated enrollment compared to pre-trial rates (<5%)

H_a Rates of patient adoption will increase with facilitated enrollment compared to pre-trial rates (<5%)

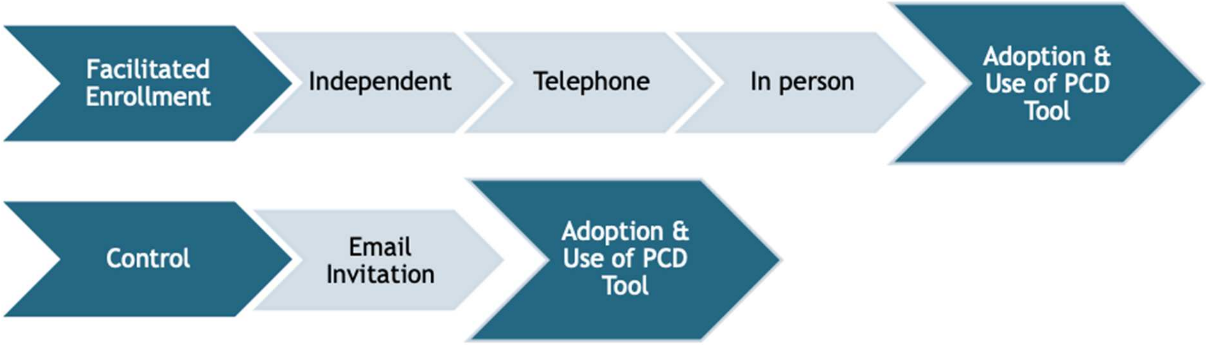


Figure 5. Aim 4 Effect of Facilitated Enrollment versus Control on Patient Adoption

Conclusion

With the decade-long promotion of the adoption and meaningful use of health information technology (HITECH Act, 2009), the infusion of the EHR into clinic workflow has changed the way providers practice. Providers often cite the burden of the EHR documentation system that impedes patient-provider communication (West et al. 2018; Guo et al. 2017; Murphy et al. 2016; Howard et al. 2013). Now, we are embarking on a time when innovators must design technology that it assists rather than impedes care (Estiri et al. 2018; Dzau et al. 2017). Design innovations include consumer informatics tools that help clinicians in their knowledge gap of their patients' perspectives and experiences of health and self-management.

The proposed dissertation study will evaluate the benefits and impact of incorporating patient contextual data using a consumer informatics tool on patient engagement. When patients' preferences and life circumstances drive healthcare decisions, their quality of involvement in their care improves (Greene & Hibbard, 2012; Higgins et al., 2017; Zhao et al., 2016). Therefore, interventions that test these relationships must be explored to understand how to optimize individuals' involvement in self-care. Researchers must also investigate if patient engagement differs in AA/Black and White patients who experience different social, political, and economic injustices that affect health (Chinn, 2018).

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Appendix A

Study Baseline Survey

Thank you for participating in the Clinical Communication Study at the [Academic Medical Center]. We thank you for completing the two surveys, before and after your primary care visit. If you have any questions, you may contact us at XXX@XXX.edu or XXX-XXX-XXXX. Thank you in advance!

Thank you for completing this survey to help the [Academic Medical Center]
better understand how to improve communication between patients and clinicians. Please answer questions to the best of your ability.

What is your date of birth? (Format is Month / Day / Year)

What sex were you assigned at birth, on your original birth certificate?

Male

Female

How do you identify yourself?

Male

Female

Transgender

Do not identify as male, female, or transgender

What is the highest grade or level of school that you have completed?

8th Grade or less

Some high school, but did not graduate

High school graduate or GED

Some college or 2-year degree

4-year college graduate

More than 4-year college degree

Are you of Hispanic or Latino origin or descent?

Yes, Hispanic or Latino

No, not Hispanic or Latino

What is your marital status?

Single, Never married

Married or domestic partnership

Widowed

Divorced

Separated

Are you currently...? Choose the best one that applies

Employed for wages

Self employed

Out of work and looking for work

Out of work but not currently looking for work

A homemaker

A student

Military

Retired

Unable to work

Last year, that is in 2018, what was your total household income from all sources, before taxes?

Less than $10,000

$10,000 to less than $20,000

$20,000 to less than $30,000

$30,000 to less than $40,000

$40,000 to less than $50,000

$50,000 to less than $75,000

$75,000 to less than $100,000

$100,000 to less than $150,000

$150,000 or more

Are you currently covered by any of the following types of health insurance or health coverage

plans?

Yes

No

1 Insurance through a current or former employer or union

2 Insurance purchased directly from an insurance company

3 Medicare, for people 65 and older, or people with certain disabilities

4 Medicaid, Medical Assistance, or any kind of government-assistance plan for those with low income or a disability

5 TRICARE or other military health care

6 VA (including those who have ever used or enrolled for VA health care)

7 Indian Health Service

8 Other

What other health insurance or health coverage do you use?

____

In the past 30 days, how difficult was it for you to meet the monthly payments on your bills?

Extremely difficult

Very difficult

Somewhat difficult

Slightly difficult

Not difficult at all

How confident are you filling out forms by yourself?

Extremely

Quite a bit

Somewhat

A little bit

Not at all

Do you ever go online to access the Internet or World Wide Web, or to send and receive e-mail?

Yes

No

When you use the Internet for work or personal use, do you access it through...

Yes

No

1 A dial-up telephone line

2 Broadband such as DSL, cable,

or FiOS

3 A cellular network (i.e.,

telephone, 3G/4G)

4 A wireless network (Wi-Fi)

5 Other

What other internet access do you use?

____

Note: If you never use the internet (web, email, or connected apps), please mark "No" for each of the items.

How often do you access the Internet through each of the following?

Daily Sometimes Never Not applicable

1 Computer at home

2 Computer at work

3 Computer in a public place

(library, community center,

other)

4 On a mobile device (cell

phone/smart phone/tablet)

5 On a gaming device/"Smart TV"

Think about your most recent visit with [baseline_survey_arm_1][doctorsname]. The next steps for my care that my provider planned for me took into account:

As much as I wanted Somewhat Not at All

Cost

Personal Preference

Needs

Values/Beliefs

Lifestyle

Personal Challenges

The following questions ask about the PatientWisdom program. You may have participated through email or a study representative. The program invites patients to share information about themselves and their needs, values, and health care preferences, with their care team.

Example image of PatientWisdom

Have you used PatientWisdom, the online tool provided by Froedtert & The Medical College of Wisconsin?

(See above for an example image.)

Yes

No

Not sure

PatientWisdom is easy to use.

Strongly agree

Somewhat agree

Neither agree nor disagree

Somewhat disagree

Strongly disagree

The information I put in PatientWisdom helps my provider(s) to follow up with me.

Strongly agree

Somewhat agree

Neither agree nor disagree

Somewhat disagree

Strongly disagree

The information I put in PatientWisdom helps my provider(s) take better care of me.

Strongly agree

Somewhat agree

Neither agree nor disagree

Somewhat disagree

Strongly disagree

Completing information that is important to me in PatientWisdom helped me prepare for my visit.

Strongly agree

Somewhat agree

Neither agree nor disagree

Somewhat disagree

Strongly disagree

PatientWisdom helps me keep track of my health.

Strongly agree

Somewhat agree

Neither agree nor disagree

Somewhat disagree

Strongly disagree

My information in PatientWisdom is secure.

Strongly agree

Somewhat agree

Neither agree nor disagree

Somewhat disagree

Strongly disagree

PatientWisdom makes it easy to share information about things that are difficult to say in person.

Strongly agree

Somewhat agree

Neither agree nor disagree

Somewhat disagree

Strongly disagree

The questions asked in PatientWisdom are too personal.

Strongly agree

Somewhat agree

Neither agree nor disagree

Somewhat disagree

Strongly disagree

The information PatientWisdom asks about is important to my care.

Strongly agree

Somewhat agree

Neither agree nor disagree

Somewhat disagree

Strongly disagree

Setting my agenda in PatientWisdom helped me prepare for my visit.

Strongly agree

Somewhat agree

Neither agree nor disagree

Somewhat disagree

Strongly disagree

N/A (I did not use this feature)

Do you think anyone at your provider's office reviewed your PatientWisdom profile?

Yes

No

Unsure

Did anyone refer to or use PatientWisdom during your appointment?

Yes

No

1 Doctor

2 Physician Assistant

3 Nurse Practitioner

4 Nurse

5 Medical Assistant

6 Front Desk Staff

Below are statements people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally.

Click the answer that is most true for you today. If the statement does not apply, select N/A.

[PAM 13- Items]

When all is said and done, I am the person who is responsible for taking care of my health.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

Taking an active role in my own health care is the most important thing that affects my health.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

I am confident I can help prevent or reduce problems associated with my health.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

I know what each of my prescribed medications do.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem

myself.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

I am confident that I can tell a doctor concerns I have even when he or she does not ask.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

I am confident that I can follow through on medical treatments I may need to do at home.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

I understand my health problems and what causes them.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

I know what treatments are available for my health problems.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

I know how to prevent problems with my health.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

I am confident I can figure out solutions when new problems arise with my health.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress.

Strongly Disagree

Disagree

Agree

Strongly Agree

N/A

The following questions pertain to the primary care provider, [baseline_survey_arm_1][doctorsname], you will see at your next appointment.

In the last 12 months, how often did this provider explain things in a way that was easy to understand?

Never

Sometimes

Usually

Always

In the last 12 months, how often did this provider listen carefully to you?

Never

Sometimes

Usually

Always

In the last 12 months, how often did this provider seem to know the important information about your medical history?

Never

Sometimes

Usually

Always

In the last 12 months, how often did this provider show respect for what you had to say?

Never

Sometimes

Usually

Always

In the last 12 months, how often did this provider spend enough time with you?

Never

Sometimes

Usually

Always

Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what

number would you use to rate this provider?

0 Worst provider possible

123456789

10 Best provider possible

Communication with patients is a very important part of quality medical care. Please use this brief survey to rate how your provider, [baseline_survey_arm_1][doctorsname], interacted with you. Your answers are completely confidential, so please be as open and honest as you can. You may receive other surveys about your care -- they are important too. Thank you very much.

The provider greeted me in a way that made me feel comfortable.

Poor

Fair

Good

Very Good

Excellent

The provider treated me with respect.

Poor

Fair

Good

Very Good

Excellent

The provider showed interest in my ideas about my health.

Poor

Fair

Good

Very Good

Excellent

The provider understood my main health concerns.

Poor

Fair

Good

Very Good

Excellent

The provider paid attention to me (looked at me, listened carefully).

Poor

Fair

Good

Very Good

Excellent

The provider let me talk without interruptions.

Poor

Fair

Good

Very Good

Excellent

The provider gave me as much information as I wanted.

Poor

Fair

Good

Very Good

Excellent

The provider talked in terms I could understand.

Poor

Fair

Good

Very Good

Excellent

The provider checked to be sure I understood everything.

Poor

Fair

Good

Very Good

Excellent

The provider encouraged me to ask questions.

Poor

Fair

Good

Very Good

Excellent

The provider involved me in decisions as much as I wanted.

Poor

Fair

Good

Very Good

Excellent

The provider discussed next steps, including any follow-up plans.

Poor

Fair

Good

Very Good

Excellent

The provider showed care and concern.

Poor

Fair

Good

Very Good

Excellent

The provider spent the right amount of time with me.

Poor

Fair

Good

Very Good

Excellent

[PROMIS Scale v1.2 – Global Health]

In general, would you say your health is:

Excellent, Very good, Good, Fair, Poor

In general, would you say your quality of life is:

Excellent, Very good, Good, Fair, Poor

In general, how would you rate your mental health, including your mood and your ability to think?

Excellent, Very good, Good, Fair, Poor

In general, how would you rate your satisfaction with your social activities and relationships?

Excellent, Very good, Good, Fair, Poor

"In the past 7 days...How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?"

Never, Rarely, Sometimes, Often, Always

In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)

Excellent, Very good, Good, Fair, Poor

In general, how would you rate your physical health?

Excellent, Very good, Good, Fair, Poor

To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?

Completely, Mostly, Moderately, A little, Not at all

"In the past 7 days...How would you rate your fatigue on average?"

None, Mild, Moderate, Severe, Very severe

"In the past 7 days...How would you rate your pain on average?"

0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10

Additional Comments

Please write any comments you would like to share.

Please click "Submit" to save these answers.

Please click "Submit" to save these answers and continue to a few more questions about your current health and well-being.

Appendix B

Patient Activation Measure – 13-item (Hibbard et al., 2005)

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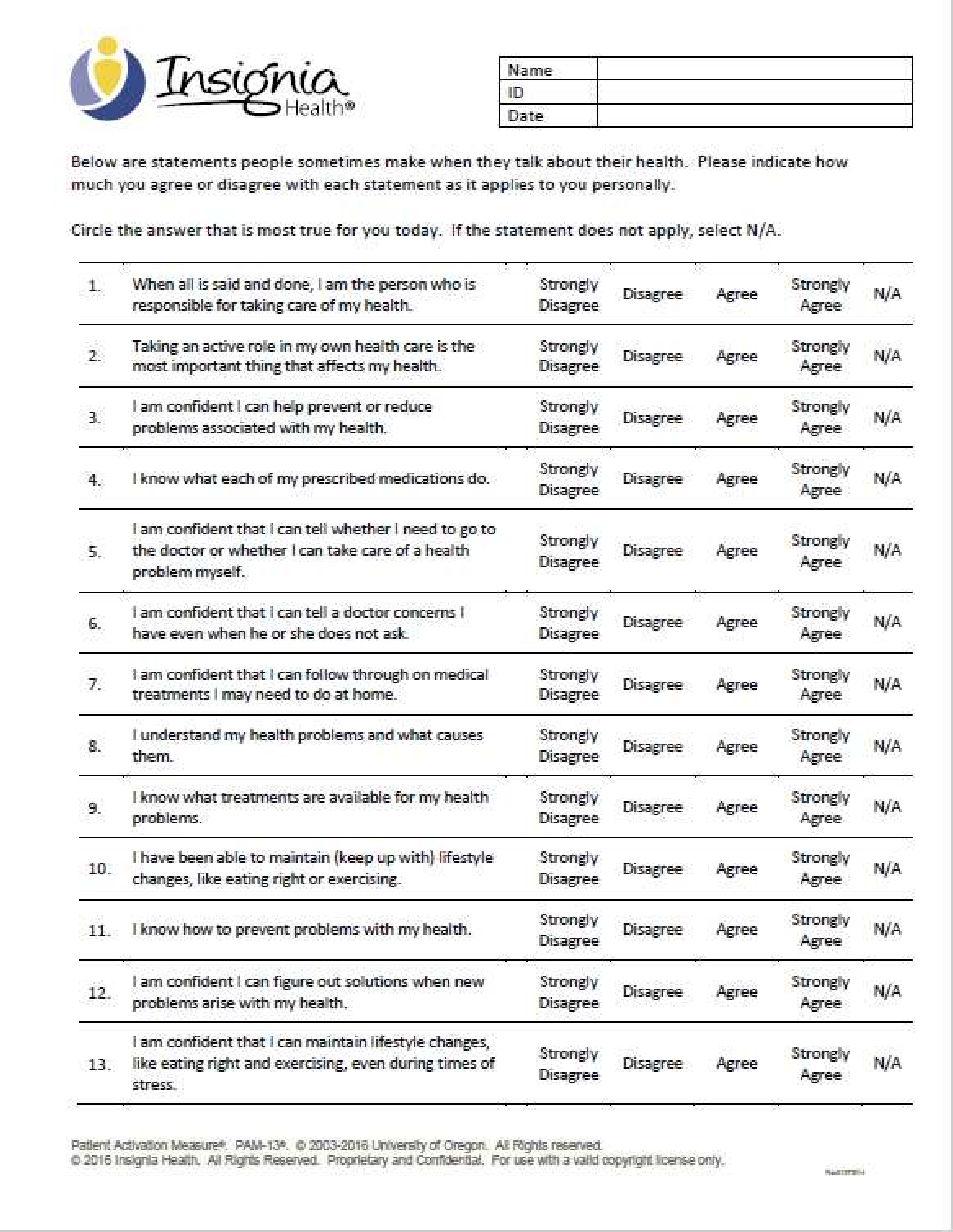

Insignia Health®

Name	
ID	
Date	

Below are statements people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally.

Circle the answer that is most true for you today. If the statement does not apply, select N/A.

1.	When all is said and done, I am the person who is responsible for taking care of my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
2.	Taking an active role in my own health care is the most important thing that affects my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
3.	I am confident I can help prevent or reduce problems associated with my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
4.	I know what each of my prescribed medications do.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
5.	I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
6.	I am confident that I can tell a doctor concerns I have even when he or she does not ask.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
7.	I am confident that I can follow through on medical treatments I may need to do at home.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
8.	I understand my health problems and what causes them.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
9.	I know what treatments are available for my health problems.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
10.	I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
11.	I know how to prevent problems with my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
12.	I am confident I can figure out solutions when new problems arise with my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
13.	I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

Appendix C

Communication Assessment Tool (Makoul et al., 2007)

1. Greeted me in a way that made me feel comfortable

2. Treated me with respect

3. Showed interest in my ideas about my health

4. Understood my main health concerns

5. Paid attention to me (looked at me, listened)

6. Let me talk without interruptions

7. Gave me as much information as I wanted

8. Talked in terms I could understand

9. Checked to be sure I understood everything

10. Encouraged me to ask questions

11. Involved me in decisions as much as I wanted

12. Discussed next steps

13. Showed care and concern

14. Spent the right amount of time with me

15. Staff treated me with respect

Scale: 1 = poor; 2 = fair; 3 = good; 4 = very good; 5 = excellent.

Reach, Adoption, and Use of an Electronic Health Record-Integrated Consumer Informatics Tool that Collects Patient-Generated Contextual Data

Abstract

Objectives: To examine patient and clinician adoption and use of a patient contextual data (PCD) Tool designed for patients to share their needs, values, and preferences with their care team ahead of their primary care visits.

Materials & Methods: Relational study to evaluate patient and clinician adoption and use of a PCD tool from June 2017 to July 2019 in a mid-western academic medical center. Logistic regression modeled the likelihood of adopting the PCD tool, accounting for multiple covariates of patients. Analyzed data on clinician use of the technology was based on the number of patients for whom clinicians accessed the tool through the EHR on the visit day and up to three days before.

Results: The final analytical sample comprised of 87,009 patients, and 8,295 (9.5%) created a PCD Tool account and 7,062 (85.1%) completed at least one content area in the PCD Tool. Logistic regression results indicated that the patient factors that increased the likelihood of completing the PCD Tool aligned with a digitally engaged population. Primary care clinicians viewed 9.7% of available PCD Tool summaries.

Discussion: The findings indicate low rates of patient and clinician adoption and the use of a consumer informatics tool designed to systematically gather share PCD despite the use of multiple evidence-based implementation strategies.

Conclusions: Completing a PCD Tool by patients was low despite the implementation strategy that was developed using the existing evidence. Interestingly, the use of information by clinicians was also very low. Further studies should inform about features, barriers, and facilitators of use for both patients and clinicians.

Primary care clinicians and patients are often time-compressed, impacting their ability to connect, explore patient goals, or discuss barriers to achieve meaningfully and adapted care plans[1–4]. Given that a patient's environment and behavior accounts for an estimated 80% of their health[5], having a comprehensive yet accessible understanding of who they are, what they want, and what challenges they face is critical to improving health outcomes[6].

Clinicians and practices are looking for ways to increase the focus on patients and their needs, from a consumer-centric approach and efficiency and outcomes-based approach[7]. One solution may be consumer information technology that elicits patient's contextual factors. Patient contextual data (PCD) are factors about a person's environment and behaviors that affect his or her health and well-being[8]. According to the World Health Organization (WHO), PCD encompass the social determinants of health, circumstances in which individuals are born, grow, work, live, and age and the full composition of forces and systems influencing the conditions of daily life, and further comprise patients' needs, values, goals, and preferences relevant to their care[6,9].

The inclusion of patient-generated contextual data in pre-visit planning and within visit discussions may raise clinicians' awareness of patients' strengths and challenges[10]. Discussing PCD during the clinic visit may also enhance patient-provider communication[11]. When clinicians fully understand the patient's context, they increasingly craft care plans that are more congruent with patient values, which has been shown to improve medication adherence, behavior changes, and health outcomes[12–15]. As a result, groups such as the National Academy of Medicine[16–18] have increasingly called for contextual data to be captured and integrated into clinical care. Yet, it is uncertain how to do this effectively and sustainably, have it be scalable across practices and specialties, and with minimal workflow disruption[6,7].

The purpose of this Research and Applications report is to describe the experience of developing, implementing, and assessing the reach, adoption, and use of a consumer informatics tool [hereafter PCD Tool] designed for patients to share their needs, values, and preferences with their care team ahead of their primary care visits.

Methods

Study Design

The study used two designs to evaluate reach, adoption, and use of a PCD Tool in 23 primary care clinics from an urban academic medical center located in southeastern Wisconsin between 6/1/2017 to 7/31/2019. First, a relational study to model the probability of PCD Tool adoption based on specific patient characteristics. Second, a descriptive study to describe clinicians' patterns of use of the PCD Tool on the day of a visit or up to three days before a visit. The following research questions guided the analysis, *Does age, sex, ethnicity/race, insurance type, number of medical or behavioral comorbidities, and healthcare utilization have an influence on PCD Tool adoption?* and *How often do clinicians (primary care providers, registered nurses, and healthcare staff) view a patient's PCD Tool profile on the day of or up to three days before a primary care visit?*

Sample

Patients

The patient sample comprised of adults, 18 years and older, who were invited by email to enroll in the PCD Tool and attended at least one visit at one of 23 primary care clinics from an urban academic medical center located in southeastern Wisconsin between 6/1/2017 to 7/31/2019.

Clinicians

The clinician sample comprised of (1) primary care providers, defined as a Medical Doctor, Nurse Practitioner, or Physician Assistant; (2) Registered Nurses (RN); and other healthcare Staff, defined as a Pharmacist, Medical Assistant, or healthcare Staff from one of 23 primary care clinics from an urban academic medical center located in southeastern Wisconsin. To be a clinician in the sample, the clinician had to have at least one patient visit with an individual between 6/1/2017 to 7/31/2019 who had completed the PCD Tool.

Intervention Description

The Medical College of Wisconsin (MCW) is an academic health care system and an integrated clinical network in Southeastern Wisconsin with over 1.1 million outpatient visits per year. MCW serves the Milwaukee metro area, which ranks the highest in the nation for Black-White segregation[19], which has profound effects on the equity of health outcomes[20,21]. With a drive to achieve cultural change toward more consumer-focused care, the organization implemented a consumer informatics tool as an innovative way to deliver individualized care by collecting and understanding the needs, values, and preferences of each patient.

With a partner (PatientWisdom® Inc., New Haven, CT), MCW co-designed and implemented a consumer informatics tool that captures contextual data and agendas[22] from patients ahead of visits through an online tool accessible through the web on mobile devices and desktop. The software is hosted in a HIPAA-compliant cloud platform. The tool asks patients to share 'stories' about themselves from a health perspective, with an emphasis on their values, challenges, and treatment preferences. The tool is comprised of three domains, My Self, My Health, and My Care, with a combination of free text and drop-down menus for responses. Patients can update their 'stories' at any time and can include information about the visit agenda for each appointment [Appendix A. PCD Tool Domains and Descriptions]. The program generates an interactive one-screen summary of the PCD for the healthcare team, which is accessible within the EHR. Patients can also view the summary created from profile data [Insert Figure 1. PatientWisdom® Inc., inSIGHT® Summary Here].

Development and Iterative Design Process

Agile processes were used to refine the software and spread the intervention[23]. The PCD Tool was started in five primary care locations in June 2016 for the initial implementation and expanded to a total of 26 clinics by April 2019. As part of the co-design process, the implementation team collected insights about the usability of the tool by clinicians [24] and patients[10] as well as tested workflows for integrating the PCD into clinic visits. Clinicians reported patients being primed for their appointments, which led to greater visit efficiency. Some clinicians expressed challenges with incorporating a review of the PCD Tool summary into their workflow, citing one more click in the EHR. Patients expressed valuing a place to share sensitive information and reflecting on health goals and priorities[10,24]. A minority of patients (n=3) shared concerns about data security and who had access to their PCD Tool summary data (e.g., insurance companies, health care clinicians)[10].

Initial Implementation

In the initial phase, the PCD Tool was not integrated with the EHR system. Patients were manually sent letters via the patient portal to invite them to set up a PCD Tool account ahead of their primary care appointment. At their appointment, patients logged into their account on a tablet or used a print-out copy to share their PCD Tool summary with their care team. There were several challenges with this method: patients forgetting their password, patients forgetting to share the print-out with clinicians during the visit, staff forgetting to review the information or handing off the tablet, and the tool auto-logging out before the provider could review the information. The manual workflows were very time consuming for staff and often interrupted clinical workflows.

EHR Integration and Feature Development

The PCD Tool web application customized for MCW was integrated into the EHR system (Epic Systems, Verona, WI) and its companion patient portal (MyChart) in June 2017. Patients could then access the PCD Tool directly through a web browser using an MCW-specific URL or through a link in the patient portal that provided a single sign-on experience for the patient. The latter process makes a direct linkage between the PCD Tool profile and the patient identity in the EHR. After a patient completed their profile, clinicians had an activity link within the EHR to view the PCD Tool's one-screen patient profile summary (Figure 1 PatientWisdom® Inc., inSIGHT® Summary). The activity link to the patient profile was only shown to providers when a patient entered data into the application.

Agile Approach: Continuous Evaluation and Improvement

Structured feedback processes, including structured observation of workflow, interviews with clinicians[24] and patients[10], and patient testing led to improvements in the user experience over time. Within the EHR, optimization feedback led to the development of a more prominent flagging when PCD data from the patient were available to be viewed, as well as an icon that could be added to the clinician's schedule to flag if a patient provided contextual data. In the PCD Tool software itself, feedback led to more clearly noting the date when the data were last updated and added highlighting when sections were updated and previously unread by the viewing clinician.

Additionally, EHR integration allowed anyone on the patient's care team across the health network to access and view the PCD. As a result, some specialty areas (e.g., bariatric surgery, nephrology, neurology, and infectious disease) who had seen the PCD in the EHR requested to be a part of the program. However, it was initially intended for primary care. The specialty clinics were added to the implementation. Consequently, patients in the specialty clinics received email invitations to enroll in the PCD Tool.

Alert Process and Workflow

To address the concern of a patient sharing distressing information (e.g., service dissatisfaction, patient harm, decompensating clinical condition) that was not addressed promptly, an integrated review process was developed that identifies concerning data and notifies clinicians independently from whether the clinical team reviewed the PCD [24]. Since the EHR-integration of the PCD Tool (6/1/2017 to 8/1/ 2019), patients submitted and/or revised 146,167 'stories.' Of those stories, 53 (.04%) included concerning patient data that was flagged as an alert, and the clinician was notified. No adverse outcomes occurred in PCD Tool users who shared concerning patient data.

Scaling the Intervention

By February 2019 (20 months after EHR integration was achieved), the health system decided to scale the program to 23 clinical locations. Multiple evidence-based educational strategies[25] were used to communicate the implementation process of the PCD Tool across sites to foster clinicians' awareness and adoption of the PCD Tool. The initial strategy was a top-down communication through established leadership meetings to garner endorsement and support from academic leaders[26]. This strategy was followed with broad organizational email communications to all care team members describing the PCD Tool. Additionally, in-person presentations were held with staff and providers to discuss and explore how the application could be applied within their workflows. Finally, at the clinic level, there were dedicated implementation managers that served as a local resource for workflow integration and program troubleshooting.

Measures

The reach and adoption domains of the RE-AIM framework[27] were used to evaluate the spread of technology in the organization at the patient and clinician levels.

Quantitative Analysis: Reach, Adoption, and Use

Patient Data

Three data sources were used to evaluate patient adoption and use of the PCD Tool. PatientWisdom® Inc. provided data containing (1) MCW patients who completed a terms of agreement form (i.e., user)[27]; (2) patients who completed a terms of use agreement form and submitted content to at least one area of the PCD Tool (i.e., adopter)[27]; and (3) visit encounter dates of PCD Tools users/adopters from 6/1/2017 to 7/31/2019. The PCD Tool data was joined with data extracted from Epic Clarity using Microsoft SQL Server Management Studio, 2016. Appendix B. displays the patient characteristic data (sex, age, number of comorbid conditions, etc.) that was extracted from Epic Clarity from 7/5/2017 to 8/21/2019. Finally, since the EHR did not contain household income data, the patient's home address listed in the EHR and the US Census geocoder were used to match the patients' addresses to geographic locations and median household income estimates containing those addresses[28].

Clinician Data

Two data sources were used to analyze clinician use of the PCD Tool. PatientWisdom® Inc. provided data containing clinician views (defined as a click of the PatientWisdom® activity tab in the EHR) of a patient's PCD Tool profile on the day of and up to three days before a visit encounter from 6/1/2017 to 7/31/2019. The PCD Tool data was joined with data extracted from Epic Clarity using Microsoft SQL Server Management Studio, 2016. Data from Epic Clarity consisted of visit encounter related characteristics (visit encounter date, clinician type, clinic location) from 7/5/2017 to 8/21/2019. The combined file provided credentials of the clinician and grouped them into three clinician categories: Provider (Physician, Nurse Practitioner, or Physician Assistant), registered nurse (RN), or staff.

Table 1 summarizes the RE-AIM domain, RE-AIM definition, target, and timeframe as they related to the study.

[Insert Table 1 *RE-AIM Domain, RE-AIM Definition, Target, and Timeframe* Here].

Analysis

To examine the research question, *Does age, sex, ethnicity/race, insurance type, number of medical or behavioral comorbidities, and healthcare utilization have an influence on PCD Tool adoption?* a binary logistic regression was conducted. To examine the research question, *How often do clinicians (Providers, RNs, and Staff) view a patient's PCD Tool profile on the day of or up to three days before a primary care visit?* a proportional analysis was conducted.

Patient Analysis

Logistic regression was used to model the probability of a patient adopting the PCD Tool based on socio-demographic, health characteristics, and healthcare utilization. The odds ratio takes into account the change in the covariate level. Each level of the categorical variables was compared to a reference level. The medical and behavioral health comorbidities were analyzed as continuous variables (i.e., slopes). Ordinal proportional odds logistic model analysis was conducted to compare patients in the reach (non-adopters of the PCD Tool) versus adoption (only registered for a PCD Tool account) and use (completed at least one content area) categories from the same time (7/5/2017 to 8/21/2019). Both regression models used the variables of race, age, gender, median household income, insurance status, healthcare utilization, and the presence or absence of medical or behavioral comorbidities as determined by the data in the EHR. Median household income was estimated using the U.S. Census Bureau's geocoder API [28] and the patient's address documented in the EHR. The analysis was conducted using R and $p \leq .05$ as values for statistical significance.

Clinician Analysis

To analyze the clinician utilization of the PCD Tool data, an opportunity to view the PCD Tool was operationalized as a click on the PCD Tool activity tab in the patient's EHR on the day of a visit and up to three days before the visit, and the number of visits over the study period.

The proportion of views per clinician type was analyzed by calculating the number of views (i.e., click on the PCD Tool activity tab) per opportunity (i.e., the patient had a PCD Tool account to be viewed). The data were aggregated by the clinic location to show clinician utilization at the clinic level. The MCW Institutional Review Board approved this study prior to data retrieval.

Results

Patient Reach, Adoption, and Use

A total of 273,478 invitations were sent by email inviting patients to enroll in the PCD Tool in the timeframe of June 1, 2017, to July 31, 2019. Some participants received multiple email invitations since email invitations were sent before every primary care or specialty appointment. Of the 96,508 unique patients who received an email invitation, approximately 90% of their home addresses were successfully converted to an approximate coordinate (longitude/latitude) to estimate median household income[28]. The final analytical sample was 87,009 unique patients. In the analytical sample, 8,295 (9.5%) patients created a PCD Tool account, and 7,062 (85.1%) patients completed at least one content area in the PCD Tool. A majority of the study sample included female patients (59%) who ranged from age 18 to 90+ years and represented diverse ethnic and racial groups. The demographics and characteristics of the study participants are presented in Table 2. [Insert Table 2 here]

Table 3 displays the results of logistic regression, which indicate the role of sociodemographic and other patient factors relevant to the PCD Tool use comparing each level of the covariate. The odds ratio represents the relative odds of PCD Tool use between the covariate levels. The ordinal proportional odds logistic model with three outcome categories: (A) PCD Tool user, (B) PCD Tool adopter, and (C) PCD Tool non-user had similar results to the two-outcome model (PCD Tool User or Non-User) and are presented in [Appendix C]. The logistic regression model contains nominal categorical covariates with a degree of freedom greater than 1; therefore, multicollinearity was assessed using the generalized variance inflation factor (GVIF)[29]. The interpretation of these values is similar to the regular VIF, and therefore these results do not indicate any multicollinearity because all the values are well below 2 [Appendix D].

The regression analysis confirmed that patients with Medicare insurance (odds ratio 1.58 [95% confidence interval 1.45 – 1.72], p<0.001; [compared to commercial insurance]), with one behavioral health comorbidity (odds ratio 1.26 [95% confidence interval 1.18 – 1.35], p<0.001; [compared to 0 behavioral health comorbidity]), and between 50 to 69 years from (odds ratio 1.5 [95% confidence interval 1.41 – 1.6], p<0.001; [compared to 30-49 years]), or 70 to 89 years (odds ratio 1.78 [95% confidence interval 1.59 – 1.99], p<0.001; [compared to 30-49 years]) were more likely to use the PCD Tool, compared to non-users. Adults with one or more medical comorbidities were more likely to use the PCD Tool in a stepwise manner (1: odds ratio 1.26 [95% confidence interval 1.18 – 1.34], p<0.001; 2-3: odds ratio 1.64 [95% confidence interval 1.53 – 1.76], p<0.001; 4-5: odds ratio 1.92 [95% confidence interval 1.70 – 2.18], p<0.001; 6+: odds ratio 2.13 [95% confidence interval 1.66 – 2.75], p<0.001) compared to patients with no medical comorbidities. It also confirmed that patients who identified as male (odds ratio 0.77 [95% confidence interval 0.75 – 0.83], p<0.001) were less likely to use the PCD Tool compared to patients who identified as female. Individuals who were categorized as being Asian (odds ratio 0.52 [95% confidence interval 0.43 – 0.62], p< 0.001), Black (odds ratio 0.62 [95% confidence interval 0.56 – 0.70], p< 0.001), or Native Hawaiian or Other Pacific Islander (odds ratio 0.50 [95% confidence interval 0.37 – 0.68], p< 0.001) were less likely to adopt the PCD Tool than patients categorized as White. Three to four urgent care visits during the study period (odds ratio 1.29 [95% confidence interval 1.06 – 1.58], p= 0.012 [compared to 0 urgent care visits]) were associated with an increased likelihood of being a PCD Tool user, but increased outpatient office utilization (5+ visits: odds ratio 0.04 [95% confidence interval 0.03 – 0.04], p<0.001 [compared to 0 office visits]) was associated with a reduction in the likelihood of PCD Tool use. Inpatient utilization (odds ratio 1.11 [95% confidence interval 0.95 – 1.29], p= 0.181 [compared to 0 inpatient stays]) and median household income (odds ratio 0.99 [95% confidence interval 0.93 – 1.06], p= 0.774 [compared to $25,000 to $55,0000]) were not significantly associated with PCD Tools use or non-use. [Insert Table 3-Logistic regression Analysis Here]

Figure 2 displays plots of the probability of PCD Tool use by patient characteristics and factors. These are the estimated marginal predicted values for the probability of PCD Tool use and their uncertainty, as computed from the logistic regression model. For example, the Age Plot displays that a 70- to 89-year-old patient was more likely to be a PCD Tool than any other age category. The Medical Comorbidities Plot displays that a patient with six medical comorbidities was more likely to be a PCD Tool user than a patient with fewer than six medical comorbidities. [Insert Figure 2 Probability Plots of PCD Tool Use by patient characteristics and factors Here].

Clinician Use

Table 4 displays the Clinician's use of the PCD Tool. There were approximately 350 unique providers, RNs, and staff who, in total, accessed 9.7% of available patient PCD Tool summary profiles available from the EHR three days before or on the primary care visit day. Providers had the highest proportion of viewed PCD Tool summaries at 5.1%. Eighty percent of the provider views were performed by 25 (12%) of the primary care providers. Clinic staff viewed 2.8% and RNs viewed 2.3% of available PCD Tool profiles.

Discussion

The findings from this relational study indicate low rates of patient adoption and use of a PCD Tool designed for patients to share their needs, values, and preferences with their care team ahead of their primary care visits despite using an implementation strategy that was developed using the existing evidence[25,27]. Interestingly, the use of the information by clinicians was also very low even with a technology that was designed using consumer-centered principles[30,31].

In the study, patients who adopted the tool were more likely to be older, White, women, with at least one chronic medical and/or behavioral health conditions compared to younger, from an ethnic and racial minority, men, and no medical and/or behavioral health conditions, respectively. Patient PCD Tool users were also more likely than non-users to have multiple urgent care visits and no primary care visits during the study period. Median household income was not significantly associated with PCD Tools use or non-use.

Clinician use of the PCD Tool was low (9.7%) across all clinician types. Providers (5.1%) viewed the highest proportion of PCD Tool summaries, then staff (2.8%) and

RNs (2.3%). Although there were some providers who were highly engaged in with the tool (n=25 providers accounted for 80% of PCD Tool summaries viewed). Patients who received primary care at the clinic where the PCD Tool implementation leader practiced (Clinic C) were more likely to adopt the tool than patients who received primary care at the other clinics (p <0.001).

Implications for Other Healthcare Systems

It is well documented that the implementation of complex health care innovations is often unsuccessful[32] because clinicians often have difficulty incorporating new, decontextualized knowledge into well-established routines[33]. Innovation implementation failure rates range from 30% to 90% depending on the implementation setting and standards to evaluate it[34–36]. Innovations may fail due to unsupportive organizational culture, lack of consumer demand, and lack of clinician endorsement[32,37–39]. In previous qualitative research[10,24], clinicians from the five pilot clinics provided some insight into the relatively low adoption of the PCD Tool at MCW[7,24,40]. One possible explanation for low clinician adoption was competing visit-based demands that imposed a barrier to integrating the review of the content of the PCD Tool into their workflow. Another possible explanation was what a clinician termed as the burden of ‘one more click’ in the EHR[24]. Another physician commented that he spent at least 50% of his workday completing EHR-based tasks, which took him away from patient care. Similar concerns have been published elsewhere. Kroth and colleagues[41] confirmed that nearly 90% of clinicians identified excessive EHR data requirements impacted clinician stress and were associated with burnout. It is also possible that in MCW’s efforts to optimize EHR usability, the PCD Tool activity tab may have been moved, making it difficult for clinicians to find.

In a previous study, PCD Tool patient-users were sensitive to the multiple demands placed on the healthcare team[10]. Focus group participants questioned whether there was infrastructure in place to support the use of a new tool in care[10]. PCD Tool patient users also expressed concerns regarding privacy and security of data[10], questioning who had access to potentially sensitive personal information. PatientWisdom®, Inc. incorporated these patient-user insights to refine the email invitation message. The critical points in the email message are that PatientWisdom®, Inc. is by you, about you, only takes 10-minutes to complete, and can only be viewed by your healthcare team. The data in this study can guide consumer informatics tool implementation efforts. The results indicate that future projects should focus on assisting patients with the initial PCD Tool registration since approximately 85% of patients who completed the terms of use agreement also completed at least one PCD Tool content area.

The results of this study indicate that a patient who adopted the PCD Tool had characteristics that align with the digitally-engaged population[42,43]. Therefore, the question remains, how can healthcare systems promote the adoption and use of consumer-facing technologies in historically non-digitally engaged populations, where PCD is arguably most important? One proven strategy is clinician endorsement of consumer-facing technology. In this study, patients were more likely to be PCD Tool users if they received their primary care at the clinic where the PCD Tool implementation leader practiced. The influential physician leader may have facilitated clinician and patient adoption. Previous studies have shown that physician encouragement of patient use of healthcare innovations is strongly associated with patients adopting the technology[44]. Other strategies include physician-level incentives to recommend and adopt the PCD Tool, consumer- and clinician-facing health information technology-specific education, explicit alignment with personal and organizational missions, and clear and robust staff support to bolster clinician and patient adoption of new health information technology[25,38,45,46].

Limitations and Future Directions

This analysis was limited by the fact that not all of the academic health care system's patients were included in the study. The study sample only included patients who (1) had a provider who practiced at one of the 23 participating primary care clinics (2) had an email documented in their EHR, and (3) had been invited by email to enroll in the PCD Tool. Additionally, the analysis did not thoroughly examine the clinician-level effects on patients' adoption and use of the PCD Tool. Only primary care clinicians were included in the clinician sample. It is probable that the use of the PCD Tool may differ in specialty clinicians, particularly those clinicians who asked to be included in the PCD Tool implementation that was intended for primary care use. Therefore, research comparing primary care and specialty care clinician use of consumer informatics tools requires further investigation. In addition, the relationship between the highly engaged clinicians (n=25) and patient PCD Tool adoption and use should be explored.

Another limitation was the patient- and clinician-level data were derived from multiple sources (PatientWisdom®, Inc., and EHR). Therefore, the combined dataset may contain errors we did not detect. Finally, the research occurred in one academic health care system that predominantly provides care to people living in the Milwaukee metropolitan region, which not transfer to other populations or locations. Research on the relationship between the type of healthcare organization (e.g. academic vs. community) and patient and clinician use of consumer informatics tools use is limited and requires further study.

Conclusion

With the decade-long promotion of the adoption and meaningful use of health information technology[47], and the infusion of the EHR into clinic workflow has changed the way providers practice. Providers often cite the burden of the EHR documentation system that impedes patient-provider communication and leads to clinician burnout[41,48–52]. Therefore, clinicians and patients must have access to technology that assists rather than hinders care[6,7]. An innovative PCD Tool designed to communicate patients' priorities, risks, challenges, and assets with their healthcare team - is a potentially powerful tool - to have meaningful conversations about the interactions between their illnesses and treatment options[53]. Healthcare organizations must implement effective methods to increase the reach, adoption, and use of such tools across all patient populations and conduct further studies to inform about features, barriers, and facilitators of use for both patients and clinicians.

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Table 1

RE-AIM Domain, RE-AIM Definition, Target, and Timeframe

RE-AIM Domain	RE-AIM Definition	Target	Study Timeframe
Reach	Number of patients invited by email	Patient	6/1/2017 – 7/31/2019
Adoption	Number of patients who enrolled	Patient	7/5/2017 – 8/21/2019
Use	Number of patients who completed at least one PCD Tool content area	Patient	7/5/2017 – 8/21/2019
Use	Number of Providers (Physician, Nurse Practitioner, or Physician Assistant), Registered Nurses, or Staff who accessed the patient's PCD Tool profile through the electronic health record	Clinicians	7/5/2017 – 8/21/2019

Note. PCD tool, Patient Contextual Data Tool

Table 2

Summary of Patient Characteristics by PCD Tool Use, Adoption, and Non-Use

Covariate	Level	PCD Tool User (%)	PCD Tool Adopter (%)	PCD Tool Non-User (%)	Total	P-value
Race						
	White	6,368 (90.2)	1,099 (89.1)	64,770 (82.3)	72,237	<.001
	American Indian or Alaska Native	18 (0.3)	2 (0.2)	248 (0.3)	268	
	Asian	118 (1.7)	20 (1.6)	2,647 (3.4)	2,785	
	Black or African American	398 (5.6)	78 (6.3)	8,223 (10.4)	8,699	
	Native Hawaiian or other Pacific Islander	4 (0.1)	1 (0.1)	73 (0.1)	78	
	Missing, Refused, or Unknown	35 (0.5)	16 (1.3)	811 (1)	862	
	Other	121 (1.7)	17 (1.4)	1,942 (2.5)	2,080	
Age						
	0-19	33 (0.5)	9 (0.7)	1,245 (1.6)	1,287	<.001
	20-29	712 (10.1)	190 (15.4)	11,748 (14.9)	12,650	
	30-49	2,053 (29.1)	415 (33.7)	28,472 (36.2)	30,940	
	50-69	3,012 (42.7)	442 (35.8)	27,614 (35.1)	31,068	
	70-89	1,236 (17.5)	174 (14.1)	9,129 (11.6)	10,539	
	90+	16 (0.2)	3 (0.2)	506 (0.6)	525	
Sex						
	Female	4,563 (64.6)	850 (68.9)	45,668 (58)	51,081	<.001
	Male	2,499 (35.4)	383 (31.1)	33,046 (42)	35,928	
Median HH Income						
	$0-$25k	118 (1.7)	18 (1.5)	1,934 (2.5)	2,070	<.001
	$25k-$55k	1,752 (24.8)	275 (22.3)	21,833 (27.7)	23,860	
	$55k-$95k	4,265 (60.4)	745 (60.4)	45,078 (57.3)	50,088	
	$95k-$125k	860 (12.2)	184 (14.9)	9,099 (11.6)	10,143	
	$125k+	67 (0.9)	11 (0.9)	770 (1)	848	
Insurance						
	Commercial	4,451 (63)	822 (66.7)	54,224 (68.9)	59,497	<.001
	Medicaid	261 (3.7)	67 (5.4)	5,389 (6.8)	5,717	
	Medicare	2,179 (30.9)	314 (25.5)	16,192 (20.6)	18,685	
	Other	171 (2.4)	30 (2.4)	2,909 (3.7)	3,110	
Behavioral Co-morbidities						
	0	5,856 (82.9)	1,003 (81.3)	66,879 (85)	73,738	<.001
	1	1,150 (16.3)	221 (17.9)	10,999 (14)	12,370	
	2+	56 (0.8)	9 (0.7)	836 (1.1)	901	
Medical Co-morbidities						
	0	2,789 (39.5)	527 (42.7)	37,483 (47.6)	40,799	<.001
	1	1,950 (27.6)	307 (24.9)	20,723 (26.3)	22,980	

	2-3	1,798 (25.5)	307 (24.9)	16,297 (20.7)	18,402	
	4-5	435 (6.2)	77 (6.2)	3,525 (4.5)	4,037	
	6+	90 (1.3)	15 (1.2)	686 (0.9)	791	
Urgent Care Utilization						
	0	5,957 (84.4)	1,041 (84.4)	65,227 (82.9)	72,225	0.01
	1-2	967 (13.7)	163 (13.2)	11,729 (14.9)	12,859	
	3-4	113 (1.6)	25 (2)	1,345 (1.7)	1,483	
	5+	25 (0.4)	4 (0.3)	413 (0.5)	442	
In Patient Utilization						
	0	6,585 (93.2)	1,140 (92.5)	73,673 (93.6)	81,398	0.19
	1-2	203 (2.9)	37 (3)	1,923 (2.4)	2,163	
	3-4	129 (1.8)	23 (1.9)	1,483 (1.9)	1,635	
	5+	145 (2.1)	33 (2.7)	1,635 (2.1)	1,813	
Office Visit Utilization						
	0	4,632 (65.6)	1,016 (82.4)	17,553 (22.3)	23,201	<.001
	1-2	1,488 (21.1)	136 (11)	32,535 (41.3)	34,159	
	3-4	592 (8.4)	48 (3.9)	15,554 (19.8)	16,194	
	5+	350 (5)	33 (2.7)	13,072 (16.6)	13,455	

Note. Patient Contextual Data, PCD; Median Household income, Median HH income

Table 3

Summary of Logistic Regression Analysis for Covariates Predicting PCD Tool Adoption or Use

					95% CI of OR	
Covariate	**Level**	**OR**	**Z**	**p-value**	**Lower 2.5%**	**Upper 97.5%**
Intercept		1.04	0.76	0.447	0.94	1.16
Race (ref: White)						
	American Indian or Alaska Native	0.67	-1.58	0.113	0.41	1.10
	Asian	0.52	-7.04	<0.001	0.43	0.62
	Black or African American	0.62	-8.04	<0.001	0.56	0.70
	Native Hawaiian or other Pacific Islander	0.50	-4.44	<0.001	0.37	0.68
	Missing, Refused, or Unknown	0.81	-0.43	0.666	0.31	2.12
	Other	0.83	-1.93	0.054	0.69	1.00
Age (ref: 30-49)						
	0-19	0.33	-6.74	<0.001	0.24	0.46
	20-29	0.82	-4.64	<0.001	0.75	0.89
	50-69	1.5	12.26	<0.001	1.41	1.6
	70-89	1.78	10.03	<0.001	1.59	1.99
	90+	0.36	-4.06	<0.001	0.22	0.59
Sex (ref: Female)						
	Male	0.79	-8.92	<0.001	0.75	0.83
Median HH Income (ref: $55k-$95k)						
	$0-$25k	0.92	-0.82	0.415	0.75	1.13
	$25k-$55k	0.99	-0.29	0.774	0.93	1.06
	$95k-$125k	0.93	-1.70	0.089	0.86	1.01
	$125k+	0.77	-1.92	0.055	0.60	1.01
Insurance (ref: Commercial)						
	Medicaid	0.77	-3.92	<0.001	0.68	0.88
	Medicare	1.58	10.67	<0.001	1.45	1.72
	Other	0.58	-6.78	<0.001	0.5	0.68
Behavioral Comorbidities (ref: 0)						
	1	1.26	6.45	<0.001	1.18	1.35
	2+	0.76	-1.91	0.057	0.58	1.01
Medical Comorbidities (ref: 0)						
	1	1.26	7.04	<0.001	1.18	1.34
	2-3	1.64	13.59	<0.001	1.53	1.76
	4-5	1.92	10.37	<0.001	1.70	2.18
	6+	2.13	5.88	<0.001	1.66	2.75

Urgent Care Utilization (ref: 0)						
	1-2	1.07	1.82	0.068	0.99	1.15
	3-4	1.29	2.51	0.012	1.06	1.58
	5+	0.98	-0.09	0.931	0.64	1.51
In Patient Utilization (ref: 0)						
	1-2	1.11	1.34	0.181	0.95	1.29
	3-4	0.91	-0.92	0.356	0.76	1.11
	5+	0.84	-1.93	0.053	0.70	1.00
Office Visit Utilization (ref: 0)						
	1-2	0.11	-67.73	<0.001	0.11	0.12
	3-4	0.07	-57.28	<0.001	0.06	0.07
	5+	0.04	-55.14	<0.001	0.03	0.04
Clinic Location (ref: Clinic C)						
	Clinic A	0.19	-12.45	<0.001	0.14	0.24
	Clinic B	0.53	-9.35	<0.001	0.46	0.60
	Clinic D	0.33	-17.50	<0.001	0.29	0.38
	Clinic E	0.17	-18.04	<0.001	0.14	0.2
	Clinic F	0.21	-19.32	<0.001	0.18	0.25
	Clinic G	0.17	-17.34	<0.001	0.14	0.21
	Clinic H	0.38	-14.36	<0.001	0.33	0.44
	Clinic I	0.18	-13.64	<0.001	0.14	0.23
	Clinic J	0.13	-22.18	<0.001	0.11	0.15
	Clinic K	0.51	-5.73	<0.001	0.40	0.64
	Clinic L	0.48	-8.91	<0.001	0.41	0.57
	Clinic M	0.29	-18.21	<0.001	0.26	0.33
	Clinic N	0.10	-24.22	<0.001	0.09	0.12
	Clinic O	0.16	-25.40	<0.001	0.14	0.18
	Clinic P	0.25	-21.14	<0.001	0.22	0.28
	Clinic Q*	N/A	N/A	N/A	N/A	N/A
	Clinic R	0.45	-11.99	<0.001	0.39	0.51
	Clinic S	0.14	-16.89	<0.001	0.12	0.18
	Clinic T	0.14	-28.86	<0.001	0.12	0.15
	Clinic U	0.51	-4.64	<0.001	0.38	0.68
	Clinic V	0.26	-25.44	<0.001	0.23	0.29
	Clinic W	0.21	-17.05	<0.001	0.17	0.25

Note. Patient Contextual Data, PCD; Median Household income, Median HH income
*Unable to calculate, only one user

Table 4

Clinician Utilization of Patient Contextual Data Tool

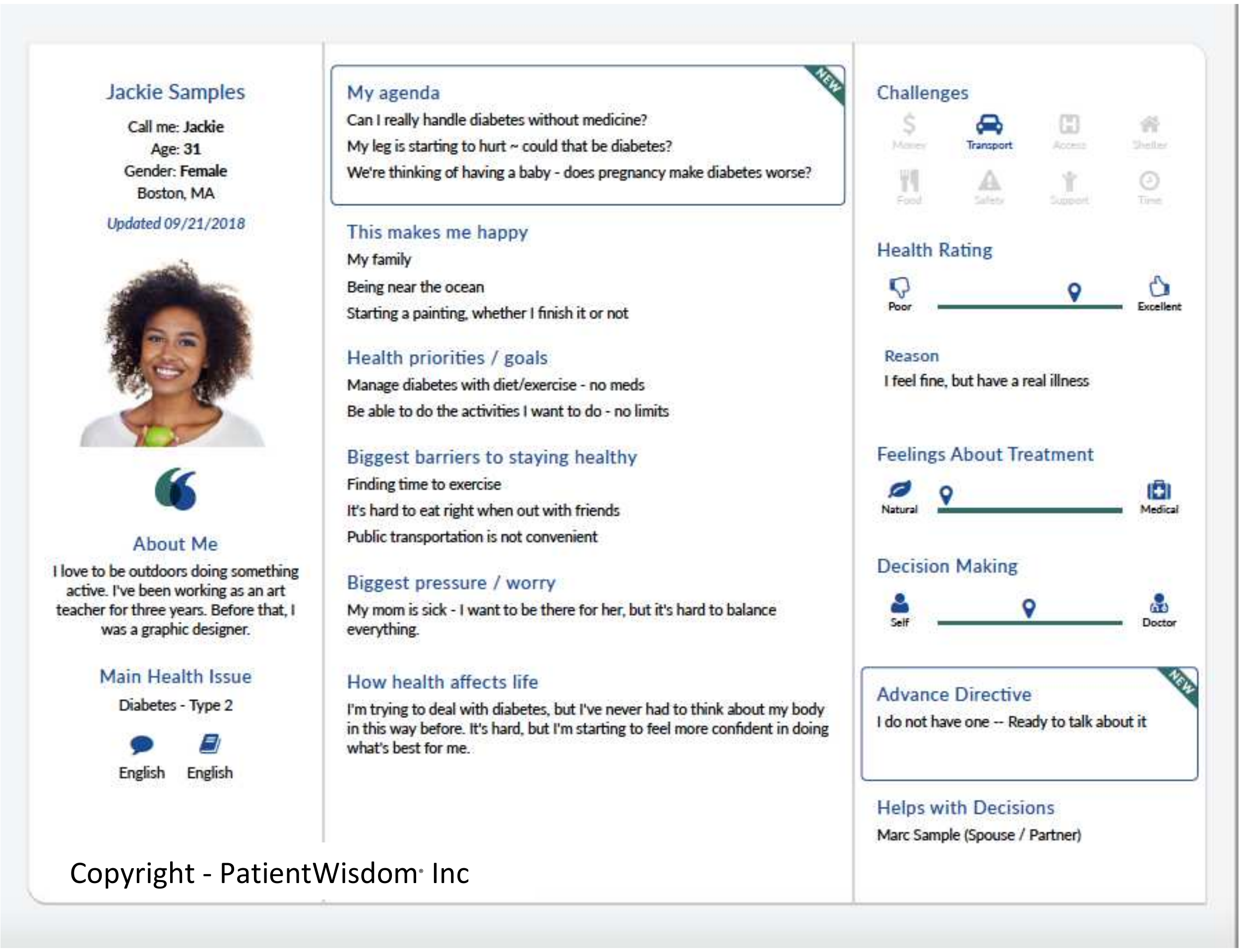
Location	Provider Views	Provider Opportunities	Provider Utilization	RN Views	RN Opportunities	RN Utilization	Staff Views	Staff Opportunities	Staff Utilization	Total Clinician Utilization
*Unavailable	5	79	6.3%	0	79	0.0%	1	79	1.3%	7.6%
Clinic A	15	127	11.8%	5	127	3.9%	8	127	6.3%	18.9%
Clinic B	40	1016	3.9%	26	1016	2.6%	30	1016	3.0%	9.0%
Clinic C	143	2089	6.8%	17	2089	0.8%	27	2089	1.3%	8.4%
Clinic D	134	1179	11.4%	53	1179	4.5%	59	1179	5.0%	19.0%
Clinic E	2	385	0.5%	4	385	1.0%	13	385	3.4%	4.4%
Clinic F	24	378	6.3%	4	378	1.1%	3	378	0.8%	7.7%
Clinic G	21	365	5.8%	10	365	2.7%	2	365	0.5%	8.8%
Clinic H	34	1513	2.2%	17	1513	1.1%	30	1513	2.0%	5.1%
Clinic I	1	269	0.4%	20	269	7.4%	7	269	2.6%	9.7%
Clinic J	61	610	10.0%	4	610	0.7%	6	610	1.0%	11.1%
Clinic K	0	76	0.0%	0	76	0.0%	0	76	0.0%	0.0%
Clinic L	2	471	0.4%	11	471	2.3%	1	471	0.2%	3.0%
Clinic M	58	1206	4.8%	19	1206	1.6%	119	1206	9.9%	15.3%
Clinic N	7	334	2.1%	4	334	1.2%	12	334	3.6%	6.3%
Clinic O	52	1220	4.3%	24	1220	2.0%	83	1220	6.8%	11.2%
Clinic P	67	873	7.7%	10	873	1.1%	11	873	1.3%	9.9%
Clinic Q	0	1	0.0%	1	1	100.0%	0	1	0.0%	100.0%
Clinic R	104	1454	7.2%	13	1454	0.9%	20	1454	1.4%	9.1%
Clinic S	5	246	2.0%	2	246	0.8%	0	246	0.0%	2.8%
Clinic T	10	791	1.3%	5	791	0.6%	7	791	0.9%	2.7%
Clinic U	28	1117	2.5%	7	1117	0.6%	12	1117	1.1%	3.8%
Clinic V	120	2261	5.3%	172	2261	7.6%	28	2261	1.2%	13.3%
Clinic W	24	541	4.4%	7	541	1.3%	51	541	9.4%	14.4%

Grand Total	957	18601	5.1%	435	18601	2.3%	530	18601	2.8%	9.7%

Note. Provider is defined as a Physician, Nurse Practitioner, or Physician Assistant; View is defined as a clinician clicked on the Patient Contextual Data Tool tab in the EHR on the day of, or up to three days before the patient primary care or specialty appointment; Opportunity is defined as a Patient Contextual Data Tool is available to be viewed at the time of the visit; Registered Nurse, RN

Figure 1

PatientWisdom® Inc., inSIGHT® Summary



Jackie Samples

Call me: **Jackie**
Age: **31**
Gender: **Female**
Boston, MA

Updated 09/21/2018

About Me

I love to be outdoors doing something active. I've been working as an art teacher for three years. Before that, I was a graphic designer.

Main Health Issue

Diabetes - Type 2

English English

My agenda

Can I really handle diabetes without medicine?

My leg is starting to hurt ~ could that be diabetes?

We're thinking of having a baby - does pregnancy make diabetes worse?

This makes me happy

My family

Being near the ocean

Starting a painting, whether I finish it or not

Health priorities / goals

Manage diabetes with diet/exercise - no meds

Be able to do the activities I want to do - no limits

Biggest barriers to staying healthy

Finding time to exercise

It's hard to eat right when out with friends

Public transportation is not convenient

Biggest pressure / worry

My mom is sick - I want to be there for her, but it's hard to balance everything.

How health affects life

I'm trying to deal with diabetes, but I've never had to think about my body in this way before. It's hard, but I'm starting to feel more confident in doing what's best for me.

Challenges

Health Rating

Reason

I feel fine, but have a real illness

Feelings About Treatment

Decision Making

Advance Directive

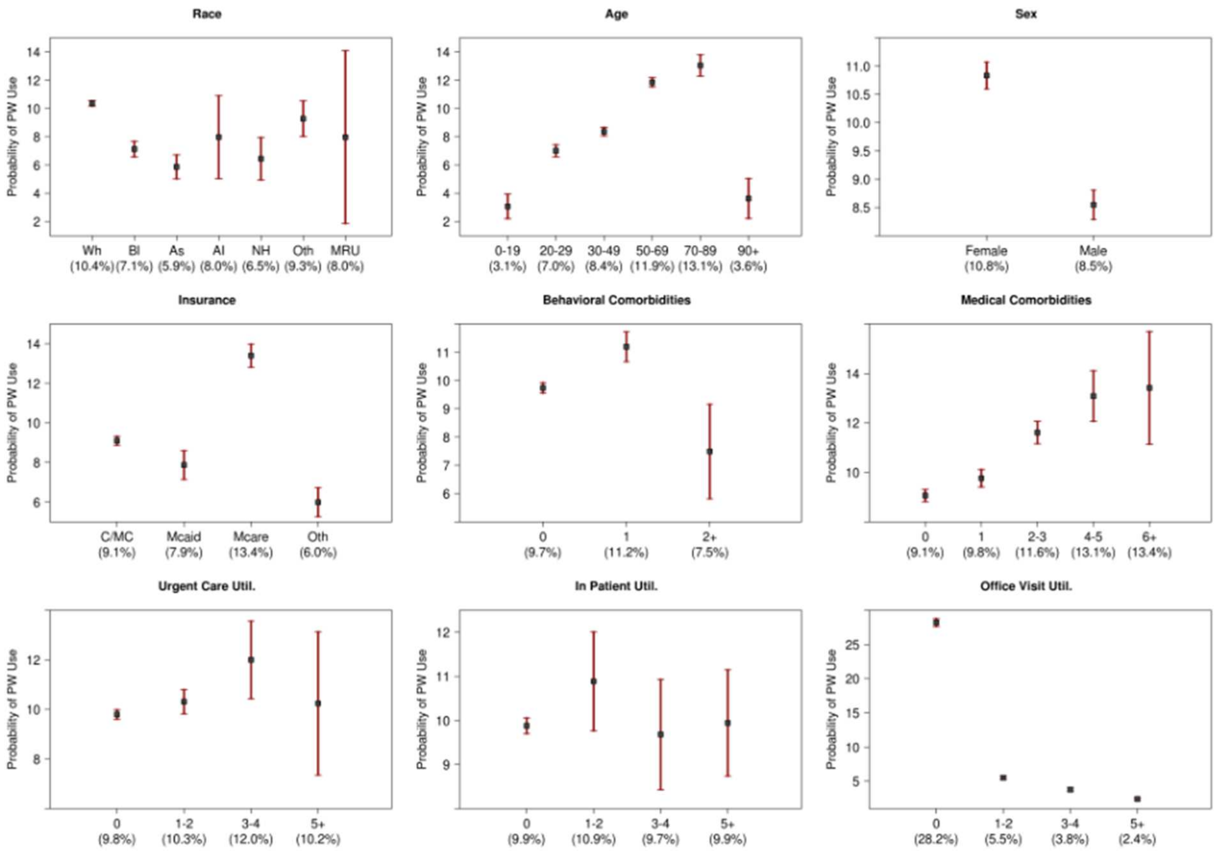
I do not have one -- Ready to talk about it

Helps with Decisions

Marc Sample (Spouse / Partner)

Figure 2

Probability Plots Depicting the Probability of PCD Tool Use by Patient Characteristics and Factors



Note. PatientWisdom®, Inc., PW; White, Wh; Black, Bl; Asian, As; American Indian or Alaskan Native, AI; Native Hawaiian or other Pacific Islander; Other, Oth; Missing, Refused, or Unknown, MRU

Appendix A

PCD Tool Domains and Descriptions

Domain	Description
My Self	
About Me	What patients want others to know about them as people
My Joys	People, places, activities, or things that make patients happy
My Pressures	Challenges, including social and personal determents of health
My Goals	Health-related priorities and goals, and barriers to reaching them
My Health	
My Agenda	Main questions/concerns that patients want to discuss with care team
My Health Rating	How patients rate their health and why
My Health Issues	Perspective on health issues, and effect on life
My Health Decisions	Orientation toward shared decision making, who helps with decisions
My Care	
My Approach to Care	Preference for natural and/or medical treatments
Planning Ahead	Advance directive status
Improving Care	Ideas for how people and places can improve the patient experience

Note. Patient Contextual Data Tool, PCD Tool. Content is provided by PatientWisdom® Inc.

Appendix B

Electronic Health Record Data Fields and Definitions for Patient Adoption and Use Analysis

Data Field	Definition or Category
PCD Tool Status	
	PCD Tool users have a specific ID in the EHR that is assigned to their record on the date they accept the Terms of Use of the PCD Tool
Index Date	
	Date that is either the date the accept the Terms of Use of the PCD Tool was recorded to the patient record (for PCD Tool users) or the last appointment with the patient's provider (for non-PCD Tool users)
Age	
	Age of the patient, in years, at the time of the Index Date
Sex	
	Female Male
Race	
	White American Indian or Alaskan Native Asian Black or African American Native Hawaiian or other Pacific Islander Missing, Refused, or Unknown Other
Ethnicity	
	Hispanic non-Hispanic
Insurance Status	
	Medicare Medicaid Commercial Other
Median Household Income	
	Home address listed in the EHR and the US Census geocoder were used to match the patients' addresses to geographic locations and median household income estimates containing those addresses
Behavioral Comorbid Conditions	
	Alcohol Abuse Drug Abuse Psychoses Depression Anxiety
Medical Comorbid Conditions	
	Heart Failure Valvular Disease

	Pulmonary Circulation Disorder
	Peripheral Vascular Disease
	Hypertension
	Paralysis
	Other Neurological Disorder
	Chronic Obstructive Pulmonary Disease
	Diabetes without Complications
	Diabetes with Complications
	Hypothyroidism
	Renal Failure
	Liver Disease
	Chronic Peptic Ulcer Disease
	HIV/AIDS
	Lymphoma
	Metastatic Cancer
	Solid Tumor without Metastasis
	Rheumatoid Arthritis
	Coagulation Defect
	Obesity
	Abnormal Weight Loss
	Electrolyte and Fluid Balance Disorders
	Blood Loss Anemia
	Deficiency Anemia
Urgent Care Utilization	
	Number of urgent care visit(s) between 6/1/2017-7/31/2019
Inpatient Utilization	
	Number of inpatient stay(s) between 6/1/2017-7/31/2019
Office Visit Utilization	
	Number of office visit(s) between 6/1/2017-7/31/2019

Appendix C

Summary of Ordinal Proportional Odds for Variables Predicting Adoption, Use, Non-use of the PCD Tool

Covariate	**Level**	**OR**	**Z**	**p-value**	**95% CI of OR** **Lower 2.5%**	**Upper 97.5%**
Intercepts		0.99	-0.19	0.846	0.89	1.1
		1.22	3.76	<0.001	1.10	1.36
Race (ref: White)						
	American Indian or Alaska Native	0.69	-1.48	0.138	0.42	1.13
	Asian	0.53	-6.92	<0.001	0.44	0.63
	Black or African American	0.62	-8.13	<0.001	0.56	0.70
	Native Hawaiian or other Pacific Islander	0.49	-4.66	<0.001	0.36	0.66
	Missing, Refused, or Unknown	0.81	-0.43	0.666	0.31	2.11
	Other	0.83	-1.93	0.054	0.69	1.00
Age (ref: 30-49)						
	0-19	0.34	-6.68	<0.001	0.25	0.46
	20-29	0.81	-4.89	<0.001	0.74	0.88
	50-69	1.5	12.34	<0.001	1.4	1.6
	70-89	1.77	10.01	<0.001	1.58	1.97
	90+	0.37	-3.98	<0.001	0.22	0.60
Sex (ref: Female)						
	Male	0.79	-8.72	<0.001	0.75	0.84
Median HH Income (ref: $55k-$95k)						
	$0-$25k	0.94	-0.63	0.53	0.77	1.15
	$25k-$55k	1	-0.14	0.885	0.93	1.06
	$95k-$125k	0.93	-1.69	0.09	0.86	1.01
	$125k+	0.78	-1.87	0.061	0.60	1.01
Insurance (ref: Commercial)						
	Medicaid	0.77	-3.95	<0.001	0.68	0.88
	Medicare	1.57	10.60	<0.001	1.44	1.70
	Other	0.59	-6.64	<0.001	0.51	0.69
Behavioral Comorbidities (ref: 0)						
	1	1.25	6.19	<0.001	1.16	1.34
	2+	0.77	-1.88	0.061	0.58	1.01
Medical Comorbidities (ref: 0)						
	1	1.25	7	<0.001	1.18	1.33

	2-3	1.60	13.10	<0.001	1.49	1.72
	4-5	1.85	9.91	<0.001	1.64	2.10
	6+	2.04	5.58	<0.001	1.59	2.62
Urgent Care Utilization (ref: 0)						
	1-2	1.07	1.77	0.076	0.99	1.15
	3-4	1.27	2.38	0.017	1.04	1.55
	5+	1.01	0.04	0.965	0.66	1.54
In Patient Utilization (ref: 0)						
	1-2	1.10	1.19	0.235	0.94	1.28
	3-4	0.93	-0.79	0.432	0.77	1.12
	5+	0.83	-2.07	0.039	0.69	0.99
Office Visit Utilization (ref: 0)						
	1-2	0.12	-67.05	<0.001	0.11	0.13
	3-4	0.07	-56.71	<0.001	0.06	0.08
	5+	0.04	-54.64	<0.001	0.03	0.04
Clinic Location (ref: Clinic C)						
	Clinic A	0.19	-12.32	<0.001	0.15	0.25
	Clinic B	0.53	-9.31	<0.001	0.47	0.61
	Clinic D	0.33	-18.04	<0.001	0.29	0.37
	Clinic E	0.17	-17.77	<0.001	0.14	0.21
	Clinic F	0.21	-19.21	<0.001	0.18	0.25
	Clinic G	0.18	-17.04	<0.001	0.14	0.22
	Clinic H	0.37	-15.03	<0.001	0.32	0.42
	Clinic I	0.19	-13.56	<0.001	0.15	0.24
	Clinic J	0.13	-21.91	<0.001	0.11	0.16
	Clinic K	0.51	-5.71	<0.001	0.41	0.65
	Clinic L	0.48	-9.03	<0.001	0.41	0.56
	Clinic M	0.29	-18.34	<0.001	0.26	0.33
	Clinic N	0.11	-23.99	<0.001	0.09	0.13
	Clinic O	0.05	-16.67	<0.001	0.04	0.08
	Clinic P	0.16	-25.08	<0.001	0.14	0.19
	Clinic Q	0.25	-21.34	<0.001	0.22	0.28
	Clinic R	0.44	-12.42	<0.001	0.39	0.50
	Clinic S	0.15	-16.75	<0.001	0.12	0.19
	Clinic T	0.14	-28.61	<0.001	0.12	0.16
	Clinic U	0.52	-4.55	<0.001	0.39	0.69
	Clinic V	0.27	-25.22	<0.001	0.24	0.30
	Clinic W	0.22	-16.82	<0.001	0.18	0.26

Note. Patient Contextual Data, PCD; Median Household income, Median HH income

Appendix D

Generalized Variance Inflation Factor

Covariate	df	pow(GVIF,1/(2*df))
Race	6	1.02
Age	5	1.10
Sex	1	1.02
Median Household Income	4	1.04
Insurance	3	1.16
Behavioral Comorbidities	2	1.02
Medical Comorbidities	4	1.05
Urgent Care Utilization	3	1.02
In Patient Utilization	3	1.02
Office Visit Utilization	3	1.05
Clinic Location	22	1.01

Note. Multicollinearity was assessed using the generalized variance inflation factor (GVIF). To make GVIF comparable across covariates with differing degrees of freedom, pow(GVIF,1/(2*df)) was used (Fox and Monette, 1992). The interpretation of these values is similar to the regular VIF and therefore these results do not indicate any multicollinearity because all the values are well below 2.

Fox J, Monette G. Generalized Collinearity Diagnostics. Journal of the American Statistical Association. 1992;87(417):178-183. doi:10.2307/2290467.

impact of pre-visit contextual data collection on patient-provider communication and patient activation: Study protocol for a randomized control trial

Abstract

Background: Patient-centered care is respectful of and responsive to individual patient preferences, needs, and values. To provide patient-centered care, clinicians need to know and incorporate the patient's context into their communication and care with patients. Patient-contextual data (PCD) encompass the social determinants of health and patients' needs, values, goals, and preferences relevant to their care. PCD can be challenging to collect as a routine component of the time-compressed primary care visit.

Methods/design: The study aims are to (1) determine if patient-provider communication and patient activation are different for patient-users and patient-non-users of the EHR-integrated PCD tool; and (2) assess if the impact of using PCD on patient-provider communication and patient activation differ for Black and White patients. We describe a randomized trial of a prospective cohort of non-Hispanic White and Black patients who receive primary care services at a mid-western academic health system in the United States. We will evaluate if pre-visit patient activation in providing PCD through a consumer informatics tool enhances patient-provider communication, as measured by the Communication Assessment Tool, and evaluate changes in patient activation, as measured by the Patient Activation Measure. Further, because of racial disparities in care and communication, we seek to determine if the adoption and use of one such tool might narrow differences between patient groups.

Discussion: Recently, there has been increased attention to the role of health information technology to enable patients to collaborate with providers through the sharing of PCD. The adoption of such tools may overcome the barriers of current EHRs by directly engaging patients to submit their contextual data. Effectively, these tools would support the EHR in providing a more holistic understanding of the patient. Research further supports that individuals who have a robust digital engagement using consumer informatics tools have higher participation in treatment follow-up and self-care across populations. Therefore, it is critical to investigate interventions that elicit and share patients' social risks and care preferences with the healthcare team as a mechanism to improve individualized care and lessen the gap in health outcomes.

Trial registration: ClinicalTrials.gov, NCT03766841. Registered on 6 December 2018

Over the past few decades, healthcare has been shifting from a paternalistic to a patient-centered model that values patient engagement and shared decision-making [1,2]. These values align with the patient-centered care model, where clinicians provide care that is tailored to the distinct needs of the patient. It is based on the development of respectful and dignified therapeutic relationships [3].

To provide patient-centered care, clinicians need to know and incorporate the patient's context into their communication and care with patients. Patient contextual data (PCD) encompass the social determinants of health (SDH) [4] and further comprise patients' needs, values, goals, and preferences relevant to their care [5]. In the primary care setting, clinicians address the majority of patient's health care needs, through a sustained partnership with patients, and within the context of family and community [6]. Therefore, care teams must have access to data about the patients' perspectives, values, and other contextual considerations to tailor patient-centered conversations and clinical decisions [1,6,7]. PCD can facilitate team-based care by enabling healthcare team members to build rapport quickly and to connect with patients on a humanistic level [8]. Evidence suggests that connecting with patients bolsters activation, which in turn leads to better health outcomes and improved health experience [9,10].

Nonetheless, PCD are often not collected as a routine component of care [11]. A barrier to the integration of PCD is linked to the current limitation of electronic health record systems (EHRs) in integrating and facilitating the retrieval of social risks and care preferences data [12] even if collected as unstructured data within clinical notes. Clinicians face several limitations in terms of time [513] allocated to clinical visits and tools to gather a comprehensive picture of their patients' needs, values, preferences, goals, and concerns. The system-level barriers lead to missed opportunities to individualize care and act upon PCD that might have a substantial impact on patient outcomes and the experience of care [14]. Studies show that these unvoiced concerns and goals for care disproportionately relate to the patient's experience of illness[15,16], patient's expectations of treatment [17], or psychosocial concerns [16,18–20]. These 'contextual errors'

[14] (i.e., disregard of PCD in care planning) are more costly to the healthcare system than biomedical errors (guideline discordant care) [11]. Conversely, when providers incorporate PCD, into the care context, patients' engagement in their care increases [21]. When individuals take an active role in managing their health, their health outcomes tend to improve, and healthcare costs decrease [10].

Strategies to Mitigate Disparities

Research has shown that disparities exist in who adopts consumer informatics tools [22–25]. In a study of a national sample of US adults, ethnic/racial minorities were less likely to be invited to use a patient portal than ethnic/racial majority populations [26]. Because patient portal usage has been shown to be associated with improved quality measures and is thought to contribute positively to patient safety, digital tools should be assessed for their capability to be adopted by a wide range of the population and to narrow, rather than grow, gaps in care across groups [27].

Given that disparities exist in the adoption and use of consumer informatics tools [26,28,29], researchers must evaluate ways to reach vulnerable populations when testing new consumer information technologies. Current trends suggest that internet access is no longer the main cause of the digital divide [30]. A simple solution is to invite all patients to use new technology. When directly asked to sign up for a patient portal, ethnic/racial minority groups used the portal at rates comparable to ethnic/racial majority groups [26]. Additional strategies to reach the most vulnerable individuals and across racial groups is for developers to employ patient-centered design strategies like a simple, clean, and aesthetically appealing interface [31]; incorporate patient education on how to use the technology [32], and promote the new technology in various ways [33]. Conceivably introducing a new consumer informatics technology, designed to improve patient activation and communication, may not achieve the desired rates of adoption, unless healthcare team members actively promote and assist in the use of the technology [8,24,33,34].

Study Objectives

In this clinical trial, we aim to evaluate the influence of PCD, collected using a consumer informatics tool, for pre-visit planning and during routine clinical visit discussions with the healthcare team. The goal is to compare patient-provider communication and patient activation among patient-users and non-users of the PCD tool, accounting for differences between non-Hispanic White and Black participants [hereafter White and Black]. We hypothesize that inviting patients directly to submit this information may help with several factors, including activation (already primed and thinking about the visit) and communication (helps prepare perspective and helps the clinician identify salient points).

This clinical trial is designed to answer several questions about how the use of a consumer informatics technology, designed to collect PCD from patients and share it with providers through the EHR, may affect patient activation and patient-provider communication. Further, evaluating impact by race (could PCD help mitigate any baseline differences in patient activation and patient-provider communication?).

The primary aims of this clinical trial are to:

(1) Assess if the effects of using PCD on patient-provider communication and patient activation are different for Black and White patients, accounting for age, gender, and other patient factors; and

(2) Evaluate if baseline measures of patient-provider communication and patient activation modify the effectiveness of PCD, accounting for age, gender, and other patient factors.

We will achieve these two aims using two outcome measures. First, to determine if patient-provider communication changes, we will use the Communication Assessment Tool (CAT) [35]. Second, to evaluate if patient-activation changes, we will use the Patient Activation Measure (PAM) [36].

Methods

Study Design

This clinical trial will assess the impact of incorporating PCD on patient-provider communication and patient activation of Black and White participants. The trial is registered at ClinicalTrials.gov (NCT03766841). The health network's ethics review board approved this trial (Registered Project - PRO00031177). The study protocol adheres to the Standard Protocol Items: Recommendations for International Trials (SPIRIT) 2013 [37] checklist [Appendix A].

We will conduct an experimental study of a prospective cohort of Black and White patients who would be eligible to receive an invitation to complete the PCD Tool before a subsequent visit to their primary care provider. Following the visit, each participant will be invited to complete self-reported surveys. The surveys assess perceptions of visit communication and patient activation. The survey results are adjusted for pre-visit measures of communication, sex, age, and other sociodemographic factors. Figure 1 presents the study design. [Insert here. Figure 1. Study design].

Sample Size Determination and Randomization

A priori power analysis was performed to estimate the required sample size using G*Power 3 [38,39] based on the study's primary outcome, the CAT [35]. These were carried out for the more straightforward two-sample t-test procedure, as this is known to yield a conservative assessment of power. For a two-sided test at alpha=0.05, a total sample size of 200 results in 80% power for a standardized effect size of 0.4 and 94% for an effect size of 0.5. Increasing the sample size to 250 raises these figures to 88% and 98%, respectively. A sample size of 250 provides 79% power to detect a standardized effect size of 0.35. To account for up to 20% potential dropout over time, we aim to enroll 300 participants (targeting 150 Black and 150 White participants). Once participants provide consent, REDcap will randomize them into one of two experimental arms: (1) PCD Tool (i.e., intervention) or (2) usual care. We will use stratified random sampling to ensure equal representation of Black and White participants in each arm.

Stratified randomization prevents an imbalance of racial representation between arms. We will use REDCap [40] for the randomization procedures.

Randomization of the study participants

Allocation process.

An allocation table was created using R to develop a block randomization scheme to balance arms and stratification by race. The block randomization scheme then was incorporated into the REDCap System. REDCap is capable of randomizing the participant at the time of formal inclusion in the study. The randomization is stratified by race in a 1:1 ratio, ensuring that we oversample Black participants based on population demographics. Blinding does not occur for either the participant or the study team. Participants are invited to join a communication study but are not told that the study will focus on their use of the PCD tool or not.

Study population.

Three hundred adults (≥18 years) with established primary care providers (i.e., at least one visit in the previous 12 months with the same provider) from two academic and community-based primary care clinics from The Medical College of Wisconsin in Milwaukee, Wisconsin, USA will be recruited for the study.

Inclusion Criteria.

Eligible participants are individuals (1) aged 18 or older; (2) who self-identify as non-Hispanic White or Black; (3) who speak and understand English; (4) who are willing and able to give informed consent; and (5) who have at the time of the study enrollment period an upcoming visit (1 to 4 weeks away), (6) the appointment is at one of the academic medical center's primary care clinics (7) the appointment is with an established provider (at least 1 previous appointment with the same provider within the last 12 months).

Recruitment

We will use consecutive convenience sampling to select every person who meets the inclusion criteria based on weekly EHR data reports. This sampling procedure minimizes selection bias (i.e., volunteerism) [41]. Using the institution's local informatics tools [42], we estimated the number of unique patients seen at the eligible clinics in 2016 to be 5,200 Black and 13,750 non-Hispanic White patients. Restricting to unique patients with a preventive service encounter in 2016 (a conservative estimate as it excludes patients for whom a preventive exam was not billed, which includes most Medicare patients), there remain over 980 Black and 3,725 non-Hispanic White patients who are eligible to participate.

We contact participants through a mailed letter or email. The invitation to participate describes the study as "a study to better understand and improve patients' experiences of care and communication with their doctors." Research staff contact eligible participants by phone up to three times to answer questions, encourage participation and facilitate the completion of the baseline survey. Recruitment will continue until we reach our target sample size of 300. We will collect the survey data using REDCap (Research Electronic Data Capture) system [40], hosted at the academic medical center.

Informed consent

The informational letter participants receive as part of the informed consent process can be found in Appendix B.

PCD Tool Arm

After completion of the pre-visit survey, all participants in the intervention group receive an email with a link to the PCD tool for participants to complete their profile. Participants are given the option to complete their PCD profile independently or with assistance from one of the research staff. Providing the participant with options to complete their PCD profile ensures the participant has access to the internet and a device. Facilitating the enrollment process may also overcome the current rates of adoption and use of the tool (about 10%) by being responsive to participants' varying degrees of computer literacy and technical skills.

For participants who do not have an email address and decline to sign up for one, a paper survey will be used to collect the PCD and share it with the healthcare team at the time of the appointment. Although completion of a paper form loses some of the elements of the trial (PCD not integrated into the EHR), it decreases the chance to add bias in the study as Blacks are less likely than Whites to have an email account [30,43].

PCD Tool Facilitation Enrollment Process

The facilitation enrollment process includes a description of the PCD tool, followed by the study team member either assisting the participant in registering a PCD tool account using the sent email link to the PCD Tool site or describing how to register a PCD tool account through the patient's portal. Next, the study team member will review types of 'stories' to share, in the domains of (a) information about me; (b) issues related to my care; (c) my upcoming visit agenda; and (d) barriers to care, to highlight them all as important pieces of data. Additionally, the study team member will share how to upload a picture to the profile. After completing the instructions, the study team member will share that the completed profile is now available to the care team. The participant can then view how their profile will appear in their EHR via the inSIGHT summary. [Figure 2. inSIGHT summary]

The research team member will document the type of PCD Tool facilitation (i.e., email link only, over the telephone, or in-person) for each participant as well as take field notes of each facilitation experience. Approximately one week before the primary care visit, research staff will re-contact the participant, either by telephone or email, up to three times. The research staff will thank the participant for being part of the study and inquire if they have questions completing or updating their PCD tool profile. Research staff will also remind the participant to complete the profile, if not yet finished.

Usual Care Arm

Participants randomized to the usual care arm will complete their pre-visit survey, scheduled primary care visit, and post-survey. The only information regarding the PCD tool they receive before their visit is the email sent automatically by the EHR system to all patients at the academic medical center to create or update their PCD account one-week before their appointment. For participants who do not have a pre-visit survey completed at least five days ahead of the appointment, a study team member will call to remind the participant to complete the survey as soon as possible. For participants who indicate a preference to complete the pre-visit survey over the telephone or in-person, the study team member will read the survey items verbatim and complete the survey in REDCap.

For both arms, after the scheduled primary care clinic visit occurs, participants will receive up to three email reminders to complete the post-survey. A study team member will call to remind the participant to complete the post-survey if it is not completed after the third email reminder. For participants who indicate a preference to complete the post-visit survey over the telephone or in-person, the study team member will read the survey items verbatim and complete the survey in REDCap.

Intervention

Electronic Health Record (EHR)-integrated PCD Tool

The Froedtert & Medical College of Wisconsin Health Network partnered with a digital health company, PatientWisdom Inc (New Haven, CT), to develop a digital online platform to engage with patients ahead of visits. After creating an account on the platform, each participant would be able to provide information about themselves and their situations (patient contextual data or PCD), as well as their agenda for the next visit through a mobile and web interface.

The PCD tool is a web-based application running on a HIPAA-compliant platform. It has a responsive design that allows for ease of use across a range of devices, from desktops to tablets and smartphones. The tool was co-developed by the Health Network, their patients, their clinicians, and an industry partner. The consumer informatics tool draws upon deep experience and evidence in patient communication [35,44]. The tool invites patients to share “stories” about themselves, their health, and their care. For example, in the ‘My Self Story’ section, patients share what they want their healthcare team to know about them as individuals, what brings them joy, and about the pressures in their life, including social and personal determinants of health. The ‘My Self Story’ section also includes the patient's health-related priorities and goals, plus barriers they experience in achieving them. In the ‘My Health Story,' patients share questions or concerns they want to discuss with the care team, rate their health and provide reasons for the rating, and provide a perspective on how identified health issues affect their lives.

Further, patients identify their preferences toward shared decision-making and identify which person(s) support them with healthcare decisions. Patients can access the application directly through a web address or through a drop-down menu embedded in the patient portal that provides a single sign-on experience for the patient. The latter process makes a direct linkage between the patient-user and the patient in the EHR. If the patient does not use the patient portal, a statistical matching algorithm links accounts between the PCD tool and the EHR. After the linkage occurs, clinicians can click on an activity tab within the EHR to view the inSIGHT summary.

EHR Integration. The EHR-integrated PCD tool synthesizes information from the 'My Self' and 'My Health' stories to create the inSIGHT summary, an at-a-glance view [Insert here. inSIGHT Figure X] of the patient, their context, and what is relevant to them. The inSIGHT summary includes content to facilitate a personal connection as well as to efficiently grasp goals of care, agenda items, barriers, social determinants of health, styles, and preferences. The one-page summary highlights elements that the patient recently updated. Since the developers designed the tool to be asynchronous, they established an alert process to flag text and notify clinicians of critical patient data (e.g., thoughts of suicide, domestic violence, or distressing symptoms) to guarantee timely interventions [5]. There are plans to transition the alert process to natural language processing once a sufficient amount of PCD is gathered for deep learning.

Data Collection

We will use self-report surveys to assess differences in patient-provider communication and patient activation between the PCD Tool and Usual Care arms and by race (Black and White). The primary outcome measure is patient-provider communication, assessed using the Communication Assessment Tool (CAT) [35] at post-visit. The 15-item measure is unidimensional and has high internal consistency (Cronbach's alpha = 0.96) with readability at or below an eighth-grade level [35]. The psychometric properties of the CAT were tested in a diverse sample. The testing revealed that the instrument has content and construct validity and reliably [35] measures patients' perceptions of physicians' interpersonal communication skills. We will examine individual items as well as the proportion of items with the top rating. The CAT was designed to be administered directly following a visit and not yet validated in a retrospective context. Therefore, we will use the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) survey [4546] communication composite questions, validated for patient's perceptions of communication with their provider within the past 12 months, as the baseline communication measure. The outcome will be the CAT adjusting for the baseline CG-CAHPS score.

We will use the Patient Activation Measure (PAM) 13-item [36] to assess changes in the secondary outcome, patient activation, examining the change in pre- and post-visit assessments. Psychometric testing revealed that the 13-item PAM questionnaire yielded a strong Rasch person reliability score (i.e., 0.85-real and 0.87 model), and Cronbach's alpha was acceptable at 0.87 [36]. Hibbard and colleagues [36] completed test-retest reliability in a pilot of 30 patients who took the measure two weeks after the initial assessment using the standard error of measurement (SEM). Hibbard et al. [47] reported an SEM of 1.96, with a 95% confidence interval for each person's measured activation. The outcome is change in the PAM score from the pre- and post-visit score.

We will collect the following independent variables on the pre-visit survey: CG-CAHPS communication composite [45], PROMIS global and physical health [48], health literacy [49], technology use/technology acceptance [50], and sociodemographic characteristics. We will measure patient experience using the communication composite of the CG-CAHPS survey [46]. The CG-CAHPS-communication composite has high internal consistency (Cronbach's alpha = 0.89) [45] that was determined using a nationally representative sample of over 21,000 patients from 450 U.S. practice sites. We will assess participants' perceptions of their global health using the Patient-Reported Outcomes Measurement Information System (PROMIS) 10-item global health short form, which includes scores on global physical health and global mental health, and a single 5-point item on global quality of life. The PROMIS 10-item global health short-form scales had internal consistency reliability coefficients of 0.81 for global physical health and 0.86 for global mental health in a large national survey [48]. Technology use/technology acceptance will be collected using the Health Information National Trends Survey (HINTS) 5 Cycle 1 [50]. Participants will report health literacy using a validated 1-item tool [49]. Sociodemographic characteristics and other hypothesized predictors of the outcome measures include income, age, sex, gender identity, health insurance status, educational attainment, number and type of chronic conditions, and length of relationship with primary care provider (in months/years).

We will monitor the use of the PCD Tool in three ways. First, we will assess whether those in the PCD Tool arm completed their profile before their appointment. Second, for participants in the Usual Care arm, we will determine if they created a profile after they entered the study, as all patients in the academic medical center have access to the PCD Tool. Third, we will assess whether any of the care team members reviewed the participant's PCD Tool profile within one clinic day before and the day of the appointment. The SPIRIT figure [37] displays an overview of study time points, intervention, and assessments of the randomized control trial. [Insert Figure 3 SPIRIT figure here]

Data Management

The research team will use REDCap for data management[40]. This system is a secure, web-based application designed by Vanderbilt University to support data collection for research. It provides data validation, audit trails, and automated export procedures to a variety of statistical packages. As necessary, branching logic and calculated fields will be created in the system to support data entry.

Data Monitoring

The data monitoring committee is comprised of the study team, the PCD tool's implementation manager, and the Department of Medicine Safety Committee (DMSC). This pragmatic trial is low risk, but several monitoring processes are in place to protect the participants. The participants are provided with the study team's phone and email contact information. Participants also have contact phone numbers for the ethics review board, who will notify the principal investigator (PI) of any harm, which will be reported to the local institution. If a participant shares concerning data (e.g., thoughts or actions of self-harm, domestic violence) in their PCD tool profile, the provider is alerted, and contact with the participant is initiated. The study team will not conduct interim analyses due to the low-risk nature of the trial. There is an independent process for the DMSC to review all PCD tool data for quality each quarter.

Ethical Considerations

The academic health network's ethics review board approved the study before enrollment. The study PI will report changes to the protocol to clinicaltrials.gov., ethics review board locally, and all study team members. All study personnel have completed training on the protection of human subjects in research. Data will be stored on a secure server with physical and technical and administrative access controls, some using academic health system approved REDCap software. Remote access is available over a secure network via encrypted connections to password-authorized users. Media will be kept in locked file cabinets in locked offices. Files with participant identifiers will be stripped of identifiers as soon as it is no longer needed. The study staff has no conflicts of interest. A subsidiary of the affiliated health system has an investment in the company that owns the PCD tool. However, the study staff are not directly employed by the health system nor have any financial ties to the company. There are no provisions for ancillary or post-care of the trial due to the nature of the use of the PCD tool, which is available to the health system's patients currently.

Analysis

The trial will evaluate differences in the change in PAM scores [36] and the CAT score [35] (a post-visit measure) adjusting for CG-CAHPS score (a pre-visit measure), respectively between the study arms. The research team will also assess differences in pre- and post-visit patient activation and after-visit patient-provider communication by race. Our primary analysis is intention-to-treat (ITT) analysis, where every randomized participant is analyzed in the group to which they were randomly assigned [5152]. Chi-square tests for categorical variables and independent-sample *t*-tests for continuous variables will be used to examine the differences between the groups at baseline and post-visit. Descriptive statistics (means and standard deviations) will be conducted for the following variables: age, CG-CAHPS communication composite score [45], and PROMIS 10-item Global Health short form [48]. Frequencies will be calculated for sex, gender identity, education, marital status, employment status, income, health insurance coverage and type, difficulty paying bills, health literacy, internet use, internet access, internet access location, and internet access device. We will also extract data from each participant's EHR to calculate their Charlson Comorbidity Index (CCC) [53] as a measure of morbidity. Pre-visit assessment of communication using CG-CAHPS [45], as a control variable, and post-visit assessment of communication using the CAT [35] will be tested within and between groups using linear regression, controlling for covariates. A linear regression model will be used to determine factors that predict changes in patient-provider communication and patient-activation controlling for covariates.

However, we expect that there will be some crossover and non-compliance between arms. For example, some individuals randomized to the PCD Tool arm may not complete a profile, and some individuals not randomized to enroll in the PCD Tool may create a profile. To overcome this limitation, we will conduct additional analyses that account for non-compliance and estimates the effect of the treatment-on-the-treated (TOT) instead of the ITT [54,55]. TOT is sometimes referred to as the local average treatment effect (LATE). We will identify this using a two-stage least squares regression (2SLS) [56,57]. The first stage of the model estimates if a person used the PCD tool in the follow-up period:

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The second stage will identify the causal impact of using the PCD tool on outcomes (patient activation and patient-provider communication). To do this, we model predicted use of the PCD tool from stage 1 in the stage 2 model, and use the results of this coefficient to interpret how the PCD tool impacts patient activation and patient-provider communication as seen in the model below:

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Missing values analysis will be conducted on the final data set to determine if data were missing completely at random, missing at random, or missing not at random [58,59]. To reduce the likelihood that missing data are not biasing our results, we will use multiple imputation by chained equations to fill in missing data stratified by race [58]. The imputation algorithm will include participant demographic and clinical characteristics. Multiple imputation has been increasingly applied to clinical research to deal with the common problem of incomplete datasets [59].

For all aims, statistical analysis will be completed using SAS [60] procedures GLM as well as MIXED to assess and account for a possible provider and center heterogeneity. A p-value of < 0.05 is considered statistically significant.

Dissemination

We intend to write and publish two manuscripts (corresponding to each outcome), adhering to the International Committee of Medical Journal Editors (ICMJE) [61] authorship recommendations. Additionally, we will communicate study results to the academic health system leadership, primary care clinics, developer of the tool, and the medical community.

Discussion

Role of consumer informatics

There is increasing attention on the role of health information technology and digital health tools to enable patients to collaborate with providers by sharing and acting upon PCD [12,62–69]. Adoption of consumer-facing informatics tools may overcome the barriers of current EHRs by directly engaging patients to share PCD. Moreover, with the advent of application programming interface (APIs) and the increasing level of interoperability of EHR systems, these consumer applications can integrate PCD information into current EHR systems to make the data available for use by clinicians and healthcare teams [1,70]. In particular, consumer informatics tools that gather and then share PCD are hypothesized to improve communication [20] and health outcomes [71]. Effectively, these tools would support the EHR in providing a more holistic understanding of the patient.

In an earlier study [8], digitally engaged patients reported that completion of their profile in a consumer informatics tool promoted reflection of their health goals, challenges, and priorities. The reflection led to actions toward goal attainment and targeted conversations with their healthcare team about issues important to them [8]. Research further supports that individuals who have a robust digital engagement using consumer informatics tools have higher participation in treatment follow-up and self-care [72,73]. When care goals were aligned, racial-ethnic minority populations experienced improvements in patient-provider communication and decision quality outcomes similar to racial-ethnic majority populations [24,74]. Therefore, it is critical to understand if interventions that elicit and share patients' social risks and care preferences with the healthcare team serve as a mechanism to improve individualized care and lessen the gap in health outcomes.

Summary, Strengths, Limitations, Contingency Strategies, and Alternative Designs

The clinical trial will provide crucial empirical evidence on the effects of a consumer informatics tool that elicits and aggregates PCD for use in the clinical exchange on patient-provider communication and patient activation across populations. The study will occur within the most racially segregated metropolitan area in the United States, where racial disparities in health and healthcare represent a significant public health concern[75–78]. The study sample may not reflect the population, nor the complex contextual issues associated with the area.

We acknowledge the following limitations and significant threats to the study and present contingency strategies. This research study will occur within one academic medical center, which may limit the generalizability of the results. To mitigate this limitation, we will recruit participants from various academic and community primary care clinics with different staff, providers, milieu, and the composition of patients who receive care. The participants in this study will be Black and White and limited to individuals who can speak English. This inclusion criterion excludes other diverse populations. This limitation is due to the population of patients served at the academic medical center. Recruitment difficulties for participation may occur. We employ several recommended strategies to recruit Black populations into this trial but lack others, including community involvement and informational sessions[79].

Additionally, patients often complete surveys, either for the patient experience metrics or other research projects. To compensate individuals for their time, participants will receive a modest financial incentive for participation in this research project. The incentives are $25 for each survey completed.

We also considered the alternative design of an efficiency trial with its advantages of high internal validity [52]. Although there are methodological advantages to this design, the real-life variability of clinical practice precludes the strict adherence to a study protocol mandated in an efficiency trial. Therefore, we chose a pragmatic clinical trial with somewhat diminished internal validity, but a high degree of external validity of the results, which is valued in implementation research [52].

Study Design Innovations

Healthcare stakeholders, clinicians, and patients increasingly call for the evaluation of clinically-relevant interventions that are tested in heterogeneous clinical settings with the inclusion of diverse study participants [55,80]. In this clinical trial, we will test an intervention (PCD tool) that is deployed across an academic health network. We focus on understanding differences by use, adjusting for problems with bias and self-selection of users for the PCD tool. The study design intends to overcome self-selection bias by creating the randomization to treatment using various facilitation processes, to improve the usage of the tool beyond its baseline. In addition to ITT analysis, typical in pragmatic trials [54], we will conduct TOT analysis [56,57] to model estimates if a participant used the PCD tool in the follow-up period and then identify the causal impact of using the PCD tool on outcomes (patient activation and patient-provider communication). In this study, TOT analysis will adjust for participant non-adherence to the group assignment, a common occurrence in pragmatic trials [55].

Conclusion

When patients' preferences and life circumstances drive healthcare decisions, their quality of involvement in their care improves [9,81–83]. PCD are essential information that, when known and incorporated, may promote the development of a person-centered plan for care [14]. Therefore, interventions that test these relationships must be explored to understand how to optimize individuals' involvement in self-care. Researchers must also investigate if outcomes differ in Black and White patients who experience different social, political, and economic injustices that affect health [84].

Trial status

The impact of patient contextual data on patient-provider communication and patient activation study began recruitment on 1 April 2019. The trial ended recruitment on 18 October 2019.

Funding

This project was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant T32HP10030, Academic Fellowship in Primary Care Research. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government. It was also supported by the Advancing a Healthier Wisconsin endowment at the Medical College of Wisconsin.

Conflicts of Interest

The author has no conflicts of interest to declare.

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Figure 1

Randomized Control Trial Study Design

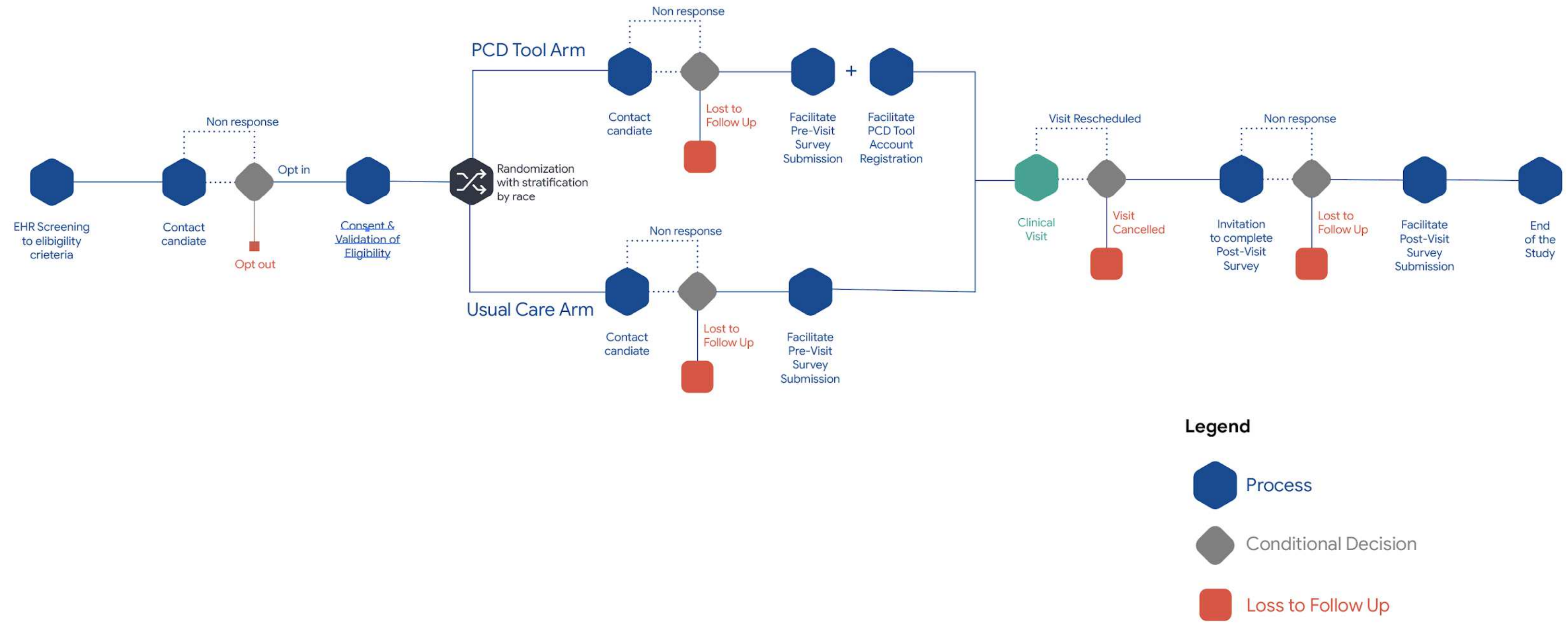
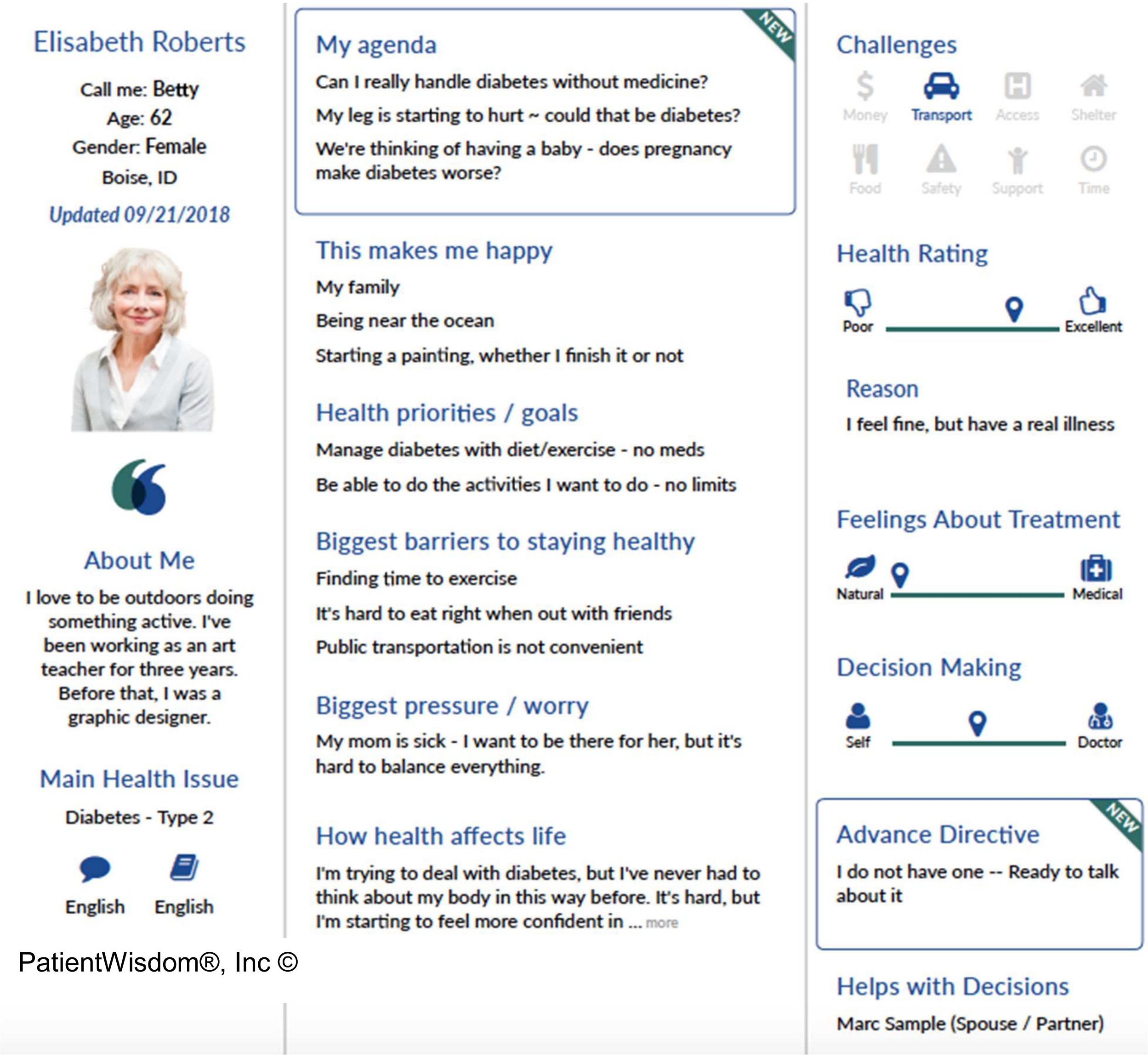


Figure 2

Patient Contextual Data Tool One-Screen View in the Electronic Health Record



Elisabeth Roberts

Call me: Betty
Age: 62
Gender: Female
Boise, ID

Updated 09/21/2018

About Me

I love to be outdoors doing something active. I've been working as an art teacher for three years. Before that, I was a graphic designer.

Main Health Issue

Diabetes - Type 2

English English

My agenda

Can I really handle diabetes without medicine?

My leg is starting to hurt ~ could that be diabetes?

We're thinking of having a baby - does pregnancy make diabetes worse?

This makes me happy

My family

Being near the ocean

Starting a painting, whether I finish it or not

Health priorities / goals

Manage diabetes with diet/exercise - no meds

Be able to do the activities I want to do - no limits

Biggest barriers to staying healthy

Finding time to exercise

It's hard to eat right when out with friends

Public transportation is not convenient

Biggest pressure / worry

My mom is sick - I want to be there for her, but it's hard to balance everything.

How health affects life

I'm trying to deal with diabetes, but I've never had to think about my body in this way before. It's hard, but I'm starting to feel more confident in ... more

Challenges

Health Rating

Reason

I feel fine, but have a real illness

Feelings About Treatment

Decision Making

Advance Directive

I do not have one -- Ready to talk about it

Helps with Decisions

Marc Sample (Spouse / Partner)

PatientWisdom®, Inc ©

Figure 3

Randomized Control Trial Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)

	Study Period					
	Enrollment	Allocation				
Timepoint	**-t_1**	**0**	**t_1**	**t_2**	**t_3**	**t_4**
Enrollment:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
Intervention:						
PCD tool			Baseline Survey	PCD Tool Via Facilitated Enrollment	Primary care visit	Post-visit Survey. Within1-month
Usual care			Baseline Survey		Primary care visit	Post-visit Survey. Within1-month
Assessments:						
Gender			X			
Age			X			
Race			X			
Ethnicity			X			
Sex			X			
Marital status			X			
Employment status			X			
Health insurance			X			
Household income			X			
Difficulty paying bills			X			
Education			X			
Health literacy			X			
Technology use/ acceptance			X			
PROMIS Global Health			X			
Length of time with provider			X			
CG-CAHPS			X			
Patient Activation Measure			X			X
Communication Assessment Tool						X
PCD tool perceived ease of use, usefulness,						X

satisfaction, and acceptance						
PCD tool use by clinician type						X

Note. The SPIRIT figure displays an overview of study time points, intervention, and assessments of the randomized control trial. PCD patient-generated contextual data, CG-CAHPS clinician group consumer assessment of healthcare providers and systems

Appendix A

SPIRIT Checklist: Recommended items to address in a clinical trial protocol and related documents

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2,6
	2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	20
	5b	Name and contact information for the trial sponsors	20
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	20
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3,4
	6b	Explanation for choice of comparators	3,4
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8,9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12,13

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8

Methods: Assignment of interventions (for controlled trials)

Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial	n/a

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	8,9
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15,16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15,16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15,16

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	14
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	14

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7,8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
	31b	Authorship eligibility guidelines and any intended use of professional writers	17
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix B
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Note. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Appendix B

Randomized Control Trial Informed Consent

If you choose to participate in this research study, we will invite you to (1) complete a short survey (Communication Study Survey) before your next scheduled visit at a Froedtert & Medical College of Wisconsin primary care clinic, (2) have a brief exchange with a research team member by phone OR email (your preference) to learn about a new initiative at Froedtert & the Medical College of Wisconsin, and then (3) complete a 2nd survey after your next scheduled primary care visit. Participation would also entail allowing the research team to look at your electronic health record for research purposes related to this communication study. We hope to include 300 people, so your answers and participation are really important to us. You are free to skip any questions or discontinue your participation in this research study at any time. Although you will not get personal benefit from taking part in this research study, your responses may help us understand how to improve communication between patients and clinicians.

Note. The following instructions are given to the participants as an informational letter as part of the informed consent process.

The impact of pre-visit contextual data collection on patient-physician communication and patient activation: Results from a randomized control trial

Abstrsct

Importance The majority of health indicators (socio-economic factors, physical environment) are outside of the healthcare system, and current electronic health records (EHR) do not capture those indicators. There is a need to test consumer informatics tools that integrate patient's life circumstances, goals, and preferences for care into their EHR.

Objective To determine whether the health care team having access to patient contextual data (PCD) using a consumer informatics tool improves patient-provider communication and patient activation.

Design, Setting, and Participants A two-armed, non-blind, randomized control trial was conducted between May 2019, and October 2019 at two urban, academically affiliated primary care clinics. 301 patients were enrolled, randomized with stratification by race to study arms. Nearly equal percentages of control and intervention group participants (60.5% vs 62.4%) and two-thirds of White vs one-third of Black participants completed both assessments (67% vs 33.0%).

Intervention The underlying mechanism of the PCD Tool was to assist patients to identify and report their values, needs, goals, supports, risks, and care preferences for point-of-care discussions.

Main outcomes and Measures The primary outcome was the post-visit Communication Assessment Tool (CAT) score. The secondary outcome was the change in Patient Activation Measure (PAM) score. Outcomes were evaluated using intention-to-treat and treatment-on-the-treated principles.

Results Using intention-to-treat analysis, we found that there was no change in overall CAT score, but there were large effects of specific items: "being treated with respect" (49.80; 95%CI=0.80, 98.79; p=0.05), "showed interest in my ideas" (55.73; 95%CI=4.83, 106.62; p=0.03), "showed care and concern" (59.65; 95%CI=9.69, 109.61; p=0.02) and "spent about the right amount of time with me" (49.82; 95%CI=0.77, 98.86; p=0.05) for participants in the intervention arm. There were no significant differences in pre-/post-visit change in PAM scores by arm (p=.079).

Conclusions and Relevance The goal of this trial was to understand if the use of a PCD tool designed to enhance the capture and sharing of PCD influenced patient-provider communication and patient activation. We found the inclusion of PCD enhanced some aspects of patient-provider communication but had little effect on patient activation.

Trial Registration Clincaltrials.gov identifier: NCT03766841

The majority of health indicators occur outside of the healthcare system,[1–3] and current electronic health records (EHR) do not capture those indicators. Clinicians are limited in the time and tools they have to efficiently and systematically gather social, behavioral, and environmental factors that often complicate adherence to treatment regimens and recommended lifestyle changes. Without these data, clinicians have an incomplete understanding of their patients, which may negatively affect patient-provider communication[4] and patient activation[5] leading to suboptimal health outcomes. Consequently, sustainable and scalable approaches to improving patient-centered care are needed to improve health across populations.[1,6,7]

An emerging trend in medicine is "flipping care," where the patient's agenda, priorities, and goals drive the treatment plan.[8–11] Lacking are consumer informatics tools that collect, store, and display patients' needs, values, goals, and preferences, in their EHR, to use these patient-centered data points across care teams and to lead health care decisions.[1,6,7,12,13] While EHRs have the potential to improve patient-centered care, they have not been designed to capture patient contextual data (PCD) and make them available for point-of-care use. PCD encompass an individual's health values, goals, and preferences and personal and social determinants of health.[14,15] Consumer informatics tools may overcome barriers within current EHRs by directly inviting patients to share such patient-centered data with care team members. Patients could interact with and update the consumer-centric digital tool, which then links the PCD data to the EHR.[7,16] Effectively, these tools would help with humanizing the electronic record and providing a basis for effective health communication and empowering patient users to engage in their health and health care.[1,17,18]

In qualitative studies[14,15] evaluating a consumer informatics tool that collects PCD for point-of-care use, research findings indicate that pre-visit collection of PCD improved patient-clinician communication and promoted a shift towards shared responsibility for information gathering and co-development of the care plan.[14] Patient-users[14] of the consumer informatics tool reported reflecting on their health goals spurred them to action. When incorporating PCD gathered from a consumer informatics tool into the visit, clinicians reported the completion of the tool supported a level of patient activation unparalleled in current methods.[15] These promising qualitative findings support the investigation of a PCD tool that elicits and shares patients' social risks and care preferences with the healthcare team as a mechanism to improve individualized care.

Research results indicate that disparities exist in who is adopting consumer informatics tools.[19–22]. The investigation must also include the monitoring of differences in outcomes across populations to ensure a disparity was not inadvertently added into care.[23] The purpose of this study was to evaluate the impact of PCD, gathered using a consumer health tool for point-of-care use, on patient-physician communication and patient activation in Black and White patients.

Methods

Design

This study was a two-armed, non-blind, randomized clinical trial with participant stratification by race. The trial was designed to assess patient-physician communication and changes in patient activation [protocol paper]. We used a pragmatic trial design to assess the impact of the PCD tool on communication and patient activation. All patients with upcoming primary care appointments at the academic medical center were invited to enroll in the PCD tool, though baseline response rates were low (9.5%). The trial designed used an intervention of facilitated enrollment to boost the patient adoption rates for participants in the PCD Tool arm. After agreeing to participate, patients were stratified by race, and then randomized to usual care (single pre-visit email to enroll in the PCD tool sent by the academic medical center) or to intervention arm, where a research coordinator prospectively assisted with enrolling and using the PCD tool. If randomized to the intervention arm, a research coordinator explained the PCD tool and assisted with account activation. All participants completed a pre-visit questionnaire. Following the visit, all participants completed a post-visit questionnaire. The institutional review board at the Medical College of Wisconsin approved the study. [Figure 1 RCT Study Design]

Participants

Participants were recruited from the largest two primary care clinics at the Medical College of Wisconsin (MCW) between May 2019 and October 2019. Eligible participants were adults 18 years or older who self-identified as non-Hispanic White or non-Hispanic Black and spoke and understood English, and who were willing and able to give informed consent. At the time of the study enrollment period, eligible participants must have had an upcoming visit (1 to 4 weeks away), at one of the participating academic medical center's primary care clinics, with an established provider (at least 1 previous appointment with the same provider within the last 12 months). Patients were screened based on data with the EHR including either the ethnic and racial categories of Non-Hispanic White or Non-Hispanic Black, an upcoming appointment with an established primary care provider during the study enrollment period, and not having a

PCD Tool profile. After the EHR screening, 1,629 patients were found to be eligible and sent an email (if an email was on file) or a postcard invitation (if no email was on file). Of those invited, 1,274 (78%) did not respond to the invitation to enroll and 54 (4%) declined to participate. In total, 301 (18%) participants were enrolled randomized with stratification by race to study arms. [Figure 2 CONSORT Participant Flow[24]].

Patient Contextual Data (PCD) Tool

The PCD Tool, integrated into the EHR, collects, summarizes, and presents information about patients' identified health values, needs, goals, supports, risks, and preferences with their health care team. The tool was designed to facilitate self-reflection and identification of health goals, values, priorities, and problems.[25,26] The reflection opens the individual to evaluate health information based on its importance for personal health thus, supporting preparation for health behavior change.[27,28]

Facilitated enrollment. Patients who were randomized to facilitated enrollment into the PCD Tool arm were contacted by telephone and/or email to review the PCD tool and help with enrollment. Participants could come for an in-person meeting, review enrollment over the telephone, or proceed on their own with the ability to contact the research coordinator with questions. For participants who chose to proceed on their own, follow-up/reminder calls were completed to encourage completion.

Data Collection

All patients were provided the option to complete their electronic surveys independently or with assistance from the research staff over the phone or in-person. Survey data were collected using REDCap (Research Electronic Data Capture) System,[29] hosted at the academic medical center, by trained research staff after confirming eligibility. Individuals who provided consent were enrolled and randomized. Participants were stratified equally by race to one of the two study arms (usual care and PCD Tool). Participants then completed their baseline survey either using an emailed link, over the telephone or in-person with one of the research staff. A study team member read the survey items verbatim and completed the survey in REDCap for participants who filled out the survey over the phone or in person.[29] The baseline survey included the constructs of patient activation (PAM 13-item),[30] technology use & acceptance (HINTS 5 Cycle 1),[31] patient experience from previous primary care visit (CG-CAHPS V 3.0 - communication composite),[32] self-reported physical, mental, and social health (PROMIS Global Health v 1.2),[33] health literacy ("How confident are you filling out medical forms by yourself?")[34] and sociodemographic items (age, sex, gender, education, marital status, employment status, income, health insurance coverage, health insurance type, and difficulty paying bills). After completion of the baseline survey, participants attended their scheduled primary care visit. Participants completed a follow-up survey within one month after their primary care appointment. The follow-up survey included the constructs of patient activation (PAM 13-item)[30] and patient-physician communication (Communication Assessment Tool).[35] Additional details describing the methods of this trial have been published previously [Protocol paper].

Outcome Variables of Interest

Patient-Provider Communication

Patients' perceptions of interpersonal and communication skills of their primary care physician were measured by using the Communication Assessment Tool (CAT).[35] The CAT was written at the fourth-grade reading level and employs a five-point response scale, with 5 = excellent to 1= poor. It was validated in a sample with varied sociodemographic characteristics and yielded a high internal consistency (Cronbach's alpha = 0.96). Responses to individual items were top-coded and then summed across all items to calculate the proportion of responses that had the highest score. Participants answered completed the CAT follow-up only.

Patient Activation

We assessed patient activation using the 13-item Patient Activation Measure (PAM), which has been validated through several studies including diverse and nationally representative samples.[30,36,37] Patient activation is the level of knowledge, skills, ability, and confidence an individual has to self-manage their day-to-day health.[36] The instrument provides two metrics for examination, a score and a level. The activation score is based on a 0–100-point scale, and people can be categorized into four levels of activation, with level 1 the least activated and level 4 the most activated.[30] We examined the change in PAM scores from baseline to follow-up.

Analysis

For descriptive analyses, we used chi-square tests for categorical variables and independent-sample *t*-tests for continuous variables were used to examine baseline differences between study arms. For the primary outcome, we used linear regression to determine the effect of the intervention on post visit communication (CAT score) adjusting for previsit communication scores (CG-CAHPS) to account for any differences between physicians. We tested if there were consistent effects between races by interacting race with the treatment receipt. For our primary analysis, we used an intention-to-treat (ITT) approach.

For the secondary outcome, patient activation, we used a t-test to determine the effect of the intervention on change in patient activation (PAM scores)[30] among complete cases using an ITT approach.[3839] We tested if there were consistent effects by race through interacting race with treatment receipt.

We used multiple imputation using chained equations[40] (alternatively known as Markov Chain Monte Carlo based imputation) stratified by the treatment arm. We required that individuals provided baseline information on basic demographic, specifically sex and race which resulted in a total sample size of 249 losing 52. The imputation algorithm included all baseline individual PAM[30] and CG-CAHPs[32] elements, patients responses on if the provider inquired about their contextual data (healthcare cost, needs, preferences, lifestyle, challenges, ability to pay bills, and values), health literacy, PROMIS scores, and demographics (age, sex, race, and employment status).

Using data from the EHR, we were able to identify if a participant completed the PCD tool. To adjust for the considerable non-compliance in the PCD Tool arm (people assigned to the PCD Tool arm who did not actually use the tool and people not assigned to the PCD Tool arm who used the tool), we used an instrumental variable approach to estimate the treatment-on-the-treated (TOT)[41,42] which is also referred to as the local average treatment effect (LATE). We used a two-stage least squares regression (2SLS)[43,44] where the first stage of the model estimated if a person used the PCD Tool in the follow-up period. The second stage identified the causal impact of using the PCD Tool on the outcomes. To do this, we predicted the use of the PCD Tool from stage 1 in the stage 2 model and used the results of this coefficient to interpret how the PCD Tool impacted the outcomes using ivregress in Stata. For all results, a p-value of < 0.05 was considered statistically significant.

Results

Study Participants

There were no demographic differences between the arms; the p-value ranged from 0.183 for marital status to 0.912 for sex. Sixty-four percent of the participants were female, 67% were White, over half were over the age of 65, with 42% retired, about 40% earning a college degree or more, and almost half with a household income of $50,000 or more, although 20% of participants reported a household income of less than $10,000 annually. In the sample, 43% of the participants reported at least some concern with meeting monthly bills. [Table 1]

To understand baseline perceptions of participants' experiences being asked to share their contextual data with their provider, we asked participants to reflect back on their most recent visit. A strong majority endorsed that their plan of care took into account their personal preferences (81%), needs (86%), lifestyle (85%), and personal challenges (84%) as much as they wanted. While 25% of participants reported that their providers did not take cost into account as part of the plan of care. There were no significant differences in the responses between the arms; the p-values ranged from 0.143 to 0.886.

Communication Assessment Tool

Table 2 reports the overall and individual item impact of the PCD Tool on patient-provider communication using the CAT[35]. The overall difference in the CAT score between the arms was not significant (9.32; 95%CI=-1.05, 19.69; p=0.08). However, we found that some aspects of communication were impacted, specifically “being treated with respect” (13.76; 95%CI=2.27, 25.25; p=0.02) and that the “provider showed care and concern” (16.39; 95%CI=4.27, 28.52; p<0.01).

The treatment-on-the-treated (TOT) results do not find a difference in the overall CAT score, but it did find large effects of specific items such as “being treated with respect” (49.80; 95%CI=0.80, 98.79; p=0.05), “showed interest in my ideas” (55.73; 95%CI=4.83, 106.62; p=0.03), “showed care and concern” (59.65; 95%CI=9.69, 109.61; p=0.02) and “spent about the right amount of time with me” (49.82; 95%CI=0.77, 98.86; p=0.05).

Patient Activation Measure

The baseline overall mean PAM[30] score was 61.5 (SD=1.2), which aligns with a level 3 of activation. When comparing the sample’s baseline mean activation level by race, there were no differences between Black and White participants (p= .282). Both groups’ responses align with a level 3 of activation. When comparing Black (M=55.3, SD=1.7) versus White (M=64.6, SD=1.5) participants baseline mean activation score, Black participants had a significantly lower baseline score (-9.32; 95%CI=-14.08, -4.57; p=0.0002). Black participants experienced an average of 5.6-point (SD=-3.5-point) increase in average change in the PAM score in both arms, which was similar to White participants average change in the PAM score in both arms (M=3-point; SD=2.15-point). These findings are presented in Table 2.

When allowing for an interaction between race and treatment arm, all interaction terms were not statistically significant for either outcome (CAT[35] p=0.795; PAM[35] score p=0.310). These findings are presented in Table 3. Results from multiple imputation

(Appendix A) using chained equations[40] and stratified by the treatment arm aligned with the results presented in Table 2. Results were also reweighted to statistically ensure equal White and Black Participants in the analysis, with no statistically significant difference in PAM[35] score (p=0.577) and no statistically significant difference in CAT[35] (p=0.092) between treatment arms (Appendix B).

Discussion

This trial assessed one scalable approach and evaluated whether a consumer informatics tool that standardizes the collection of PCD, to be shared with the healthcare team, may affect patient-physician communication and patient activation. The findings indicate that an intervention that invited participants to share their preferences, goals, and challenges with their health resulted in a statistically significant improvement in some elements of patient-physician communication (treated me with respect (p=0.019); showed interest in my ideas (p=0.019); paid attention to me (p=0.050); and showed care and concern (p=0.008), but did not influence patient activation significantly (p=0.156). Discussed below are three main findings from this trial that may assist healthcare organizations enhancement of point-of-care (POC) discussions.

First, few interventions systematically collate and integrate patient-identified goals, risks, and supports with their EHR for general POC discussions.[45–47] Commonly, discussion or decision aids are designed to target one health condition (AIDS,[48] chest pain,[49] diabetes mellitus,[50] heart failure[51]). Decision aids may be useful for addressing specific treatment options but compartmentalize a patient’s care into isolated diagnoses. The intervention tested in this trial allows patients to reflect on and identify their priorities, which fosters the healthcare team's pre-visit planning and increases efficiency during the visit.[14,15]

Second, the TOT results of the CAT.[35] suggest that the PCD Tool users reported large improvements in elements of communication. These findings support the importance of interventions aimed at increasing the patient's ability to communicate effectively with their provider.[52] Nathan and colleagues[53] observed that using a patient-prioritization discussion aid as part of the primary care visit enhanced decision-quality outcomes and patient-provider communication across diverse populations. In this study, patients who completed the PCD Tool felt their provider treated them respectfully, valued their ideas, and showed care and concern. Despite the often published time constraints imposed on primary care clinicians,[54] PCD Tool users felt their visit was the appropriate length of time to meet their needs. These results in conjunction with focus group results from PCD Tool users previously published[14] affirm the PCD Tool added efficiency to the clinic visit without compromising the patient-provider relationship. Our findings suggest the benefit of a PCD Tool, especially related to facilitating effective communication skills and effective relationship dynamics, the core components of patient-centered care.[55–57]

Third, an essential element of this research was to avoid adding a disparity into care by incorporating a consumer informatics tool. The results indicate that when allowing for an interaction between race and treatment arm, all interaction terms were not significant, suggesting that there is no evidence of the treatment effect varying by race. Further, when we reweighted the analyses to ensure that there were equal White and Black participants statically, the findings do not indicate racial differences. Similar increases in the change in the PAM score in both races suggests that including a PCD Tool as part of the primary care visit did not introduce a disparity or barrier for some individuals.

Clinicians who empowered patients to self-manage their health through multiple supportive counseling and educational mechanisms had patients with the largest increases in activation compared to clinicians who did not engage in patient empowerment.[58] Notably, clinicians, who reported using more holistic strategies to support behavior change, had patients who experienced a 5.5-point median increase in PAM score compared to lower-performing clinicians.[58] Commonly, a difference of 5 points on the PAM separated patients who engaged in healthy from less healthy behaviors,[37,59] which translates to better chronic condition outcomes and lower healthcare costs.[60–65] The implication for healthcare organizations is the need to educate clinicians about strategies to coach patients on behavior change,[58] such as developing a caring relationship and co-creating small and achievable goals. Healthcare systems must optimize the use of technology in the workflow by designing technology that fits the social and clinical environment[66] and de-implementing[67] ineffective functions or technologies that impede clinician's ability to provide holistic care. Finally, clinicians must be trained on optimal usage of technology during pre-visit planning and within visit discussions to yield proposed efficiency gains.[15]

Limitations and Strengths

The study has several limitations. First, we are unable to comment on how effective the intervention would be in other settings or populations. Milwaukee, Wisconsin is a unique geographical area noted for its segregation and disparities among populations.[68,69] The results require replication in other geographic or healthcare settings and with a nationally representative sample. Second, to test the intervention in real-world clinical setting[39], primary care clinicians were not informed that their patients were part of the study and asked to include the PCD Tool content as part of the visit. Assuming there was not participation from all clinicians, we may have seen greater differences in elements of patient-physician communication and some differences in patient activation. Third, we did not reach parity in recruiting and retaining equal numbers of Black (33%) and White (67%) participants, which may have influenced the results. Additional strategies for recruiting and retaining Black study participants such as community information sessions, snowball sampling, and a research team member assisting with in-person survey completion before and after the primary care visit[70] may have improved the number of Black participants and yielded different results.

Despite these limitations, there are meaningful implications for the redesign of HIT to meet the needs of patients and clinicians. Assisting patients to complete the PCD Tool using their preferred method (email, telephone, face-to-face) increased the adoption of the tool (9.5% academic medical center rate to 36% trial rates). We found that most people preferred to receive the PCD Tool sign-on information via email, but they needed to make calls to remind them to complete the tool. Salient to research using digital health tools, clinician encouragement[71] is the strongest predictor of portal access and use.

Conclusion

With the decade-long promotion of the adoption and meaningful use of health information technology, the infusion of the EHR into clinic workflow has changed the way providers practice. Providers often cite the burden of the EHR documentation system that impedes patient-provider communication.[72] Now, we are embarking on a time when innovators must design technology that it assists rather than impedes care. Consumer informatics tools that prioritize patients’ perspectives on health/illness and management are one such innovation. Healthcare systems must evaluate organizational- and clinician-level contextual factors that support and hinder clinicians’ ability to participate in or their desire to implement an innovation in their workflow.[73] Then use that data to support and reward the innovation implementation.[73]

The goal of this clinical trial was to understand if the use of a PCD Tool designed to enhance capture and sharing of patient-contextual data was able to improve patient-physician communication and patient activation for both Black and White patients. We found that there was significant improvement in elements of patient-physician communication with those who used the PCD tool. Although we found no difference between arms on patient activation, there was also no evidence that the inclusion of a consumer informatics tool as part of pre-visit planning and use during the visit – added a disparity in care. Future research should investigate the influence of socioeconomic position (i.e., income and financial security), education, and health literacy, on baseline racial differences of patient activation.

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Table 1

Baseline Patient Characteristics

	Percentages			P-Value
	Total (N = 185)	Usual Care (n =92)	PCD Tool (n = 93)	
Sex				0.912
Male	35.87	36.26	35.48	
Female	64.13	63.74	64.52	
Age (in years)				0.445
50 of less	20.00	18.48	21.51	
51 – 65	28.65	23.91	33.33	
66 – 75	32.43	34.78	30.11	
75 +	15.68	19.57	11.83	
Race				0.603
Black / African American	32.97	34.78	31.18	
White	67.03	65.22	68.82	
Education				0.882
Some High School	4.32	4.35	4.3	
High School or GED	18.38	20.65	16.13	
Some College or 2 Year Degree	28.11	25	31.18	
4-Year College Grad	18.38	18.48	18.28	
More than 4 Years of College	30.81	31.52	30.11	
Marital Status				0.183
Single, Never married	34.05	34.78	33.33	
Married or domestic partnership	43.24	36.96	49.46	
Widowed	9.73	10.87	8.6	
Divorced	11.35	14.13	8.6	
Separated	1.62	3.26	0	
Employment Status				0.527
Employed for wages	31.89	28.26	35.48	
Self employed	3.78	5.43	2.15	
Out of work and looking	1.62	1.09	2.15	
Out of work but not currently looking	2.7	3.26	2.15	
A homemaker	1.62	0	3.23	
A student	1.08	1.09	1.08	
Retired	42.16	45.65	38.71	
Unable to work	15.14	15.22	15.05	
Household Income				0.714
Less than $10,000	20.11	24.18	15.91	
$10,000 to less than	10.61	12.09	9.09	

$20,000 to less than	8.94	5.49	12.5	
$30,000 to less than	4.47	4.4	4.55	
$40,000 to less than	7.82	6.59	9.09	
$50,000 to less than	12.29	13.19	11.36	
$75,000 to less than	11.73	12.09	11.36	
$100,000 to less than	11.73	9.89	13.64	
$150,000 or more	12.29	12.09	12.5	
Insurance Details				
Commercial	26.89	27.12	26.67	0.956
Medicaid, Med Assistance or any kind of governmental assistance	33.09	32.88	33.33	0.954
Any Difficulty to meet monthly payments				0.670
Extremely difficult	6.01	5.43	6.59	
Very difficult	9.29	11.96	6.59	
Somewhat difficult	13.66	11.96	15.38	
Slightly difficult	13.66	11.96	15.38	
Not difficult at all	57.38	58.7	56.04	
Confident Filling Out Forms by Yourself				0.543
Extremely	65.76	67.03	64.52	
Quite a bit	23.37	21.98	24.73	
Somewhat	7.07	5.49	8.6	
A little bit	2.72	3.3	2.15	
Not at all	1.09	2.2	0	
Baseline CG-CAHPS	0.689	0.759	0.687	0.883
PROMIS v1.2				
Physical Health, mean (SD)	44.66 (10.18)	43.90 (9.79)	45.40 (10.56)	0.320
Mental Health, mean (SD)	47.02 (9.63)	46.83 (9.90)	47.22 (9.35)	0.781
Baseline PAM score, mean (SD)	61.5 (1.2)	59.3 (1.8)	63.7 (1.5)	0.058
Baseline PAM Level				0.228
Level 1	12.97	16.3	9.68	
Level 2	23.24	27.17	19.35	
Level 3	41.08	36.96	45.16	
Level 4	22.7	19.57	25.81	

Note. Overall CG-CAHPS was scored as the proportion of items with "excellent " as the response. Individual items are scored as “excellent” = 1 and all other responses = 0; Clinician and Group - Consumer Assessment of Healthcare Providers and Systems, CG-CAHPS (Dyer et al., 2012); Patient Reported Outcomes Measure Information System, PROMIS (Hays et al., 2017); Patient Activation Measure, PAM (Hibbard et al., 2005)

Table 2

Impact of Patient Contextual Data Tool on Patient-Provider Communication and Patient Activation

					Intent to Treat			Treatment on the Treated		
	UC		PCD Tool		Difference	95% CI	P-Value	Difference	95% CI	P-Value
N	92		93							
Change in PAM score	5.65	(1.312, 9.978)	1.862	(-1.164, 4.889)	-1.225	(-5.777, 3.326)	0.596	-4.413	(-19.903, 11.077)	0.577
Overall CAT	0.687	(0.603, 0.771)	0.772	(0.704, 0.840)	0.093	(-0.011 - 0.197)	0.078	0.398	(-0.065 - 0.861)	0.092
Individual Items										
Greeted me and made me feel comfortable	0.707	(0.612, 0.801)	0.806	(0.725, 0.888)	0.107	(-0.015 - 0.229)	0.086	0.421	(-0.105 - 0.947)	0.117
Treated me with respect	0.728	(0.636, 0.821)	0.860	(0.788, 0.932)	0.138	(0.023 - 0.252)	0.019	0.529	(0.014 - 1.043)	0.044
Showed interested in my ideas	0.630	(0.53, 0.731)	0.774	(0.688, 0.861)	0.153	(0.026 - 0.281)	0.019	0.591	(0.057 - 1.126)	0.030
Understood my main health concerns	0.685	(0.588, 0.782)	0.742	(0.651, 0.833)	0.066	(-0.062 - 0.194)	0.311	0.311	(-0.209 - 0.832)	0.241
Paid attention to me	0.728	(0.636, 0.821)	0.839	(0.763, 0.915)	0.117	(0.000 - 0.234)	0.050	0.462	(-0.056 - 0.981)	0.081
Let me talk without interruptions	0.728	(0.636, 0.821)	0.774	(0.688, 0.861)	0.055	(-0.067 - 0.177)	0.373	0.320	(-0.194 - 0.835)	0.223
Gave me as much information as I wanted	0.630	(0.530, 0.731)	0.720	(0.628, 0.813)	0.101	(-0.029 - 0.231)	0.127	0.382	(-0.136 - 0.899)	0.149
Talked in terms that I could understand	0.761	(0.672, 0.850)	0.806	(0.725, 0.888)	0.051	(-0.067 - 0.170)	0.393	0.245	(-0.275 - 0.764)	0.356
Checked to be sure I could understand everything	0.674	(0.576, 0.772)	0.710	(0.616, 0.804)	0.043	(-0.089 - 0.176)	0.520	0.231	(-0.300 - 0.762)	0.395
Encouraged me to ask questions	0.641	(0.541, 0.741)	0.699	(0.604, 0.794)	0.068	(-0.065 - 0.200)	0.316	0.304	(-0.218 - 0.827)	0.253
Involved me in decisions as much as I wanted to be	0.641	(0.541, 0.741)	0.720	(0.628, 0.813)	0.088	(-0.045 - 0.220)	0.194	0.406	(-0.116 - 0.928)	0.127
Discussed next steps, including follow-up plans	0.707	(0.612, 0.801)	0.731	(0.639, 0.823)	0.034	(-0.093 - 0.161)	0.598	0.209	(-0.308 - 0.726)	0.428
Showed care and concern	0.663	(0.565, 0.761)	0.817	(0.737, 0.897)	0.164	(0.043 - 0.285)	0.008	0.633	(0.104 - 1.162)	0.019
Spent the right amount of time with me	0.696	(0.600, 0.791)	0.806	(0.725, 0.888)	0.120	(-0.002 - 0.241)	0.054	0.529	(0.001 - 1.047)	0.046

Note. Intent to treat and treatment on the treated CAT related results are estimated using a linear regression model adjusting for baseline top coded CG-CAHPS.

Overall CAT was scored as the proportion of items with "excellent " as the response. Individual CAT items are scored as "excellent"=1 and all other responses = 0.

Usual Care, UC; Patient Contextual Data, PCD; Communication Assessment Tool, CAT (Makoul et al., 2007); Clinician and Group Consumer Assessment of Healthcare Providers and Systems, CG-CAHPS (Dyer et al., 2012); Patient Activation Measure, PAM (Hibbard et al., 2005)

Table 3

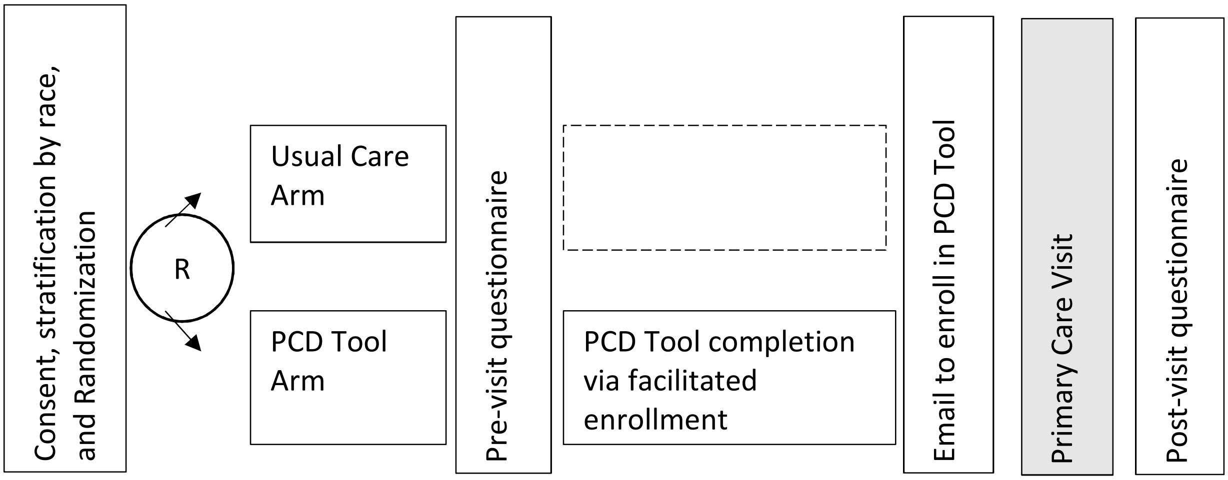
Interaction Between Race and Treatment Effect in the Intention-to-Treat Analysis

	P-value
N	185
Change in PAM score	0.310
Overall CAT	0.795
Individual Items	
Greeted me and made me feel comfortable	0.110
Treated me with respect	0.725
Showed interested in my ideas	0.638
Understood my main health concerns	0.228
Paid attention to me	0.261
Let me talk without interruptions	0.904
Gave me as much information as I wanted	0.055
Talked in terms that I could understand	0.233
Checked to be sure I could understand everything	0.526
Encouraged me to ask questions	0.281
Involved me in decisions as much as I wanted to be	0.640
Discussed next steps, including follow-up plans	0.407
Showed care and concern	0.063
Spent the right amount of time with me	0.506

Note. Intention-to-treat PAM[35] related results are estimated using a linear regression model adjusting for race, treatment, an interaction between race and treatment and baseline PAM[35] score. We report the p-value on the interaction term.
Intention-to-treat CAT[34] related results are estimated using a linear regression model adjusting for race, treatment, an interaction between race and treatment and baseline top coded CG-CAHPS[32]. We report the p-value on the interaction term.
Overall CAT was scored as the proportion of items with "excellent " as the response.
Individual items are scored as "excellent"=1 and all other responses = 0.
Patient Activation Measure, PAM[35]; Communication Assessment Tool, CAT[34]; Clinician and Group Consumer Assessment of Healthcare Provides and Systems, CG-CAHPS[32]

Figure 1

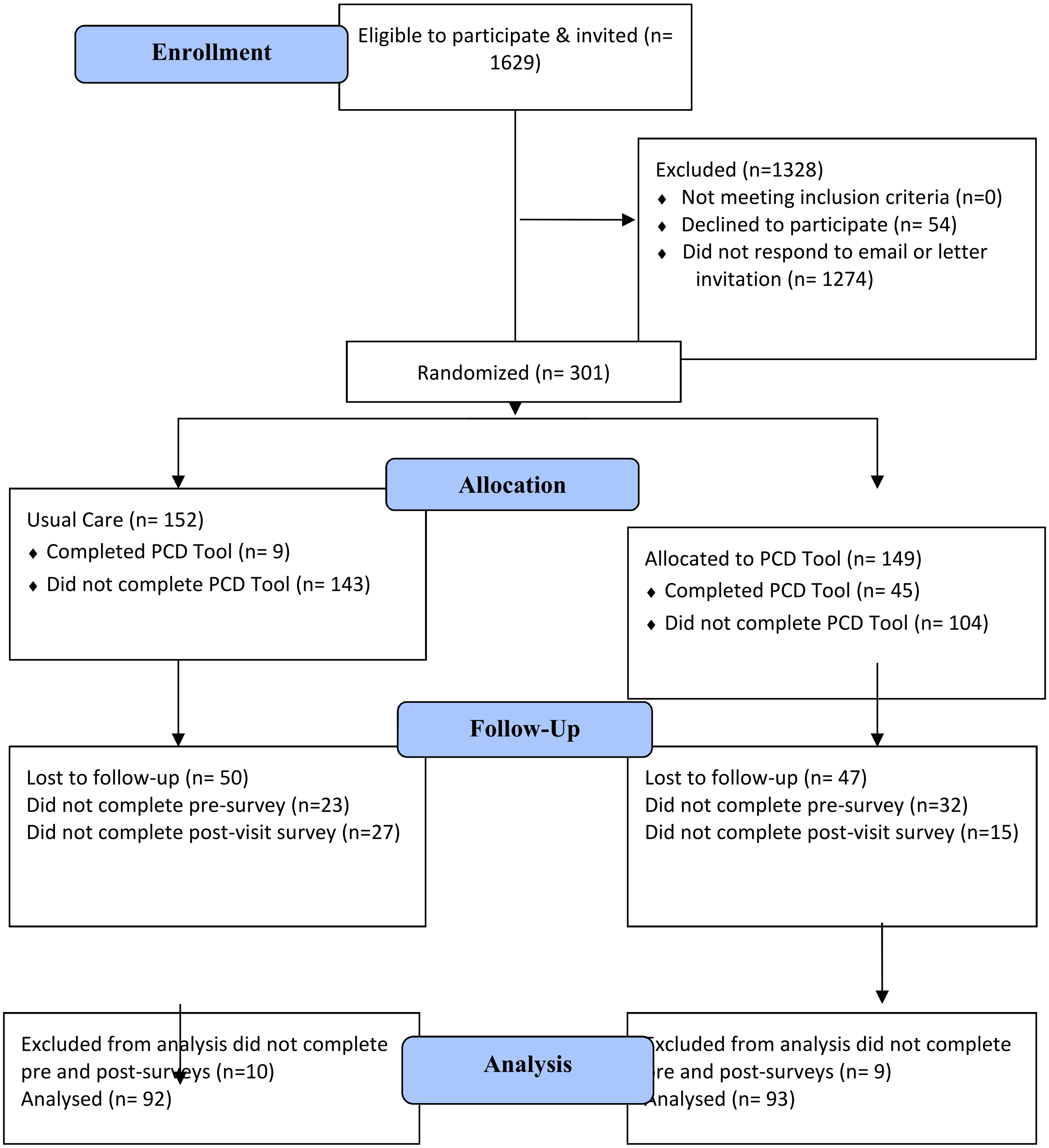
Randomized control trial study design



Note. R, Randomization; PCD, Patient Contextual Data

Figure 2

CONSORT Flowchart of Participants



Appendix A

Impact of PCD Tool on Patient-Provider Communication and Patient Activation Based on Multiple Imputation Results

					Intention-to-Treat		
	UC		PCD Tool		Difference	95% CI	P-value
N	127		113				
Change in PAM score	4.404	(-0.412, 9.219)	2.923	(-0.868, 6.714)	-0.542	(-6.699, 5.616)	0.860
Overall CAT	0.698	(0.588, 0.807)	0.759	(0.673, 0.845)	0.052	(-0.078, 0.182)	0.43
Individual Items							
Greeted me and made me feel comfortable	0.693	(0.602, 0.785)	0.792	(0.709, 0.874)	0.097	(-0.02, 0.215)	0.104
Treated me with respect	0.713	(0.623, 0.803)	0.853	(0.78, 0.925)	0.138	(0.026, 0.25)	0.016
Showed interested in my ideas	0.633	(0.535, 0.73)	0.777	(0.691, 0.862)	0.143	(0.021, 0.265)	0.022
Understood my main health concerns	0.67	(0.576, 0.764)	0.729	(0.639, 0.82)	0.058	(-0.065, 0.181)	0.353
Paid attention to me	0.71	(0.619, 0.801)	0.823	(0.745, 0.901)	0.113	(-0.001, 0.226)	0.052
Let me talk without interruptions	0.707	(0.616, 0.798)	0.768	(0.682, 0.855)	0.06	(-0.058, 0.178)	0.319
Gave me as much information as I wanted	0.63	(0.534, 0.726)	0.716	(0.623, 0.808)	0.083	(-0.041, 0.207)	0.187
Talked in terms that I could understand	0.752	(0.667, 0.838)	0.8	(0.718, 0.882)	0.046	(-0.068, 0.16)	0.431
Checked to be sure I could understand everything	0.663	(0.57, 0.757)	0.705	(0.612, 0.799)	0.041	(-0.086, 0.167)	0.527
Encouraged me to ask questions	0.64	(0.544, 0.736)	0.695	(0.6, 0.789)	0.051	(-0.076, 0.178)	0.428
Involved me in decisions as much as I wanted to be	0.63	(0.534, 0.726)	0.716	(0.623, 0.808)	0.084	(-0.042, 0.211)	0.189
Discussed next steps, including follow-up plans	0.697	(0.605, 0.789)	0.719	(0.627, 0.81)	0.025	(-0.097, 0.147)	0.689
Showed care and concern	0.66	(0.566, 0.754)	0.802	(0.721, 0.883)	0.14	(0.024, 0.255)	0.018
Spent the right amount of time with me	0.693	(0.602, 0.785)	0.792	(0.709, 0.874)	0.097	(-0.02, 0.215)	0.104

Note. Intention-to-treat PAM related results are estimated using a linear regression model adjusting for baseline PAM score.

Intent to treat CAT related results are estimated using a linear regression model adjusting for baseline top coded CG-CAHPS. Overall CAT was scored as the proportion of items with "excellent " as the response. Individual items are scored as “excellent” = 1 and all other responses = 0
Usual Care, UC; Patient Contextual Data, PCD; Communication Assessment Tool, CAT[34]; Clinician and Group Consumer Assessment of Healthcare
Providers and Systems, CG-CAHPS[32]; Patient Activation Measure, PAM[35]

Appendix B

Impact of PCD Tool on Patient-Provider Communication and Patient Activation Reweighted to Ensure Equal White and Black Participants

					Intention-to-Treat			Treatment-on-the-Treated		
	UC		PCD Tool		Difference	95% CI	P-value	Difference	95% CI	P-Value
Change in PAM score	5.639	(1.206, 10.071)	1.862	(-0.957, 6.703)	-0.437	(-5.586, 4.710)	0.867	-1.897	(-24.150 - 20.360)	0.577
Overall CAT	0.697	(0.608, 0.786)	0.763	(0.680, 0.847)	0.063	(-0.052 - 0.177)	0.281	0.277	(-0.233 - 0.787)	0.092
Individual Items										
Greeted me and made me feel comfortable	0.687	(0.585 - 0.790)	0.819	(0.733 - 0.905)	0.131	(0.002 - 0.261)	0.047	0.544	(-0.0480 - 1.136)	0.071
Treated me with respect	0.711	(0.611 - 0.812)	0.863	(0.782 - 0.945)	0.151	(0.025 - 0.277)	0.020	0.612	(0.066 - 1.159)	0.028
Showed interested in my ideas	0.634	(0.527 - 0.742)	0.788	(0.694 - 0.883)	0.154	(0.019 - 0.290)	0.026	0.664	(0.0182 - 1.310)	0.044
Understood my main health concerns	0.664	(0.559 - 0.768)	0.743	(0.644 - 0.842)	0.0789	(-0.060 - 0.218)	0.263	0.327	(-0.245 - 0.900)	0.261
Paid attention to me	0.711	(0.611 - 0.812)	0.842	(0.759 - 0.925)	0.131	(0.006 - 0.257)	0.040	0.544	(-0.012 - 1.101)	0.055
Let me talk without interruptions	0.719	(0.619 - 0.818)	0.773	(0.675 - 0.870)	0.051	(-0.084 - 0.185)	0.456	0.216	(-0.356 - 0.788)	0.457
Gave me as much information as I wanted	0.610	(0.501 - 0.718)	0.740	(0.641 - 0.839)	0.129	(-0.008 - 0.266)	0.067	0.526	(-0.081 - 1.132)	0.089
Talked in terms that I could understand	0.736	(0.637 - 0.836)	0.816	(0.726 - 0.905)	0.078	(-0.051 - 0.208)	0.235	0.321	(-0.219 - 0.861)	0.243
Checked to be sure I could understand everything	0.670	(0.567 - 0.773)	0.732	(0.633 - 0.831)	0.061	(-0.077 - 0.199)	0.386	0.266	(-0.344 - 0.876)	0.391
Encouraged me to ask questions	0.633	(0.526 - 0.740)	0.707	(0.604 - 0.811)	0.073	(-0.071 - 0.219)	0.318	0.313	(-0.304 - 0.931)	0.318
Involved me in decisions as much as I wanted to be	0.623	(0.516 - 0.730)	0.714	(0.609 - 0.818)	0.090	(-0.056 - 0.235)	0.226	0.367	(-0.228 - 0.962)	0.225
Discussed next steps, including follow-up plans	0.687	(0.585 - 0.790)	0.725	(0.624 - 0.827)	0.037	(-0.103 - 0.177)	0.599	0.155	(-0.420 - 0.730)	0.596
Showed care and concern	0.652	(0.546 - 0.758)	0.836	(0.755 - 0.917)	0.185	(0.060 - 0.309)	0.004	0.768	(0.162 - 1.375)	0.013

Spent the right amount of time with me	0.679	(0.576 - 0.783)	0.814	(0.724 - 0.904)	0.135	(0.006 - 0.265)	0.041	0.547	(-0.004 - 1.099)	0.052

Note. Intention-to-treat and treatment-on-the-treated CAT related results are estimated using a linear regression model adjusting for baseline top coded CG-CAHPS.

Overall CAT was scored as the proportion of items with "excellent " as the response. Individual items are scored as "excellent"=1 and all other responses = 0.

Usual Care, UC; Patient Contextual Data, PCD; Communication Assessment Tool, CAT[34]; Clinician and Group Consumer Assessment of Healthcare Providers and Systems, CG-CAHPS[32]; Patient Activation Measure, PAM[35]

Racial Disparities in Patient Activation: The Role of Economic Diversity

Abstract

The Patient Activation Measure (PAM) assesses a person’s level of knowledge, skills, and confidence to self-manage their day-to-day health. A mediation analysis was conducted to explore the effect of income, difficulty paying bills, health literacy, and education as mediators of significantly lower baseline PAM scores in Black than White participants ($p<0.001$) who were a subset of 184 adults who participated in a consumer informatics tool interventional study. In the analysis, the continuous outcome was PAM scores, and the mediators were income, education, ability to pay bills and health literacy, and race (Black or White) was the “exposure.” The results indicate that income ($p=0.025$) and difficulty paying monthly bills ($p=0.04$), when treated as continuous variables, mediated the relationship between race and baseline PAM score, whereas health literacy ($p>0.05$) and education ($p>0.05$) did not mediate the relationship. Researchers must further investigate the role of economic diversity on patient activation and health outcomes.

Empowering individuals to be engaged and active in their health is critically essential for improved health outcomes and healthcare cost containment (Cutler et al., 2018; Greene & Hibbard, 2012; Hibbard et al., 2017; Lindsay et al., 2018). Hibbard and colleagues (Hibbard et al., 2005, 2004) developed the Patient Activation Measure (PAM) to measure a person's level of knowledge, skills, and confidence to self-manage their day-to-day health. Research results indicate that an individual's level of activation in their daily health behaviors predicts their health outcomes (Greene et al., 2013; Hibbard & Greene, 2013). Researchers propose the mechanism works as follows, highly engaged patients excel at goal setting and achievement, adherence to agreed-upon plans of care, engaging in preventative screenings, and navigating their health even in times of stress (Greene & Hibbard, 2012; Greene et al., 2015; Hibbard, 2008; Hibbard & Greene, 2013). Conversely, individuals with low levels of activation may demonstrate poor goal setting, low adherence to medical regimens, and being overwhelmed by personal health circumstances (Hibbard et al., 2013, 2017, 2004). Recent research has established that there is an enduring association between an individual's low level of activation and future progression in chronic disease burden and avoidable healthcare costs (Greene et al., 2015; Hibbard et al., 2017, 2015; Lindsay et al., 2018; Sacks et al., 2017).

Unfortunately, certain groups such as ethnic/racial minorities (National Center for Health Statistics (US), 2016), individuals with low income (United States Census Bureau, 2019), and individuals with low educational attainment (Eneanya et al., 2016) have a higher proportion of disease burden compared to Whites, top income earners, and college graduates (Coylewright et al., 2014; O'Malley et al., 2018; Singh-Manoux et al., 2003). Disparities in patient activation also exist among populations. In several studies, Black individuals had a lower level of patient activation than White individuals (Alexander et al., 2012; Eneanya et al., 2016; Hibbard et al., 2008; Lubetkin et al., 2010). Lower engagement in self-managing behaviors in Black populations may contribute to differences in health outcomes between people (Lindsay et al., 2018). Promisingly, when the difference in PAM level decreases between populations, models predict parity in health outcomes regardless of race (Hibbard et al., 2008).

The study occurred in an academic medical center that serves the Milwaukee Metropolitan area. There is considerable variance in poverty rates among Wisconsin's counties and regions. In Milwaukee county, poverty rates ranged from 7.0% in one southern sub-county area to 34.4% in the central city of Milwaukee, suggesting significant segregation of the poor and the affluent within the county (Smeeding & Thornton, 2019). Milwaukee also has disproportionately high rates of chronic disease and obesity compared to the nation (*About Chronic Diseases | CDC*, 2019; CDC, 2019). Respondents of Milwaukee's 2018 health assessment (JKV Research, 2019) reported their top four health problems in the last three years to be high blood pressure, mental illness, high cholesterol, and diabetes. According to the Wisconsin Department of Health and Human Services (WI-DHS, 2018), just over 10% of the population of Wisconsin has diabetes. Still, the prevalence in Milwaukee County is estimated up to 36%. Eighty-seven percent of adults with diabetes are overweight, and 53% have a body mass index greater than or equal to 30.0 kg/m^2. The modifiable risk factors for diabetes also place Wisconsin residents at risk for cardiovascular disease. In Milwaukee County, 73% of residents eat less than five servings of fruits and vegetables a day. Compound this with 42% lacking physical activity, 23% with high cholesterol, 29% with hypertension, and 16% current smokers, the risk for cardiovascular disease in the future is high (WI-DHS, 2018).

The setting of this study provides a unique opportunity to explore the influence of socioeconomic position (i.e., income and financial security), education, health literacy, and race on patient activation (Figure 1). When researchers fail to assess the possibility of a mediator effect in the data, "a more exact explanation for an outcome may be missed" (Bennett, 2000). The purpose of this analysis was to show empirically the extent to which SES, education, and health literacy contributed to the observed patient activation disparities in a cohort of primary care patients.

Purpose

The purpose of this sub-analysis was to explore potential mediators of Black respondants significantly lower baseline PAM score compared to White respondents' baseline PAM score ($p<0.001$). The specific aim was to evaluate if self-reported income, financial security, health literacy, or education meditated the relationship of race on baseline PAM score using a natural direct and natural indirect effects approach.

Methods

Design

The sub-analysis was from a two-armed, non-blind, randomized clinical trial with repeated measures collected between May and October 2019. The clinical trial reported on: (1) patient-provider communication and patient activation of patient-users and patient-non-users of an electronic health record (EHR)-integrated consumer informatics tool; and (2) the impact of using the consumer informatics tool on patient-provider communication and patient activation for Black and White patients.

The consumer informatics tool used in the trial collected patient-generated contextual data (PCD). Patients entered information into the tool about their health preferences, goals, assets, and challenges (e.g., social support, transportation concerns, caregiver stress). The PCD was linked to the patient's EHR to be used by the healthcare team for pre-visit planning and within visit discussions. The tool was designed to improve patient-provider communication. In previously published qualitative research with patient-users, patients reported being more activated in the self-management of their chronic health conditions after using the tool (Cusatis et al., 2019; Holt et al., 2019). Therefore, the secondary outcome of the trial analyzed the change in PAM (Hibbard et al., 2005) score of the patient-users and non-users of the tool. An unexpected finding of the trial's baseline survey was the statistically significant difference in baseline PAM score of Black and White participants ($P<0.001$). Hence, this sub-analysis explores if income, financial security, health literacy, or education meditate the relationship of race on baseline PAM score. The institutional review board at the Medical College of Wisconsin (MCW) approved the study.

Inclusion Criteria and Recruitment

To be eligible for the clinical trial, participants were adults 18 years or older who self-identified as non-Hispanic White or non-Hispanic Black and spoke and understood English, and who were willing and able to give informed consent. At the time of the study enrollment period, eligible participants must have had an upcoming visit (1 to 4 weeks away), at one of the academic medical center's two largest primary care clinics, with an established provider (at least one previous appointment with the same provider within the last 12 months).

Patients who met the inclusion criteria were contacted by email or mail, if an email was not on file. If eligible patients did not respond, research staff called the patients, up to three times, to answer questions about the study and consent for the study, if applicable. Recruitment continued until the pre-determined sample size of 300 was reached.

Sample

The sample for this sub-analysis consisted of 184 patients who completed socio-demographic data (e.g., race, income, financial security, health literacy, education) and the 13-item PAM at baseline and the 13-item PAM after their primary care appointment. The study sample consisted of 66 men and 117 women who at baseline had a mean age of 61.49 (14.87) years and 77% had some college or higher educational level. The patients were 67% White and 33% Black. There were statistically significant differences in all demographic variables between White and Black participants except sex (p= 0.774). Table 1 presents the participants baseline characteristics and PAM score by race [Insert Table 1 here].

Data Collection and Instruments

Data were collected by trained research staff using a structured research protocol after confirming eligibility. Individuals who provided consent were enrolled, randomized one of the two study arms (usual care or consumer informatics tool), and completed a baseline questionnaire. Participants then completed their baseline questionnaire using an emailed link, over the telephone or in-person with one of the research staff. A study team member read the survey items verbatim and completed the survey in REDCap for participants who filled out the survey over the phone or in-person (Harris et al., 2009). The baseline questionnaire included the patient activation (PAM 13-item) (Hibbard et al., 2005), technology use & acceptance (HINTS 5 Cycle 1) (Greenberg-Worisek et al., 2019), patient experience (CG-CAHPS V 3.0 - communication composite) (Dyer et al., 2012), self-reported physical, mental, and social health (PROMIS Global Health v 1.2) (Hays et al., 2009), health literacy ("How confident are you filling out medical forms by yourself?") (Chew et al., 2008) and sociodemographic items (age, sex, gender, education, marital status, employment status, income, health insurance coverage, health insurance type, and difficulty paying monthly bills (Hanmer & Cherepanov, 2016).

After completion of the baseline questionnaire, participants attended their scheduled primary care visit. Participants completed a follow-up questionnaire within one month after their primary care appointment. Additional details describing the methods of this trial have been published previously [Chapter 3 Protocol paper].

Analysis

Analysis Plan

Predictor Variables of Interest

Socioeconomic status. Socioeconomic status is a composite measure often comprised of a person's income, occupation, wealth, and/or educational attainment (Krieger et al., 1997). Due to the large percentage of retired study participants, we operationalized socioeconomic status as the participant's income and financial security.

Education. Education was measured by participants' responses to the following question, What is the highest grade or level of school that you have completed? Participants chose one of six responses: 8th Grade or less; Some high school but did not graduate; High school graduate or GED; Some college or 2-year degree; 4-year college graduate; More than a 4-year college degree.

Health literacy. Health literacy was measured by participants' responses to the following question, How confident are you filling out medical forms by yourself? Participants chose one of five responses: Extremely; Quite a bit; Somewhat; A little bit; Not at all. (Chew et al., 2008)

Income. Income was measured by participants' responses to the following question, "In the last year, that is 2018, what was your total household income from all sources, before taxes?", Household income for the previous year was grouped into nine categories: < $10,000; $10,000 to < $20,000; $20,000 to < $30,000; $30,000 to < $40,000; $40,000 to < $50,000; $50,000 to < $75,000; $75,000 to < $100,000; $100,000 to < $150,000; and $150,000 or more.

Financial security. Financial security was assessed using a validated 1-item measure that provides a broader assessment of wealth than the traditional income question. Financial security was measured by participants' responses to the following question. "In the past 30 days, how difficult was it for you to meet the monthly payments on your bills?" 1- Extremely difficult to 5-Not difficult at all. (Hanmer & Cherepanov, 2016)

Race. Race was measured by participants' responses to the following question, What is your race? Mark one or more. Black or African American; White.

Outcome Variable of Interest

Patient Activation. I assessed patient activation using the 13-item Patient Activation Measure (PAM), which has been validated through several studies, including diverse and nationally representative samples (Fowles et al., 2009; Hibbard et al., 2005, 2004). Patient activation is the level of knowledge, skills, ability, and confidence an individual has to self-manage their day-to-day health (Hibbard et al., 2004). The instrument provides two metrics for examination, a score, and a level. The activation score is based on a 0–100-point scale, and people can be categorized into four levels of activation, with level 1 the least activated and level 4 the most activated (Hibbard et al., 2005).

Mediation Analysis

A mediation analysis was conducted that examined if there were direct effects of race on PAM scores or if race operated through socioeconomic factors, education, and/or health literacy. The analysis explored the impact of several socioeconomic related mediators on PAM and the impact of the race on PAM that does not operate through mediators using a counterfactual approach, often referred to as the natural direct and the natural indirect effects (Robins & Greenland, 1992). The outcome for this study was a continuous outcome, PAM scores (range 0-100); and the mediators including income, education, ability to pay bills and health literacy. Race (Black or White) was the “exposure.”

To conduct the analysis, first, the impact of race on income, education, and ability to pay bills and health literacy was explored (Figure 1 Mediation Conceptual Model). Each mediator was explored in isolation. The analysis took the following form, where A is the race, M are mediators, C are additional covariates:

$$Equation\ 1: E(M|A = a, C = c) = \beta_0 + \beta_1 a + \beta_2' c$$

Next, to understand the relationship between the outcome and other factors, the association with the mediator and the outcome were examined. The primary outcome has the following form, where Y is PAM, A is the Race, M are mediators, C is additional covariates (age, age squared sex, and being married):

$$Equation\ 2: E(Y|A = a, M = m, C = c) = \theta_0 + \theta_1 a + \theta_2 m + \theta_3 am + \theta_4' c$$

It is worth noting that this expression of the relationship between race, a mediator, and PAM allows for an interaction between the race and mediators, where typical approaches to mediation, such as the Baron Kenny approach (Baron & Kenny, 1986), does not allow this relationship. The exposure mediator interactions are needed to fully account for the mediated effect and can increase the power to detect mediation even if the interaction term is not significant (VanderWeele, 2015). From this approach, the natural direct effect (NDE) was assessed, which examines the effect of the race on PAM by disabling the relationship from race to mediators. The NDE was assessed by examining how much PAM would change if by estimating the counterfactual of a patient having similar characteristics but being White instead of Black if the mediator levels are at the level they would take if a patient was White. Building off of equation 1 and 2, the generalized equation of the NDE takes the following form (VanderWeele, 2015):

$$Equation\ 3: NDE = (\theta_1 + \theta_3\beta_0 + \theta_3\beta_1 a^* + \theta_3\beta_2' c)(a - a^*)$$

The analysis was extended to test the effect of the race that is due to socioeconomic factors and health literacy, which was assessed by determining the natural indirect effect (NIE). To measure the NIE, how PAM changes if everyone was White but then set socioeconomic status and health literacy were set to the levels we would expect if they were Black were examined. Put another way, NIE measures the effect of the race on PAM that is observable by changing socioeconomic status or health literacy. Again building off of equation 1 and 2, the generalized formula of the NIE takes the following form (VanderWeele, 2015):

$$Equation\ 4: NIE = (\theta_2\beta_1 + \theta_3\beta_1 a)(a - a^*)$$

To estimate these effects, the Stata package paramed was used where models were fitted for PAM and socioeconomic status/health literacy (equations 1 and 2) and then estimated the potential outcomes to estimate the NDE and NIE and generate our standard error and confidence intervals using the delta approach. For the base case analyses, mediators were treated as continuous variables and estimating a linear model. However, the mediators were not continuous variables but instead categorical variables. Therefore, to examine the robustness of our results to modeling assumptions mediators were also treated as binary variables and estimate logistic regression models.

Results

The sub-analysis sample included 184 participants who completed the baseline and post-visit survey. The majority of the sample was White (67%), female (64%), and over the age of 51 (80%). Forty-three percent of the sample were married, 78% were retired or employed for wages, and three-fourths of participants completed at least some college.

Table 1 presents the unadjusted baseline characteristics, where there were significant racial differences across multiple variables. Black participants were more likely to report having a form of governmental insurance ($p<0.001$), difficulty filling out forms independently ($p=0.018$), lower global physical health ($p<0.001$), and lower global mental health (0.002). More White than Black participants reported they had higher educational attainment ($p<0.001$), income ($p<0.001$), and the ability to meet monthly bill payments ($p<0.001$). Black participants had a lower baseline PAM score compared to White participants ($p<0.001$).

In the adjusted linear regression results shown in Table 2, NIE results indicate that a participant having a college education or more did not statistically significantly moderate the direct effect of Black race on baseline PAM score (-1.3, CI -4.58, 1.97; $p=0.436$). Similarly, responding “Extremely” to the Health Literacy item *How confident are you filling out medical forms by yourself?* did not statistically significantly moderate the direct effect of Black race on baseline PAM score (-0.74, CI -2.15, 0.67; $p=0.301$).

In separate adjusted linear regression models with income or the ability to make monthly payments as continuous variables, a significant relationship was demonstrated. NIE results indicate income (-4.48, CI -8.4, -0.56; $p=0.025$) or the ability to make monthly payments (-2.54, CI -4.96, -0.11; $p=0.04$) statistically significantly moderated the direct effect of Black race on baseline PAM score. In summary, using this approach (VanderWeele, 2015), income and difficulty paying monthly bills, when treated as continuous variables, mediated the relationship between race and baseline PAM score, whereas a college degree or greater and the highest level of health literacy response did not.

Discussion

The findings from this study provide evidence that income and ability to pay monthly bills (i.e., financial security) significantly mediated baseline racial disparities in patient activation. In this study sample, income and financial security more thoroughly explained the baseline difference in participants' patient activation scores than race, health literacy, or education, alone. The findings indicate that financial capability and strength mediate racial disparities in patient activation, which affirm that the assigned group membership of the social construct of race is only one type of group membership that may influence explanatory models of health outcomes (Weller et al., 2012). Indeed, social and economic factors are the largest group of factors that contribute to overall health at 40% compared to health behaviors (30%), clinical care (20%), and physical environment (10%) (University of Wisconsin Population Health Institute, 2014).

There is a growing consensus that wealth is a primary driver of health outcomes (Krieger et al., 1997). In the literature, the connection between income and health is referred to as the health-wealth loop (Khullar & Chokshi, 2018). There is growing scholarly and public recognition that many nonclinical factors—availability of resources, living wage and healthy foods, social supports, social norms, discrimination, social disorders, exposure to crime, quality schools (and housing, homes, neighborhoods)—affect physical and behavioral health outcomes (Bourgois et al., 2017; County Health Rankings & Roadmaps, 2018; Green, 2018; University of Wisconsin Population Health Institute, 2014; Vila et al., 2007). In a national survey, adults with low incomes were five times as likely as those with incomes above 400 percent of the federal poverty level to report being in poor or fair health (Robert Wood Johnson Foundation, 2008). According to the American Community Survey Data (US Census Bureau, 2019), income inequality in the United States continues to grow with a negative impact on health and life expectancy by those in the lowest income groups. Pertinent to this research, income and wealth mediated the relationship between baseline PAM scores and race, providing additional evidence of the impact of economic status and outcomes not previously reported in the literature (Couture et al., 2018; Eneanya et al., 2016; Lubetkin et al., 2010; Salgado et al., 2017).

Researchers report relatively high rates of missing income data and concerns about the accuracy of income data in studies (Kim & Tamborini, 2014; Moore et al., 2000). Therefore, the baseline survey used in this study included a question on household income and a single difficulty with paying bills question, which directly assessed financial security. According to Hamner and Cherepanov (2016), individual's responses to the difficulty with paying bills item has lower rates of missing values, therefore yielding more accurate income data, than the income items used traditionally. Thus, the results of this study may provide a more accurate view of the relationships between income and financial security and patient activation than if the survey used self-reported household income alone.

Healthcare and Clinical Practice Implications

When providers do not address patients' social and economic challenges, patients tend to be less engaged in the self-management of their care, leading to poor health outcomes (Hibbard et al., 2008). Therefore, health care clinicians must understand the individual and structural challenges facing their patients, often defined as the social determinants of health, to facilitate the co-creation of attainable and actionable health goals (Bourgois, Holmes, Sue, & Quesda, 2016; Ivey, Shortell, Rodriguez, & Wang, 2018). Current EHRs structures do not collect financial capability data and make that information available to clinicians at point-of-care (Cantor & Thorpe, 2018; Kruse et al., 2018). The implications of not knowing how cost affects a patient's healthcare actions are stark. According to the NPR-Truven Health Analytics Health Poll, 94% of patients who earned under $25,000 annually reported that they did not fill their prescriptions due to cost (Hobson, 2017). In a recent Kaiser Family Foundation poll (Kirzinger et al., 2019), 8% of Americans report their health condition worsened as a result of not taking their medications as prescribed (Kirzinger et al., 2019). Collectively, the annual adjusted disease-specific economic costs for medication and treatment non-adherence of 19 of the most common chronic conditions, such as diabetes, cardiovascular disease, and hyperlipidemia, ranged from $949 to $44,190 (in 2015 US$) (Cutler et al., 2018).

Clinicians must continue to develop and test consumer informatics tools' as well as understand the underlying mechanisms that affect differences in patient outcomes when using those tools. There is evidence that developing individualized plans of care, based on patient activation scores, improves patient outcomes (Greene et al., 2015; Hibbard et al., 2017, 2015; Lindsay et al., 2018; Sacks et al., 2017); however, further research is needed to evaluate if the mediating effects of income and financial security on patient activation found in this research persist in other samples. Clinicians must have access to their patient's financial capability data to co-develop plans of care that are sensitive to this social determinant of health. Without this information, clinicians may incorrectly assume differences in health outcomes are derived from specific racial categories, when, in truth, economic disparity is the underlying mechanism of differences in outcomes.

Conclusion

Clinicians and researchers must understand the myriad of factors within and outside the healthcare system that affects a person's wellbeing and ability to self-manage their health. The political, societal, and environmental factors that impact health extend beyond healthcare access and accessibility to the availability of community resources (Canedo et al., 2018; Lurie et al., 2008). It may be time to develop further understanding of economic diversity on patient activation and health outcomes.

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Table 1

Baseline Participant Characteristics and Patient Activation Score by Race

	Total	White	Black	P-value
N	184	123	61	< 0.001
PAM Score				< 0.001
Mean (SD)	61.5 (1.2)	64.6 (1.5)	55.3 (1.7)	
Sex				0.744
Male	66	45	21	
Female	117	77	40	
Age				< 0.001
Mean (SD) in years	61.49 (14.87)	64.38 (14.22)	55.51 (14.37)	
Marital Status				< 0.001
Single, never married	63	25	38	
Married or domestic partner	79	67	12	
Widowed	18	13	5	
Divorced	21	16	5	
Separated	3	2	1	
Education				<0.001
Some high school, but did not graduate	8	2	6	
High school graduate or GED	34	13	21	
Some college or 2-year degree	51	31	20	
4-year college graduate	34	25	9	
More than 4-year college graduate	57	52	5	
Employment Status				<0.001
Employed for wages	59	44	15	
Self employed	7	6	1	
Out of work and looking	3	1	2	
Out of work but not currently looking	5	1	4	
A homemaker	3	2	1	
A student	2	0	2	
Retired	77	60	17	
Unable to work	28	9	19	
Last Year HH Income				< 0.001
Less than $10,000	36	14	22	
$10,000 to less than	19	9	10	
$20,000 to less than	16	7	9	
$30,000 to less than	8	5	3	
$40,000 to less than	14	9	5	
$50,000 to less than	22	17	5	
$75,000 to less than	20	18	2	
$100,000 to less than	21	17	4	

$150,000 or more	22	22	0	
Insurance Details*				< 0.001
Commercial	99	78	21	
Medicare	94	68	26	
Medicaid, Med Assistance or any kind of gov assistance	46	20	26	
Any Difficulty to meet monthly payments				< 0.001
Extremely difficult	11	4	7	
Very difficult	17	3	14	
Somewhat difficult	25	15	10	
Slightly difficult	25	14	11	
Not difficult at all	104	86	18	
Confident Filling Out Forms by Yourself				0.018
Extremely	120	88	32	
Quite a bit	43	26	17	
Somewhat	13	5	8	
A little bit	5	3	2	
Not at all	2	0	2	
PROMIS Global				
Physical Health t-score	44.56	46.53	40.59	<0.001
Mental Health t-score	46.99	48.50	43.96	0.002

Note. Patient Activation Measure, PAM; *Participants could choose multiple insurance categories

Table 2

Mediation adjusted linear regression results using Natural Direct Effect

Model	Linear	Logistic		Linear	Linear	
	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value
Covariate	Income			Income		
	Income over 20k			Income (treated continuous)		
	Outcome	Mediator	Decomposition	Outcome	Mediator	Decomposition
Black	-6.35 (-14.65, 1.96); p=0.133	-1.28 (-2.05, -0.51); p<0.001		-7.91 (-17.01, 1.19); p=0.088	-2.05 (-2.82, -1.28); p<0.001	
Mediator	5.47 (-1.83, 12.76); p=0.141			1.28 (0.17, 2.39); p=0.025		
Black * Mediator	2.11 (-8.41, 12.64); p=0.692			0.9 (-1.03, 2.84); p=0.358		
Sex	-0.14 (-4.85, 4.57); p =0.955	-0.18 (-0.96, 0.59); p=0.646		-0.52 (-5.11, 4.07); p=0.822	-0.12 (-0.83, 0.59); p =0.737	
Age	0.03 (-0.83, 0.9); p =0.944	0.03 (-0.1, 0.16); p =0.664		-0.06 (-0.9, 0.78); p=0.889	0.1 (-0.03, 0.23); p =0.139	
Age^2	0 (-0.01, 0.01); p=0.952	0 (0, 0); p =0.573		0 (-0.01, 0.01); p=0.797	0 (0, 0); p=0.06	
Married	6.2 (1.13, 11.27); p=0.017	1.72 (0.85, 2.58); p<0.001		3.74 (-1.6, 9.08); p=0.169	2.66 (1.94, 3.38); p<0.001	
Cumulative Direct Effect			-4.23 (-10.98, 2.52); p=0.219			-7.01 (-14.58, 0.57); p=0.07
Natural Direct Effect			-4.62 (-10.39, 1.16); p=0.117			-2.91 (-9.25, 3.42); p=0.368
Natural Indirect Effect			-1.99 (-4.38, 0.41); p=0.105			-4.48 (-8.4, -0.56); p=0.025
Marginal Total Effect			-6.6 (-20.31, 7.1); p=0.345			-7.39 (-12.59, -2.19); p=0.005

Table 2 (continued)

Mediation adjusted linear regression results using Natural Direct Effect

Model	Linear	Logistic		Linear	Linear	
	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value
Covariate	Education College or More			Education Education (treated as continuous)		
	Outcome	Mediator	Decomposition	Outcome	Mediator	Decomposition
Black	-2.19 (-8.69, 4.3); p=0.506	-1.54 (-2.31, -0.77); p<0.001		3.68 (-15.01, 22.37); p=0.698	-0.99 (-1.37, -0.61); p<0.001	
Mediator	9.17 (3.58, 14.76); p=0.001			3.44 (0.99, 5.89); p=0.006		
Black * Mediator	-5.55 (-16.1, 4.99); p=0.3			-1.83 (-6.12, 2.47); p=0.402		
Sex	0.37 (-4.29, 5.02); p=0.876	-0.39 (-1.06, 0.29); p=0.264		0.02 (-4.66, 4.69); p=0.994	-0.11 (-0.46, 0.24); p=0.537	
Age	0.02 (-0.83, 0.87); p=0.96	0.02 (-0.11, 0.15); p=0.758		0.03 (-0.83, 0.89); p=0.942	0.01 (-0.06, 0.07); p=0.838	
Age^2	0 (-0.01, 0.01); p=0.911	0 (0, 0); p=0.612		0 (-0.01, 0.01); p=0.949	0 (0, 0); p=0.765	
Married	6.67 (1.9, 11.44); p=0.006	0.74 (0.07, 1.41); p=0.031		6.84 (2.04, 11.63); p=0.005	0.36 (0.01, 0.71); p=0.045	
Cumulative Direct Effect			-7.74 (-16.37, 0.89); p=0.079			1.86 (-12.68, 16.39); p=0.802
Natural Direct Effect			-5.58 (-11.57, 0.4); p=0.068			-5.18 (-11.41, 1.04); p=0.103
Natural Indirect Effect			-1.3 (-4.58, 1.97); p=0.436			-1.6 (-5.14, 1.95); p=0.377
Marginal Total Effect			-6.89 (-16.25, 2.48); p=0.15			-6.78 (-11.94, -1.62); p=0.01

Table 2 (continued)

Mediation adjusted linear regression results using Natural Direct Effect

Model	Linear	Logistic		Linear	Linear	
	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value
Covariate	Difficulty Paying Bills			Difficulty Paying Bills		
	No Problem			Difficulty Paying Bills (treated as continuous)		
	Outcome	Mediator	Decomposition	Outcome	Mediator	Decomposition
Black	-3.13 (-9.94, 3.67); p=0.364	-1.3 (-2.04, -0.56); p=0.001		5.62 (-10.11, 21.35); p=0.481	-0.74 (-1.1, -0.37); P<0.001	
Mediator	10.29 (4.35, 16.23); p=0.001			5.87 (3.08, 8.65); p=0		
Black * Mediator	-1.93 (-12.16, 8.3); p=0.71			-2.42 (-6.26, 1.43); p=0.216		
Sex	-0.93 (-5.56, 3.7); p=0.692	0.35 (-0.37, 1.06); p=0.339		-0.73 (-5.32, 3.86); p=0.754	0.26 (-0.07, 0.6); p=0.121	
Age	0.14 (-0.71, 0.98); p=0.747	-0.05 (-0.19, 0.09); p=0.507		-0.02 (-0.85, 0.82); p=0.969	0.03 (-0.03, 0.09); p=0.342	
Age^2	0 (-0.01, 0.01); p=0.736	0 (0, 0); p=0.299		0 (-0.01, 0.01); p=0.976	0 (0, 0); p=0.674	
Married	5.91 (1.14, 10.69); p=0.015	1.02 (0.31, 1.72); p=0.005		4.1 (-0.7, 8.89); p=0.094	0.65 (0.31, 0.99); P<0.001	
Cumulative Direct Effect			-5.07 (-12.88, 2.75); p=0.204			3.2 (-8.88, 15.29); p=0.603
Natural Direct Effect			-4.45 (-10.25, 1.36); p=0.133			-4.86 (-10.35, 0.62); p=0.082
Natural Indirect Effect			-2.61 (-5.62, 0.4); p=0.089			-2.54 (-4.96, -0.11); p=0.04
Marginal Total Effect			-7.06 (-25.93, 11.81); p=0.463			-7.4 (-12.6, -2.2); p=0.005

Table 2 (continued)

Mediation adjusted linear regression results using Natural Direct Effect

Model	Linear	Logistic		Linear	Linear	
		ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value	ß (95% CI); p-value
Covariate	Health Literacy			Health Literacy Health Literacy (treated as continuous)		
	Best Health Literacy					
	Outcome	Mediator	Decomposition	Outcome	Mediator	Decomposition
Black	-4.96 (-13, 3.08); p=0.225	-0.59 (-1.31, 0.14); p=0.112		-8.04 (-18.02, 1.94); p=0.114	0.27 (0, 0.55); p=0.053	
Mediator	7.1 (0.97, 13.24); p=0.024			-4.67 (-8.68, -0.67); p=0.022		
Black * Mediator	-1.52 (-11.48, 8.44); p=0.764			1.66 (-3.9, 7.22); p=0.557		
Sex	-1.14 (-5.87, 3.58); p=0.633	0.6 (-0.09, 1.28); p=0.087		-0.85 (-5.59, 3.89); p=0.724	-0.21 (-0.46, 0.04); p=0.099	
Age	0.15 (-0.72, 1.01); p=0.74	-0.06 (-0.19, 0.07); p=0.388		0.02 (-0.84, 0.88); p=0.962	0 (-0.05, 0.04); p=0.89	
Age^2	0 (-0.01, 0.01); p=0.838	0 (0, 0); p=0.418		0 (-0.01, 0.01); p=0.962	0 (0, 0); p=0.972	
Married	6.39 (1.5, 11.28); p=0.011	1.12 (0.39, 1.84); p=0.002		6.9 (2.04, 11.76); p=0.006	-0.33 (-0.58, -0.07); p=0.012	
Cumulative Direct Effect			-6.48 (-12.87, -0.09); p=0.047			-6.38 (-12.32, -0.44); p=0.035
Natural Direct Effect			-6.04 (-11.27, -0.81); p=0.024			-5.69 (-10.9, -0.48); p=0.032
Natural Indirect Effect			-0.74 (-2.15, 0.67); p=0.301			-0.82 (-2.16, 0.52); p=0.23
Marginal Total Effect			-6.78 (-19.14, 5.58); p=0.282			-6.51 (-11.72, -1.31); p=0.014

Note. Analysis completed using process described by VanderWeele (2016) “to assess the relative magnitude of different pathways and mechanisms by which an exposure may affect an outcome” (p. 16).

VanderWeele, T. J. (2016). Mediation Analysis: A Practitioner’s Guide. *Annual Review of Public Health*, *37*, 17–32. https://doi.org/10.1146/annurev-publhealth-032315-021402

Figure 1

Conceptual model of the mediation effect of socioeconomic status on patient activation disparities in Black primary care patients

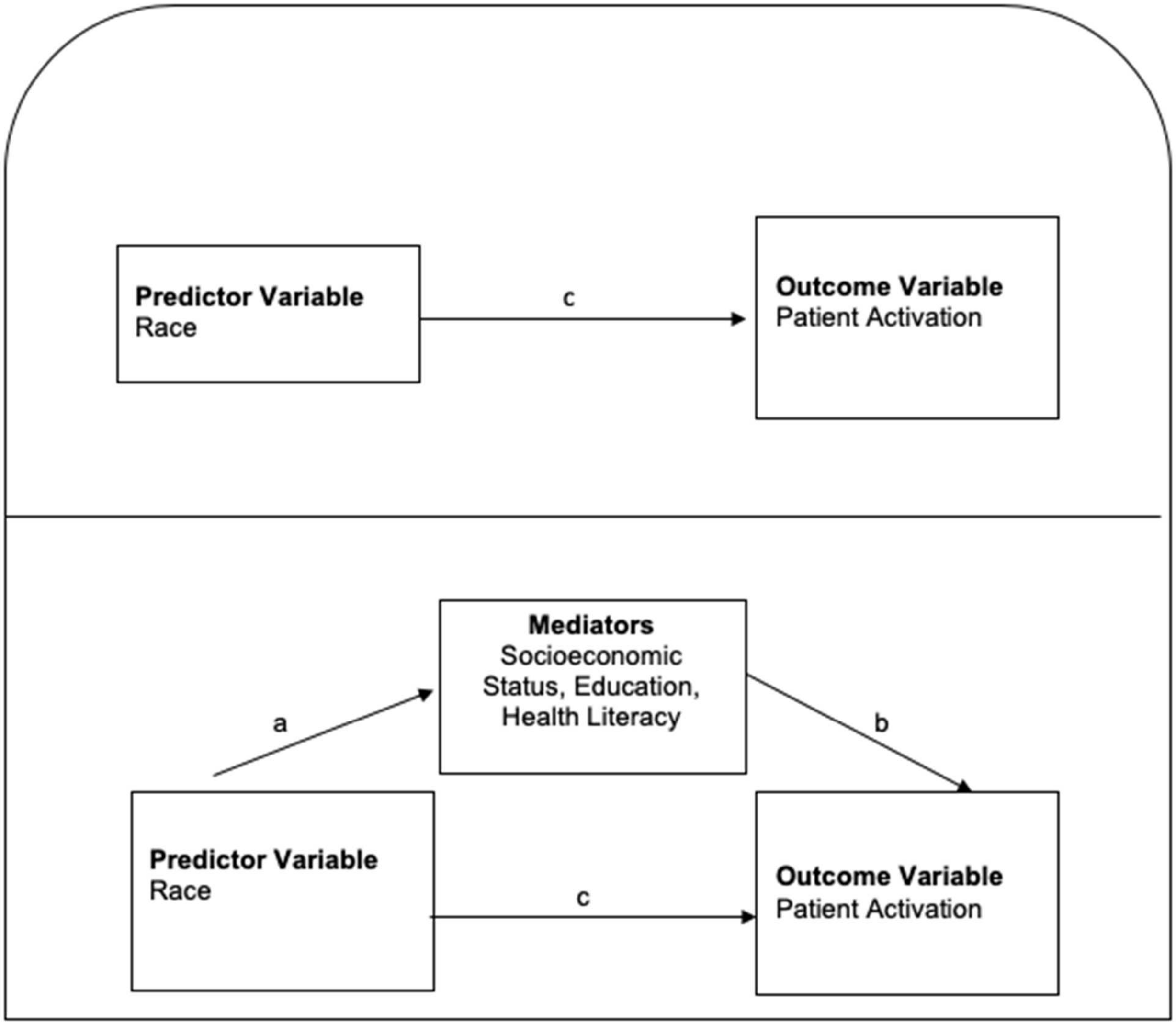
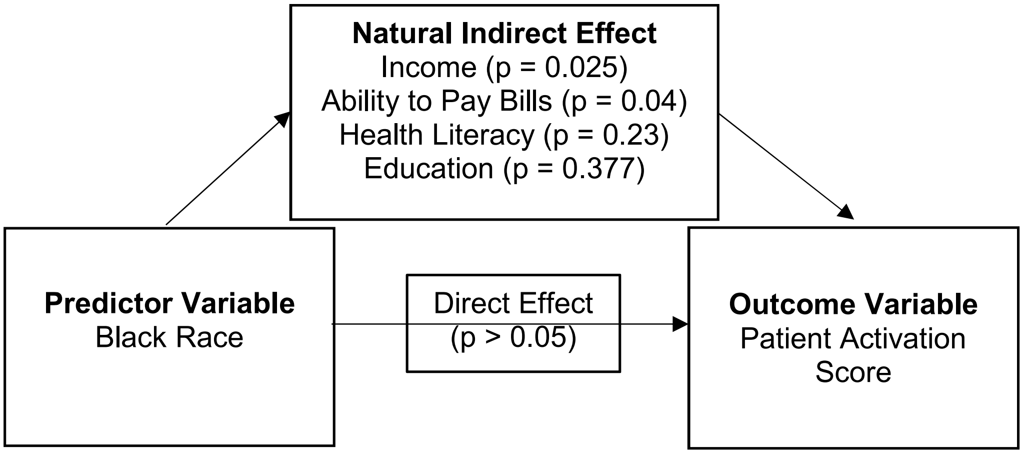


Figure 2

Natural Indirect Effect of Socio-economic Status and Health Literacy on Baseline Patient Activation Disparities in Black Patients



Conclusion

Population health literature and research repeatedly cite the social determinants of health (SDH) as driving health indicators (Cantor & Thorpe, 2018; Green, 2018; Institute of Medicine, 2001; Marmot et al., 2012). Health determinants (i.e., social, economic, environmental, health behaviors, and health care) provide insight into population-level health outcomes (University of Wisconsin Population Health Institute, 2014). An accurate understanding of a patient's SDH, along with their health goals and preferences, defined as patient-generated contextual data (PCD), may assist the primary healthcare team in co-developing a plan of care that is congruent with a patient's life circumstances. Research findings indicate that patients are more adherent to medication regimens (Young et al., 2017), treatment recommendations (Parchman et al., 2010), and behavior changes (Finney Rutten et al., 2016) when the negotiated care plan reflects a patient’s SDH, goals, and preferences. Research findings directly link treatment adherence to patient outcomes (Kim et al., 2016; McGrady et al., 2015; Shi et al., 2016).

The study aimed to investigate whether a digital health tool that standardizes the collection of PCD for point-of-care use impacted patient activation. Additionally, the study evaluated the impact of a technology that captures PCD for point-of-care use on patient activation between Black and White primary care patients.

Previous theory and empirical evidence that demonstrates how social, political, economic, gender, and professional forces (Chinn, 2018) and SDH (Marmot et al., 2012) affect patient activation (O’Malley et al., 2018; H. S. Shah et al., 2018; V. O. Shah et al., 2015) informed this project. The ultimate goal of the intervention is the delivery of high-quality healthcare that is effective, timely, efficient, safe, equitable, and patient-centered (Institute of Medicine, 2001).

Summary of Findings

Four research questions (RQ) motivated this research: RQ1 - Will changes in post-visit patient activation differ for users and non-users of a PCD tool? RQ2 - Will changes in post-visit patient activation differ for Black and non-Hispanic White participants, after using the PCD Tool? RQ3 - What patient characteristics and factors will be significant mediators of the baseline PAM score? RQ4 - Does patient adoption of a consumer informatics tool increase with facilitated enrollment?

RQ1 and RQ2 - Will changes in post-visit patient activation differ for users and non-users of a PCD tool? Will changes in post-visit patient activation differ for Black and non-Hispanic White participants after using a PCD tool? In brief, the answer to both of these questions is no. Patient activation did not differ by experimental arm or by race. Further explanation of these results is presented in Chapter 4.

RQ3 - What patient characteristics and factors will be significant mediators of the baseline PAM score? There was a statistically significant difference when comparing the Black versus White participants' baseline PAM score. Black participants had a lower baseline score by nearly 10-points (-9.32; 95%CI=-14.08, -4.57; p=0.0002). An analysis was conducted to examine if there were direct effects of race on PAM or if they operated through socio-demographic factors that are due to historical legacies and current aspects of systemic and personally experienced racism (Bourgois et al., 2017; Hammond, 2010). In using a medication analysis approach (VanderWeele, 2015), the results indicated that income (-4.48, CI -8.4, -0.56; p=0.025) and difficulty paying monthly bills (-2.54, CI -4.96, -0.11; p =0.04), when treated as continuous variables, mediated the relationship between race and PAM score. These data indicate that further study of the relationships among markers of economic status and patient activation is needed. The findings also indicate that interventions targeting patient activation need to account for, or at least be sensitive to, a patient's level of income and perceived ability to pay monthly bills regardless of the patient's racial or ethnic background. Further explanation of these results is presented in Chapter 5.

RQ4 - Does patient adoption of a consumer informatics tool increase with facilitated enrollment? The answer to this question is yes. The pre-trial rate of patient adoption, defined as completing the terms of agreement form of the PCD Tool, was 9.5%. In the trial, the rate of patient adoption in the PCD tool arm was 36%. This was a 279% increase in the adoption of the PCD Tool that may be attributed to facilitated enrollment by the research team. The facilitated enrollment process was an evidence-based approach that drew on research findings that indicated patient training and assistance with initial account registration significantly increased patient adoption of consumer informatics tools (Grossman et al., 2019). In the study, facilitated enrollment included a study team member describing the PCD tool, followed by the study team member either assisting the participant in registering a PCD tool account using the sent email link to the PCD Tool site or describing how to register a PCD tool account through the patient's portal. Next, the study team member reviewed types of 'stories' to share, in the domains of (a) information about me; (b) issues related to my care; (c) my upcoming visit agenda; and (d) barriers to care, to highlight them all as important pieces of data. After completing the instructions, the study team member shared that the completed profile was now available to the care team.

The substantial increase in PCD Tool adoption with facilitated enrollment indicates that a subset of patients in this academic health system were more likely to register for an account when assisted by a healthcare team member. As a result of these findings, consumer informatics tool adoption and patient activation efforts should include implementation science strategies that support individual assistance with registering for and the first use of consumer informatics tools (Leisy et al., 2017; Lyles et al., 2019; Phelps et al., 2014; Stein et al., 2018).

Implications for Health Policy

A significant body of research informs us that a composition of forces comprise health (Bourgois et al., 2017; Marmot et al., 2012; University of Wisconsin Population Health Institute, 2014). The current tools that clinicians have to understand the intersections of those forces, at the individual level, are limited (Estabrooks et al., 2012). The National Academies of Medicine convened the Committee on the Recommended Social and Behavioral Domains and Measures for Electronic Health Records (2014, 2015) to establish a core set of data points EHRs should systematically gather to inform clinicians of their patient's personal, social, and behavioral determinants of health. For example, sexual orientation, financial resource strain, health literacy, and stress (Committee on the Recommended Social and Behavioral Domains and Measures for Electronic Health Records et al., 2015).

Further, the Committee made recommendations to revise the EHR to connect the patient's context to the broader clinical evidence, public health, and community resources to work in tandem (Committee on the Recommended Social and Behavioral Domains and Measures for Electronic Health Records et al., 2015). The parsimonious list of domains and measures include race/ethnicity, tobacco use, alcohol use, and residential address, which current EHR infrastructures collect. New factors include education, financial resource strain, stress, depression, physical activity, social isolation, intimate partner violence, and neighborhood median household income (Committee on the Recommended Social and Behavioral Domains and Measures for Electronic Health Records et al., 2015). These eight new factors bridge traditional public health data with clinical health data to provide a more comprehensive view of the influences of health for point-of-care use. The PCD Tool used in this dissertation included items regarding financial resource strain (money and shelter), social support, and safety. The PCD Tool also gathered information on the patient's visit agenda, what makes them happy, health goals, barriers to achieving the health goal, biggest worry, and how that worry affects health. Further, the PCD Tool includes a self-reported health rating with rationale for the rating, natural vs. medical treatment preference, and shared decision-making preference.

To incentivize the inclusion of the 12-core social and behavioral determinants of health, the Committee recommends the revision of Meaningful Use regulations (Committee on the

Recommended Social and Behavioral Domains and Measures for Electronic Health Records et al., 2015). Meaningful use is a concept established to define a standard set of EHR data elements and interoperability components (Department of Health and Human Services, 2015). When a healthcare system provides evidence that their EHR meets or exceeds Meaningful Use criteria, they receive enhanced reimbursements for Medicare and Medicaid services rendered. It is the Committee’s recommendation that Medicare and Medicaid tie reimbursement to an augmented standard set of EHR data elements that include social and behavioral data (Committee on the Recommended Social and Behavioral Domains and Measures for Electronic Health Records et al., 2015) .

Value-based health policies (Dzau et al., 2017) will further assist in the uptake of the collection and use of social and behavioral data. In a value-based reimbursement payment model, providers are accountable for the patient- and population-specific metrics over a specific timeframe and across the continuum of care (Miller, 2009). Health insurance organizations then tie reimbursement to the achievement of those metrics. Although policymakers (Dzau et al., 2017) caution that policy reform must include the judicious use of patient- and population-specific parameters since the ad hoc use of such measures places a tremendous burden on the clinician. Value-based care must consist of the engagement of the patient, where the patient can contribute to, access, and own their EHR data. The patient 'empowered' by personal health data would have the tools to use, apply, and garner the most worth from their health information (Krumholz et al., 2016).

Implications for Clinical Practice

In the nearly 20-years since the publication of the Institute of Medicine’s (2001) six domains of healthcare quality, team-based care emerged as a leading mechanism to increase healthcare quality. Highly effective healthcare teams develop mutual goals, understand defined roles, build collective trust, engage in effective communication, and measure processes and outcomes (P. H. Mitchell et al., 2012). Interventions that include the entire work system, including patient work (Mundt & Swedlund, 2016), may be more effective than interventions that isolate healthcare roles and fail to recognize the importance of patient engagement (Dentzer, 2013; Holden et al., 2015). Recently, health care technology developers designed technology to foster collaboration among patient and professional work (Valdez et al., 2015a, 2015b). Collaborative work technologies aim to improve patient-clinician communication, shared decision-making, and patient engagement (Valdez et al., 2015a, 2015b).

The PCD Tool tested in this study was developed to improve patient-provider communication, as well as help providers and health organizations, learn what matters most to patients. The innovative EHR-integrated application aimed to facilitate a personal connection between the patient and healthcare team as well as to efficiently grasp goals of care, agenda items, barriers, social determinants, and preferences of care. The results of qualitative studies with clinician users of the PCD Tool (Cusatis et al., 2019; Holt et al., 2019), supported that the elicitation and inclusion of PCD impacted patient activation and care teams' connection with patients. Although, in the clinical trial, patients who used or did not use the PCD Tool did not differ significantly on their patient activation scores ($p>0.05$).

Previous qualitative data also revealed healthcare teams perceived an improvement in team-based efficiencies and the ability to deliver patient-centered care (Cusatis et al., 2019; Holt et al., 2019). As researchers further explore ways to enhance the participatory model of healthcare (Dzau et al., 2017), the need for an engaged, active patient role remains essential (Post et al., 2002). We need to understand further if the introduction of new technology into the clinic visit, honed clinician's ability to connect with patients on a humanistic level (Singh Ospina et al., 2019) or if clinicians beliefs about the value of the patients' role in self-management relate to their engaging in collaborative and rapport-building behaviors with patients (Alvarez et al., 2016).

Implications for Nursing Research

The HITECH (Act, 2009) drastically changed the way healthcare professionals practice. The promise of the EHR to improve patient safety and quality (Ancker et al., 2014) is tempered by diminishing provider satisfaction and burnout of primary care providers (Arndt et al., 2017; Han et al., 2019; Kroth et al., 2019; Montanari et al., 2019; West et al., 2018). Patients and clinicians also have differing views about the use of technology in the exam room. Clinicians perceive within visit computer use as a barrier to patient-physician communication, whereas patients have a favorable perception (Sobral et al., 2015). Research using video analysis of the clinical encounter has shown that technology may affect collaboration among patients and professionals (Singh Ospina et al., 2019).

To further research studying the effects of technology during the primary care visit, a qualitative study using video analysis of patient-provider interactions to identify critical communication components that operationalize person-centered care is needed. The proposed study would use video elicitation (Asan & Montague, 2014; Henry & Fetters, 2012), and after the visit, patients and providers could watch the encounter and provide feedback on the communication exchange, this would provide another analytical lens to the patient-provider relationship. These two analytical techniques (video analysis and video elicitation) will provide insight into the use of the PCD Tool and how components contributed (or not) to communication, shared decision-making process, agenda-setting, and patient experience. Combining qualitative and quantitative research methodologies could reveal the intricacies involved in the interactions using reductionist and holistic approaches (Post et al., 2002).

Researchers have used qualitative and quantitative research approaches to understand the directly observable facets of patient-provider interactions and the subjective experiences of patients and physicians’ shared decision-making processes (Saba et al., 2006). They found that effective communication skills and behaviors and perceived relationship dynamics (trust, power, rapport, engagement) both affected shared decision-making (Saba et al., 2006). Patients from ethnic and racial minorities placed different levels of importance on communication skills and relationship dynamics than patients from the ethnic and racial majority (Hawkins & Mitchell, 2018; Post et al., 2002). Further research is needed to extend the understanding of how different populations perceive their communication and relationship with their provider and how the use of a consumer informatics tool within the primary care visit influences those perceptions and patient activation.

Implications for Nursing Theory

The Institute of Medicine (2001) six domains of healthcare quality and Chinn's (2018) nursing theory of emancipatory knowing grounded this research. The theoretical frameworks provided concepts to identify contributing factors that influence patient activation. Indeed, healthcare quality is often measured by an individual's access to and affordability of care, even though far more significant determinants are an individual's economic, social, and physical environments (Robert Wood Johnson Foundation, 2008). The theoretical concepts were represented in the variables collected in the surveys. Patient-centered care was measured using the CG-CAHPS (Dyer et al., 2012) items. The CG-CAHPS instrument is the leading patient experience measure that healthcare organizations use to evaluate and benchmark their delivery of patient-centered care (Holt, 2018). Potential social, educational, economic, gender, and racial influences of patient activation were measured across a variety of items, including measures of social support, financial security, and health literacy. I found that income and wealth factors mediated the effect of baseline racial differences in patient activation. These results provide additional evidence of the impact of economic status and patient activation not previously reported in the literature (Couture et al., 2018; Eneanya et al., 2016; Lubetkin et al., 2010; Salgado et al., 2017).

To further theoretical development, scientists must continue to expose and measure the social, political, economic, gender, and professional structures that impede the full implementation of person-centered care. Person-centered care embraces the ontological position of the existence of not just one reality, but of multiple realities that are created and can be changed by the person. Reality is contextual, individual, and uniquely constructed (Laverty, 2003). There is consensus surrounding the ontology of person-centered care, which recognizes the reality of the human being, who possesses rational thought, free will, opinions, and desires (Ekman et al., 2011). Person-centered care embodies a humanistic and holistic view. The individual garners respect as a whole person with multifaceted needs and is empowered to promote and protect their health (WHO, 2014). It is a caring environment that restores harmony and balance within the individual, and among people and environments (Organization & Others, 2014; Rogers, 1988). The theory of emancipatory knowing is ideally suited to identify the social, economic, and political patterns that are amenable to change (Chinn, 2018). The approach should guide research which intends to illuminate the origins of social injustice and provide a pathway through which reflective action can evoke social change (i.e., nursing praxis) (Peart & MacKinnon, 2018) to augment the patient's health trajectory (Bender, 2018). The findings from this dissertation support the continued use of Chinn's (2018) theory of emancipatory knowing and further exploration of the impacts of the social and behavioral determinants of health (WHO, 2014) in other geographical locations and healthcare settings.

Implications for Nursing Education

This study demonstrates the importance of a personal connection between the patient, the environment, and the healthcare team. Up to 80% of health outcomes are derived from the context and circumstances of individuals' lives (University of Wisconsin Population Health Institute, 2014), underscoring the importance of recognizing and incorporating patients' structural vulnerabilities, values, goals, and preferences into the plan of care. As technology continues to permeate the clinical space, the need for the nurse to communicate effectively with patients remains paramount. Students must reveal and address their implicit biases using implicit association test (IAT) tools like those offered freely from *Project Implicit* (2020). Research findings indicate that healthcare professionals manifest similar levels of implicit bias as the general population, which directly affect behavior. In a review of the literature, 80% (20 out of 25) of studies investigating how implicit bias affects health professional clinical judgment and behavior revealed that some type of bias was apparent (FitzGerald & Hurst, 2017). Healthcare professionals' preference(es) affected "diagnosis, the treatment recommendations, the number of questions asked of the patient, the number of tests ordered, or other responses indicating a bias against the characteristic of the patient under examination" (FitzGerald & Hurst, 2017, p. 13).

As part of implicit bias training, students must learn how to uncover potential social and structural inequities that impact an individual's ability to follow a co-developed treatment plan or pursue healthy lifestyle habits (Bourgois et al., 2017). Students must also develop advocacy skills to assist patients who may need resources outside of the traditional health care system (e.g., secured housing to store medication properly) (Bourgois et al., 2017). Notably, individuals who experience housing instability, food insecurity, low literacy, and social vulnerability, which negatively impact health (National Academies of Sciences, 2019). Disproportionately, ethnic and racial minorities experience the structural challenges of poverty, racism, and economic disinvestment, which leaves individuals with few resources to self-manage their health (Alvidrez et al., 2019; Noonan, 2020; Vila et al., 2007). The student nurse can apply the nursing metanarrative, which is person-oriented, sensitive to context, alert to patterns, and participatory (Reed, 1995), as they advocate for individuals, families, and communities as they re-envision ecosystems of care (Noonan, 2020).

Strengths and Limitations

The major strengths and limitations of this study are discussed in Chapter 4. An additional discussion of strengths and limitations is presented in this section.

The randomization in the RCT design minimizes the potential bias of confounding (Booth & Tannock, 2014). The randomization procedure, which stratified participants by race, recognized the concern of the racial digital divide (Campos-Castillo, 2015; U. A. Mitchell et al., 2019; Walker et al., 2019). Although the study's recruitment strategies (email and postcards to eligible primary care patients) did not reach racial parity in the study participants, it did assist in the successful oversampling of Black patients (n=117, 39%) who comprised only 26% of the eligible population at the academic medical center. Further, the trial secondarily tested the impact of facilitated enrollment on the adoption of a consumer-facing digital health tool. Facilitated enrollment increased the pre-trial rate of adoption from 9.5% to the 36% trial adoption rate, answering the question that people may need a guide to adopt digital health tools. Similar to other research that investigated approaches to increase adoption of consumer informatics tools, tailored support with registering for and the initial use of consumer informatics tools bolstered patient adoption (Leisy et al., 2017; Lyles et al., 2019; Phelps et al., 2014; Stein et al., 2018).

A limitation of the longitudinal design of the study included the loss to follow-up of participants. The loss to follow-up occurred early in the trial, with 18.2% (n=55) of participants who did not complete their baseline survey. Early in the recruitment of participants in the trial, the research assistant randomized participants when he received an email response indicating the individual wanted to participate. The majority of people who did not complete their baseline survey did not respond to further contact via email or telephone to explain the tenets of the study. Since there was no baseline data from these individuals, I was unable to determine if they had different socio-demographic (income, difficulty paying bills, education, health literacy, internet access, baseline PAM score etc.) factors than participants who completed their baseline survey. After identifying the trend of a participant acknowledging interest in the study, but never completing the informed consent process, the research team did not randomize participants until they spoke with the person. The communication assisted with answering questions and confirmed consent to participate. The early loss to follow-up led to an overall attrition rate of 38.5% (n=116).

Attrition may be problematic if the characteristics of participants lost to follow-up differ between arms (Dumville et al., 2006; Polit & Beck, 2017). In this study, differential attrition was defined as the difference between attrition rates for the PCD Tool arm and the usual care arm on post-visit survey completion rates, which did not differ significantly. However, there was a differential attrition rate by race (47% of Black participants compared to 33% of White participants did not complete both surveys; p=0.008). Other statistically significant differences between participants who completed and did not complete the trial included: receives Medicaid (N=184); p=0.003; has a computer at home (N=221); p=0.007; accesses the internet on a gaming device/smart TV (N=178); and the highest positive response on the PROMIS item, Able to carry out your everyday physical activities (N=245); p=0.0069. Since the missing survey data was not missing at random, a multiple imputation analysis was conducted for the larger study outcome, patient-provider communication and the dissertation study outcome, patient activation. The intention-to-treat results did not differ when demographic and baseline PAM scores were imputed to address the missing data. I explained these results further in Chapter 4. Future research should explore indirect and direct relationships of variables that may mediate differential attrition by race.

The trial was designed to examine if the inclusion of PCD, collected using a digital health tool before a primary care visit, was associated with an increase in patient activation. It is unknown if and how PCD was used during the clinical encounter. Therefore, the lack of observation of the primary care visit encounters in this trial limits the ability to understand the use of PCD during the visit. A secondary analysis of clinical encounters recorded as part of six practice-based trials examined the effect of shared decision-making (SDM) tools on the elicitation of the patient's agenda (Singh Ospina et al., 2019). SDM tools did not affect the likelihood of eliciting the patient’s agenda (p=.09). The researchers estimated that primary care physicians elicited agendas (What brought you to the clinic today?) from patients in only 49% of visits (Singh Ospina et al., 2019). When agendas were elicited, physicians interrupted the patient in 27 of the 40 (67%) encounters that were viewed as part of the study, with a median time to interruption of 11 seconds (Singh Ospina et al., 2019). Singh Ospina and colleagues

(2019) reported that when patients were not interrupted, they completed their agenda in a median of 6 seconds. There are research findings that support clinician engagement affects patient activation. Characteristics of highly engaged clinicians include co-developing the visit agenda, self-management goals, and strategies to overcome barriers to self-care (Alvarez et al., 2016; Greene et al., 2016). Further, clinicians, who incorporated more healthy behavior education and counseling during the encounter, had patients with increases in activation scores (Greene et al., 2016). Therefore, future research studies should include analysis of observed clinic visits to assess how clinicians may change their approach when including PCD using an EHR-integrated consumer informatics tool and understand factors that contribute to its use.

Further, the research study occurred within one urban academic medical center located in a highly segregated metropolitan area (City of Milwaukee Health Department, 2016; County Health Rankings & Roadmaps, 2019; Vila et al., 2007), which may limit the generalizability of the results. Relatedly, participants were only English-speaking non-Hispanic White and non-Hispanic Black, which excludes other diverse populations and limits generalizability. Although the study was designed to oversample Black participants for equal representation by race in both arms; recruitment, and retention of Black patients was less than Whites. Finally, there was a high level of nonadherence to the research protocol by participants in the intervention arm. When we compared all of the participants against a list of Epic users, with a PCD Tool flag, 45 of 149 (30%) study participants in the PCD Tool arm completed the tool and 9 of 152 (6%) study participants in the Usual Care arm completed the PCD Tool. The nonadherence to the study protocol may have caused a Type II Error; that is, we failed to reject the null hypothesis when the null hypothesis was false. Thus, missing the actual effect of the PCD Tool on patient activation.

Summary

The goals of this dissertation were to understand if the use of a consumer informatics tool designed to enhance the capture and sharing of patient-contextual data improved patient activation. Overall, the results revealed a null effect of patient contextual data, gathered using a consumer informatics tool for point-of-care use, on patient activation. A possible explanation of this finding is the clinicians may not have used or referenced the PCD Tool during the visit. Findings also negate the perception of potential added disparity with the use of consumer-facing technology as part of the pre-visit process. Further research is needed to understand how economic diversity affects patient activation, including if socioeconomic status is a primary driver of patient activation. Additionally, future research should investigate if findings differ in community healthcare settings who serve as primary healthcare sites in most communities (Fleishon et al., 2017). Finally, research is required to determine how clinician engagement at point-of-care may affect patient activation regardless of technology use (Alvarez et al., 2016; Greene et al., 2016).

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Vila, P. M., Swain, G. R., Baumgardner, D. J., Halsmer, S. E., Remington, P. L., & Cisler, R. A. (2007). Health disparities in Milwaukee by socioeconomic status. *WMJ: Official Publication of the State Medical Society of Wisconsin*, *106*(7), 366–372. https://www.ncbi.nlm.nih.gov/pubmed/18030822

Walker, D. M., Hefner, J. L., Fareed, N., Huerta, T. R., & McAlearney, A. S. (2019). Exploring the Digital Divide: Age and Race Disparities in Use of an Inpatient Portal. *Telemedicine Journal and E-Health: The Official Journal of the American Telemedicine Association*. https://doi.org/10.1089/tmj.2019.0065

West, C. P., Dyrbye, L. N., & Shanafelt, T. D. (2018). Physician burnout: contributors, consequences and solutions. *Journal of Internal Medicine*, *283*(6), 516–529. https://doi.org/10.1111/joim.12752

World Health Organization. (2014). People-Centered Health Care: A Policy Framework 2007. *WHO: Geneva*.

Young, H. N., Len-Rios, M. E., Brown, R., Moreno, M. M., & Cox, E. (2017). How does patient-provider communication influence adherence to asthma medications? *Patient Education* *and Counseling*, *100*(4), 696–702. https://doi.org/10.1016/j.pec.2016.11.022

Curriculum Vitae

Jeana M. Holt

EDUCATION

University of Wisconsin-Milwaukee Milwaukee, WI	PhD in Nursing	Expected May 2020
University of Wisconsin-Milwaukee Milwaukee, WI	Doctor of Nursing Practice	2012
University of Wisconsin-Milwaukee Milwaukee, WI	Master of Science in Nursing Family Nurse Practitioner	2005
Winona State University Winona, MN	Bachelor of Science in Nursing	1997

POST-DOCTORAL FELLOW

Medical College of Wisconsin Milwaukee, WI	Academic Fellowship in Primary Care Research T32HP10030	2019

RESEARCH INTEREST

Evaluate how to best empower patients through digital health tools within the context of existing systems of care.

RESEARCH EXPERIENCE

Title: Identification of the principal characteristics and services of nurse-managed clinics within Donabedian's Healthcare Quality Structure-Process-Outcomes Model
Source: Harriet H. Werley Research Faculty Award
Grant Number: N/A
PI: Mary Jo Baisch, PhD
Role: Research Assistant (10% FTE)
Dates: September 2011-May 2012
Total funds: $1,500
Goal/ Purpose: To conduct an integrative review of the nurse-managed health center literature.

Title: Teaching Today's Students for Tomorrow's America
Source: U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professionals, Division of Nursing, Nurse Education, Practice, Quality, and Retention - Interprofessional Collaborative Practice.
Grant Number: UD7HP28542
PI: Bev Zabler PhD, RN
Role: Co-Investigator (20%-50% FTE)
Dates: July 2015-December 2018
Total funds: $1,300,000

Goal/ Purpose: To expand health services for local immigrants and refugees while developing a model of interprofessional education.

Title: Advancing the Village
Source: UWM Social Entrepreneurship, Justice & Equity Compact (SEJEC) and the University of Wisconsin System
Grant Number: N/A
Role: Principle Investigator (10% FTE)
Dates: September 2016-May 2017
Total funds: $25,000
Goal/ Purpose: To reduce perceived stress of parents living in poverty through group education classes led by an inter-professional team of clinicians.

Title: Primary Care Behavioral Health
Source: U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professionals, Division of Nursing, Nurse Education, Practice, Quality, and Retention - Interprofessional Collaborative Practice
Grant Number: UD7HP30930
PD: Bev Zabler PhD, RN/Jean Bell-Calvin, MS, RN
Role: Co-Investigator (20-40% FTE)
Dates: July 2017-July 2020
Total funds: $999,950
Goal/ Purpose: To integrate behavioral health into nurse-led primary health care services.

Title: Perceptions of the Blood Pressure Program
Source: Advancing a Healthier Wisconsin Endowment
Grant Number: FP00004811
PI: John Meurer, MD, MBA
Role: Co-Investigator (10% FTE)
Dates: September 2017, March 2018
Total funds: $1,500
Goal/ Purpose: To evaluate employee perceptions of practice-wide changes in health care delivery to improve identification, referral to primary care or emergency services, and management of patients with elevated blood pressure.

Title: Integrating Patient Values into Care
Source: Medical College of Wisconsin Center for Patient Care and Outcomes Research (PCOR)
Grant Number: N/A
PI: Bradley Crotty, MD, MPH
Role: Co-investigator/Post-doctoral fellow (10% FTE)
Dates: March 2017-June 2018
Total funds: $30,000

Goal/ Purpose: To identify important facilitators and barriers to use and incorporate patient contextual data from an integrated electronic health record application into routine care in a scalable and sustainable way.

Title: Avoiding Health Disparities When Collecting Patient Data for Clinical Care and Pragmatic Research
Source: Advancing a Healthier Wisconsin Endowment
Grant Number: N/A
PI: Bradley Crotty, MD, MPH
Role: Co-investigator/Post-doctoral fellow (25% FTE)
Dates: January 2018-January 2020
Total funds: $200,000
Goal/ Purpose: To determine the barriers and facilitators to collecting electronic patient-reported data and whether adoption and results of use differ by race.

Title: The State of Health and Healthy Behaviors in Big 10 Health Sciences Faculty and Students
Source: The Ohio State University
Grant Number: N/A
PI: Bernadette Melnyk, Ph.D., RN, APRN-CNP, FAANP, FNAP, FAAN
Role: Co-investigator/site PI (0% FTE)
Dates: April 2019- April 2020
Total funds: Non-funded
Goal/ Purpose: To describe and compare the health and healthy lifestyle behaviors of Big 10 health sciences faculty and students.

TEACHING EXPERIENCE

Medical College of Wisconsin

Foundations of Clinical Medicine	Preceptor	2017
Leadership in Academic Health Care II: Organizations and Change" Diffusion of Innovations & Implementation Science: Tools for Organizational Change	Guest Lecturer	2018
Leadership in Academic Health Care II: Organizations and Change" Diffusion of Innovations & Implementation Science: Tools for Organizational Change	Guest Lecturer	2020

University of Wisconsin-Milwaukee College of Nursing

NURS 729: Organizational Systems, Online	Course Instructor	2015, 2016
NURS 767: Family Nurse Practitioner Theory I, Traditional & Online	Course Instructor	2015, 2016, 2017, 2018, 2019
NURS 768: Family Nurse Practitioner Theory II, Hybrid & Online	Course Instructor	2013, 2014, 2015, 2016, 2017, 2018, 2019
NURS 769: Family Nurse Practitioner Theory III	Course Instructor	2013, 2017, 2018, 2019
NURS 290: Special Studies in Nursing: Community-Engaged Health Research, Traditional	Course Instructor	2014, 2015

NURS 390: Special Studies in Nursing: Community-Engaged Health Research, Traditional	Course Instructor	2014, 2015, 2016
NURS 490: Special Studies in Nursing: Community-Engaged Health Research, Traditional	Course Instructor	2014
NURS 490: Special Studies in Nursing: Introduction to Health Promotion, Planning & Implementation in a Nurse-Managed Health Center	Course Instructor	2014

PROFESSIONAL EXPERIENCE

Clinical Assistant Professor (PIAS)	University of Wisconsin-Milwaukee College of Nursing Milwaukee, WI	08/15-Present
Clinical Assistant Professor	University of Wisconsin-Milwaukee College of Nursing Milwaukee, WI	08/13-7/15
Family Nurse Practitioner	University of Wisconsin-Milwaukee College of Nursing Institute for Urban Health Partnerships House of Peace and Silver Spring Community Nursing Centers Milwaukee, WI	06/12-Present
Director, House of Peace Community Nursing Center	University of Wisconsin-Milwaukee College of Nursing Institute for Urban Health Partnerships Milwaukee, WI	06/16-1/17
Director, Primary Care Services	University of Wisconsin-Milwaukee College of Nursing Institute for Urban Health Partnerships Community Nursing Centers Milwaukee, WI	07/13-1/17
Project Coordinator	U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professionals, Division of Nursing, Nurse Education, Practice, Quality, and Retention, Interprofessional Collaborative Practice, Grant # UD7HP28542 Milwaukee, WI	07/15-1/17
Acting Director, House of Peace Community Nursing Center	University of Wisconsin-Milwaukee College of Nursing Institute for Urban Health Partnerships House of Peace Community Nursing Center Milwaukee, WI	01/13-08/13
Clinical Instructor	University of Wisconsin-Milwaukee College of Nursing Milwaukee, WI	06/12-07/13
Director, Nurse Practitioner-Led Clinics	Free and Community Clinic Collaborative, Innovative Workforce Development Grant, Faye McBeath Foundation, Milwaukee, WI	06/12-07/13
Graduate Student Research Asst	Harriet H. Werley Faculty Research Award University of Wisconsin-Milwaukee	10/11-05/12

	College of Nursing Milwaukee, WI	
Family Nurse Practitioner	Southside Primary Care Milwaukee, WI	09/05-08/08
Staff Nurse	University of Wisconsin Hospital & Clinics Madison, WI	06/97-04/00

PEER REVIEWED PUBLICATIONS

Crotty, B. H., Asan, O., **Holt, J. M**., Tyszka, J., Erickson, J., Stolley, M., Pezzin, L., & Nattinger,A. (in press). A Qualitative Assessment of Unmet Information Management Needs of Informal Cancer Caregivers - 4 Themes to Inform Oncology Practice. *Clinical Cancer Informatics.*

Cusatis, R., **Holt, J. M**., Asan, O., Williams, J., Nukuna, S., Flynn, K. E., Neuner, J., Moore, J., Flynn, K. E., Makoul, G., & Crotty, B. (in press). “Tell Me Straight”: Clinicians and Patient Perspectives on How Patient Generated Contextual Data Impacts In-visit Communication. *Patient Education and Counseling.* https://doi.org/10.1016/j.pec.2019.10.020

Holt, J. M., Brooke, K. L., Pryor, N. S., Cohen, S. M., Tsai, P., & Zabler, B. (2020). Using the Omaha System for a Formative Evaluation of the Integration of Behavioral Health Services into Nurse-Led Primary Care. *Journal of Community Health Nursing, 37*(1) https://doi.org/10.1080/07370016.2020.1693115

Mutitu, A., Zabler, B., & **Holt, J. M.** (2019). Refugees' Perceptions of Primary Care: What Makes A Good Doctor's Visit? *Patient Experience Journal, 6*(3), 33-41. https://doi.org/10.35680/2372-0247.1382

Holt, J. M., Cusatis, R., Asan, O., Williams, J., Nukuna, S., Flynn, K. E., … Crotty, B. H. (2019). Incorporating patient-generated contextual data into care: Clinician perspectives using the Consolidated Framework for Implementation Science. *Healthcare*, https://doi.org/10.1016/j.hjdsi.2019.100369

Holt, J. M. (2019). Patient Experience in Primary Care: A Systematic Review of CG-CAHPS Surveys. *Journal of Patient Experience*, *6*(2), 93-102. https://doi.org/10.1177/2374373518793143

Holt, J. M., Johnson, T. S., Zabler, B. (2018). Engaging African American women in community based health promotion programs: Key-informant recommendations. *Journal of Community Health Nursing, 35*(3), 137-147. https://doi.org/10.1080/07370016.2018.1475800

Holt, J. M. (2018). An evolutionary view of patient experience in primary care: A concept analysis. *Nursing Forum 53*(4), 555-566. https://doi.org/10.1111/nuf.12286

Holt, J. M., Zabler, B., & Baisch, M. J. (2014). Evidence-based characteristics of nurse managed health centers for quality and outcomes. *Nursing Outlook*, 62(6), 428-439 https://doi.org/10.1016/j.outlook.2014.06.005.

PUBLISHED CONFERENCE ABSTRACTS

Holt, J. M., Meurer, J., Williams, K., Sparapani, R., Mitchell, J. (2019). Leaders, Providers, and Care Team Perceptions of a Population Health Improvement Initiative. *Ethnicity & Disease, 29* (Supp 1), 217. https://doi:10.18865/ed.29.S1.209

Crotty, B., **Holt, J.M.,** Cusatis, R., Asan, O., Williams, J., Flynn, K., … & Makoul, G. (2018). Humanizing the Chart: Becoming More Responsive to Patient Needs Through Implementation of PatientWisdom. *Iproceedings*, *4*(2), e11793. https://doi.org/10.2196/11793

REFEREED PODIUM PRESENTATIONS AND POSTERS

Holt, J.M., Cusatis, R. C., Onur, A., Williams, J. S., Flynn, K. E., Crotty, B. (2019, June) Can patients humanize their electronic health record to facilitate stronger connections with care teams? Podium Presentation. 28th Annual Department of Family and Community Medicine Research Forum, Milwaukee WI.

Holt, J.M., Cusatis, R. C., Onur, A., Williams, J. S., Flynn, K. E., Crotty, B. (2019, May) Can patients humanize their electronic health record to facilitate stronger connections with care teams? UWM Health Research Symposium. Podium and Poster Presentation. Milwaukee, WI.

Holt, J.M., Cusatis, R. C., Onur, A., Williams, J. S., Flynn, K. E., Crotty, B. (2019, May) Can patients humanize their electronic health record to facilitate stronger connections with care teams? Society of General Internal Medicine 2019 Annual Meeting, Washington, DC.

Holt, J.M., Bell-Calvin, J. Brooke, K. L. (2019, April). Use of The Omaha System to Examine Health Equity Among Low-Income Adults Receiving Nurse-Led Primary Health Care Services. Poster Presentation. Omaha System International Conference, Eagan, MN.

Holt, J.M., Bell-Calvin, J. Brooke, K. L., Pryor, N. M., Zabler, B. (2019, April). Using the Omaha System to Evaluate the Integration of Behavioral Health Services into Nurse-Led Primary Health Care. Poster Presentation. Omaha System International Conference, Eagan, MN.

Faltinson, M., **Holt, J. M.,** Bell-Calvin, J. (2019, April). Use of the Omaha System to Describe Nurse-Led Prenatal Care Coordination. Poster Presentation. Omaha System International Conference, Eagan, MN.

Holt, J. M., Cusatis, R. C., Onur, A., Williams, J. S., Nukuna, S., Flynn, K. E., Moore, J., Crotty, B. (2019, March). Clinician Identified Facilitators and Barriers to Adopting An EHR Integrated Patient Contextual Data Application into Primary Care. Poster Presentation. MCW Department of Medicine Research Retreat, Milwaukee, WI.

Holt, J. M., Cusatis, R. C., Onur, A., Williams, J. S., Nukuna, S., Flynn, K. E., Moore, J., Crotty, B. (2019, March). Clinician Identified Facilitators and Barriers to Adopting An EHR Integrated Patient Contextual Data Application into Primary Care. Poster Presentation. MCW Fusion Conference, Milwaukee, WI.

Holt, J. M., Cusatis, R. C., Onur, A., Williams, J. S., Nukuna, S., Flynn, K. E., Moore, J., Crotty, B. (2019, March). Barriers and Facilitators to Integrating Patient Contextual Data into Primary Care. Poster Presentation. Midwest Nursing Research Society 43rd Annual Research Conference, Kansas City, MO.

Cusatis, R. C., **Holt, J. M.,** Onur, A., Williams, J. S., Nukuna, S., Flynn, K. E., Crotty, B. (2018, November). Understanding how patient contextual data augments patient & clinician communication from the clinician's perspective. Poster presentation, *North American Primary Care Research Group Annual Meeting,* Chicago, IL.

Holt, J. M., Cusatis, R. C., Onur, A., Williams, J. S., Nukuna, S., Flynn, K. E., Crotty, B. (2018, November). Barriers & facilitators to integrating patient contextual data into primary care. Poster presentation, North *American Primary Care Research Group Annual Meeting,* Chicago, IL.

Crotty, B., **Holt, J. M.,** Cusatis, R. C., Onur, A., Williams, J. S., Flynn, K. E., Moore, J., Makoul, G. (2018, October). Humanizing the chart: Becoming more responsive to patient needs through the implementation of PatientWisdom. Poster presentation, *2018 Connected Health Conference*, Boston, MA.

Holt, J. M., Meurer, J., Williams, K., Sparapani, R., Mitchell, J. (2018, June). *Leaders, Providers, and Care Team Perceptions of a Population Health Improvement Initiative* Poster presentation for Medical College of Wisconsin, 27th Annual Department of Family & Community Medicine Research Forum, Milwaukee, WI.

Holt, J. M., Meurer, J., Williams, K., Sparapani, R., Mitchell, J. (2018, May). *Leaders, Providers, and Care Team Perceptions of a Population Health Improvement Initiative* Podium presentation for University of Wisconsin-Milwaukee Research Symposium, Milwaukee, WI.

Holt, J. M., Meurer, J., Williams, K., Sparapani, R., Mitchell, J. (2018, May). *Leaders, Providers, and Care Team Perceptions of a Population Health Improvement Initiative* Poster presentation for Saunders-Watkins Leadership Workshop, NHLBI, NIH, Bethesda, MD.

Welch, G., Camenga, E., Zabler, B., **Holt, J. M.** (2018, April). Creating an Asynchronous Interprofessional Learning Environment to Improve Refugee Health. Poster presentation for Wisconsin Nurses Association 32nd Annual APRN Forum: Pharmacological & Clinical Update, Madison, WI.

Holt, J. M., Sanders, J., Bell-Calvin, J., Zabler, B. (2018, April). A community-centered health home model providing culturally responsive care to serve refugees: Barriers to full implementation. Poster presentation for 4th Annual Medical College of Wisconsin Community Engagement Spring Conference, Milwaukee, WI.

Holt, J. M., Meurer, J., Williams, K., Sparapani, R., Mitchell, J. (2018, April). *Moving Towards Practice-wide Blood Pressure Screening* Poster presentation for Society of General Internal Medicine National Conference, Denver, CO.

Holt, J. M., Meurer, J., Williams, K., Sparapani, R., Mitchell, J. (2018, April). *Leaders, Providers, and Care Team Perceptions of a Population Health Improvement Initiative* Poster Presentation for Midwest Nursing Research Society 42nd Annual Research Conference, Cleveland, OH.

Holt, J. M., Meurer, J., Williams, K., Sparapani, R., Mitchell, J. (2018, March). *Moving Towards Practice-wide Blood Pressure Screening* Poster presentation for the Medical College of Wisconsin Department of Medicine Research Retreat Milwaukee, WI

Holt, J. M., Mitchell, J., Williams, K., Fangman, J., Stulac Motzel, W., Sigrist, B. (2017, December) Should All Specialty Clinics Measure Blood Pressure? Poster presentation; Peer reviewed. Institute for Healthcare Improvement National Forum, Orlando, FL.

Holt, J. M. (2017, November). Using the Omaha System to Describe the Health of the Newly Insured. Poster presentation; Peer reviewed. Sigma Theta Tau International Nursing Honor Society, Eta Nu Chapter 3rd Annual Poster Symposium 2017, Milwaukee, WI

Holt, J. M., Mitchell, J., Williams, K., Fangman, J., Stulac Motzel, W., Sigrist, B. (2017, October). Should All Specialty Clinics Measure Blood Pressure? Poster presentation; Peer reviewed. Physician and APP Recognition Event, Froedtert Hospital & Medical College Physicians, Milwaukee, WI

Mitchell, J., **Holt, J. M.,** Williams, K. J., Fangman, J. J., Stadter, G. (2017, September). Screening for and Control of Hypertension in Primary and Specialty Care. Oral Presentation; Peer Reviewed. Society of General Internal Medicine 2017 Midwest Regional Meeting, Chicago, IL

Holt, J. M., Mosley, A., Cohen, S. M., Baldwin, V., Barnes, L., Muhammad, C. (2017, June). Advancing the Village to Build Healthy Families. Poster presentation; Peer reviewed. Medical College of Wisconsin, 26th Annual Department of Family & Community Medicine Research Forum, Milwaukee, WI

Holt, J. M. (2017, June). Transitioning from a Registered Nurse to a Family Nurse Practitioner. Poster presentation; Peer reviewed. Medical College of Wisconsin, 26th Annual Department of Family & Community Medicine Research Forum, Milwaukee, WI

Holt, J. M. (2017, April). Using the Omaha System to Describe the Health of the Newly Insured. Poster presentation; Peer reviewed. Omaha System International Conference, Eagan, MN

Holt, J. M., Mosley, A., Cohen, S. M., Baldwin, V., Barnes, L., Muhammad, C. (2017, April). Advancing the Village to Build Healthy Families. Poster presentation; Peer reviewed.

Medical College of Wisconsin, Community-Engagement Week Conference, Milwaukee, WI

Holt, J. M., Zabler, B., Welch, G., Camenga, E. (2016, November). Emerging Trends in Nursing Education. Oral presentation; Peer reviewed, National Nursing Center Consortium Annual Conference, Philadelphia, PA

Zabler, B., & **Holt, J. M.** (2016, November). Data Driven Quality Improvement in a Small Low Resource Nurse-led Clinic. Oral presentation; Peer reviewed, National Nursing Center Consortium Annual Conference, Philadelphia, PA

Holt, J. M., Thompson, G. (2016, May). Teaching Today's Students for Tomorrow's America: An Evaluation of an Interprofessional Education Curriculum; Poster presentation; Peer reviewed. 18th Annual Building Bridges to Research Based Nursing Practice Conference, Milwaukee, WI

Holt, J. M. & Zabler, B. (2015, November). Exploring the impact of a 20-Year health & wellness in a low-income African American community served by a nurse-managed health center. Oral presentation; Peer reviewed, National Nursing Center Consortium Annual Conference, Philadelphia, PA

Holt, J. M., Zabler, B., & Tsai, P. (2015, May). Client experience and satisfaction in nurse managed health centers. Poster presentation; Peer reviewed. 17th Annual Building Bridges to Research Based Nursing Practice Conference, Milwaukee, WI

Holt, J. M., Johnson, T. S., & Zabler, B. (2015, April). Exploring the impact of a twenty-year health promotion program in an African American underserved community: A mixed methods study. Poster presentation; Peer reviewed. Omaha System International Conference, Eagan, MN

Holt, J. M. & Zabler, B. (2014, June). Client Experience and Satisfaction in Nurse-Managed Heath Centers. Oral presentation; Peer reviewed, National Nursing Center Consortium Annual Conference, Alexandria, VA

Holt, J. M., Johnson, T. S., & Zabler, B. (2013, November). An Evaluation of a Culturally Sensitive Lifestyle Modification Program in a Community Nursing Center. Poster presentation; University of Wisconsin Milwaukee, College of Nursing Fall Convocation, Milwaukee, WI

Holt, J. M., Johnson, T. S., & Zabler, B. (2013, September). An Evaluation of a Culturally Sensitive Lifestyle Modification Program in a Community Nursing Center. Poster presentation; Peer reviewed. Wisconsin Health Improvement and Research Partnerships Forum, Madison, WI

Holt, J. M., Johnson, T. S., & Zabler, B. (2013, May). An Evaluation of a Culturally Sensitive Lifestyle Modification Program in a Community Nursing Center. Poster presentation; Peer reviewed. 15th Annual Building Bridges to Research-Based Nursing Practice, Milwaukee, WI

Holt, J. M. & Zabler, B. (2012, November). Evidence-based Characteristics of Nurse-Managed Health Centers for Quality and Outcomes, Oral presentation; Peer reviewed, National Nursing Center Consortium Annual Conference, Philadelphia, PA

INVITED PRESENTATIONS

Holt, J. M. (2019, December). Using patient-generated contextual data to enhance patient activation: Preliminaryresults from a clinical trial, Invited Presentation. Medical College of Wisconsin, Center for Healthy Communities & Research/Academic Fellowship in Primary Care Grand Rounds, Milwaukee, WI

Holt, J. M. (2019, April). Transforming data into Wisdom in Nurse-led community clinics, Invited Presentation. Omaha System International Conference, Eagan, MN

Holt, J. M. (2019, February). Humanizing the Electronic Health Record: Incorporating Context into Care. Vizient: Redefining Patient and Provider Relationships webinar series.

Holt, J. M. (2018, October). Humanizing the patient chart: Becoming more responsive to patient needs in primary care. HRSA NRSA fellow research webinar series: webinar #2.

Holt, J. M. & Morzinski, J. (2018, April). Diffusion of Innovations & Implementation Science: Tools for Organizational Change. Medical College of Wisconsin Graduate School Clinical and Translational Science Program, Dept of Population Health, Course Title: Leadership in Academic Health Care II: Organizations and Change, Milwaukee, WI

Holt, J. M. (2017, April). Transforming Data to Wisdom: Nurse-Led Community Clinics, Omaha System International Conference, Eagan, MN

Holt, J. M. (2017, January). Teaching Today's Students for Tomorrow's America, Center for Healthy Communities & Research, Medical College of Wisconsin, Milwaukee, WI

Holt, J. M. (2016, October). Love Yourself, Holiday Empowerment Class, Capuchin Community Services House of Peace, Milwaukee, WI

Holt, J. M. (2016, September). Research and Scholarship Academy: Scholarship of Writing Workshop, University of Wisconsin-Milwaukee College of Nursing

Holt, J. M. (2016, October). Core Value of Excellence, University of Wisconsin College of Nursing, Milwaukee, WI

Zabler, B., & **Holt, J. M.** (2016, May). The Journey of Practice Transformation in Low-Resource Settings. Invited Oral Presentation; Center for Medicare & Medicaid, Innovation Day: Transforming Clinical Practice Initiative, Baltimore, MD

Holt, J. M. (2015, November). How to Boost Your Immune System, Department of Children & Families Special Needs Program, Milwaukee, WI

Holt, J. M., Kallio, P., & Hartlaub, J. W. (2015, May). Role of the DNP Nurse Plenary Panel Session. Invited Panel Presenter; 17th Annual Building Bridges to Research Based Nursing Practice Conference, Milwaukee, WI

Holt, J. M. (2015, March). Therapeutic Touch Presentation, University of Wisconsin College of Nursing Academic Staff Meeting, Milwaukee, WI

Holt, J. M. (2014, October). Goal Setting for Healthier Living. Holiday Empowerment Class, Capuchin Community Services House of Peace, Milwaukee, WI

Holt, J. M. (2013, October & November). Living Well, Holiday Empowerment Class, Capuchin Community Services House of Peace, Milwaukee, WI

Holt, J. M. (2013, September). Sneezes, Wheezes, Colds, & Flu, Department of Children and Families Special Needs Program, Milwaukee, WI

Holt, J. M. (2013, June). Caring for Mildly Ill Children, Department of Children and Families Special Needs Program, Milwaukee, WI

Holt, J. M. (2012, January-May). Someone to Care for me: 6-Part Educational Series, Department of Children and Families Special Needs Program, Milwaukee, WI

HONORS/AWARDS

Medical College of Wisconsin Department of Family & Community Medicine Community Partnership Award	2018
Sigma Theta Tau International Nursing Honor Society, Eta Nu Chapter 3rd Annual Poster Symposium 2017, 2nd place Award, University of Wisconsin-Milwaukee Milwaukee, WI	2017
Sigma Theta Tau International Nursing Honor Society, Eta Nu Chapter Mentorship Award, University of Wisconsin-Milwaukee	2016
15th Annual Building Bridges to Research-Based Nursing Practice, 1st Place Research Poster Award, Milwaukee, WI	2015
Graduate School Chancellor's Award, University of Wisconsin-Milwaukee	2010 & 2011
Milton and Joan Morris Graduate Scholarship, University of Wisconsin-Milwaukee	2003
Advanced Education Nurse, University of Wisconsin-Milwaukee College of Nursing Traineeship	2004-05

Magnum Cum Laude, Winona State University 1997
Sigma Theta Tau International Nursing Honor Society, Winona State University Chapter 1997
Vice-President, Minnesota Nursing Student Association, Winona State University Chapter 1996-97
Dean's List, Winona State University 1995-97

UNIVERSITY SERVICE

University of Wisconsin-Milwaukee
Academic Staff Awards Committee 2017-2020
University of Wisconsin-Milwaukee – College of Nursing
Committee for Practice and Partnership 2019-2022
Committee for Practice and Partnership, Co-Chair 2019-2020
Community-Engaged Health Research Scientific Focal area, Chair 2015-2019
Community-Engaged Health Research Scientific Focal area, Member 2013-2019
Doctor of Nursing Practice Task Force, Member 2015-Present
Committee for Practice and Partnership, Member 2013-2016
Committee for Practice and Partnership, Partnership Survey *Ad Hoc* Committee, 2015-2016
Working Well Initiative Subcommittee, Academic Policy Committee, 2013-2017
Practice Committee, Community Nursing Centers 2013-2017
Quality Improvement Committee, Community Nursing Centers 2012-2017

DNP ADVISOR

M. D., DNP Student University of Wisconsin-Milwaukee, College of Nursing 2018

DNP COMMITTEE MEMBER
D. V., DNP Student University of Wisconsin-Milwaukee, College of Nursing 2017
J. R., DNP Student University of Wisconsin-Milwaukee, College of Nursing 2017
M. K., DNP Student University of Wisconsin-Milwaukee, College of Nursing 2017
L. M., DNP Student University of Wisconsin-Milwaukee, College of Nursing 2016
A. B., DNP Student University of Wisconsin-Milwaukee, College of Nursing 2016
G. P., DNP Student University of Wisconsin-Milwaukee, College of Nursing 2015

DNP COMMITTEE MENTOR

A. M., DNP Student University of Wisconsin-Milwaukee, College of Nursing 2017
C. Z., DNP Student University of Wisconsin-Milwaukee, College of Nursing 2015

PROFESSIONAL SERVICE

2019 Omaha System International Conference: A Key to Practice, Documentation, and Information Management, Planning Committee 2019
20th Annual Building Bridges to Research-Based Nursing Practice Conference, Planning Committee, UWM College of Nursing Representative 2018
Our City of Nations II: Supporting Refugees and Recent Immigrants Conference, Planning Committee 2017
19th Annual Building Bridges to Research-Based Nursing Practice Conference, Planning Committee, UWM Representative 2017
Standards of Excellence, Wisconsin Association of Free & Charitable Clinics, Advisory Panel 2016-2017
2017 Omaha System International Conference: A Key to Practice, Documentation, and Information Management, Planning Committee 2017
Omaha System Board Member 2016-Present

Metro Milwaukee Nurse Practitioners, Board President	2016-2017, 2018-2019
Metro Milwaukee Nurse Practitioners, Board President-Elect	2015-2016, 2017-2018
Metro Milwaukee Nurse Practitioners, Board Past President	2017-2018, 2019-2020

PROFESSIONAL ORGANIZATIONS

Midwest Nursing Research Society	2017-Present
Society of General Internal Medicine	2017-Present
Metro Milwaukee Nurse Practitioners, Member	2005-08, 2015-Present
National Organization of Nurse Practitioner Faculties, Member	2014-Present
National League for Nurses	2014-Present
Sigma Theta Tau International Honor Society of Nursing – Eta Nu Chapter	1997-Present
Community-based Research Network for the Clinical and Translational Science Institute of Southeastern WI, Member	2012-Present
American Nurses Association, Member	2003-Present
Wisconsin Nurses Association, Member	2003-Present
American Academy of Nurse Practitioners, Member	2003-Present
Wisconsin Public Health Research Network, Member	2019-Present

JOURNAL REVIEWER

Nursing Outlook
Western Journal of Nursing Research
Journal of Patient Experience

CERTIFICATION/LICENSE

American Nurse Credentialing Center	Family Nurse Practitioner	2005-Present
Wisconsin Department of Safety And Professional Services	Advance Practice Nurse Prescriber	2005-Present
Wisconsin Department of Safety And Professional Services	Registered Nurse	1997-Present
BLS Healthcare Provider-American Heart Association		1997-Present