

Optimizing the Collection and Use of Patient-Generated Health Data

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ABSTRACT

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This dissertation aims to examine the collection and use of digital patient-generated health data (PGHD) in real-world settings, including existing barriers from the perspectives of patients and healthcare providers, and possible approaches to optimizing the process. In Chapter One, the potential of PGHD to improve health and wellness, particularly for individuals with chronic conditions, as well as known barriers to PGHD collection and use, are described. One chronic condition in particular, atrial fibrillation (AF), is then introduced as a use case for PGHD. Chapter Two contains an integrative review synthesizing findings from eleven studies reporting patients' and providers' needs when collecting and using PGHD, and identifying convergence and divergence between needs. Chapter Three contains a quantitative evaluation of sustained engagement, currently a major barrier to collection of PGHD, in a group of adults self-monitoring AF, as well as predictors and moderators of engagement that come from an adapted version of the Unified Theory of Acceptance and Use of Technology (UTAUT). These individuals were previously enrolled in the randomized, controlled trial, the iPhone® Helping Evaluate Atrial Fibrillation Rhythm through Technology (iHEART). In Chapter Four, the adapted UTAUT model is explored in more detail through a qualitative investigation of sustained engagement with patients, healthcare providers, and research coordinators involved in the iHEART trial. Chapter Five summarizes the findings of this dissertation, including strengths and limitations, and elicits implications for the intersection of health policy and clinical practice, design, nursing, and future research from the findings.

Table of Contents

List of Tables	vi
List of Figures	vii
Acknowledgements	ix
Funding	x
Dedication	xi
Chapter One: Introduction	1
Chronic Disease Burden in the United States	1
Patient-Generated Health Data (PGHD)	3
The Promise of Patient-Generated Health Data (PGHD)	3
Challenges to Collecting and Using PGHD	5
AF as a Use Case for PGHD	7
The iHEART Trial	9
Institutional Review Board Approval	11
Theoretical Framework	11
Unified Theory of Acceptance and Use of Technology	11
Dissertation Aims and Organization	14
Conclusion	16
Chapter Two: Converging and Diverging Needs between Patients and Providers who are	
Collecting and Using Patient-Generated Health Data: An Integrative Review	18
Abstract	18
Background and Significance	19

Objective	21
Methods.....	21
Information Sources and Search strategy	21
Eligibility Criteria	22
Data Screening, Extraction, and Synthesis	23
Methodological Quality Assessment of Studies	23
Data Extraction and Qualitative Synthesis	24
Results.....	25
Search Results.....	25
Risk of Bias.....	27
Characteristics of Included Studies.....	29
Characteristics of PGHD in Included Studies.....	34
Qualitative Synthesis	35
Discussion	45
Convergence and Divergence of Perspectives	45
Sustained patient engagement as a major barrier.....	46
Significance of this review.....	46
Implications for policy and design.....	47
Conclusion	48
Chapter Three: A Theory-Driven Exploration of Factors Associated with Sustained ECG Self-Monitoring in a Post-Intervention Atrial Fibrillation Population	49
Abstract	49
Background and Significance	50

Objectives	53
Methods.....	53
Study Design and Sample	53
Data sources and Measures	55
Data Analysis	58
Results.....	60
Description of the Sample.....	60
Description of AliveCor™ Use	62
Heart Rhythm Data collected with AliveCor™.....	62
Simple Linear Model of Association between Time (Week) and AliveCor™ Use.....	64
Predictors of AliveCor™ use.....	65
Final Parsimonious Model	67
Moderation Effects.....	68
Discussion	69
Conclusion	73
Chapter Four: Factors Influencing Sustained Engagement with ECG Self-Monitoring:	
Perspectives from Patients and Healthcare Providers.....	74
Background and Significance	75
Objectives	77
Methods.....	77
Theoretical Model.....	77
Study Design and Sample	78
Recruitment and Data Collection.....	79

Data Analysis	79
Results	80
Description of the Sample and Overall Engagement	80
Factors Associated with Engagement in the adapted UTAUT Model.....	82
New Findings	88
Discussion	89
Summary of Findings.....	89
Fit With the Adapted UTAUT Model.....	90
Relationship to Prior Work	91
Implications for Design.....	92
Implications for Research	94
Conclusion	95
Chapter Five: Conclusions	97
Summary of Results and Key Findings	97
Chapter Two.....	97
Chapters Three and Four.....	98
Themes from the Findings of this Dissertation.....	101
Limitations and Strengths	104
Implications.....	105
Implications at the Intersection of Clinical Practice and Health Policy	105
Implications for Design.....	108
Implications for Nursing	114
Implications for Future Research.....	116

Conclusion	118
References	119
Appendices.....	134

List of Tables

Table 1.1: <i>Dissertation Chapters, Manuscript Titles, and Aims Addressed</i>	14
Table 2.1: <i>Risk of bias for 11 studies based on criteria from the Mixed Methods Appraisal Tool (Pluye & Hong, 2014)</i>	28
Table 2.2: <i>Studies reporting evidence on patient and provider needs regarding patient generated health data</i>	30
Table 2.3: <i>Claims Generated from Qualitative Synthesis*</i>	36
Table 2.4: <i>Synthesis of claims according to theme and user group</i>	41
Table 3.1: <i>Summary of Sample Characteristics (n=132)</i>	61
Table 3.2: <i>Descriptive statistics of the study participants' AliveCor™ use over one year (n=132)</i>	62
Table 3.3: <i>The number and percentage of ECG transmissions collected by participants over the one-year period in sum and stratified by rhythm type identified by the Kardia® algorithm</i>	63
Table 3.4: <i>Estimates and Person-Time Incidence Rate Ratios of associations between variables in the adapted UTAUT model and AliveCor™ Use over One Year</i>	66
Table 3.5: <i>Parsimonious Model of Associations between variables in the adapted UTAUT model and AliveCor™ Use over One Year with Person-Time Incidence Rate Ratios</i>	68
Table 3.6: <i>Person-time Incidence Rate Ratios of Associations between Interactions of variables in the adapted UTAUT model with Time (Week) and AliveCor™ Use over One Year</i>	69
Table 4.1: <i>Design Options for Sustained Patient Engagement guided by the Adapted UTAUT Model</i>	94
Table 5.1: <i>Summary of existing mHealth design options and system requirements with potential to address the needs expressed by patient and providers regarding PGHD</i>	109

List of Figures

Figure 1.1. AliveCor mobile ECG monitor and smartphone application	10
Figure 1.2. The Adapted Unified Theory of Acceptance and Use of Technology (UTAUT) model targeting ECG mHealth Technology used in this dissertation.....	12
Figure 2.1. Flow Diagram of Study Selection Process	26
Figure 3.1: The Adapted UTAUT model.....	53
Figure 4.1. The Adapted UTAUT model.....	78
Figure 4.2. Trajectories of engagement among iHEART participants interviewed in this study .	82
Figure 5.1. The Adapted UTAUT Model	99

List of Appendices

Appendix A: Published Version of Chapter Two Manuscript.....	134
Appendix B: Table of Variables from the Adapted UTAUT Model used in the study in Chapter Three	147
Appendix C: iPhone® Helping Evaluate Atrial Fibrillation Rhythm through Technology (iHEART) Trial Surveys providing data for the study in Chapter Three	148
Appendix D: Interview/ Focus Group Guides used in data collection in the study in Chapter Four	156
Appendix E: Illustrative Quotes from Participants in the study in Chapter Four	158

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Dedication

This dissertation is dedicated to the nurses in my life who embody the most exceptional elements of the nursing profession with their hard work, fierce patient advocacy, and endless appetite for learning. My aunts, Catherine McLoughlin and the late Jane Kern; my nursing colleagues at NYU Langone, especially Celeste Turchioe; my good friends from Boston College Connell School of Nursing; and my mentors at Columbia University School of Nursing. You are a daily inspiration.

Chapter One: Introduction

Chapter one outlines the organization and background of this dissertation. It begins by describing the public health burden of chronic disease in the United States and the potential for patient-generated health data (PGHD) to improve management of chronic disease. Barriers to collecting and using PGHD in practice are then discussed, with a focus on engagement with mobile health (mHealth) technologies used to collect PGHD. Subsequently, one chronic disease in particular, atrial fibrillation (AF), is highlighted as a use case for PGHD. Then, the theoretical model utilized in this research will be described. Finally, the plan for three separate manuscripts and their respective aims that comprise this dissertation will be summarized. The first manuscript (Chapter Two) was published in the Journal of the American Medical Informatics Association. The second manuscript (Chapter Three) is planned for submission to the Journal of Cardiovascular Nursing. The third manuscript (Chapter Four) is currently under review at Applied Clinical Informatics. Together these papers report on PGHD collection and use in real-world settings and reveal possible design options for optimizing the process, especially with regards to sustained patient engagement.

Chronic Disease Burden in the United States

Chronic diseases are the most common and costly of all health problems. There are 150 million individuals living with at least one chronic disease in the United States (U.S.), and more than 100 million have more than one (Buttorff, 2017). These individuals account for 90% of all healthcare spending in the U.S. (Buttorff, 2017; CDC, 2016). An estimated seven out of ten deaths are caused by chronic disease (CDC, 2016). Furthermore, the number of adults with multiple chronic diseases is increasing, and the more chronic diseases an individual has, the more frequent and costly their care is (Buttorff, 2017). Adults 65 years of age and older are

disproportionally affected by chronic diseases with prevalence rates greater than 80% in this population. In addition, chronic diseases are more common among non-Hispanic whites (63% prevalence) and non-Hispanic blacks (58% prevalence) than among Hispanics and other race/ethnic groups (Buttorff, 2017). However metabolic syndrome, a cluster of conditions that increases the risk of chronic conditions including heart disease, stroke, and diabetes, is higher in Hispanics (Heiss et al., 2014).

Chronic diseases may last for years or even decades of a person's life. An individual's daily decisions regarding diet, physical activity, medication adherence, and other behaviors all impact the long-term trajectory of a chronic disease (CDC, 2016; Milani, Bober, & Lavie, 2016). Self-monitoring is a critical component of effective chronic disease self-management because it allows changes in health status to be addressed in a timely manner, thereby reducing the risk of hospitalization, complications, and in some cases, death (Lasorsa et al., 2016; Milani et al., 2016). In fact, currently many evidence-based guidelines for specific chronic diseases recognize self-monitoring as an important component of disease management (CDC, 2016; January et al., 2014; Lasorsa et al., 2016). Effective self-monitoring requires real-time data on health status and behaviors, and ongoing health professional facilitation of the patient as they self-monitor (Milani et al., 2016; Shaw, Bonnet, Modarai, George, & Shahsahebi, 2015).

However the healthcare structure in the U.S. only affords individuals with chronic diseases periodic visits with healthcare providers that leave little to no time for self-monitoring data to be reviewed (Gee, Greenwood, Paterniti, Ward, & Miller, 2015; Milani et al., 2016). Additional barriers to self-monitoring are limited health literacy and inadequate communication with providers (Bauer, Thielke, Katon, Unutzer, & Areal, 2014). There is a clear need for more frequent and comprehensive support of individuals living with chronic diseases that addresses

these modifiable barriers (e.g., health literacy, communication) (Bauer et al., 2014). Furthermore, there is a need for this care to be personalized due to the complex combinations of behavioral, environmental, and biological factors that influence the trajectory of chronic diseases (Lavalley et al., 2016).

Patient-Generated Health Data (PGHD)

The Promise of Patient-Generated Health Data (PGHD)

Mobile health (mHealth) technologies, which capitalize on the popularity, affordability, and sophistication of smartphones and other mobile devices, are increasingly being recognized as a tool that may improve management of chronic disease (Ali, Chew, & Yap, 2016; Bonoto et al., 2017). In the U.S. 89% of adults report owning a smartphone and the average user checked their smartphone 46 times per day in 2015 (Deloitte, 2015; Pew, 2017). In addition, smartphone use is reportedly similar across socioeconomic groups and geographic locations (Garabedian, Ross-Degnan, & Wharam, 2015). Thus, there is potential for individuals from diverse backgrounds who may be medically underserved to benefit from mHealth technologies. Examples of mHealth include health applications (apps), wearable devices, and other connected health monitors.

mHealth can be used to push health education, notifications, and data to patients (Bhavnani, Narula, & Sengupta, 2016). Individuals can also use mHealth to digitally collect health data about themselves, creating what is known as *patient-generated health data (PGHD)*. This is longitudinal, high frequency health-related data recorded by a patient or caregiver outside of clinical settings to address a health concern (Wood, Bennett, & Basch, 2015). Patient-reported outcomes (PROs) are a structured form of PGHD (Howie, Hirsch, Locklear, & Abernethy, 2014). Self-monitoring and the generation of PGHD is not new but previously was limited to paper-based documentation shared with providers at discrete time points. The increasing

availability of smartphones and mobile devices in recent years has allowed for self-monitoring data to be continuously recorded, stored, and transmitted to healthcare providers digitally.

Digital PGHD has the potential to improve information exchange between patients and providers, increase patient satisfaction, and enhance the provider's overall understanding of the patient (Arsoniadis et al., 2015; Lavalley et al., 2016). Moreover, patients report improved understanding of their disease and factors that contribute to it because they are able to collect and visualize their data more efficiently with digital technologies (A. E. Chung & Basch, 2015; Howie et al., 2014). Though still in its nascent stages, there is already some evidence of PGHD improving health outcomes. A recent systematic review of individuals with diabetes using mHealth technology to self-manage, which included collecting and using digital PGHD, found a significant improvement in hemoglobin A1c, a marker of diabetes control (Greenwood, Gee, Fatkin, & Peeples, 2017).

In recognition of the value of digital PGHD, a series of recent policy efforts are prioritizing the exchange of PGHD between patients and providers by way of the electronic health record (EHR). In 2015, the Office of the National Coordinator of Health Information Technology (ONC) began a ten-year project to develop a patient- and provider-centered policy framework for sharing PGHD (HealthIT.gov, 2016). Patients may soon be able to view, download, and transmit their health data to the EHR as part of Stage 3 of the Health Information Technology Certification Criteria for Meaningful Use (MU3) and the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA) (HealthIT.gov, 2015). Additionally, the Precision Medicine Initiative has prioritized funding projects that integrate new forms of health data, including PGHD, into the EHR (NIH, 2018).

Finally, in 2018 the Centers for Medicare and Medicaid Services (CMS) initiated changes to healthcare provider reimbursement that incentivized review of PGHD (CMS, 2017a).

Challenges to Collecting and Using PGHD

Despite aligning efforts to support the collection and use of PGHD, barriers to implementation in clinical practice remain. Differences in methods of measuring and collecting data between patients generate concerns about data quality (Lavallee et al., 2016). Compliance with privacy and confidentiality regulations of patient data (e.g., Health Insurance Portability and Accountability Act, or HIPAA) is variable between mHealth apps and devices, and developers may not fully understand or comply with these regulations (A. E. Chung & Basch, 2015). Current clinical workflows are not designed to accommodate PGHD, and questions of reimbursement, time, staffing, roles, and scope of practice have yet to be fully answered (Howie et al., 2014). Furthermore, few institutions have successfully integrated PGHD into the EHR (Kumar, Goren, Stark, Wall, & Longhurst, 2016; Lobelo et al., 2016). While a lack of EHR integration limits the utility of PGHD in clinical settings, efforts to advance EHR integration are complicated by interoperability requirements and concerns about data quality and security (A. E. Chung & Basch, 2015; Kumar et al., 2016).

One major problem affecting the utility of PGHD is high rates of abandonment among patients who are self-monitoring (ONC, 2016). Studies measuring self-monitoring over an extended period of time show that many patients who are using mHealth to self-monitor discontinue use within three to six months of initiation, suggesting that patients are not engaged in the process for a sustained period of time (Coa & Patrick, 2016; Glasgow et al., 2011; Mattila et al., 2013). The length of time that mHealth users must sustain engagement with the technology is pre-specified depending on the ultimate goal of use (K. Anderson & Emmerton, 2015; Goyal

et al., 2016). For individuals living with one or more chronic diseases, the potential health benefits of self-monitoring are unlikely to be immediate or obvious, but rather manifested in long-term successes (e.g., improved overall wellness and reduced risk of complications) (Chouvarda, Goulis, Lambrinoudaki, & Maglaveras, 2015; Milani et al., 2016).

Therefore longitudinal data collection for individuals with chronic diseases is often more valuable than brief, discrete periods of monitoring, because trends and correlations between factors that may affect chronic diseases over time can be uncovered (Kevin Anderson, Burford, & Emmerton, 2016). However, longitudinal data collection is only possible if patients remain engaged with self-monitoring for a sustained period of time. Furthermore, part of the promise of PGHD is that both the provider and the patient collaboratively learn from their data about how best to manage the disease. Therefore patient engagement with self-monitoring is a necessary precursor for patients to be engaged in their care overall (Gee et al., 2015; Milani et al., 2016). Finally, sustained engagement is arguably the most urgent of barriers to PGHD being utilized in clinical practice because all other barriers are distal to sustained engagement; they rest on the assumption that PGHD is being collected in the first place (ONC, 2016).

Little is known about personalized approaches to improve sustained engagement. Much of the existing literature on user engagement focuses on strategies to improve initial uptake rather than sustained engagement (Ford et al., 2015; Lasorsa et al., 2016). The few studies that have examined sustained engagement have focused almost exclusively on mHealth features, such as gamification and incentives, rather than intrinsic qualities of the user (King et al., 2013; Shimada, Allison, Rosen, Feng, & Houston, 2016). These approaches have largely failed to sustain user engagement. A promising alternative approach is focusing on individual user characteristics that may predict sustained engagement. Previous studies have demonstrated that

individual characteristics, such as age and disease status, affect sustained engagement with mHealth (Mattila et al., 2013; Muessig, Baltierra, Pike, LeGrand, & Hightow-Weidman, 2014; Pavliscsak et al., 2016). This is supported by focus group findings suggesting that control over mHealth features, context provided with health data, and data shared with healthcare providers would improve sustained engagement (Horvath, Alemu, Danh, Baker, & Carrico, 2016; Miyamoto, Henderson, Young, Pande, & Han, 2016). These reported factors demonstrate the need for mHealth technologies to be personalized.

Because systems to collect and display PGHD are still evolving, now is the optimal time to incorporate patient and provider feedback into iterative design processes (Peres, Pham, & Phillips, 2013). Nurses in particular have a major opportunity in clinical and research settings to help develop PGHD-integration systems and incorporate both the patient's voice and provider's perspective into them (Hull, 2015). Two core areas of nursing informatics work are: (1) the development of approaches for presenting and retrieving information, and (2) leading the development, design, and implementation of health information technologies (AMIA, 2009). As patient advocates, PGHD can be a tool for patient empowerment, and will be increasingly importantly to all nurses.

AF as a Use Case for PGHD

The studies in Chapters Three and Four focus on one specific chronic condition, atrial fibrillation (AF), as a use case for PGHD. AF is the most common cardiac arrhythmia encountered in clinical practice, affecting between 2.7 and 6.1 million people in the U.S. (CDC, 2015). Prevalence estimates vary enormously due to difficulty detecting AF in "real world" settings. Current approaches for detecting and managing AF typically include brief (24-72 hours) electrocardiogram (ECG) monitoring and prescheduled health visits (Turakhia & Kaiser, 2016).

These approaches are inadequate given the sporadic, unpredictable nature of the arrhythmia, so that AF often goes undetected and thus untreated (Olgun Kucuk, Kucuk, Yalcin, & Isilak, 2015; Turakhia & Kaiser, 2016). Failure to detect and treat AF can lead to heart failure, myocardial infarction, stroke, and death (Olgun Kucuk et al., 2015). As such, AF represents a major public health problem, accounting for more than 750,000 hospitalizations, 130,000 deaths, and \$6 billion in costs each year (CDC, 2015). Innovative methods that integrate real world approaches and utilize advances in technology for monitoring and detecting AF in real time are needed to facilitate timely treatment and prevent adverse cardiovascular outcomes, hospitalization, and death.

Mobile health technology (mHealth) represents a major opportunity to assist AF patients with self-management. Electrocardiogram (ECG) mHealth technology, such as the AliveCor™ device, allows individuals with AF to easily record and transmit an ECG to their healthcare provider for review using a device that works with smartphones. Studies have demonstrated that this technology can accurately detect and identify arrhythmias such as AF (McManus et al., 2016; Steinhubl et al., 2016). The SEARCH-AF study found that use of this technology in community settings was both cost-effective and feasible (Lowres et al., 2014). This indicates that the technology is mature enough for real world integration in the community. ECG mHealth technology has the potential to assist patients with AF through timely detection of AF episodes. Timely detection is needed to restore normal sinus rhythm earlier, improve disease management through medication and lifestyle adjustments, and reduce health risks of AF such as hospitalization, stroke, or death (Olgun Kucuk et al., 2015; Steinhubl et al., 2016). For these reasons, timely detection may also facilitate improved quality of life and reduced public health burden of AF (Olgun Kucuk et al., 2015; Steinhubl et al., 2016). Furthermore, individuals with

AF perceive a need for ECG mHealth technology. In a recent survey, most individuals living with a cardiac condition, such as AF, reported a need for technology-based support to increase health knowledge, decrease travel and accessibility restraints, and better utilize peer support (Disler RT, 2015).

Sustained engagement with self-monitoring via ECG mHealth technology is a critical issue for individuals with AF. The goal of ECG mHealth technology is to better detect and treat AF episodes in a timelier manner (Steinhubl et al., 2016; Turakhia & Kaiser, 2016). However AF is spontaneous, unpredictable, and most likely to recur in the first six months after an intervention to restore normal sinus rhythm (Heidenreich et al., 2016; January et al., 2014). Therefore, users of ECG mHealth technology must sustain engagement for at least six months after restoration of normal sinus rhythm for AF to be detected and treated in a timely manner (Steinhubl et al., 2016). Furthermore, individuals living with AF are unique and differ from the general population (Heidenreich et al., 2016). There is a need to understand the unique characteristics of individuals with AF to improve understanding on sustained engagement in this population. Understanding individual user characteristics that influence sustained engagement will facilitate the development of personalized approaches to mHealth-based self-management.

The iHEART Trial

The iPhone® Helping Evaluate Atrial Fibrillation Rhythm through Technology trial (iHEART) is a single-center, randomized, controlled trial (RCT) supported by the National Institute of Nursing Research (NINR; R01NR014853). It is a five-year trial that began in 2014 (Hickey et al., 2016). Planned enrollment in the iHEART trial is 300 individuals (to date all 300 have been enrolled) with a history of AF who have undergone an intervention to restore normal sinus rhythm in the last 30 days. Inclusion criteria in the original iHEART trial are English or

Spanish speaking, age 18 or older, and have a history of AF in the last 30 days for which treatment successfully restored normal sinus rhythm. Exclusion criteria are documented permanent or chronic AF, and patient found to be unstable or have other arrhythmias on day of enrollment.

Participants are randomized 1:1 to receive usual cardiac care or usual care plus the iHEART intervention for six months. Participants randomized to the iHEART intervention receive an AliveCor™ Heart Monitor (Figure 1.1) and iPhone® (if they do not own one) preloaded with the accompanying Kardia® application. They are asked to transmit ECGs at least once daily using the technology for six months. Through a separate application, intervention arm participants also receive personalized behavioral altering motivational (BAM) text messages three times per week targeting their individual cardiac risk factors, but do not need to reply to text messages.

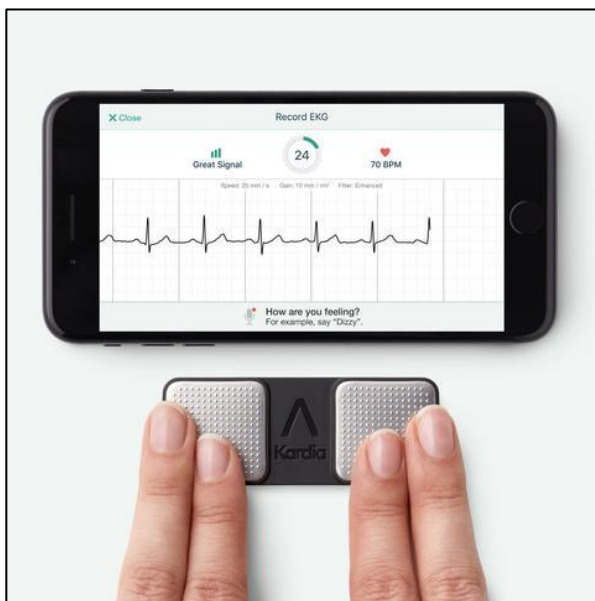


Figure 1.1. AliveCor mobile ECG monitor and smartphone application

Data from the patient's EHR and validated surveys is collected for six months. Validated surveys inquire about quality of life, AF knowledge, symptoms, and experience using ECG

mHealth technology. Actual technology use is documented in the form of time-stamped, dated ECGs recorded using the AliveCor™ device, and stored in a HIPPA-compliant, encrypted, and secure AliveCor™ database. The primary endpoint of the iHEART trial is detection of AF recurrence. Secondary endpoints are treatment changes resulting from AF detection, changes in survey scores, and improvement in clinical cardiac measurements (i.e., weight, blood pressure) and AF knowledge from baseline to six months. As the iHEART trial nears completion, there is a need to determine the real-world utility of PGHD collected with the AliveCor™ device and integrated in everyday clinical practice to improve outcomes.

Institutional Review Board Approval

This study obtained approval from the Institutional Review Board at Columbia University Medical Center (CUMC, Protocol AAAO2555).

Theoretical Framework

Unified Theory of Acceptance and Use of Technology

The studies in Chapters Three and Four were guided by an adapted version of the Unified Theory of Acceptance and Use of Technology (UTAUT) model (Figure 1.2).

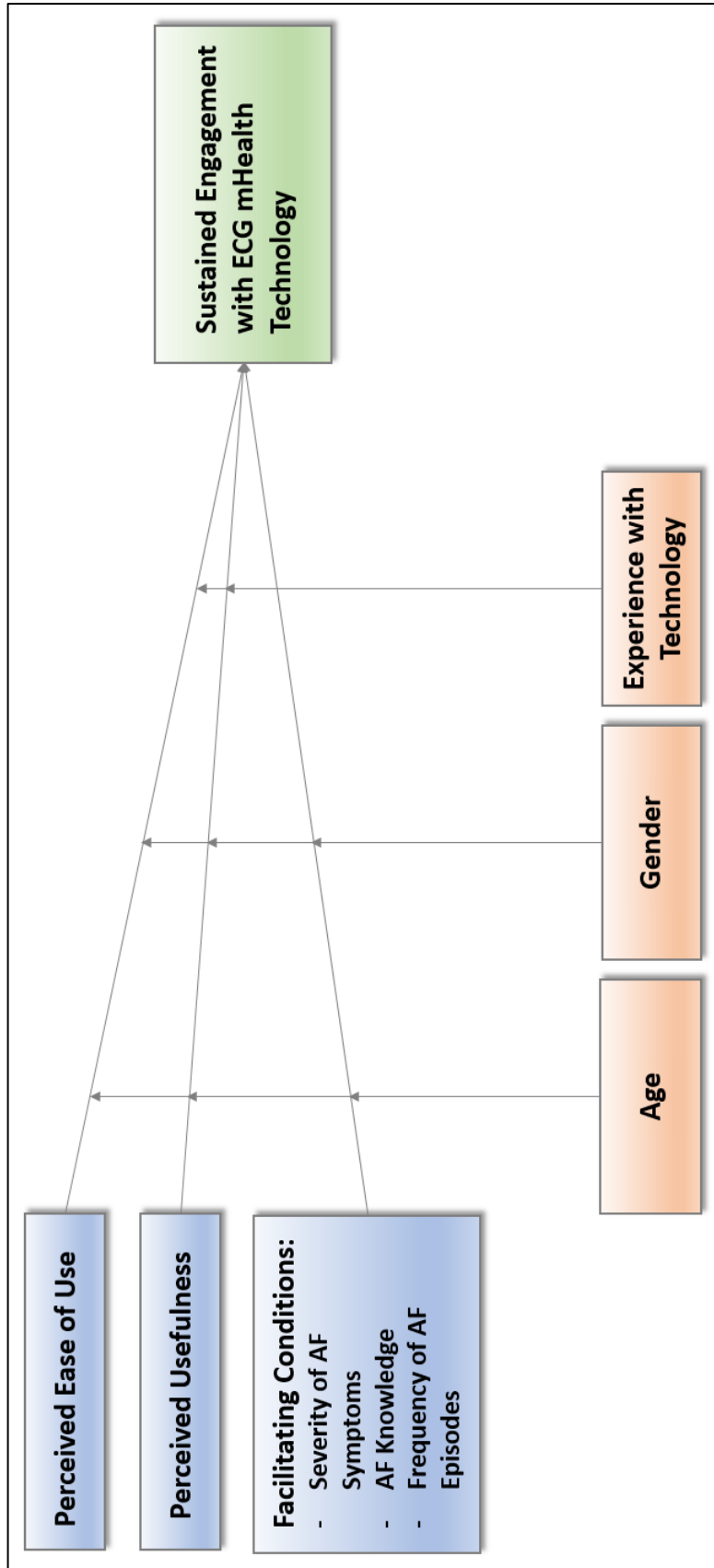


Figure 1.2. The Adapted Unified Theory of Acceptance and Use of Technology (UTAUT) model targeting ECG mHealth Technology used in this dissertation

Venkatesh et al. first developed the UTAUT model in 2003 by combining elements from eight models and theories of behavior change and technology acceptance, including the theory of reasoned action, the technology acceptance model, and the theory of planned behavior.

Validation of the model demonstrated that it explains variation in technology acceptance and use better than its component models ($R^2 = 0.69$ compared to 0.17-0.53). The UTAUT model has been used extensively to understand technology acceptance and use in non-healthcare settings, such as education, banking, and 3G mobile communication (Attuquayefio & Addo, 2014). The model has begun to appear in healthcare research settings in recent years. One study has used UTAUT in ECG monitoring in a community-dwelling cardiac population (Lin, Wong, & Tseng, 2016). However this study measured technology acceptance but not sustained engagement.

Recently, UTAUT was adapted to explain sustained engagement with mHealth technology for lung transplant recipients after surgery (Jiang, Sereika, Dabbs, Handler, & Schlenk, 2016). The adapted UTAUT model validated by Jiang et al. (2016) will be used in this dissertation because it predicts sustained engagement (Figure 1.2). It includes three predictors of sustained engagement: (1) perceived usefulness, (2) perceived ease of use, and (3) facilitating conditions. It also includes three moderating factors: (1) age, (2) gender, and (3) experience with technology. Jiang et al. (2016) included intention to use technology as a predictor of sustained engagement. This predictor was omitted from the adapted UTAUT model that is used in this dissertation because data on actual technology use is available from the parent iHEART study.

The facilitating conditions predictor can be operationalized differently depending on the population being studied (Attuquayefio & Addo, 2014; Venkatesh, Morris, Davis, & Davis, 2003). Based on the facilitating conditions included by Jiang et al. (2016) and the variables

available from the parent iHEART study, the facilitating conditions used in this dissertation are:

(1) severity of AF symptoms, (2) frequency of AF episodes, and (3) AF knowledge.

Dissertation Aims and Organization

This dissertation is comprised of three manuscripts that comprise the next three chapters.

The manuscript title and aims of each chapter are presented in Table 1.1.

Table 1.1: *Dissertation Chapters, Manuscript Titles, and Aims Addressed*

Chapter	Title	Aim
2	Converging and Diverging Needs described by Patients and Providers that collect and use Patient-Generated Health Data: An Integrative Review	1. Identify (a) needs of both healthcare providers and patients concerning the collection and use of digital PGHD and (b) identify areas of convergence and divergence between them.
3	A Theory-Driven Exploration of Factors Associated with Sustained ECG Self-Monitoring in a Post-Intervention Atrial Fibrillation Population	2. Evaluate engagement with ECG mHealth technology among adults with AF over one year, as well as predictors and moderators of sustained engagement.
4	Factors Influencing Sustained Engagement with ECG Self-Monitoring: Perspectives from Patients and Healthcare Providers	3. Explore (a) individual patient differences in sustained engagement among adults with AF who are collecting and using PGHD, and (b) potential approaches for improving sustained engagement.

Chapter Two is an integrative review that synthesizes the needs of patients and healthcare providers when collecting and using PGHD. Specifically, this reviewed aimed to identify convergent and divergent patient and provider needs in using PGHD in real-world settings (Aim 1). This provides a baseline understanding of facilitators and barriers to PGHD collection and use, and set the stage for understanding one major problem in particular, sustained engagement.

In the study described in Chapter Three, factors from the adapted UTAUT model were quantitatively tested to determine their relationship to sustained engagement in a population of patients collecting and using PGHD for AF management. This study aimed to evaluate engagement with ECG mHealth technology among adults with AF over one year, as well as predictors and moderators of sustained engagement (Aim 2). It is a secondary data analysis of AliveCor™ usage data and surveys from 132 adults with AF who participated in the intervention arm of the iHEART randomized controlled trial. Hierarchical generalized linear models (HGLM) were used to evaluate engagement, as well as predictors and moderators of engagement that came from the adapted UTAUT model.

In the study described in Chapter Four, factors in the adapted UTAUT model were further explored, as were additional factors related to sustained engagement that were not included in the adapted UTAUT model. Qualitative focus groups with providers and patients utilizing PGHD for management of AF were conducted to substantiate the quantitative findings with further insight on factors that may contribute to sustained engagement with ECG mHealth technology in this population, but that may not have been measured or fully understood in the quantitative analysis. Specifically, the focus group guides aimed to elicit: (1) individual patient differences in sustained engagement among adults with AF who are collecting and using PGHD, and (2) potential approaches for improving sustained engagement (Aim 3). Qualitative data was analyzed using directed content analysis, which allowed the adapted UTAUT model to guide exploration of concepts that emerge from the data.

Together these papers report on multiple aspects of motivation and barriers to the collection and use of PGHD by both patients and providers, and identify potential approaches for optimizing the process.

Conclusion

The research aims to find ways to optimize the process of PGHD collection and use for both patients and providers by identifying their common needs and potential approaches to meet these needs. A review of the needs of patients and providers who are collecting and using PGHD is presented in Chapter Two. Currently, a major barrier to PGHD collection is patient sustained engagement with self-monitoring. Therefore, sustained engagement is studied in detail in the studies described in Chapters Three and Four.

The implications of understanding factors associated with sustained engagement are the potential to increase use of point-of-care self-monitoring devices, improve self-management of AF, and optimize the positive health outcomes resulting from use of mHealth technology. The findings of this research suggest design options for systems that collect and display PGHD in general (Chapter Two) and specifically such that patient sustained engagement is optimized (Chapters Three and Four). Given the continued popularity and availability of mHealth technologies among patients and recent policy changes that incentivize healthcare providers to review PGHD (CMS, 2017a), the findings of this research will continue to be disseminated to peer-reviewed journals in a timely manner.

Additionally, the findings will be presented at conferences in biomedical informatics, cardiology, and nursing, including the American Medical Informatics Association (AMIA) and American Heart Association (AHA) annual scientific sessions. Preliminary findings on iHEART trial participants' AliveCor™ usage patterns and the influence of AliveCor™ use on cardiac endpoints have been presented at the AHA 2017 Scientific Sessions, Eastern Nursing Research Society 2018 Scientific Sessions, and Heart Rhythm Society 2018 Scientific Sessions, and an abstract has been published in the journal *Circulation* (M. Reading, Biviano, Mitrani, & Hickey,

2017). In sum, findings from this research provide insights into real-world approaches for improved management of chronic conditions such as AF, as well as potential strategies to optimize user engagement with mHealth applications over an extended period of time.

Chapter Two: Converging and Diverging Needs between Patients and Providers who are Collecting and Using Patient-Generated Health Data: An Integrative Review

The study in Chapter Two addresses the first aim of the dissertation in an integrative review that examines convergent and divergent areas of need for collecting and using patient-generated health data (PGHD) identified by patients and healthcare providers. The final manuscript was accepted for publication in the Journal of the American Medical Informatics Association (JAMIA) on January 29, 2018 (doi: 10.1093/jamia/ocy006). The published version is included in Appendix A.

Abstract

Objective: This integrative review identifies convergent and divergent areas of need for collecting and using patient-generated health data (PGHD) identified by patients and providers (i.e. physicians, nurses, advanced practice nurses, physician assistants, and dietitians).

Materials and Methods: A systematic search of nine scholarly databases targeted peer-reviewed studies published after 2010 that reported patients' and/or providers' needs for incorporating PGHD in clinical care. The studies were assessed for quality and bias with the Mixed-Methods Appraisal Tool. The results section of each article was coded to themes inductively developed to categorize patient and provider needs. Distinct claims were extracted and areas of convergence and divergence identified.

Results: Eleven studies met inclusion criteria. All had moderate to low risk of bias. Three themes (clinical, logistic, and technological needs) and 13 subthemes emerged. Forty-eight claims were extracted. Four were divergent and twenty were convergent. The remainder was discussed by only patients or only providers.

Discussion: In examining patients' and providers' needs concurrently, the findings demonstrate interplay between patients' and providers' needs. Patients need feedback and reassurance, and providers need to manage the flow of PGHD in their clinical practice. Convergent needs may serve as the basis for an initial set of requirement specifications for information systems that satisfy both users. Divergent needs highlight the necessity of incorporating transparency and strategies for patients and providers to communicate about the PGHD process.

Conclusion: As momentum gains for integrating PGHD into clinical care, this analysis of primary source data is critical to understanding the needs of the two groups directly involved in collection and use of PGHD.

Background and Significance

As of January 1, 2018 the Centers for Medicare and Medicaid Services (CMS) initiated policy changes that will incentivize and reimburse healthcare providers for reviewing and interpreting patient-generated health data (PGHD), which is expected to accelerate adoption and use of these data in clinical practice (CMS, 2017a, 2017b). PGHD is a term to describe “health-related data... created, recorded, gathered, or inferred by or from patients or their designees (e.g., care partners or those who assist them) to help address a health concern” (Wood et al., 2015). Key features of PGHD are: (a) the patient, not the healthcare provider, captures the data, (b) the data are obtained outside of clinical settings, and (c) the data are both longitudinal and capable of being collected at high-frequency intervals. Patient-reported outcomes (PROs) are considered a controlled form of PGHD, typically consisting of structured data elements captured at discrete intervals (Howie et al., 2014).

Increasingly PGHD are collected and stored digitally via ubiquitous smartphone applications (apps), connected devices, and cloud-based platforms (C. F. Chung et al., 2016;

Howie et al., 2014; Lavalley et al., 2016; Shaw et al., 2015). PGHD produces not only information and knowledge to support clinical decision-making for individual health care providers, but also a context for those decisions (A. E. Chung & Basch, 2015; Shaw et al., 2015). For instance, knowledge of circumstances external to a patient's clinical situation may call for adjustments to therapeutic decisions made by any provider within a health care team (e.g. physicians, nurses, advanced practice nurses, physician assistants, and dietitians). Current evidence on the clinical benefit of PGHD is sparse but emerging as technology and policy provide the means to incorporate it into clinical practice (Greenwood et al., 2017; Lai, Hsueh, Choi, & Austin, 2017; Lv et al., 2017).

On a policy level, digital PGHD may contribute to healthcare quality by augmenting the type, amount, and detail of health information exchanged between patients and providers (Bauer et al., 2014; Chouvarda et al., 2015). Healthcare costs associated with unnecessary office visits and hospitalizations may decrease when patients share PGHD by allowing the provider to proactively manage illnesses and prevent complications (Howie et al., 2014). Patients with previous barriers to healthcare for cost- or location-related reasons may now exchange health information more easily and affordably with providers because mobile device ownership is prevalent across diverse populations (Bauer et al., 2014; Howie et al., 2014; Lavalley et al., 2016).

The U.S. Office of the National Coordinator for Health Information Technology (ONC) has identified the value and existing challenges for patients and providers regarding PHGD, and called for evidence-based strategies to facilitate its adoption and use (ONC, January 2018b). An understanding of PGHD from the patient and provider perspectives is needed to align concurrent policy efforts that aim to incorporate PGHD into clinical care, such as the Medicare and

Medicaid Electronic Health Record Incentive Programs Stage 3 and Modifications to Meaningful Use (MU3), and the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015 (MACRA) (ONC, January 2018b).

Objective

A synthesis of the evidence regarding patient and provider needs for information systems that incorporate PHGD can inform their optimal development (Lavalley et al., 2016; Woods, Evans, & Frisbee, 2016). To our knowledge there is no review that examines empirical evidence on the needs of the two primary users of PGHD. Therefore, the aims of this integrative review are to (1) summarize needs of both healthcare providers and patients concerning the collection and use of digital PGHD and (2) identify areas of convergence and divergence between them. The review follows procedures and recommendations detailed by Whittemore and Knafl (2005).

Methods

Information Sources and Search strategy

Nine scholarly databases (Pubmed, Scopus, Applied Science, Medline, PsycINFO, Science Direct, CINAHL, Cochrane and ACM Digital Library) were searched in November 2016 using the terms: "Patient generated health data," "Patient generated data," "Patient reported outcome(s) [AND] digital," "Patient reported data [AND] digital," and "Self-monitoring data." Search terms were determined in consultation with a biomedical librarian and two experts engaged in research involving PGHD, and iteratively by examining key words in retrieved publications. Patient reported outcomes (PROs) are a type of patient-generated health data, which in some cases are recorded digitally (Forsberg et al., 2015; Howie et al., 2014). Therefore PROs were included in the search terms for thoroughness. No filters or additional search criteria were applied. Scopus was searched for grey literature using the same terms. An inspection of

reference lists from retrieved articles identified any relevant publications not obtained through the database search.

Eligibility Criteria

Publications were evaluated against the following criteria: (a) documented patients' or providers' needs, (b) PGHD was used in a "real world" rather than study setting, (c) addressed any type of digital PGHD collected for any health-related purpose (e.g. chronic disease management, post-operative monitoring, etc.), and (d) any study design (qualitative, quantitative, or mixed-methods). Exclusion criteria were: (a) published prior to 2011, (b) not a peer-reviewed article, (c) non-digital PGHD, (d) PGHD not used in "real world setting" and clinical workflow and (e) not reporting patients' and/or providers' perspectives. We define workflow as "a modular sequence of tasks, with a distinct beginning and end, performed for the specific purpose of delivering clinical care" (HealthIT.gov). Studies with samples of only patients or only providers were included provided they met other inclusion criteria.

The specification of "digital" data was thought to automatically exclude older studies, so publication year search filters were not initially applied. However this approach retrieved several studies published between 1980 and 2010 reporting on now obsolete technology. The publication date criterion was added in acknowledgement of the rapid development of patient- and provider-facing health information technology within the past five years. Unlike non-electronic (e.g., verbal or written) information generated by patients, digital PGHD can be collected with greater frequency and detail and computationally summarized. These features present unique opportunities and challenges, which are the focus of this review.

Data Screening, Extraction, and Synthesis

Two reviewers used Covidence, a Cochrane technology platform, to select eligible studies from the pool of retrieved records ("Covidence systematic review software," 2016). Covidence automatically removes most duplicate records. The reviewers removed any missed duplicate records. Then the reviewers screened titles and abstracts against the inclusion/exclusion criteria. Full texts of the records included were rescreened using the same criteria. Any discrepancies between the reviewers were discussed and resolved.

Methodological Quality Assessment of Studies

Quality was evaluated with the Mixed Methods Appraisal Tool (MMAT) (Pluye, Gagnon, Griffiths, & Johnson-Lafleur, 2009), which is specifically designed for concomitantly appraising quantitative, qualitative, and mixed-methods research. MMAT was chosen for its ability to produce comparable scores across study designs (Pace et al., 2012; Pluye et al., 2009), with highly reliable inter-class correlations (ICC) ranging from 0.84 to 0.94 (Johnston et al., 2016; Mey et al., 2016; Tretteteig, Vatne, & Rokstad, 2016).

The MMAT consists of two initial screening questions and subsequent question sets that are specific to the study design (quantitative; qualitative; or mixed-methods). The screening questions identify studies for which further appraisal may not be feasible or appropriate (e.g. no clear research question.) Studies failing either or both screening questions do not proceed to domain-specific appraisal. Domain-specific questions number four for qualitative studies and four questions for each of the three quantitative study designs (randomized controlled, non-randomized, or descriptive). Mixed-methods studies are evaluated using both the qualitative and appropriate quantitative study questions. There are three additional questions specific to mixed-methods studies. The quality appraisal score is determined by dividing n criteria met by N

criteria in each applicable domain. Scores are typically converted to percentages for comparison across studies (Pace et al., 2012; Pluye et al., 2009). Following this protocol, two reviewers (M.R., J.M.) independently appraised and calculated scores for each study. As in the earlier stage, discrepancies between the reviewers were discussed and resolved.

Data Extraction and Qualitative Synthesis

The goals of data analysis in integrative reviews are first, to provide an unbiased and complete interpretation of primary source data, and second, to critically synthesize this data (Whittemore & Knafl, 2005). The primary author (M.R.) reviewed and extracted relevant characteristics from each study including: sample characteristics, setting, context, PGHD collected, HIT used, study design, data collection methods, data analysis methods, and study findings.

Both reviewers (M.R., J.M.) analyzed the quantitative and qualitative data using a general inductive approach to develop a unified response to the objectives of the integrative review. The steps include: (1) data reduction, (2) data display, (3) data comparison, (4) conclusion drawing and verification (Whittemore & Knafl, 2005). During data reduction, text containing the qualitative and/or quantitative findings was excerpted from each article and combined into a single corpus. The primary author (M.R.) coded this text using a general inductive approach in which codes were developed, consolidated if warranted, and then organized into a hierarchy. From this process, a set of thematic axes emerged. The second reviewer (J.M.) independently coded 50% of the records using this preliminary schema with the freedom to identify new or alternative codes. Alternative codes were discussed until consensus was reached on a final coding schema, which was used for inter-rater reliability calculation. To further distill the findings for subsequent comparison, both reviewers revisited the coded text to identify distinct

expressions of a need related to PGHD, which they extracted in the form of declarative statements, or “claims.” NVivo Version 11.4.1 (QSR International, Inc., Burlington, MA) was used to code the data and calculate inter-rater reliability.

Second, a table of findings was created to display the data and visualize claims according to the coding theme/sub-theme and patient/provider perspectives on each claim. Third, the claims were reviewed and discussed to determine the presence of patterns and relationships. The perspectives of individual claims were reviewed and discussed to evaluate if the viewpoints expressed were convergent, divergent, or identified by only patients or only providers. Finally, each declarative claim was verified with primary source(s) to ensure accuracy. Specifically, the primary author (M.R.) mapped the claims back to the theme they were originally coded under, and both reviewers participated in reordering or consolidating claims if warranted.

Results

Search Results

A total of 996 records were retrieved from nine databases (Figure 2.1). Removal of duplicate records (n=274) left 722 articles for the title/abstract screening. During title/abstract screening, 644 records were excluded for: publication date prior to 2011 (n=356), not peer-reviewed (n=122), not digital PGHD (n=86), and not about integrating PGHD into clinical workflow (n=80). A full text screening of 78 remaining records excluded 67 for: reporting neither patient nor provider perspective (n=37); not digital PGHD (n=17); and not about integrating PGHD into the clinical workflow (n=13). A total of 11 records were accepted for review (Cheng, Hayes, Hirano, Nagel, & Baker, 2015; C. F. Chung et al., 2016; Cohen et al., 2016; Hartzler, Izard, Dalkin, Mikles, & Gore, 2016; Hochstenbach, Zwakhalen, Courtens, van Kleef, & de Witte, 2016; Huba & Zhang, 2012; Kummerow Broman et al., 2015; Lind, Carlgren, & Karlsson, 2016; Nundy, Lu, Hogan, Mishra, & Peek, 2014; Sanger et al., 2016; Thompson &

Valdez, 2015). The provider perspectives covered in these records included physicians, nurses, advanced practice nurses, physician assistants, and dietitians.

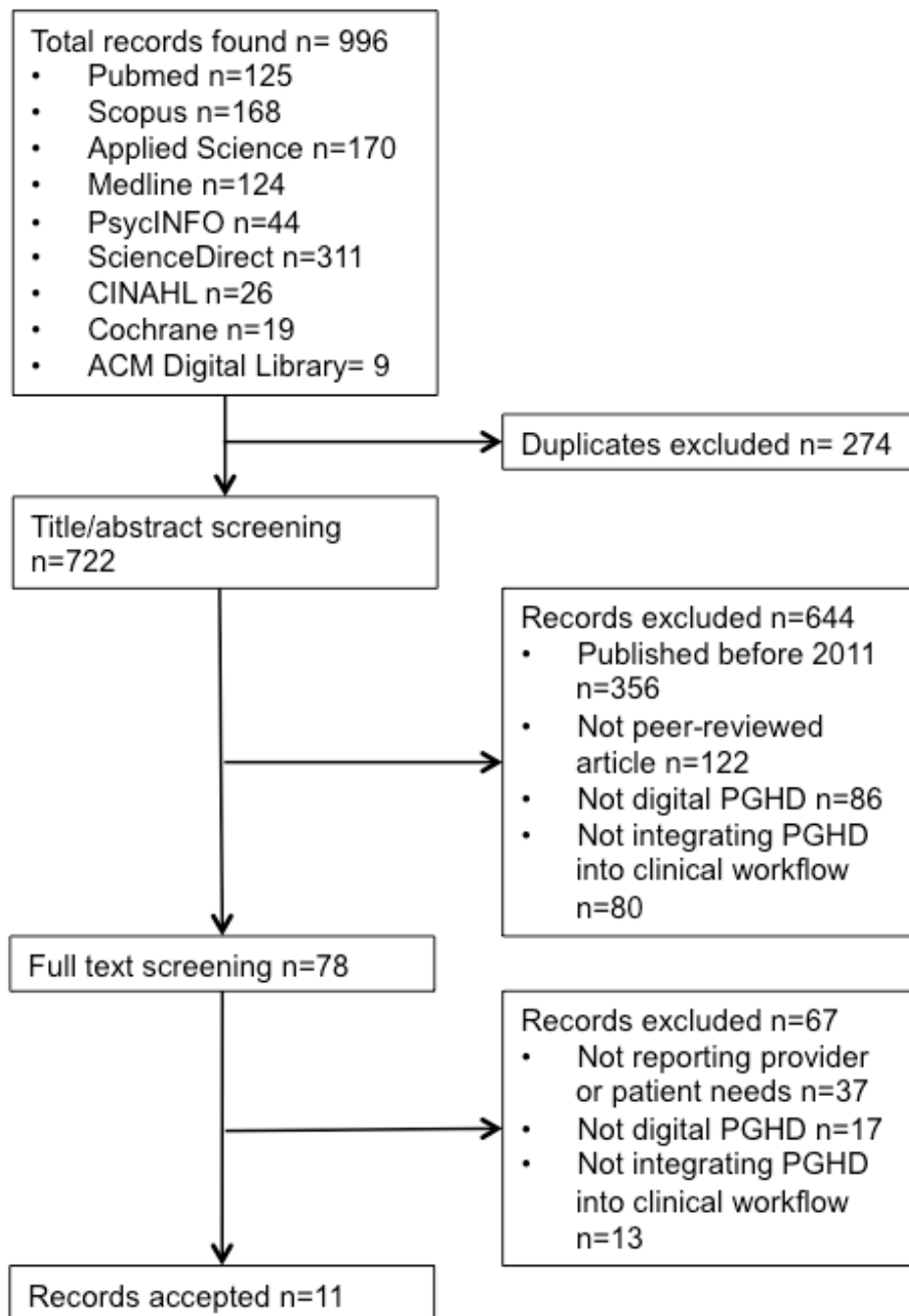


Figure 2.1. Flow Diagram of Study Selection Process

Risk of Bias

Quality appraisal results of the four qualitative and seven mixed-methods studies are summarized in Table 2.1.

Table 2.1: Risk of bias for 11 studies based on criteria from the Mixed Methods Appraisal Tool (Pluye & Hong, 2014)

Domain	Criterion	Cheng, 2015*	Chung, 2016	Cohen, 2016*	Hartzler, 2015	Hochstenbach, 2016	Huba, 2012*	Kummerow Broman, 2015	Lind, 2016	Nundy, 2014	Sanger, 2016*	Thompson, 2015
Screening questions	Clear research questions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Data adequate to address research questions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Qualitative	Relevant data sources	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓
	Relevant data analysis methodology	✓	✗	✓	✗	✓	✓	✗	✗	✓	✗	✓
	Consideration to setting of data collection	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Consideration to researchers' influence	✗	✓	✗	✗	✗	✓	✗	✗	✓	✓	✓
	Relevance of sampling strategy	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✗
Quantitative descriptive	Representative sample	✓	✓	✗	✗	✗	✓	✓	✓	✗	✓	✓
	Validated measures	✗	✓	✓	✓	✓	✓	✗	✗	✗	✓	✗
	Acceptable response rate (60% or above)	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mixed-methods	Appropriateness of mixed-methods design	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Adequate integration of quantitative and qualitative data	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Consideration to divergent quantitative and qualitative findings	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Total Scores	5/6	10/13	5/6	10/13	11/13	6/6	8/13	10/13	11/13	5/6	11/13
	Percentages	83%	77%	83%	77%	85%	100%	62%	77%	85%	83%	85%

*These studies had qualitative designs and were only evaluated with qualitative domain questions.

Qualitative studies received five to six of six possible points, and the mixed-methods studies received eight to eleven of thirteen possible points. When converted to percentages, studies scored from 62% to 100%. Studies lost points in the qualitative domain for claiming a specific method (e.g., grounded theory) but describing data analysis inconsistent with that method, or for failing to acknowledge, or “bracket,” their interaction with study participants as a potential source of bias. Studies lost points in the quantitative domain for sampling strategies that introduced bias, or surveys not psychometrically validated.

Characteristics of Included Studies

The characteristics of 11 studies are summarized in Table 2.2.

Table 2.2: Studies reporting evidence on patient and provider needs regarding patient generated health data

#	Author (year)	Method and design	Participants	n	Setting/ Context	Focus	Tool	PGHD collected	PGHD user	Outcomes
1	Cheng 2015	Qualitative Interviews Observation	MDs, RNs, RDs Patients	15 35	Post discharge Neonatal Intensive Care Unit	Follow-up of clinically “high-risk” infants	Estrellita: a mobile and web-based system for monitoring and supporting development of high-risk infants	Infant diaper usage, weight, behaviors, milestones, complications, attendance at infant medical appointments	Providers	Provider experiences and reflections Actual provider use of PGHD
2	Chung 2016	Mixed-Methods, descriptive Surveys Interviews	MDs, APRNs, RDs Patients (mean age 44)	21 18 inter-view 211 survey	University health system and a health maintenance organization	Data sharing practices	Investigates general perspectives, no specific tool	Investigates general perspectives, no specific PGHD	Patients Providers	Expectations, concerns re: actual and potential PGHD collection and use
3	Cohen 2016	Qualitative Semi-structured interviews	MDs, RNs Resear- chers*	12 13	Evaluation of 5 projects funded by RWJF Project Health Design	(1) asthma (2) elders at risk for cognitive decline (3) overweight young adults (4) people living w/ Crohn’s disease (5) caregivers of premature infants	mHealth apps and passive sensors used to collect PGHD; Summary sheets and web-based portals used to share data with providers	Medications Physiological data (peak expiratory flow, weight) Passive sensor data (physical activity, task completion), Self-reports on mood, behavior, diet, symptoms	Patients Caregivers Providers	Challenges, benefits, and general experiences of using PGHD

4	Hartzler, 2015	Mixed-Methods, descriptive Surveys Semi-structured interviews	MDs Male patients	50 50	Academic medical center	Prostate cancer; long term follow-up of patient status post treatment	Web-based dashboard displaying PGHD over time compared to similar patients based on age and treatment plan	Health-related quality of life; urinary, bowel, sexual symptoms	Patients Providers	Patient self-efficacy Satisfaction Communication Compliance w/ quality indicators Helpfulness of visualizations Experience using PGHD
5	Hochstenbach, 2016	Mixed-Methods, descriptive Surveys Usage Data Semi-structured interviews	RNs Patients	3 11	Outpatient oncology clinic Feasibility study of PGHD-based intervention	Self-management of pain for home-dwelling cancer patients	Mobile and web-based application for collecting and reviewing PGHD, patient education, and messaging provider	Pain level, adverse effects, pain interference with sleep or activity, satisfaction with pain treatment, medication adherence	Providers	Learnability, usability, desire to use app to collect PGHD Adherence (usage data) General experiences using PGHD
6	Huba, 2012	Qualitative Semi-structured interviews	MDs, RNs	21	Large hospitals and outpatient clinics	Clinical practice	Investigates general perspectives (no specific tool)	Investigates general perspectives (no specific PGHD)	Providers	Current or theoretical use of PGHD
7	Kumrow Broman, 2015	Mixed-Methods, descriptive Surveys with open and close ended questions	MDs Patients	5 50	Surgical outpatient clinic Pilot study of PGHD-based intervention	Post-operative follow-up of patients post laparoscopy for cholecystectomy; hernia repair (ventricular, umbilical, or inguinal)	Patient portal for collecting and viewing PGHD, messaging provider	Symptoms survey, wound photos	Patients Providers	Acceptance of PGHD Use of PGHD Visit times of online (PGHD-based) versus in-person clinic visits

8	Lind, 2016	Mixed-Methods, descriptive Surveys with open and close ended questions Usage data	Patients	14	Hospital-based homecare clinic at an academic hospital Pilot study of PGHD-based intervention	Home-based management of patients with severe heart failure	Anoto™ digital pen-and-paper technology linked to a web-based application for receiving and storage PGHD	Responses to health diary forms (symptoms and medications) and physiological measurements (blood pressure, heart rate, oxygen saturation, weight)	Providers	Experience using PGHD Actual usage of app to collect PGHD
9	Nundy 2014	Mixed-Methods, descriptive Semi-structured interviews Surveys	MDs	12	Outpatient management program affiliated with an academic medical center Feasibility and utility study of PGHD-based intervention	Diabetes (type I or II) self-management	CareSmarts: automated text messaging, Text-back responses to record PGHD; viewed by providers in summary sheet	Medication adherence, glucose monitoring adherence, barriers to diabetes self-management, progress on CareSmarts educational modules	Providers	Usability Helpfulness Influence on care Willingness to use General experiences and reflections

10	Sanger 2016	Qualitative Semi- structured interviews	MDs, APRNs, PAs, RNs Patients	11 13	Outpatient surgical clinic affiliated with an academic medical center Design of tool to collect and display PGHD	Post- operative surgical site infection monitoring in patients with a prior history of surgical site infections	mPOWER: mobile Post- Operative Wound Evaluator: application for collecting PGHD and viewing PGHD, and messaging	Longitudinal detailed symptom data, wound photos, miscellaneous free-text data entry	Patients and providers	General experience using PGHD Feedback on mockups of different systems to collect/ display PGHD
11	Thompson 2015	Mixed- Methods, descriptive	Patients	87	Web-based survey	Patient mHealth use	Investigates general perspectives (no specific tool)	Investigates general perspectives (no specific tool)	Patients	Preferences and experiences collecting/using PGHD for self and for provider

MD= physicians, RN= registered nurses, APRN= advanced practice registered nurses, PA= physician assistants, RD= registered dietitians

*These participants spoke about the patients' and/or providers' experiences collecting and using PGHD in the study

Six studies included both patients and provider participants (Cheng et al., 2015; C. F. Chung et al., 2016; Hartzler et al., 2016; Hochstenbach et al., 2016; Kummerow Broman et al., 2015; Sanger et al., 2016). Two included participants who were not patients or providers but were closely involved with them during the study period and could speak to their perspectives (Cohen et al., 2016; Sanger et al., 2016).

Providers included physicians (surgeons, primary care physicians, specialists), nurses, advanced practice nurses, physician assistants, and dieticians. Their mean clinical experience ranged from 7 to 17 years. Patients' mean ages ranged from 44 to 71 years old and gender breakdown ranged from 30% to 100% male. The study settings ranged from large, academic medical center to outpatient clinic. Eight of the 11 studies examined a specific tool to collect and use PGHD being tested. Qualitative data collection involved individual semi-structured interviews, open-ended survey questions, and observations. Quantitative data was collected through surveys and application usage reports.

Characteristics of PGHD in Included Studies

The characteristics of PGHD in the eight studies that tested an actual data tool are summarized in Table 2.2. PGHD included physiological, self-report, and passive sensor data targeting a wide range of clinical problems. PGHD was collected in a mobile format and/or through web-based platforms. Some tools allowed both patients and providers to visualize data while others only had a provider view. PGHD collection included manual entry into an application, automated entry from connected devices, photographs taken with digital cameras or mobile phones, text messaging, and a proprietary pen-and-paper technology. In five studies providers were the only intended users of PGHD, even if patients or their caregivers could view

the data. In these five studies, patients were reportedly not acting upon their data but deferring to the provider's interpretation of it.

Qualitative Synthesis

Qualitative synthesis results are provided in Tables 2.3 and 2.4.

Table 2.3: *Claims Generated from Qualitative Synthesis**

Claim	Explanation (Source)
Clinical sub-theme: Effect of PGHD on the patient-provider relationship	
PGHD can enhance the working relationship between patients and providers.	Patients reported PGHD involved them in their care, and informed providers of their day-to-day experience.(2,8)
PGHD can facilitate provider monitoring.	A significant positive correlation ($r = 0.79$) was observed between frequency of abnormal PGHD and patient-provider communication.(8)
Patient emotional needs can be met by providing PGHD.	Examples of emotional needs include empathy for symptoms and praise for progress.(2,3)
PGHD can worsen the patient-provider relationships.	Communication, thoroughness and rapport were lost when review of PGHD was substituted for clinic visits; it is not a substitute for “face-to-face” with providers.(7,11)
Clinical sub-theme: Contextual metadata is helpful for patients and providers	
PHGD not directly pertaining to a clinical problem, or “contextual metadata,” can be valuable for understanding the relevant PGHD.	For patients, value was in provider understanding their daily life, comorbidities, and anxieties.(2,10) For providers value was in decision making supported by contextual metadata: patient goals, moods, experiences, behaviors, perceptions, and quality of life.(1,6,9)
Contextual metadata can be used for decision making to improve care.	As in the case of a pediatrician who received images of babies on a scale to convey weight data, and incidentally noted signs and symptoms that prompted follow up. (1)
Providers may want access to PGHD collected for other purposes or for other providers.	Especially for conditions that are rare or that transcend specialties, such as psychiatric disorders, to facilitate referrals and communication with colleagues.(1,6)
PGHD has value in emergency situations.	When no one can provide a medical history. One provider said, “Something’s better than nothing.”(6)
Clinical sub-theme: Patients need guidance	
Patients need training and support before collecting PGHD.	Patients lack understanding of how to take health-related measurements and record them, leading them to incorrectly report their data. (5) One patient said, “I don’t trust myself... I don’t know what to look for.”(7,8)
Patients need help interpreting their data.	Patients need to identify trends and correlations in their data to interpret in context of average values.(2,4) Providers can guide patients on which data are/are not significant (with a goal of patient independence).(2,4,10)
Providers can leverage PGHD for health education and counseling.	For example, one provider noticed a patient non-adherence to calorie requirements and used the data to reinforce education on calorie counting and weight management.(2)
Patients may want providers to constantly monitor their PGHD to dispel their doubts.	Patients may distrust their own ability and/or the ability of software algorithms to detect abnormal data.(4,10,11) Patients react positively to the idea of multiple providers monitoring (e.g. nurse, physician, and pharmacist), e.g., “someone looking over your shoulder every day.”(5)

Clinical sub-theme: Providers need guidance	
PGHD is not customary in current provider workflows. Providers need protocols to guide their responses to PGHD.	For instance one nurse described an algorithm her group practice devised to categorize PGHD into acuity “zones” each with corresponding actions.(3)
Providers may have questions about their role when responding to PGHD.	A nurse said, “At times I’m not sure... What is allowed? When do I intervene? ... What does the treating physician want? When do I interfere and take over care?”(3)
Providers have legal and ethical concerns about receiving PGHD that is outside of their scope of practice.	Patients may not be aware of the scope of a provider’s expertise, both in terms of clinical specialty and provider type (RN, MD, etc.). Providers are concerned that once they receive the data, they are responsible for it.(1,2,10)
Providers may need to delegate data management.	Providers delegate when they don’t have the knowledge or experience to manage data themselves.(2,10)
Logistic sub-theme: Motivation and incentives	
Patients and providers can lose motivation to collect and use PGHD.	They are motivated to collect and use PGHD when it saves time (e.g., not missing work, fewer office visits) and is easy, but not when the process is distracting, time-consuming, or inconvenient.(7,9,10,11)
Patient motivation can wane if benefits from self-monitoring are not immediate.	Providers recognized this and reported trying to help patients see value in collecting PGHD even if benefits were not immediate.(2,11)
Patient motivation to collect PGHD can increase with peer and provider support.	However fear of being “judged” by peers or providers can decrease motivation.(2,11)
Provider motivation to review PGHD can improve with incentives.	Examples of incentives include saved time and financial reimbursement.(2,7,10)
Providers’ current clinical workflows and incentive structures reduce their motivation to review PGHD.	Providers lost motivation because they felt the work that went unrecognized and was not billable. (2,10) One provider said the incentive structure “has a perverse, mixed message: collect the data but you don’t have time to do it.” (2)
Logistic sub-theme: Time	
Providers need to make time for PGHD data review.	Practices varied greatly; some providers continuously monitored PGHD, some reviewed before a patient visit, and some only reviewed during the visit. Some providers resorted to evenings and weekends to catch up on data review.(1,2)
Providers need methods to reduce the time burden for PGHD review.	Alerts when at-risk patients generate abnormal data (1,10), and brief summary reports (9,10) were two reportedly successful methods to reduce the burden for providers.
Providers have concerns about liability and the risk of “information overload.”	They feel they need to negotiate with patients on data received. They saw this as a fluid process of negotiating data elements based on the patients’ evolving status.(1,2,10)
Logistic sub-theme: Transparency	
Patients have concerns about how their data is used, re-used and how extensively it might be shared.	This concern is exacerbated by use of mHealth apps for which privacy and confidentiality standards can vary enormously.(2,11)

Patients want a timely response (e.g., within 4 hours) while providers fear a requirement for rapid response may disrupt workflows and care of other patients.	When patients were unaware of the provider response process they are anxious: “Because sometimes you’re just sitting there waiting . . . and it’s like God, what am I supposed to do?” (10) Providers wanted patients to have “realistic expectations of how available I am to them.” (10)
Providers need to manage patient expectations regarding the review process.	Patients want to know who will review their data and if/when they will be contacted. (10) Many times providers felt communication was only warranted if the data was abnormal. (1,10)
Goals for collecting and using PGHD may be different.	Patients want to indefinitely monitor their health with their provider, while providers aim to empower the patient so that they will transition to more independently monitor. (2,10)
Logistic sub-theme: Patient selection varies by provider	
Providers may need to select a subset of patients from whom to receive PGHD.	Examples of patient subsets included: those whose disease is poorly controlled (3,9), those who are poor historians (9), and those who are at increased risk for complications per an objective risk measure. (10)
Providers may need to encourage all of their patients to self-monitor.	One provider said, “So anyone who has a phone and can text I think . . . let’s use it . . . offer this to anyone who wants to really.” (9)
Technology sub-theme: Customization	
Patients and providers need visualizations to be customizable.	The need the ability to: <ul style="list-style-type: none"> • Vary amount of detail seen (4) • View data in different ways (graphs, tables, etc.) (3,4,5) • Mark-up visualizations with notes and color-coding. (4,5)
Providers need to customize visualizations to save time.	One provider said, “Just going through this much data was going to be so time consuming. [would help if] we could see all the graphs at once, and see if anything correlated.” (3)
Patients can use visualizations to help them make lifestyle adjustments that improve their health condition.	If the visualization didn’t facilitate this type of insight patients often stopped using them. General visualization preferences included charts and line graphs over data tables or pictographs, and data visualized in chronological order. (2,4,5)
Patients may need to customize data entry.	A lack of customizable data entry can discourage patients from self-monitoring and cause non-use, especially for patients who need to track multiple, specific data points, and can lead to errors in data entry. (2,5)
Providers may need customized patient data entry to support clinical decision-making.	Some providers noted that data entry that is too open-ended could cause data to be unnecessarily complex and irrelevant, so they favored some form of structure to “nudge [the patient] in the right direction.” (5,10)

Technology sub-theme: Interoperability/ EHR integration	
Patients and providers need PGHD integrated into existing systems.	There was a strong preference for systems that integrate PGHD to “building on existing technical systems” so that the review process would be streamlined. (3,6,10)
PGHD integrated into existing systems may reduce confusion and frustration.	Commonly providers must use different systems and modes of communication to view and respond to PGHD. Providers become less willing to use PGHD and patient-provider communication about PGHD was increasingly complex when the provider workflow was not streamlined. (2,3,10)
PGHD integrated into existing EHRs could improve care coordination and communication across providers.	Care plans and patient instructions generated by one provider can be viewed and taken into account by other providers caring for the same patient. (1,6)
Technology sub-theme: Data summaries	
Patients and providers need a summary of the data that is rapidly understandable and cues them to action.	PGHD can be complex, heterogeneous, and high frequency. Data summaries that help providers quickly make sense of large amounts of data could save time, inform decision-making, and improve patient care. (4,5,6)
Patients expect data summaries may answer their questions without having to contact their provider.	For instance, longitudinal trends can answer their questions about their progress quickly. (2,4,10)
Patients and providers may not trust automated data summaries.	They reported skepticism about the algorithms used to condense and present PGHD. (2,10,11)
Technology sub-theme: Quality, security, confidentiality	
Patients are confused about whether their PGHD collection is private and confidential.	Patients did not know if the mHealth apps they were using to collect and view PGHD fully complied with privacy and confidentiality regulations. (2,11) One study showed that over 20% of patients were concerned about the privacy and confidentiality of their PGHD.(11)
Providers are concerned about privacy issues with PGHD from minors.	One provider said, “There are some things that when they talk to us about sexually related issues, substance abuse, mental health, after age 12, they’re protected from us talking to their parents about it. There would be a selective bias... about what they enter.” (3)
Providers are concerned about the quality of PGHD.	For instance, photographs in a post-operative wound monitoring study were poor quality or only show part of the wound. (7) In one study 76% of providers worried that patients could incorrectly measure or report PGHD. (6)
Providers need to distinguish data recorded by patients versus by healthcare professionals in other settings.	Objective measurements can be more accurate when recorded by healthcare professionals. (7,9) However patient-reported data (e.g., medication adherence) can be more accurate because there is less pressure to “please the doctor” with answers as there is in face-to-face visits.(9)

Technology sub-theme: Desired additional features vary by patient and provider	
Patients want the option to electronically communicate with providers about their PGHD while providers fear it could compromise the professional relationship.	Patients liked the ability to electronically communicate with their provider for non-urgent questions that would help them understand their health conditions. (1,5) Providers felt text messages and other free-text data would be, “totally disruptive . . . I don’t want that kind of access with patients,” but in one study this perception was more common in physicians than nurses.(10)
Providers need standardized data summaries to reduce the time burden of sifting through PGHD.	They acknowledged that some data types lend themselves to standardization (e.g., blood glucose) while varied and complex data do not (e.g. nutrition data).(2,10)
Providers need standardized definitions of data types.	For instance, “physical activity” can mean any movement or vigorous exercise.(2)

**Sources refer to the numbered studies listed in Table 2.2.*

Table 2.4: *Synthesis of claims according to theme and user group*

Theme	Convergence: Patients and providers identified a need and shared similar perspectives	Divergence: Patients and providers identified a need and held opposite perspectives	Patient identified need	Provider identified need
Clinical	<p>PGHD can enhance the working relationship between patients and providers.</p> <p>PGHD can facilitate provider monitoring.</p> <p>Patient emotional needs can be met by providing PGHD.</p> <p>PGHD can worsen the patient-provider relationships.</p> <p>PHGD not directly pertaining to a clinical problem, or “contextual metadata,” can be valuable for understanding the relevant PGHD.</p> <p>Contextual metadata can be used for decision making to improve care.</p> <p>Patients need help interpreting their data.</p> <p>Providers can leverage PGHD for health education and counseling.</p>		<p>Need training and support before collecting PGHD.</p> <p>May want providers to constantly monitor their PGHD to dispel their doubts.</p>	<p>May want access to PGHD collected for other purposes or for other providers.</p> <p>PGHD has value in emergency situations.</p> <p>PGHD is not customary in current provider workflows. Need protocols to guide responses to PGHD.</p> <p>May have questions about their role when responding to PGHD.</p> <p>Legal and ethical concerns about receiving PGHD that is outside of their scope of practice.</p> <p>May need to delegate data management.</p>

Logistic	<p>Patients and providers can lose motivation to collect and use PGHD.</p> <p>Patient motivation can wane if benefits from self-monitoring are not immediate.</p> <p>Patient motivation to collect PGHD can increase with peer and provider support.</p>	<p>Patients want a timely response (e.g., within 4 hours) while providers fear a requirement for rapid response may disrupt workflows and care of other patients.</p> <p>Providers need to manage patient expectations regarding the review process.</p> <p>Goals for collecting and using PGHD may be different.</p>	<p>Concerns about how their data is used, re-used and how extensively it might be shared.</p>	<p>Motivation to review PGHD can improve with incentives.</p> <p>Current clinical workflows and incentive structures reduce motivation to review PGHD.</p> <p>Need to make time for PGHD data review.</p> <p>Need methods to reduce the time burden for PGHD review.</p> <p>Concerns about liability and the risk of “information overload.”</p> <p>May select a subset of patients from whom to receive PGHD.</p> <p>May encourage all of their patients to self-monitor.</p>
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Technology	<p>Patients and providers need visualizations to be customizable.</p> <p>Patients can use visualizations to help them make lifestyle adjustments that improve their health condition.</p> <p>Patients may need to customize data entry.</p> <p>Providers may need customized patient data entry to support clinical decision-making.</p> <p>Patients and providers need PGHD integrated into existing systems.</p> <p>PGHD integrated into existing systems may reduce confusion and frustration.</p> <p>PGHD integrated into existing EHRs could improve care coordination and communication across providers.</p> <p>Patients and providers need a summary of the data that is rapidly understandable and cues them to action.</p> <p>Patients and providers may not trust automated data summaries.</p>	<p>Patients want the option to electronically communicate with providers about their PGHD while providers fear it could compromise the professional relationship.</p>	<p>Expect data summaries may answer their questions without having to contact provider.</p> <p>Confusion about whether their PGHD collection is private and confidential.</p>	<p>Need to customize visualizations to save time.</p> <p>Uncertain about privacy issues with PGHD from minors.</p> <p>Providers are uncertain about the quality of PGHD.</p> <p>Need to distinguish data recorded by patients versus by healthcare professionals in other settings.</p> <p>Need standardized data summaries to reduce the time burden of sifting through PGHD.</p> <p>Need standardized definitions of data types.</p>
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Inter-rater reliability between the two coders was acceptable ($\kappa = 0.73$). All coding discrepancies were discussed and resolved.

Three high level themes emerged regarding patient/provider needs: clinical, logistic, and technological (Table 2.3). Thirteen sub-themes also emerged. Clinical sub-themes address patient-provider relationships, contextual metadata, and patient/provider needs for guidance. Logistic sub-themes address motivation and incentives, time, transparency, and provider preferences for patient selection. Technological sub-themes address customization, interoperability/EHR integration, data summaries, quality, security, confidentiality, and variation in features desired by patient/provider. A total of 48 distinct claims were extracted. Claims were grouped under one of the three major themes (16 clinical, 14 logistic, and 18 technological) and appropriate sub-theme (Table 2.3). Each claim was classified as convergent, divergent, or identified by only patients or only providers (Table 2.4).

There are 20 convergent claims in which patients and providers both acknowledge a need and share similar views (8 clinical, 3 logistic, and 9 technological). This includes claims that pertain only to patient or to provider, but that both groups discuss. For instance, in a patient-provider relationship, emotional needs are directly pertinent to the patient, but providers acknowledge that patient emotional needs must be met.

There are 4 divergent claims that both groups discussed from opposing perspectives (0 clinical, 3 logistic and 1 technological). For example, patients want a response to their PGHD within a few hours, while providers fear responding that quickly would disrupt their work.

There are 5 claims identified only by patients (2 clinical, 1 logistic, and 2 technological). There are 19 claims identified only by providers (6 clinical, 7 logistic, and 6 technological).

Discussion

Convergence and Divergence of Perspectives

This integrative review identified three broad themes concerning patient and provider needs around collecting and using PGHD, from 11 primary sources of quantitative and qualitative data. Synthesis of the findings produced a set of 48 distinct claims. Half of the claims (24 of 48) were discussed by one group only, suggesting a mutual unawareness of each other's needs. There were several points of convergence on claims pertinent to one group but acknowledged by the other. For example, patients acknowledged that providers need interoperability and EHR integration, and providers recognized that patients need education and guidance on PGHD collection. This suggests that collection and use of PGHD is a bi-directional relationship: patients and providers are cognizant of at least some of the other's needs and are inextricably linked in the PHGD process. Thus well-designed informatics solutions must include capability for patients and providers to work with PGHD collaboratively, not in isolation.

Unsurprisingly, there were many more instances of providers noticing a patient need than vice versa. This may reflect providers' awareness of patient needs as a clinical skill, and of patients' limited knowledge of provider workflows and clinical practices. For instance, all three claims that referred to time limitations were provider-generated; patients did not specify time as an issue in these 11 studies.

An analysis of points of convergence and divergence found that patients and providers agree more about clinical and technological needs than they do about logistic needs. Our analysis suggests a general tension between patients needing more: more support, more guidance, more feedback on data, and providers needing less: less time burden, less data to review, less liability. There is also a suggestion that underlying anxieties surrounding PGHD and the health problems

for which it is collected are also at odds: patients are anxious to understand their health status, while providers are anxious about the implications of PGHD for their clinical practice, including liability, reimbursement, and time. Finally, the findings suggest that while patients want more flexibility with the data (which providers supported in some cases), providers still need methods for standardizing and limiting the data received.

Sustained patient engagement as a major barrier

Patients indicated that if the data and/or the tools to collect and view it did not meet their needs or produce some immediate benefit, their participation would be dampened or discontinued altogether. This corroborates recent evidence suggesting that sustained engagement with self-monitoring is a critical problem (Alkhaldi et al., 2016; Glasgow et al., 2011; Goyal et al., 2016). There is evidence that certain subsets of patients only collect data because providers ask them, rather than out of a natural curiosity or desire to learn (Dlugasch & Ugarriza, 2014; Lee, 2014). In 5 of the 8 studies that evaluated a tool, the PGHD was intended for provider use only (Table 2.4). As healthcare shifts to a patient-provider collaboration model (A. E. Chung & Basch, 2015; Nundy et al., 2012; Schroeder et al., 2017), research is needed on factors that contribute to sustained patient engagement with the process of collecting and using PGHD.

Significance of this review

Our analysis draws upon prior research that compared the perspectives of patients and providers on PGHD (Cheng et al., 2015; C. F. Chung et al., 2016; Hartzler et al., 2016; Hochstenbach et al., 2016; Kummerow Broman et al., 2015; Sanger et al., 2016), and extends that work by generating an integrated set of needs substantiated by multiple primary sources that may inform system requirements in future work. The findings of this review substantiate findings from a federally-commissioned report which relied on expert opinion (ONC, January 2018b),

with an analysis of primary source data from the two groups directly involved in collection and use of PGHD. Rich primary data from patients and providers offers increased validity and depth of understanding of the technical challenges, policy and reimbursement issues, need for clinical guidelines, and lack of sustained engagement by patients recording PGHD. Furthermore, by analyzing patient and provider needs in relation to each other, points of convergence and divergence emerged. This information may be applied to developing systems to improve the collection and use of PGHD through accommodating the needs of both user groups, thereby potentially increasing the likelihood of success.

Implications for policy and design

Overall the findings suggest that expectations should be set between patients, providers, and other relevant stakeholders (e.g., administrators, reimbursing agencies, technology vendors) from the very beginning of the process—including identifying and reconciling differences in those expectations. Transparency in this process may be an approach to avoid frustration and confusion. Goals for collecting and using PGHD need to be explicit, as our findings illustrate that these can be different. Technology vendors are advised to follow best practices for engaging patients and providers in specifying system requirements for flexibility, standardization, visualizations, messaging, data summarization, and integration before implementing a tool (AHRQ, 2012; HHS, 2017). Administrators can identify and seek to mitigate workflow barriers such as scheduling, role delegation, and scope of practice. Policymakers should analyze current incentive structures for patients and reimbursement for providers. Future research that examines health outcomes and cost-benefit of PGHD compared to standard care can produce the evidence to drive policy towards incentivizing the collection and use of PGHD.

Conclusion

Patients and providers share many common needs when collecting and using PGHD in practice. These needs are clinical (maintain a relationship, data interpretation, contextual metadata), logistic (motivation, negotiation, convenience/usability, and transparent provider roles), and technological (customizable visualizations, flexible data input, electronic integration, simple actionable data summaries, and management of data quality and security concerns). Differences between patients and providers arose in these three main categories as well, mainly centering on patients' needs for reassurance, instruction, and communication with providers, as compared to providers' needs to limit scope of PGHD, standardize it, receive it from only certain patients (in many cases), and have clear clinical guidelines to follow in responding to it.

Patients and providers are the two primary stakeholders directly involved with PGHD collection and use, and their needs in this process are inextricably linked. As momentum gains for PGHD to become fully integrated into the healthcare system, these perspectives are critical to ensure their needs are concurrently being met.

Chapter Three: A Theory-Driven Exploration of Factors Associated with Sustained ECG Self-Monitoring in a Post-Intervention Atrial Fibrillation Population

In Chapter Three, the second aim of this dissertation is addressed in a quantitative secondary data analysis evaluating associations between predictors and moderators from the adapted UTAUT model and use of ECG mHealth technology over one year. The target journal for this manuscript is the Journal of Cardiovascular Nursing.

Abstract

Background: Self-monitoring using electrocardiogram mobile health (ECG mHealth) has the potential to improve detection, treatment, and management of atrial fibrillation (AF). However, there is evidence that sustained engagement with mHealth is low, and little research has examined reasons for low engagement, preventing the benefits of self-monitoring for adults with AF from being realized.

Objective: To describe engagement, as well as predictors and moderators, with mHealth technology among adults with AF during the first year of use.

Methods: We conducted a secondary analysis of data from adults with AF enrolled in the iHEART trial who used ECG mHealth to self-monitor. Hierarchical generalized linear modeling was used to characterize AliveCor™ use, a measure of engagement with mHealth, over one year, and identify possible predictors and moderators of AliveCor™ use that came from an adapted version of the Unified Theory of Acceptance and Use of Technology (UTAUT).

Results: We evaluated 132 adults with AF (mean age 62, 77% male). Subjects who experienced more frequent AF episodes had 87% more AliveCor™ use over one year than those who experienced fewer episodes. Perceived usefulness and AF knowledge were also associated with

AliveCor™ use. We also found evidence of complex relationships between the distinct variables in the adapted UTAUT model.

Conclusions: Patients who can view and understand their own data (as subjects could with “frequency of AF episodes” in this study) may be more engaged with self-monitoring via ECG mHealth technology over time. Due to limitations of secondary data, the complex relationships between variables in the adapted UTAUT model may be better evaluated using data captured at the time of most reliable data, such as during an ECG recording with mHealth.

Background and Significance

Atrial fibrillation (AF) is the most common cardiac arrhythmia encountered in clinical practice, affecting between 2.7 and 6.1 million people in the United States (CDC, 2015). However prevalence estimates vary enormously due to difficulty detecting AF in “real world” settings, and current approaches for detecting and managing AF typically include brief (24-72 hours) ECG monitoring and prescheduled health visits (Turakhia & Kaiser, 2016). These approaches are often inadequate given the sporadic, unpredictable nature of the arrhythmia, so that AF often goes undetected and thus untreated (Olgun Kucuk et al., 2015; Turakhia & Kaiser, 2016). Failure to detect and treat AF can lead to heart failure, myocardial infarction, stroke, and death (Olgun Kucuk et al., 2015). In fact, stroke is one of the most disabling first presentations of undetected AF (Jaakkola et al., 2016). As such, AF represents a major public health problem, accounting for more than 750,000 hospitalizations, 130,000 deaths, and \$6 billion in costs each year (CDC, 2015).

Mobile health technology (mHealth) is a promising approach to detect AF in a timelier manner. As of 2018, 77% of adults in the U.S. own a smartphone and these rates are similar across gender, race/ethnicity, income, and geographic region (Pew, 2018). Timely detection is

needed to restore normal sinus rhythm earlier, improve disease management through medication and lifestyle adjustments, and reduce health risks of AF such as hospitalization, stroke, or death (Olgun Kucuk et al., 2015; Steinhubl et al., 2016). mHealth technologies, such as smartphones and mobile devices, are ideal for assisting with self-management because they are convenient, affordable, and widely used by many Americans (Bender et al., 2014; Pew, 2018). ECG mHealth technology, such as the AliveCor™ device, allows individuals with AF to easily record and transmit an ECG to their healthcare provider for review using a device that works with smartphones. Studies have demonstrated that this technology can accurately detect and identify arrhythmias such as AF (McManus et al., 2016; Steinhubl et al., 2016), and therefore has the potential to assist patients with AF through timely detection of AF episodes.

However, a major barrier to timely AF detection is low sustained engagement with mHealth. Measures of mHealth use over an extended period of time show that many users discontinue use within three to six months of initiation, suggesting low sustained engagement (Coa & Patrick, 2016; Glasgow et al., 2011; Mattila et al., 2013). This is a critical issue for individuals with AF, because they must regularly record and transmit ECG data to healthcare providers in order for AF to be detected and treated in a timely manner (Steinhubl et al., 2016; Turakhia & Kaiser, 2016). The spontaneous, unpredictable nature of AF and its high rates of recurrence after an intervention to restore normal sinus rhythm make sustained engagement all the more critical for individuals with AF (Olgun Kucuk et al., 2015; Steinhubl et al., 2016).

Little is known about approaches to improve sustained engagement. Much of the existing research on user engagement focuses on strategies to improve initial uptake rather than sustained engagement (Ford et al., 2015; Lasorsa et al., 2016). Those that have focused on mHealth features, such as gamification and incentives, rather than the user, have largely failed to sustain

user engagement (King et al., 2013; Shimada et al., 2016). Recent studies have uncovered correlates of sustained engagement, but these vary widely between studies and range from individual characteristics (age, gender, disease characteristics, motivation, experience with technology) to technology-related characteristics (ease of use, usefulness) (Alkhaldi et al., 2016; Hermesen, Moons, Kerkhof, Wiekens, & De Groot, 2017; Sharpe, Karasouli, & Meyer, 2017). In some cases study findings contradict one another, as in the case of younger versus older age in relation to sustained engagement (Mattila et al., 2013; Pavliscsak et al., 2016; Shimada et al., 2016). As such, there remains a lack of a clear framework for understanding and intervening upon sustained engagement.

Therefore, we take a unique approach by guiding our investigation with a relevant theory. The Unified Theory of Acceptance and Use of Technology (UTAUT) is a validated model that considers individual characteristics in predicting technology acceptance and use (Venkatesh et al., 2003). UTAUT is widely used in other applied technology settings (e.g., business, education) and is increasingly being used in healthcare (Attuquayefio & Addo, 2014). In this study, we used an adapted UTAUT model that is based on a model previously used to explain sustained engagement with mHealth among an acute post-surgical population of lung transplant recipients (Jiang et al., 2016). The specific “facilitating conditions” that Jiang et al. (2016) measured were chosen based on the study population, and we tailored this variable as well.

In the adapted UTAUT model (Figure 3.1; see Figure 1.2 for full-size image), the outcome of interest is sustained engagement with ECG mHealth technology. The adapted UTAUT model contains three independent predictors of technology use. These are perceived usefulness, perceive ease of use, and facilitating conditions: severity of AF symptoms, frequency of AF episodes, and AF knowledge. Additionally there are three independent moderators of

technology use: age, gender, and experience with technology. Age and gender independently moderate the effect of all independent predictors on the outcome. Experience with technology only moderates the effects of perceived ease of use and perceived usefulness.

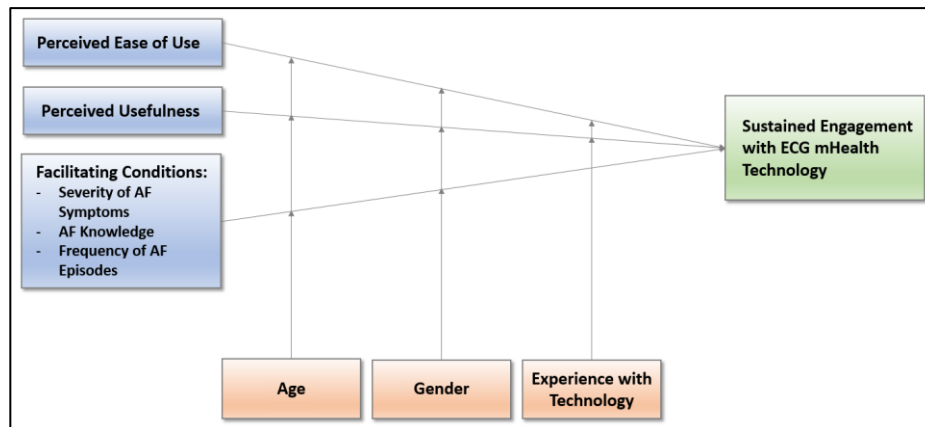


Figure 3.1: The adapted UTAUT model

Objectives

Using self-monitoring with AliveCor™ as a use case for sustained engagement, the overall purpose of this study was to describe engagement over time among adults with AF self-monitoring using ECG mHealth technology. Specifically, we aimed to: (1) describe engagement with self-monitoring during the first year after an intervention to restore normal sinus rhythm to the heart, (2) identify possible predictors of sustained engagement with self-monitoring over one year, and (3) identify possible moderation effects of age, gender, and experience with technology on relationships between hypothesized predictors and sustained engagement with self-monitoring.

Methods

Study Design and Sample

We conducted a secondary analysis of data collected during a single center, randomized, controlled trial (RCT) called *iPhone® Helping Evaluate Atrial Fibrillation Rhythm through Technology* (iHEART, R01NR014853, PI: Hickey). The original iHEART sample consists of

adults with a history of AF. Inclusion criteria in the original iHEART trial are English or Spanish speaking, age 18 or older, and have a history of AF in the last 30 days for which treatment successfully restored normal sinus rhythm (Hickey et al., 2016). Exclusion criteria are documented permanent or chronic AF, and patient found to be unstable or have other arrhythmias on day of enrollment.

iHEART trial participants are randomized 1:1 to receive either usual cardiac care (control group) or usual care plus mHealth (intervention group). Specifically, participants randomized to the intervention arm received an iPhone® and cellular service plan with unlimited data/text messaging and the AliveCor™ Mobile ECG device. The AliveCor™ device is FDA-approved and captures a highly sensitive (98%), specific (97%), and accurate (97%) single-lead ECG recording (Hickey et al., 2016). ECGs are recorded when the user places his or her fingertips on the AliveCor™ device. This device is novel in that previous non-invasive remote ECG monitors must be worn by the patient and often are too cumbersome for extended use, thus limiting the window of time for arrhythmias to be detected (Olgun Kucuk et al., 2015; Turakhia & Kaiser, 2016).

ECG recordings captured with the AliveCor™ device are documented in a free accompanying smartphone application (app), Kardia®, and are automatically uploaded via WiFi or cellular network transmission to the HIPAA-compliant, secure AliveCor™ cloud. An algorithm in the Kardia® app uses the regularity of R-to-R intervals and presence or absence of p-waves in an ECG to identify the rhythm of each recording as either normal sinus rhythm, atrial fibrillation, or “unclassified,” meaning the algorithm could not identify the rhythm (Javed, Ahmad, Albert, & Stavrakis, 2018). The rhythms identified by the algorithm are reviewed and confirmed by a cardiologist. Other arrhythmias unknown to the algorithm can be manually

identified by viewing the 30-second rhythm strip of the recording. Study coordinators trained in ECG interpretation review AliveCor™ data daily through a secure portal and immediately send clinically significant arrhythmias to the participant's healthcare provider, and are responsible for follow-up. During the iHEART trial, all participants received in-person training on use of the device prior to enrollment.

In this study, we specifically examined data from the iHEART participants who were randomized to the intervention group and have completed the trial. Inclusion criteria for the quantitative analysis were: (1) randomized to the intervention group in the iHEART trial (and therefore used AliveCor™), and (2) completion of iHEART study including six-month follow-up surveys (for data completeness).

The study protocol approved by the institutional review board at Columbia University Medical Center (CUMC, Protocol AAAR3165).

Data sources and Measures

Data came from the secure AliveCor™ database and surveys/demographic measures contained in a separate iHEART database. Appendix B contains a summary of the variables from the adapted UTAUT model and data sources used in this analysis, and Appendix C contains the iHEART trial surveys providing data for this analysis. We collaborated with account executives at AliveCor™ to coordinate an export of iHEART participants' data in January 2018. The export included images of each rhythm strip that participants captured with AliveCor™ and a file of each user's dated, time-stamped ECG transmissions with heart rhythm identified by the Kardia® algorithm for each transmission. Survey data was collected on paper-based surveys at baseline and six months. Participants completed surveys in person at CUMC, or at home and returned them by mail. Study coordinators entered responses into a secure iHEART database that is

separate from the AliveCor™ database. We exported survey and demographic data directly from the iHEART database.

Each of the variables except the outcome (use of AliveCor™) was transformed into a binary variable to improve model efficiency and allow for easier comparison of incidence rate ratios (IRR) in models with interaction terms. Mean and median values of each variable were consulted in creating its binary form.

Outcome: Use of AliveCor™ for self-monitoring. In this study, ECG recordings are a proxy for the outcome variable, AliveCor™ use over time. We selected a one-year time frame of AliveCor™ use after examining descriptive statistics of usage data, which showed that many participants continued using the device after completing the six-month iHEART trial. We chose not to include all usage data because the few participants who used AliveCor™ for several years would have skewed the outcome variable appreciably. To account for rolling recruitment in the iHEART trial, we normalized each participant's start date to "day zero." We then calculated the number of recordings in each seven-day period since first use (e.g., week one, week two, etc.) to create the variable: count of ECG recordings per week. Monthly use was calculated using the same process, and histograms of counts of daily, weekly, and monthly use were compared. The distributions of daily and monthly use were highly skewed, so weekly use was used in analyses.

Perceived Ease of Use and Perceived Usefulness. Data for perceived ease of use and perceived usefulness came from the iHEART Patient Experience Survey, which is administered to all participants randomized to the iHEART intervention at study completion (six months). It inquires about the patient's experience using AliveCor™ during the trial. Perceived usefulness is a binary variable measured according to the individual's response ("yes/no") to the question: "Do you feel the device is beneficial?" Perceived ease of use was measured according to the

individual's responses to eight Likert-type questions on perceived ease of use of various aspects of the technology (for example, portability). Response options range from one (poor) to five (great). Overall ease of use was calculated as the mean of the responses to these eight questions. It was then converted into a binary variable based on the mean score (less than or equal to three indicates low perceived ease of use, greater than three indicates high perceived ease of use).

Facilitating Conditions. Data for *Severity of AF Symptoms* came from the individual's class of AF severity on Canadian Cardiovascular Society Severity in Atrial Fibrillation scale (CCS- SAF, Cronbach's α 0.81). This scale queries the individual's symptoms and impact on quality of life, and places them in a "class" of AF severity, ranging from 0 (asymptomatic) through 4 (severe effect of symptoms on individual's quality of life) (Harden et al., 2009). This survey was administered at baseline and study completion (six-months), however due to a large amount of missing data from study completion surveys, only baseline CCS-SAF data was used in this analysis. Participants' CCS-SAF class was converted into a binary variable in which classes zero and one indicate low severity, and classes two through four indicate high severity.

AF Knowledge was assessed using the AF Knowledge Survey (Cronbach's α 0.58). This survey contains 11 items concerning AF in general, symptom recognition, and treatment (Hendriks, Crijns, Tieleman, & Vrijhoef, 2013). AF Knowledge was measured as the number of correct answers out of 11. This survey was administered at baseline and study completion, however similar to CCS-SAF surveys, only baseline data was used due to missing data at study completion. This was converted into a binary variable in which zero through seven correct answers indicate low AF knowledge, and eight through eleven correct answers indicate high AF knowledge.

Frequency of AF Episodes was assessed using the cardiac rhythm of each ECG recording (e.g., normal, AF, or unclassified) identified by the Kardia® algorithm and documented in the AliveCor™ database. The frequency of AF episodes was calculated as the average number of AF episodes per week over the first year of use. The weekly average provided adequate granularity for demonstrating frequency based on preliminary data. For the final binary variable, an average of less than or equal to one AF episode per week was considered low frequency, and greater than one AF episode per week was considered high frequency.

Age and Gender. Age was calculated by the birthday reported on the patient’s electronic medical record. This was converted into a binary variable in which age less than or equal to 62 years old indicated younger age, and age greater than 62 years old indicated older age. Gender was recorded as the individual’s stated gender on demographic surveys. None of the participants reported a non-binary gender.

Experience with Technology. Experience with technology was recorded for iHEART study participants at baseline using a survey with ten “yes/no” questions about ownership and use of various technologies (smartphones, Internet, text messaging). We categorized experience according to the number of “yes” responses out of ten. A binary variable was created with eight or greater “yes” responses indicating experience and fewer than eight “yes” responses indicating a lack of experience.

Data Analysis

The outcome variable to represent participants’ overall engagement with technology is the weekly count of incidents of AliveCor™ use (i.e. ECG transmissions) from baseline to one year, and the main predictor is time (measured in weeks, from baseline to one year). Other

predictors come from the adapted UTAUT model: perceived ease of use, perceived usefulness, severity of AF symptoms, AF knowledge, and frequency of AF episodes.

All identifiable information was removed prior to statistical analysis. Next, descriptive statistics of frequency, dispersion, and central tendency were calculated to characterize the sample and AliveCor™ use. Missing data were then evaluated for randomness. Because we only used baseline data for most of the predictors and moderators, missing data are not related to the participants' engagement and therefore are missing completely at random (MCAR). Two variables, perceived ease of use and perceived usefulness, were assessed only at six-month follow up because it required the participant to reflect on their perceptions of AliveCor™. This missing data was therefore potentially non-random and is a limitation of the analysis.

After evaluating missing data, hierarchical generalized linear modeling (HGLM) with Poisson distribution was used to estimate parameters of AliveCor™ use over time. This approach was chosen because the outcome is a repeated measure (count of incidents of use) and we were interested in examining changes over time (Dickey, 2010). First, the linear, quadratic, cubic models of AliveCor™ use over time (i.e., linear, quadratic, and cubic terms of time as independent variables) were evaluated. The quadratic and cubic models did not provide estimates and the linear term was used for subsequent analyses. Second, relationships between each predictor from the adapted UTAUT model and AliveCor™ use were tested in bivariate models (week plus one predictor). During this step, moderators (age, gender, and experience with technology) were also tested as main effects in bivariate models. Only predictors with $p < 0.25$ in bivariate analyses were included in a final parsimonious model (Bendel, 1977; Mickey & Greenland, 1989). Third, moderators were tested in multivariate models (main effects plus one interaction term). The significance level was set at $p < 0.10$ for exploration of moderation effects

(Baron & Kenny, 1986). Finally, the parsimonious model was iteratively run until all predictors were significant at the $p < 0.05$ level.

For reporting purposes, β estimates from HGLMs were converted to person-time incidence rate ratios (IRR) using the formula: $[\exp(\beta)]$. IRR are an approach for understanding the number of new incidents of a phenomenon in a population over a given time period (Dicker, Coronado, Koo, & Parrise, 2006). IRR are described in the results as the percent difference in AliveCor™ use between high and low values of a predictor. These percent difference estimates were calculated using the following formula: $[\exp(\beta) - 1] \times 100$ (Dicker et al., 2006; Gaskins, Sundaram, Buck Louis, & Chavarro, 2018).

All statistical analyses were conducted using SAS statistical software version 9.4 (SAS Institute, Inc., Cary, NC).

Results

Description of the Sample

Table 3.1 shows descriptive statistics for 132 iHEART participants who had completed the intervention arm of the trial. Study participants were 62 years old on average and predominantly male, White, and English-speaking. Demographic information such as income or education level is not available through the iHEART trial database. Study participants had a mean body mass index (BMI) of 29 kg/m². Participants' mean ejection fraction (percentage of ventricular blood pumped with each contraction, an indicator of cardiac functioning) was 52%. The mean CHADS₂ score, which predicts likelihood of stroke based on past medical history and age, was 1.88. Common co-morbid conditions among participants were hypertension (75%), coronary artery disease (43%), sleep apnea (40%), and anxiety (27%). Nearly all participants

reported that they owned a smartphone (91%) and a computer or tablet (93%), had high-speed Internet access at home (96%), and were comfortable browsing the Internet (99%).

Table 3.1: *Summary of Sample Characteristics (n=132)*

Category	Characteristic	Mean (SD)	Range	n (total)*	%
Demographic Characteristics	Age	62.41 (11.15)	27-85		
	Gender (male)			101 (132)	77
	Race (white)			89 (105)	85
	Primary Language (English)			108 (109)	99
Clinical Characteristics	BMI	29.15 (5.05)	22-42		
	LVEF	52.61 (11.98)	15-74		
	CHADS2 score	1.88 (1.36)	0-5		
	Procedure on enrollment (ablation)			35 (65)	54
	Comorbid Conditions				
	Coronary artery disease			18 (42)	43
	Sleep apnea			14 (35)	40
	Hypertension			30 (40)	75
	Diabetes Mellitus			4 (35)	11
	Heart Failure			8 (53)	15
	TIA or stroke			7 (43)	16
	Anxiety			11 (41)	27
Experience with Technology	Own cell phone			75 (76)	99
	Own smartphone			69 (76)	91
	Use smartphone to browse Internet			64 (76)	84
	Use smartphone for email			62 (76)	82
	Ever download smartphone app w/o assistance			59 (75)	79
	Send/receive text messages			73 (77)	95
	Ever followed link to website from text message			59 (77)	77
	Access and use computer or tablet at home			70 (75)	93
	High speed Internet access at home			74 (77)	96
	Comfortable using computer to browse Internet			75 (76)	99

Description of AliveCor™ Use

Table 3.2 shows descriptive statistics of the study participants' AliveCor™ use over one year. The iHEART protocol asked participants to transmit at least once daily for six months, or a minimum target of 30 transmissions per person per month. Among 132 participants, 76 (58%) used the device for the entire six-month iHEART trial. After one year, 55 participants (42%) were still using the device. The mean transmissions per person per month was about 23 after one month, 32 after six months, and 20 after one year. The median transmissions per person per month was 9 after one month, 12 after six months, and 9 after twelve months.

Table 3.2: *Descriptive statistics of the study participants' AliveCor™ use over one year (n=132)*

Month	Active users for entire month		Transmissions per person per month		
	Number (n)	Percentage of Total (%)	Mean	SD	Median
1	111	84	23.02	40.41	9
2	104	79	21.80	46.03	6
3	96	73	23.73	50.26	6
4	88	67	22.84	45.54	7
5	79	60	26.24	47.40	8
6	76	58	32.41	54.55	12
7	79	60	31.02	54.76	9
8	69	52	35.73	58.27	9
9	68	52	28.92	51.35	9
10	63	48	29.45	55.56	8
11	57	43	24.80	52.25	9
12	55	42	20.35	40.27	9

Heart Rhythm Data collected with AliveCor™

Table 3.3 shows the number ECG transmissions by participants over the one-year period in sum and stratified by rhythm type per the Kardia® algorithm. In total the 132 participants recorded 36,810 ECGs with AliveCor™ over one year. The percentage of transmissions

identified by the algorithm as normal sinus rhythm was 37% after one month, 44% after six months, and 47% after one year. The percentage of transmissions identified as atrial fibrillation was 12% after one month, 8% after six months, and 16% after one year. The percentage of transmissions that the Kardia® algorithm was unable to identify (“unclassified”) was 51% after one month, 48% after six months, and 37% after one year.

We also examined the proportion of participants who experienced each type of heart rhythm during each month. The percentages were not mutually exclusive because users may have experienced more than one rhythm type during a given month. The percentage of users with normal sinus rhythm per the Kardia® algorithm was 71% after one month, 75% after six months, and 73% after one year. The percentage of users with atrial fibrillation per the Kardia® algorithm was 42% after one month, 38% after six months, and 24% after one year. The percentage of users with “unclassified” transmissions was 92% after one month, 50% after six months, and 27% after one year.

Table 3.3: *The number and percentage of ECG transmissions collected by participants over the one-year period in sum and stratified by rhythm type identified by the Kardia® algorithm*

Aggregated by ECG Transmissions (n=36,810)							
Month	Total	Normal Sinus Rhythm		Atrial Fibrillation		Unclassified	
	n	n	%	n	%	n	%
1	6,392	2,385	37	768	12	3,239	51
2	4,703	1,888	40	528	11	2,287	49
3	3,712	1,617	44	391	11	1,704	46
4	3,175	1,333	42	340	11	1,502	47
5	3,208	1,217	38	394	12	1,597	50
6	3,029	1,326	44	242	8	1,461	48
7	2,812	1,294	46	218	8	1,300	46
8	2,716	1,303	48	249	9	1,164	43
9	2,213	1,269	57	176	8	768	35
10	1,729	966	56	177	10	586	34
11	1,536	829	54	159	10	548	36
12	1,585	745	47	260	16	580	37

Aggregated by Users (n=132)*							
Month	Total	Normal Sinus Rhythm		Atrial Fibrillation		Unclassified	
	n	n	%	n	%	n	%
1	111	79	71	47	42	102	92
2	104	76	73	39	38	90	68
3	96	68	71	34	35	81	61
4	88	63	72	28	32	74	56
5	79	61	77	27	34	68	52
6	76	57	75	29	38	66	50
7	79	58	73	26	33	56	42
8	69	54	78	23	33	57	43
9	68	55	81	15	22	46	35
10	63	48	76	19	30	47	36
11	57	47	82	22	39	40	30
12	55	40	73	13	24	36	27

**Percentages are calculated using the number of active users during the month (not all users)*

Simple Linear Model of Association between Time (Week) and AliveCor™ Use

Figure 3.2 shows the simple linear model of the association of time and AliveCor™ use over one year. The parameters for this model are reported in Table 3.4. The model shows a statistically significant but not meaningful decline in AliveCor™ use over time (IRR= 1.00; $p<0.01$) among all iHEART trial intervention arm participants.

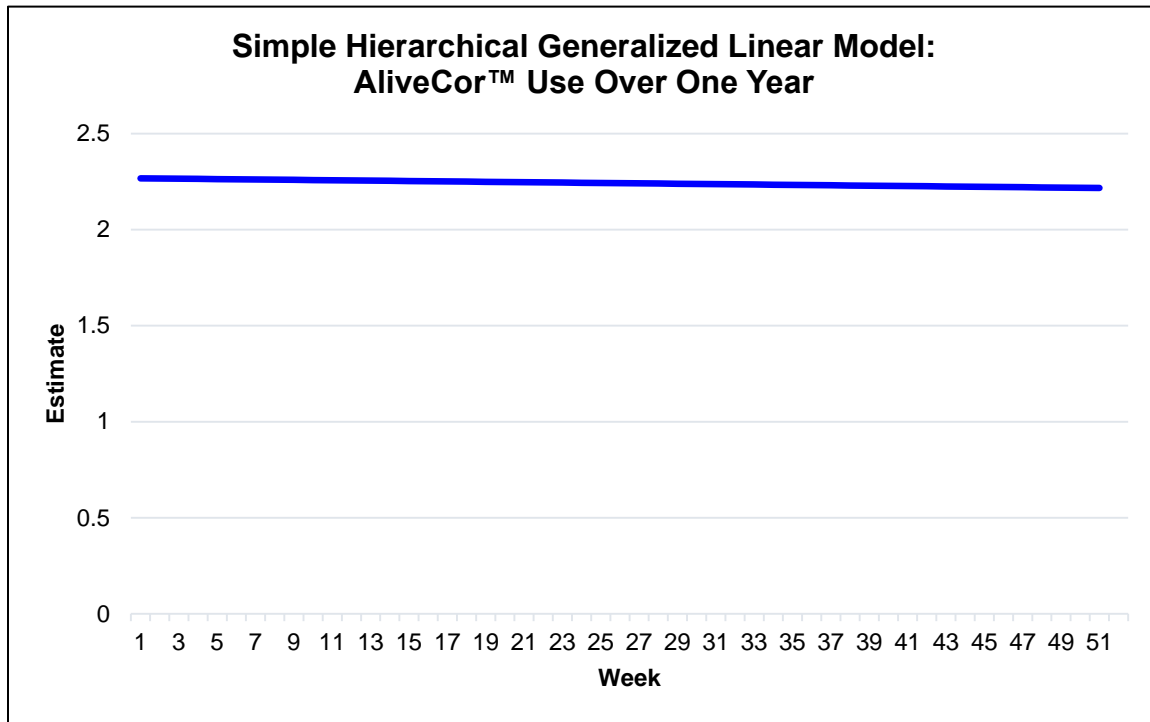


Figure 3.2. Simple Linear Model of AliveCor™ use over Time

Predictors of AliveCor™ use

The main effects of perceived usefulness, severity of AF symptoms, AF knowledge, frequency of AF episodes, and experience with technology tested in bivariate models were significant at the $p < 0.25$ level (Table 3.4). Subjects who perceived AliveCor™ as useful recorded 50% more incidents of AliveCor™ use than those who did not perceive the device as useful. Subjects who reported greater severity of AF symptoms recorded 36% more incidents of AliveCor™ use than those who reported less severity. Subjects who had more AF knowledge recorded 28% more incidents of AliveCor™ use than those who had less knowledge. Subjects who experienced more frequent AF episodes recorded 94% more incidents of AliveCor™ use than those who experienced fewer episodes. Subjects who reported greater experience with technology recorded 52% fewer incidents of AliveCor™ use than those who reported less experience.

Table 3.4: Estimates and Person-Time Incidence Rate Ratios of associations between variables in the adapted UTAUT model and AliveCor™ Use over One Year

Model	Effects	β	SE	IRR	95% CI	p
Basic Linear Model						
1	Week	-0.001	0.001	1.00	(1.00, 1.00)	<0.01
Main Predictors of AliveCor™ use						
2	Week	-0.001	0.001	1.00	(1.00, 1.00)	<0.01
	Perceived Ease of Use	0.08	0.12	1.12	(0.89, 1.41)	0.34
3	Week	-0.001	0.001	1.00	(1.00, 1.01)	<0.01
	Perceived Usefulness	0.43	0.23	1.50	(0.98, 2.40)	0.06
4	Week	-0.001	0.001	1.00	(1.00, 1.00)	<0.01
	Severity of AF Symptoms	0.10	0.13	1.36	(1.06, 1.75)	0.02
5	Week	-0.001	0.001	1.00	(1.00, 1.00)	<0.01
	AF Knowledge	0.10	0.12	1.28	(1.01, 1.61)	0.04
6	Week	-0.001	0.001	1.00	(1.00, 1.00)	<0.01
	Frequency of AF Episodes	0.03	0.004	1.94	(1.93, 1.96)	<0.01
7	Week	-0.001	0.001	1.00	(1.00, 1.00)	<0.01
	Age	-0.02	0.10	1.00	(0.80, 1.19)	0.84
8	Week	-0.001	0.001	1.00	(1.00, 1.00)	<0.01
	Gender	0.03	0.14	1.03	(0.78, 1.36)	0.84
9	Week	-0.001	0.001	1.00	(1.00, 1.00)	<0.01
	Experience with Technology	-0.74	0.46	0.48	(0.19, 1.17)	0.10

Final Parsimonious Model

Construction of a final parsimonious model was based on significance levels of the associations for each variable (Table 3.4). The initial iteration included severity of AF symptoms. This variable was removed for $p > 0.05$ and $\beta = 0$, and results are reported in Table 3.5. Perceived usefulness, AF knowledge, and frequency of AF episodes were significantly related to AliveCor™ use at the $p < 0.05$ level. Subjects who perceived AliveCor™ as useful recorded 57% more incidents of AliveCor™ use than those who did not perceive the device as useful. Subjects who had more AF knowledge recorded 48% more incidents of AliveCor™ use than those who had less knowledge. Subjects who experienced more frequent AF episodes recorded 87% more incidents of AliveCor™ use than those who experienced fewer episodes.

Experience with technology was not significantly related to AliveCor™ use but was collinear with perceived usefulness and AF knowledge in the parsimonious model. When it was removed from the model, there was a large ($>10\%$) change in the β estimates of perceived usefulness and AF knowledge and these variables became insignificant at the $p < 0.05$ level. An analogous change in β estimates was observed when comparing bivariate (i.e., week and perceived usefulness or AF knowledge) and multivariate models (i.e., week, experience with technology, and perceived usefulness or AF knowledge). The β estimate of frequency of AF episodes did not change when experience with technology was removed and the variable remained significant at the $p < 0.05$ level.

Table 3.5: *Parsimonious Model of Associations between variables in the adapted UTAUT model and AliveCor™ Use over One Year with Person-Time Incidence Rate Ratios*

Effects	β	IRR	95% CI	p
Week	0.002	1.00	(1.00, 1.00)	<0.01
Perceived Usefulness	0.45	1.57	(1.07, 2.30)	0.02
AF Knowledge	0.39	1.48	(1.13, 1.94)	<0.01
Frequency of AF Episodes	0.63	1.87	(1.85, 1.89)	<0.01
Experience with Technology	-0.16	0.85	(0.35, 2.06)	0.73

Moderation Effects

Hypothesized moderators of AliveCor™ use specified by the adapted UTAUT model (age, gender, experience with technology) were tested in multivariate models (main effects plus one interaction term). The following models testing interactions did not converge even when less stringent convergence criteria was specified: perceived usefulness with age and with experience with technology, frequency of AF episodes with age and with gender, and perceived ease of use with gender and with experience with technology. The remaining models were not significant at the $p < 0.10$ level. Therefore none of the hypothesized moderators were reported.

Additionally, we tested the interactions between week and high versus low values for each predictor (Table 3.6). The models testing the interactions of week with perceived ease of use and with severity of AF symptoms did not converge even when less stringent convergence criteria was specified. These models were therefore not reported. Although the remaining interactions were statistically significant at the $p < 0.10$ level, the differences in IRR between different values of the interaction term were extremely small and did not warrant inclusion in the final parsimonious model.

Table 3.6: *Person-time Incidence Rate Ratios of Associations between Interactions of variables in the adapted UTAUT model with Time (Week) and AliveCor™ Use over One Year*

Interaction Term	Effects	IRR	p
Perceived Usefulness * Week	Low Perceived Usefulness	0.98	<0.01
	High Perceived Usefulness	1.00	
AF Knowledge * Week	Low AF Knowledge	0.99	<0.01
	High AF Knowledge	1.00	
Frequency of AF Episodes * Week	Low Frequency of AF Episodes	1.00	<0.01
	High Frequency of AF Episodes	1.01	
Age * Week	Younger Age (≤ 62 years)	1.00	<0.01
	Older Age (>62 years)	0.99	
Gender * Week	Male	0.99	<0.01
	Female	1.00	
Experience with Technology * Week	Low Experience with Technology	1.00	<0.01
	High Experience with Technology	1.00	

Discussion

We conducted a secondary analysis of data from the AliveCor™ smartphone device and survey data from 132 adults with AF who completed the intervention arm of the iHEART study. We found that subjects who experienced more frequent AF episodes reported 87% more incidents of AliveCor™ use over one year than those who experienced fewer episodes. We also found that subjects who perceived the device as useful reported 57% more incidents of AliveCor™ use than those who did not perceive it as useful. Finally, we found that subjects who had more AF knowledge reported 48% more incidents of AliveCor™ use than those who had less knowledge. However the nature of these relationships is difficult to assess due to limitations in the data and the sample of subjects.

The data from survey responses (used to measure all predictor variables except frequency of AF episodes) were collected at a single time point, thereby failing to capture fluctuation over time. There were also missing data due to ongoing processes in the parent study. As we have explained, most missing data were MCAR *except* for two variables: perceived ease of use and perceived usefulness, which were missing due to loss to follow up. This missing data was likely non-random and may have biased our analysis toward higher perceived ease of use and usefulness, because those who were lost to follow up may have been less engaged due to low perceived ease of use and usefulness. Finally, we quantified engagement as AliveCor™ use, which was based on ECG transmissions, but we did not have access to data on participants' use of other functions of the Kardia® app, such as messaging healthcare providers and reviewing past data. Therefore some participants' engagement may have been underestimated depending on the features they preferred to use.

These data limitations cause us to conclude that secondary analysis of survey data collected for other purposes may not have adequate content validity to fully characterize AliveCor™ use. For example, the simple linear model showed no meaningful difference in AliveCor™ use over time. However there were wide disparities between the mean and median number of transmissions per person per month, and large standard deviations from the mean (Table 3.2), indicating differences within the sample but no stable pattern of AliveCor™ use overall. Additionally, frequency of AF episodes was the only variable that was not captured via survey, and it was consistently significantly associated with AliveCor™ use over one year. This variable was calculated based on AF rhythms identified by the Kardia® algorithm and was therefore captured at extremely high frequencies. Future research should explore measurement of constructs from the adapted UTAUT model at the time of the most reliable data, which is likely

at the time of transmission. Data capture via smartphone app may improve upon the limitations of survey data (e.g., missing values, recall bias, inadequate frequency of data capture).

Ecological momentary assessment (EMA) is one emerging approach for capturing real-time data via smartphone that could overcome such limitations (Hand & Perzynski, 2016; Juengst et al., 2015; Shiffman, Stone, & Hufford, 2008).

Our findings highlight complex relationships between the distinct variables in the adapted UTAUT model in this unique patient population. Many of the significant independent associations between variables from the adapted UTAUT model and AliveCor™ use later dampened when entered together in the final parsimonious model. However none of the adapted UTAUT moderators (age, gender, experience with technology) significantly moderated any predictors' relationships with AliveCor™ use. We detected collinearity between perceived usefulness, AF knowledge, and experience with technology in the final parsimonious model. Yet experience with technology and AliveCor™ use were negatively associated, indicating that users with less technology experience had more incidents of AliveCor™ use over time. Together these variables may be revealing a phenomenon that we were unable to directly measure with the data.

However, such a conclusion must be considered in light of selective criteria of the parent RCT, which sought to limit the variability of participants with respect to demographic characteristics, health status, experience with technology, and engagement in their care. To be enrolled in iHEART, participants must have undergone a procedure (cardioversion or radiofrequency ablation) to restore normal sinus rhythm to the heart. This invasive treatment may have influenced participants to become more engaged in their care than a patient pursuing medical management alone (e.g., medications). Moreover, to be enrolled participants had to agree to use AliveCor™, which may have excluded subjects who were less comfortable with technology.

Overall, our findings corroborate prior studies that characterize the relationships between variables associated with sustained engagement as complex and unique to the patient population being studied (Hermesen et al., 2017; Park et al., 2018; Sharpe et al., 2017). For instance, clinical research has demonstrated that gender, age, severity of AF symptoms, and frequency of AF episodes are interrelated in adults with AF (Dagres et al., 2007; Kaiser et al., 2016; Lip et al., 2015). The complex relationships between variables from the adapted UTAUT model, and the influence of these interrelationships on sustained engagement, should be explored in future research using more complete data collected at more frequent time points.

Frequency of AF episodes was the only variable for which iHEART participants could view their results, as they could immediately see the rhythm identified by the algorithm through the Kardia® app. Moreover, there was a slight increase in the number of AF transmissions towards the end of the one-year period, while the number of users with AF transmissions declined (Table 3.3). This may suggest that the few users who continued to experience AF documented it more frequently with AliveCor™ over time. One possible interpretation is that visualizing one's own data and, through it, understanding current health status, may be a powerful motivator for continued use of mHealth technologies. Others have found preliminary evidence that viewing and understanding one's own self-monitoring data is a motivating factor in sustaining engagement with self-monitoring (Miyamoto et al., 2016; Muessig et al., 2014; Sharpe et al., 2017). This is an approach that has yet to be well explored and warrants future investigation given the explosion of available PGHD in recent years (Lai et al., 2017; Wood et al., 2015).

Our findings also suggest that AF knowledge and perceived usefulness, which are modifiable factors, are related to AliveCor™ use. mHealth design is one approach to target these

factors. For instance, educational modules can be embedded in applications to enhance AF knowledge. Consistent with the interpretation that health data presented back to the user may motivate further self-monitoring, an individual's own data can serve to increase AF knowledge, as well. For example, data can be used to teach patients about the well-documented poor correlation between AF episodes and perceived symptoms (Barrett et al., 2014; Simantirakis et al., 2017). These data could also increase perceived usefulness by demonstrating how continued self-monitoring positively influences an individual's health outcomes. Qualitative research with AliveCor™ users may uncover additional design opportunities to target AF knowledge and perceived usefulness.

Conclusion

In this study we found some qualified evidence of differences in AliveCor™ use among adults self-monitoring AF using ECG mHealth technology. Additionally, we found some evidence validating the predictors in the adapted UTAUT model in relation to AliveCor™ use. In future work approaches for frequent, real-time data capture through mHealth technology, such as EMA, may provide more robust data for the adapted UTAUT model to be evaluated in the context of sustained engagement. Importantly, we found that the sole variable that was consistently significantly related to AliveCor™ use, frequency of AF episodes, is also the only variable that was shared with patients via mHealth after being collected (compared to survey data that is not shared). Given the rapid increase in PGHD and mHealth technologies to capture PGHD, the possibility that viewing and understanding one's own data is a motivating factor in sustaining self-monitoring warrants further investigation.

Chapter Four: Factors Influencing Sustained Engagement with ECG Self-Monitoring: Perspectives from Patients and Healthcare Providers

Chapter Four of this dissertation addresses the third aim by exploring individual patient differences in sustained engagement among adults with AF who are collecting and using PGHD, as well as potential approaches for improving sustained engagement. This manuscript is currently under review at Applied Clinical Informatics.

Abstract

Background: Patient-generated health data (PGHD) collected digitally with mobile health (mHealth) technology has garnered recent excitement for its potential to improve precision management of chronic conditions such as atrial fibrillation (AF), a common cardiac arrhythmia. However sustained engagement is a major barrier to collection of PGHD. Little is known about barriers to sustained engagement or strategies to intervene upon engagement through application design.

Objectives: To investigate individual patient differences in sustained engagement among individuals with a history of AF who are self-monitoring using mHealth technology.

Methods: This qualitative study involved patients, healthcare providers, and research coordinators previously involved in a randomized, controlled trial involving ECG self-monitoring of AF. Patients were adults with a history of AF randomized to the intervention arm of this trial who self-monitored using ECG mHealth technology for six months. Semi-structured interviews and focus groups were conducted separately with healthcare providers and research coordinators, engaged patients, and unengaged patients. A validated model of sustained engagement, an adapted Unified Theory of Acceptance and Use of Technology (UTAUT), guided data collection and analysis through directed content analysis.

Results: We interviewed 13 patients (7 engaged, 6 unengaged), 6 healthcare providers, and 2 research coordinators. In addition to finding differences between engaged and unengaged patients within each predictor in the adapted UTAUT model (perceived ease of use, perceived usefulness, facilitating conditions), four additional factors were identified as being related to sustained engagement in this population. These are: (1) personality/ behavioral tendencies, (2) relationship with healthcare provider, (3) supportive environments, and (4) feedback and guidance.

Conclusions: Although it required some modification, the adapted UTAUT model was useful in improving understanding of the parameters of sustained engagement. The findings of this study provide options for the design of applications that engage patients in this unique population of adults with AF.

Background and Significance

An increasing number of patients are using mobile health (mHealth) technology, including smartphones and other connected devices, to generate data that provide a rich account of their day-to-day health (Bhavnani et al., 2016; NIH, 2015; Silva, Rodrigues, de la Torre Diez, Lopez-Coronado, & Saleem, 2015). These data, termed patient-generated health data (PGHD), may include physiologic measures, symptoms, and lifestyle data (Lai et al., 2017; Woods et al., 2016). PGHD has garnered excitement for its ability to uncover fluctuations in health-related factors that may play an important role in an individual's health and wellness (Arsoniadis et al., 2015; Howie et al., 2014; Lavalley et al., 2016; Shapiro, Johnston, Wald, & Mon, 2012). PGHD also is valuable for centering care on the patient and their unique environmental, lifestyle, and biological circumstances (Lavalley et al., 2016; Sanger et al., 2016). As such, PGHD holds

particular promise for precision management of individuals living with chronic conditions (Antman & Loscalzo, 2016; Hull, 2015).

One condition for which PGHD could be particularly valuable is atrial fibrillation (AF), the most common cardiac arrhythmia encountered in clinical practice (CDC, 2015). AF is difficult to capture outside the clinical setting because it requires documentation via electrocardiogram (ECG) and is poorly correlated with patient-reported symptoms (Kirchhof et al., 2017; Simantirakis et al., 2017; Verdino, 2015). Moreover, AF is deeply influenced by modifiable lifestyle factors such as alcohol use and obesity (Go et al., 2001; Huxley et al., 2011). Thus, PGHD can improve patient self-management of the arrhythmia, while also offering clinical benefits to providers seeking to improve detection and tailor care based on the unique characteristics of the patient (Olgun Kucuk et al., 2015; Turakhia & Kaiser, 2016).

Sustained patient engagement with self-monitoring using mHealth technology is necessary to generate adequate health data to enable precision management (ONC, 2016). Yet evidence shows that patient engagement is low over time, with many patients abandoning self-monitoring within three to six months of initiation (Glasgow et al., 2011; Mattila et al., 2013). There is a gap in understanding factors that contribute to sustained engagement, as much of the extant literature focuses solely on initial uptake of technology (Ford et al., 2015; Lasorsa et al., 2016). Moreover, engagement research has had minimal success improving sustained engagement mainly using generic design tactics, such as gamification and incentives (e.g., points, money), that forgo consideration of unique patient characteristics (King et al., 2013; Shimada et al., 2016).

Objectives

The purpose of this study was to investigate individual patient differences in sustained engagement among individuals with a history of AF who are self-monitoring using mHealth technology. Specifically, we aimed to uncover factors that are associated with sustained engagement in this unique patient population through qualitative focus groups and interviews guided by a theoretical model. We also aimed to uncover potential approaches for improving sustained engagement.

Methods

Theoretical Model

Our investigation of sustained engagement was guided by the Unified Theory of Acceptance and Use of Technology (UTAUT) model (Venkatesh et al., 2003), which has been used in multiple health care studies (Kim, Lee, Hwang, & Yoo, 2016; Lin et al., 2016; Ma, Chan, & Chen, 2016). In our study we used a version of UTAUT that was adapted specifically for sustained engagement (Jiang et al., 2016). In the adapted model (Figure 4.1; see Figure 1.2 for full-size image), the predictors of sustained engagement with ECG mHealth technology are perceived ease of use, perceived usefulness, and three facilitating conditions tailored for our patient population: (1) AF knowledge, (2) severity of AF symptoms, and (3) frequency of AF episodes. Age and gender moderate the relationships between all predictors and the outcome, sustained engagement. Experience with technology moderates only the relationships of perceived ease of use and perceived usefulness with the outcome.

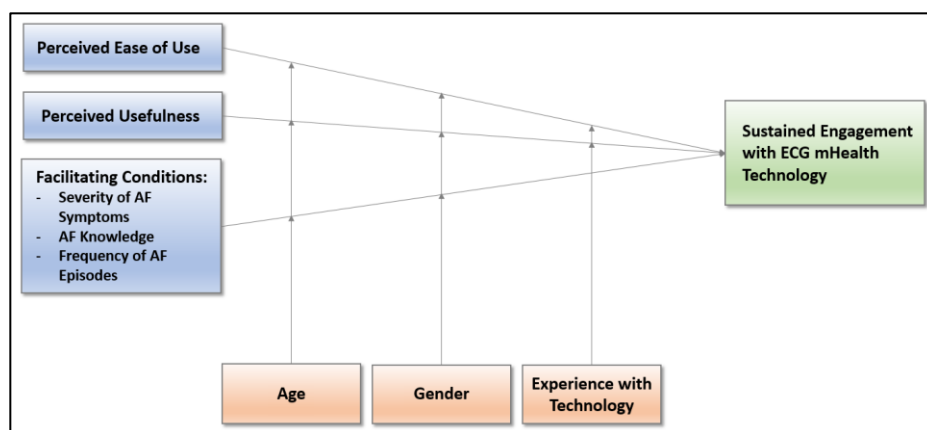


Figure 4.1. The adapted UTAUT model

Study Design and Sample

This qualitative descriptive study used focus groups and individual interviews with patients, healthcare providers (nurse practitioners and physicians), and research coordinators involved in the iPhone® Helping Evaluate Atrial Fibrillation Rhythm through Technology trial (iHEART; R01NR014853, PI: Hickey). This is an ongoing, five-year randomized, controlled trial of adults with a history of AF who have undergone a procedure to restore normal sinus rhythm to the heart (Hickey et al., 2016). They are randomized 1:1 to receive usual cardiac care of periodic electrocardiograms (ECGs) during office visits (control group) or usual cardiac care plus remote monitoring using the AliveCor™ device (intervention group). This device works with an accompanying smartphone application (app) to capture heart rate and rhythm via a single-lead ECG. Patients can use the app to document symptoms experienced during an ECG recording, or potential triggers of an AF episodes (e.g., exercise). iHEART intervention arm participants were asked to use the AliveCor™ device once daily for six months but had the option of continuing beyond this period.

We recruited a convenience sample of iHEART intervention group participants who completed the trial within the past two months (to minimize recall bias). Healthcare providers

and research coordinators were recruited because of their potential for insights into patient engagement stemming from their close connection to patients during the trial.

Recruitment and Data Collection

After obtaining institutional review board approval, the primary author (M.R.) and the iHEART principal investigator (K.H.) identified potential participants and contacted them via telephone. Engaged patients, unengaged patients, and healthcare providers/research coordinators were recruited into separate sessions to facilitate candidness and comparison of engaged and unengaged patients. The level of engagement was determined by examining the HIPPA-compliant, web-based AliveCor™ portal. We defined the engaged patient as one who used AliveCor™ at least once per day on average during the trial. We defined the unengaged patient as one who used the device less than once per day on average.

Focus groups and interviews were conducted and analyzed until data saturation was reached. Each session lasted 30-60 minutes and was conducted in a private space at a large, urban academic medical center or over the phone when needed due to travel or scheduling reasons. The primary author moderated all sessions. A second researcher (K.T.H. or J.M.) was present for a subset of the sessions to ensure rigor in data collection. Participants received a \$20 Visa gift card for participation. Discussions were guided by interview/focus group guides developed to elicit understanding on each factor in the adapted UTAUT model (Appendix D). All focus groups and interviews were audio-recorded, transcribed verbatim, and spot-checked by the primary author (M.R.) for accuracy.

Data Analysis

The transcripts were analyzed by directed content analysis. This method uses factors from a relevant theory to guide data collection and analysis. Research/interview questions are

focused to allow rich exploration of the theory, but the technique does not preclude findings that may not fit the pre-selected theory (Graneheim & Lundman, 2004; Hsieh & Shannon, 2005). Following this approach, the primary author (M.R.) created a preliminary codebook of themes based on the factors described in the adapted UTAUT model, with separate sections for each participant group (engaged patients, unengaged patients, and providers/research coordinators). She then coded all transcripts to this codebook and separately reported new themes that emerged. Two additional analysts (D.B., M.B.) with no prior knowledge of the adapted UTAUT model independently coded two transcripts using open coding (e.g., no a priori codes) to verify that the emergent themes they identified were congruent with the preliminary codebook. The primary author then provided them with the preliminary codebook and they used directed coding to analyze three additional transcripts each, while identifying and separating themes that emerged outside of this codebook.

At each stage, codes were compared and any discrepancies in coding were discussed and resolved. Inter-rater reliability was calculated to quantify coder agreement during directed coding, which was high (0.87-0.98). In addition, all analysts identified and reported on similarities and differences between participant groups because both variability and consistency in perspectives were considered valuable in advancing understanding of the theoretical model. All data was analyzed using NVivo 11 (QSR International, Inc., Burlington, MA).

Results

Description of the Sample and Overall Engagement

We interviewed a total of 21 individuals: 13 patients (7 engaged, 6 unengaged); 6 healthcare providers; and 2 research coordinators. We conducted 13 individual interviews: 10 via phone with patients; 1 in-person with a patient; and 2 in-person with healthcare providers. We

also conducted two in-person focus groups: one with 2 unengaged patients; and one with 4 healthcare providers and 2 research coordinators.

Healthcare providers in this study included 4 nurse practitioners and 2 physicians. They had, on average, 22.7 years (range: 20-27) of clinical experience and 18.3 years (range: 13-25) working in the electrophysiology clinic from which iHEART participants were recruited. The 2 iHEART research coordinators reported 3 and 25 years of clinical research experience respectively.

Patients were predominantly male (85%) and middle- to older-age (mean 65.3 years, range 50-76), which reflects the demographics in the electrophysiology clinic from which they were recruited. Engaged and unengaged patients had approximately the same age and gender composition. Participants were asked a series of questions regarding their experience with technology at baseline in the iHEART trial. The patients in this study reported having experience with technology: all reported owning a cell phone and 78% owned a smartphone. All reported experience searching the Internet for health-related information, and all had a computer or tablet in their homes.

Engaged patients used AliveCor™ 31.2 times per month for an average of 11.9 months, compared to 24.1 times per month and for an average of 9.3 months among unengaged patients. Figure 4.2 illustrates trajectories of AliveCor™ use over time, showing a clear difference in engagement between two groups despite a high level of engagement overall. Most engaged patients expressed intention to continue using the device indefinitely: “I’m still using it right now. And I’m planning to sign up to use it after the trial period...it’s a big help for me!” – Patient 3 (engaged). Conversely several unengaged participants used the device for shorter

periods of time: “I would take a guess it was three weeks, maybe four weeks.” –Patient 1 (unengaged).

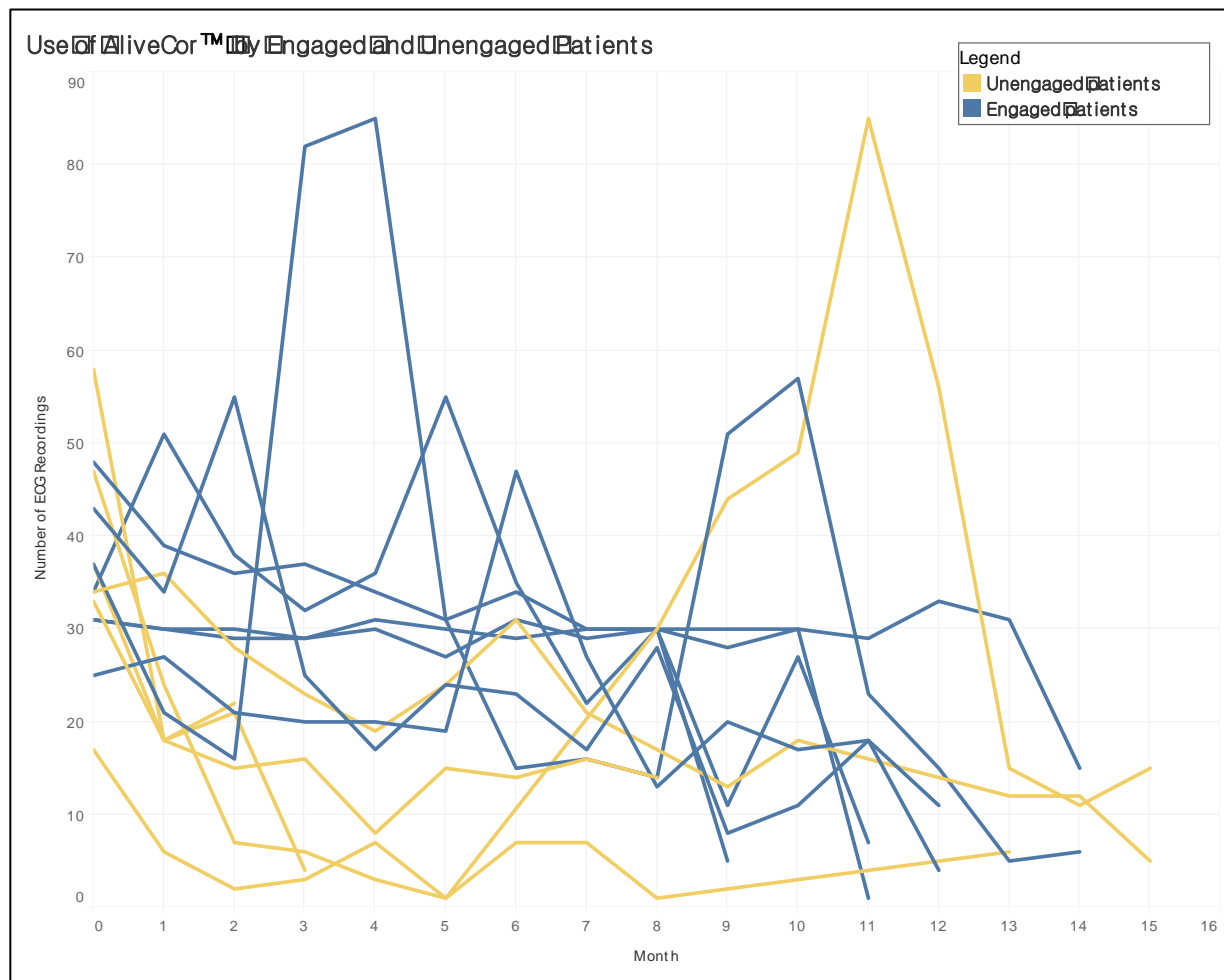


Figure 4.2. Trajectories of engagement among iHEART participants interviewed in this study

Factors Associated with Engagement in the adapted UTAUT Model

First, we describe themes associated with sustained engagement found in the adapted UTAUT model. We then describe emergent themes not specified in the adapted UTAUT model. Illustrative quotes by theme and sub-theme are presented in Appendix E.

Ease of Use.

Similarities in Ease of Use. Both engaged and unengaged patients reported that the AliveCor™ device was easy to use with minimal, if any, learning curve. They reported that data

capture and sharing was simple with the device, and the lightweight design made it portable and therefore easy to capture ECGs quickly, easily, and virtually anywhere. Despite general ease of use, some technical challenges arose for most patients. The primary challenge they reported was difficulty transmitting an ECG due to poor connectivity between fingertips and the device, or the device and the application. This led to poor-quality readings and vague output from the rhythm-identifying algorithm (e.g., “Unclassified”). Another problem they described was background noise interference when symptoms were recorded through voice-enabled technology. Healthcare providers and research coordinators also reported that patients experienced these technical issues.

Differences in Responses to Technical Issues. The main difference between engaged and unengaged patients was in their attitude towards handling technical issues. All engaged patients reported on the strategies they used for dealing with challenges related to transmission and connectivity, such as moving away from other electronic devices or cleaning their fingers. Some stated that this helped them avoid becoming anxious. Conversely, many unengaged patients expressed frustration and anxiety as a result of technical issues, as one patient described: “I didn’t feel safe in my ability to get accurate readings.” –Patient 1 (unengaged).

Differences in Healthcare Provider Feedback. Many engaged patients reported receiving a small yet adequate amount of guidance from healthcare providers, which allowed them to handle abnormal readings and vague algorithm output: “I did have several false readings...[the doctor] said don’t pay attention to those...He took that off the table for me to worry about.” –Patient 9 (engaged). Most unengaged patients, however, reported little to no feedback from healthcare providers to help them overcome these technical issues. In fact, many stated they were unsure if healthcare providers or study coordinators were even receiving their data. For some, this was the direct reason for abandoning the device, as one participant

explained: “I stopped because it said unclassified and...nothing was happening. And I was going insane. What was going on? I wanted feedback.” –Patient 11 (unengaged). All providers stated they acknowledged this need but also pointed to time being a limiting factor in their ability to provide constant feedback to patients.

Usefulness of the Technology.

Similarities in Usefulness of Identifying Rhythm. Most participants in both groups understood how difficult AF is to identify without an ECG. For this reason, they reported that AliveCor™ was useful in giving definitive rhythm identification, or “proof,” as one patient called it. As a result, most patients stated that these data had a comforting effect, which providers also reportedly recognized.

Differences in Insights and Perceived Value of the Data. A major difference we found between engaged and unengaged patients was their ability to independently use the data they were collecting. Many engaged patients reported seeking further insights from the data beyond basic heart rhythm, and stated that the value of the data was a reason for sustained use: “Sometimes I’ll forget to take the medication but I never forget [AliveCor™]... Because I value the feedback that it gives me tremendously.” –Patient 13 (engaged). Conversely many unengaged patients described confusion and difficulty interpreting their data: “When I stopped, I think part of it was getting the message unclassified kind of made wonder what the utility of this thing was.” –Patient 10 (unengaged). Even if confusion did not arise, some unengaged patients did not attach value to insights beyond rhythm identification: “I’m blissfully unaware of other stuff that I should want to know... I don’t know if there’s any other data that would be meaningful to me.” –Patient 2 (unengaged).

Differences in Healthcare Provider Feedback. Many engaged patients reported sharing insights about their data (described as “the signals and symptoms” by one patient) with their healthcare providers to tailor their self-management and medical care. Most providers recognized this as supporting the usefulness of the device: “We can try to sort out why they’re having this rhythm problem and identify any triggers.” –Provider 5. Most unengaged patients reported the need for interpretation to make the data useful, but expressed that they lacked adequate provider feedback. This led to anxiety and even distrust towards providers and researchers: “It seemed like a one-way street where you guys were just taking my information and I’m out there on my own.” –Patient 1 (unengaged). All providers recognized a tendency for data to cause anxiety and distrust, and sometimes reportedly discouraged anxious patients from continuing to monitor as frequently: “I, in fact, encourage them to not check it as often– it just doesn’t serve any purpose besides potentially causing more anxiety about it.” –Provider 5.

Facilitating Conditions.

AF Severity: Long AF histories but varying proactive behaviors. Many patients in both groups reported living with AF for long periods of time but differed in how they reacted. Most engaged patients proactively changed behaviors, including healthier diets, abstaining from known AF “triggers” (e.g. drinking alcohol), and self-monitoring using AliveCor™ more frequently depending on clinical acuity: “I tried to use it every morning right after the ablation...As my rhythm returned to just a bunch of more normal kind of activity it became something I checked less.” –Patient 9 (engaged). In contrast many unengaged patients reported being easily discouraged by their AF recurrence, which they said caused them to self-monitor less and instead rely on office visits with providers for rhythm monitoring: “I’m no longer in AF,

at least, each time that I've been checked... I go in about every six weeks, just to be checked.” – Patient 1 (unengaged).

Some providers observed that patients might appropriately decrease use over time if their heart rhythms became stable, indicating less AF severity: “It’s not that they lost interest. The issue is that for the clinical part... treatment is achieved and the patients are doing well... They’re not less engaged, they’re appropriately using it.” –Provider 1. They also pointed out, however, that this was only the case for patients who were truly clinically stable. If patients did not consider their clinical acuity, they could inappropriately discontinue use.

AF Knowledge: Differences in Uncovering Self-knowledge. Most patients had high levels of knowledge about AF in general. In fact, healthcare providers described the participating patients as “very sophisticated and educated” (Provider 6). However patients’ knowledge of personal physiology and self-management needs (self-knowledge) varied. Approximately half of engaged patients stated that their self-knowledge improved through self-monitoring: “I think that what changed was my sense of how this problem was affecting my day to day life” –Patient 13 (engaged). Most unengaged patients, however, relied on healthcare providers to understand their unique physiology and needs “[My doctor] had told me that relatively speaking [caffeine is] the least effective trigger for me. He said alcohol is the worst and it definitely is, there's no question.” –Patient 7 (unengaged).

AF Symptoms: Driving Use for Unengaged Patients. The majority of the patients in both groups understood that poor correlation between AF symptoms and AF episodes (Barrett et al., 2014; Dekker et al., 2016; Simantirakis et al., 2017) was a reason to use AliveCor™ to identify their true cardiac rhythm. Many engaged patients appropriately considered their actual ECG data versus their symptoms in determining whether to continue using AliveCor™.

Conversely, for many unengaged patients, use was driven by symptoms. They interpreted lack of symptoms as a sign of wellness and a reason to stop using AliveCor™. Alternatively, some patients experienced symptoms that they attributed to AF when they were in a normal rhythm, causing them to use AliveCor™ too frequently. One unengaged patient described how perceived symptoms caused anxiety: “I probably used it too much because every time I have chest pain, I just pull it out. And after a while, I just stop that...Because I can’t be doing it all the time.” – Patient 5 (unengaged). Healthcare providers noticed this tendency: “They are not always in A fib when they do document symptoms... what they perceive to be something is not always the case.” –Research Coordinator 2. Most unengaged patients expressed more confusion about their symptoms, describing them as unclear, inconsistently related to AF, and shifting over time.

Moderators: Age, Gender, and Experience with Technology. Some healthcare providers and patients stated that they thought that age would influence ease of use and usefulness. Yet no patient described their own age as being an impediment to AliveCor™ use, and most providers expressed confidence in their patients’ ability to use the device regardless of age: “I’ve been surprised by how easily patients even in their 60’s, 70’s and 80’s have adopted using this.” –Provider 6. Similarly, both engaged and unengaged patients described comfort with technology, and many even reported tracking other aspects of their health with wearable devices and mobile applications. Even patients who did not consider themselves ‘tech savvy’ expressed comfort using AliveCor™, commenting on its simple design: “I picked it up very easily. It was simple. And I’m not very good—I can’t even program a remote control.” –Patient 5 (unengaged). Healthcare providers and research coordinators agreed that tech savvy was unimportant if patients’ “enthusiasm for their care is there” -Research Coordinator 1. Unlike

these other moderating factors, no participant explicitly discussed gender in the context of engagement with technology.

New Findings

Personality traits and behavioral tendencies. Common patient personality traits and behaviors emerged during the analysis. Most patients in both groups expressed as a sense of concern about their health. All considered themselves a part of the collaborative disease management process: “I’d like to live a long healthy life and being 50 years old, it’s time to make a change. I’m hoping...I can continue to have a quality of life as I grow older.” –Patient 4 (engaged). However, concern for one’s health tended to escalate to anxiety for many unengaged patients, which healthcare providers corroborated: “Once they see something unusual from the baseline...they panic...they call right away.” –Provider 1.

Relationship with Healthcare Provider. Most engaged patients described positive working relationships with their healthcare providers. They stated that either they had a strong relationship prior to using AliveCor™, or the device and the data it generated improved the collaborative relationship between the patient and the providers. One patient said: “With the AliveCor™ device at Columbia, I feel like I am, you know, 99% in tune with them, or they with me, because it just gives them such important information.” –Patient 6 (engaged). Some engaged patients also stated that the device improved collaboration between members of their care team. Unengaged patients more frequently described relationships with providers that were less collaborative and more patriarchal. They described skepticism and a need to advocate for themselves: “I wish they would listen to me. I don’t think they have any idea what to do with me. They’re not looking at the whole picture.” –Patient 5 (unengaged).

Creating Supportive Environments. Both engaged and unengaged patients described routines and reminders to integrate self-monitoring into daily habits. Many kept the device in the same place as a physical cue to make self-monitoring with AliveCor™ part of their “daily ritual,” as one patient called it. Others took the device with them to spot-check if they experienced symptoms.

However all engaged participants reported they maintained these environments, even when busy or travelling: “If I’ve missed the night I know to do it early in the morning and then just do twice the next day. It’s rare...If I’m traveling I’ll take it with me.” –Patient 8 (engaged). Moreover, most engaged patients, as well as healthcare providers, described supportive networks of friends and family as being critical in sustaining engagement with technical support and reminders: “Remembering was difficult but my wife was very helpful in the evenings and in the mornings.” – Patient 13 (engaged). Alternatively, most unengaged participants described busy schedules and travelling as interfering with use: “On weekends I didn’t do it...from the beginning I wasn’t doing it every day. I guess, I just forgot it. I don’t take it to work.” –Patient 11 (unengaged). Few discussed support from family members, friends, or providers to help them to use the device regularly.

Discussion

Summary of Findings

In this study we found similarities and differences between engaged and unengaged patients who used AliveCor™ mHealth ECG technology to self-monitor their AF, which were corroborated by their healthcare providers and research coordinators. All patients described the technology as easy to use and useful on a basic level. All had long AF histories and high AF knowledge, including about the poor correlation between AF episodes and AF symptoms. Nonetheless, distinct and nuanced patterns emerged that distinguished engaged patients from

unengaged patients. Unengaged patients were generally frustrated by technical issues and confused by their heart rhythm data. Most lacked a supportive environment and strong relationships with their healthcare providers to help mitigate these issues, and their concern for their health tended to escalate into anxiety, causing abandonment. Their clinical characteristics, such as their long AF histories, AF symptoms, and knowledge of their unique physiologies (self-knowledge), were also related to their low sustained engagement. Conversely, most engaged patients were uninhibited by technical issues and able to interpret their data on deeper levels. They described supportive environments that promoted engagement, including reminders and habits, social support, and strong relationships with healthcare providers. They viewed self-monitoring as important in addressing their long AF histories, regardless of their perception of symptoms, and reported the data they collected increased their self-knowledge.

Fit With the Adapted UTAUT Model

This study found that the adapted UTAUT model adequately describes predictors of sustained engagement in this population. We found differences in the hypothesized predictors of sustained engagement (ease of use, usefulness, and the three facilitating conditions: severity of AF symptoms, AF knowledge, frequency of AF episodes) between engaged and unengaged patients. For our population, the hypothesized moderators (age, gender, and experience with technology) appeared less influential in the relationship between predictors and sustained engagement than we anticipated. This could be a reflection of a lack of variability within the study sample, as survey data indicated that participants were similar in age and experience with technology, and were predominantly male.

Our findings suggest that four additional factors may contribute to sustained engagement in this population. Three of the four appear to operate as facilitating conditions. First, patients'

personalities and behavioral tendencies, particularly concern about health, were either a motivating force (as they were for engaged patients), or a mitigating force when concern escalated into anxiety (for some unengaged patients). Second, supportive environments, when present, fostered sustained engagement. A lack of such an environment was described as a reason for non-use among unengaged patients. Third, patients' relationships with their healthcare providers, which ranged from collaborative (engaged patients) to deferential (unengaged patients), influenced sustained engagement. The fourth factor, feedback from healthcare providers, was discussed in the context of both perceived ease of use and perceived usefulness, and thus may have a moderating effect on these predictors. Specifically, unengaged patients wanted healthcare providers' feedback to mitigate technical issues and improve understanding of data, and stated that a lack of feedback was a primary reason for non-use.

The original, unadapted UTAUT model contained factors that were condensed or eliminated in the adapted UTAUT model upon which we based our study (Jiang et al., 2016). Three of the four additional factors that emerged in this study align with those eliminated from the original UTAUT model. Specifically, individuals' internal values and supportive environments are two facilitating conditions in the original UTAUT model. "Social influence" is also present in the unadapted UTAUT model, which broadly aligns with the patient-provider relationship factor that we identified (Venkatesh et al., 2003).

Relationship to Prior Work

To our knowledge this is the first study to use qualitative, primary source data to generate a comprehensive list of factors related to sustained engagement with mHealth in a specific patient population. Jiang et al. (2016) first used an adapted UTAUT model to predict sustained engagement among lung transplant patients. We extend their work by validating the utility of the

adapted model in a different patient population and, by doing so, identified additional factors relevant to sustained engagement.

Recent studies that examined sustained engagement using quantitative methods (such as surveys) have not captured nuanced influences on engagement. For instance, technology-related factors such as perceived ease of use and perceived usefulness have previously been identified as important correlates of sustained engagement (Hermsen et al., 2017; Sharpe et al., 2017). Our qualitative study uncovered subtle differences between engaged and unengaged patients, such as the depth of their insights from the data or their ability to troubleshoot technical issues. Another study found evidence that internal motivation, a construct from self-determination theory, is critical for sustained engagement (Coa & Patrick, 2016). While this aligns with our finding that concern for one's health was an internal motivator for all our patient subjects, some became frustrated or confused by self-monitoring, and the resulting anxiety dampened their engagement over time. The relationship between internal motivation and sustained engagement therefore warrants future research in different populations in which internal motivation may be more variable.

Implications for Design

An understanding of factors related to sustained engagement may be useful in tailoring design of self-monitoring applications. Table 4.1 maps these factors to specific design implications, which include two major approaches. A first set of approaches focuses on feedback that unengaged patients reportedly lacked. These include links to online communities that might facilitate patient-to-patient communication, or application-based messaging with healthcare providers that might improve patient-provider communication and overall relationship. This is a controversial option, however, given the well-documented time, liability, reimbursement, and

scope of practice issues that providers cite in response to application-based messaging (M. J. Reading & Merrill, 2018).

A second set of approaches focuses on automation to satisfy needs described by patients. These include tested solutions that have yet to be implemented for self-monitoring. For instance, clinical decision support, previously developed to support healthcare providers (Beeler, Bates, & Hug, 2014; O'Sullivan, Fraccaro, Carson, & Weller, 2014), could guide patients' interpretation and evaluation of their own clinical presentation through the data. Infobuttons, which are widely used in electronic health records (EHRs), merit application to mobile health applications (Long, Hulse, & Tao, 2015; Teixeira, Cook, Heale, & Del Fiol, 2017). Interactive visualizations that help individuals make sense of large amounts of complex data, have potential applications to patient-generated health data (Gotz & Borland, 2016; Woods et al., 2016).

In this study all subjects, including providers and research coordinators, noted that the feature for recording symptoms and triggers within Alivecor™ was difficult to use. However the relationship between AF symptoms, episodes, and triggers varies by individual (Barrett et al., 2014). If application design eases capture of AF symptoms and triggers, those data points could be triangulated with ECG data to discover manifestations of AF unique to the individual. Visualizations developed to enhance understanding of these triangulated data could improve AF management (Gotz & Borland, 2016).

Table 4.1: *Design Options for Sustained Patient Engagement guided by the Adapted UTAUT Model*

Factor	Feedback		Automation			
	Online communities	Messaging with provider	Patient decision-support	Info Buttons	Additional relevant data capture	Interactive data visualizations
Perceived Ease of Use			✓	✓		
Perceived Usefulness			✓	✓	✓	✓
AF Severity*			✓			✓
AF Knowledge*				✓	✓	✓
AF Symptoms*			✓	✓	✓	✓
Personality/behavioral tendencies*			✓	✓		
Relationship with provider*		✓				
Supportive environment*	✓	✓	✓	✓		
Feedback and guidance**	✓	✓				

*Facilitating Condition; **Moderator

Implications for Research

Our findings suggest a number of new lines of inquiry regarding sustained engagement. Healthcare providers observed there is a time to appropriately stop self-monitoring (if clinically stable for an extended period of time). For what length of time do patients actually need to self-monitor to receive a clinical benefit for specific conditions? Previous work has identified exact durations of remote monitoring necessary to diagnose or manage arrhythmias with implantable cardiac devices (Cheung, Kerr, & Krahn, 2014; Tung, Su, Turakhia, & Lansberg, 2014; Turakhia et al., 2013), but overall this issue is inadequately studied in the self-monitoring space. While we have identified a number of application design features that can target engagement, there remains the larger philosophical question of whether sustained engagement should be the goal for each

patient. Patients and healthcare providers alike noted that anxiety could overcome utility for some patients. Others have found similar negative emotional responses to self-monitoring (Ancker et al., 2015; Purtzer & Hermansen-Kobulnicky, 2016). While thoughtful design of applications that improve communication and information regarding the data may help, it will not mitigate anxiety for all patients. In such cases, the risk of continued anxiety, which itself is a risk factor for AF recurrence, may outweigh any clinical benefit of self-monitoring for the patient.

Limitations

This study had some limitations. First, while we attempted to classify patients' engagement from their behavior recorded in the AliveCor™ portal, more precise classification of engagement was not possible because raw usage data was not available. We may have inadvertently misclassified some patients' engagement. Second, this patient population was uniquely well educated regarding their arrhythmia and highly engaged in their care overall. They were also predominantly male, middle- to older-age, and moderately to extremely comfortable with technology. Our sample therefore had little variability and tended towards high engagement with self-monitoring. While we made every attempt during our analysis to bracket biases that resulted from these sample characteristics, our findings are likely not generalizable to other patient populations. We have demonstrated that theoretical models guiding data analysis always need to consider the unique patient population being studied.

Conclusion

This study provides insights on factors related to sustained engagement in a unique population of adults living with AF. We found evidence that the UTAUT model can serve as a valid framework for understanding sustained engagement, though it requires modifications to

account for the patient population in consideration. The theory-driven findings we elicited can guide design and development of mobile application interfaces for self-monitoring to engage adults living with AF for a sustained period of time. The UTAUT model also may guide establishment of parameters for sustained engagement for different patient populations in future work. Theory-based evidence for application design may be useful in facilitating potential health benefits of PGHD collected with mHealth technology.

Chapter Five: Conclusions

This dissertation aims to examine patients' and providers' collection and use of digital patient-generated health data (PGHD) in real-world settings, which includes their expressed needs and possible approaches to meeting these needs. This dissertation is composed of Chapter Two, an integrative review examining convergent and divergent areas of need for collecting and using patient-generated health data (PGHD) identified by patients and healthcare providers; Chapter Three, a quantitative study evaluating predictors and moderators of sustained engagement in a post-intervention population of adults self-monitoring their AF; and Chapter Four, a qualitative study exploring the utility of the adapted UTAUT model in characterizing sustained engagement in this unique patient population. In Chapter Five, key findings from each of the preceding chapters are summarized and discussed in the context of related work. We then elicit implications for the intersection of health policy and clinical practice, design, nursing, and future research from our findings.

Summary of Results and Key Findings

Chapter Two

Chapter Two consists of an integrative review that examined convergent and divergent needs when collecting and using patient-generated health data (PGHD) identified by patients and providers (i.e. physicians, nurses, advanced practice nurses, physician assistants, and dietitians). By synthesizing findings from eleven studies (seven mixed-methods, four qualitative), we found that patients and providers converged on clinical and technological needs and diverged on logistic needs. We also found evidence of interplay between patients' and providers' needs. Patients need feedback and reassurance, and providers need to manage the flow of PGHD in their clinical practice.

This review compiles a detailed description of patients’ and providers’ needs that may serve as the basis for an initial set of requirement specifications for systems that collect and display PGHD in future work. Recently, ONC published a practical guide for providers and researchers seeking to use PGHD (ONC, January 2018a). This guide provides high-level considerations for engaging patients to collect these data, and integrating these data into clinical workflows from a technical, functional, and financial perspective. The findings of our integrative review of primary source data from important stakeholders (patients and providers) supplement ONC’s guide with more detailed considerations for addressing stakeholders’ concerns. Importantly, in an updated white paper on PGHD, ONC acknowledged continued reticence to adopt PGHD among patients and providers due to ongoing concerns about unmet needs (ONC, January 2018b). In fact, CMS recently proposed removing the integration of PGHD into the EHR from its quality measures due to providers’ reports that this criteria was too burdensome, which we discuss in more detail below (CMS, 2018a). The findings of our review may provide timely recommendations to allay patients’ and providers’ concerns about PGHD.

Chapters Three and Four

The studies in Chapters Three and Four are discussed together because they offer complementary perspectives on sustained engagement. Areas of alignment between each study substantiate parts of the adapted UTAUT model (Figure 5.1; see Figure 2.1 for full-size image), while discordant findings indicate areas for further exploration. The triangulation and integration of findings from these quantitative and qualitative studies offers a more complete understanding of the results (Scott, 2016).

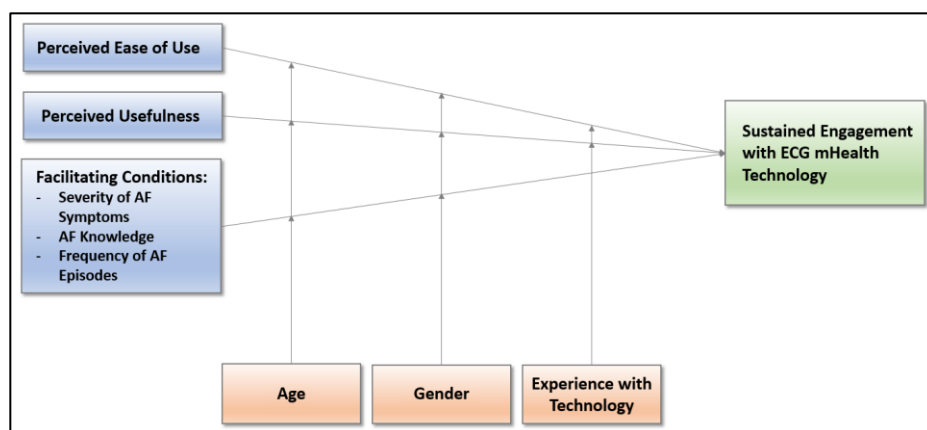


Figure 5.1. The Adapted UTAUT Model

Patient sustained engagement with self-monitoring is studied in detail in the studies described in Chapters Three and Four as a major barrier to PGHD collection. Chapter Three consists of a quantitative evaluation of the adapted UTAUT model among adults who are self-monitoring AF in the context of the iHEART trial using Hierarchical Generalized Linear Modeling (HGLM). Chapter Four explores the adapted UTAUT model more deeply through qualitative investigation using directed content analysis of focus groups and interviews with patients, providers, and research coordinators in the iHEART trial. The quantitative study provided preliminary evidence that some of the predictors (frequency of AF episodes, AF knowledge, and perceived usefulness) in the adapted UTAUT model are related to sustained engagement. The qualitative study found support for all of the predictors with nuanced explanations for differences between engaged and unengaged patients. We also identified four additional factors in the qualitative study: (1) personality/ behavioral tendencies, (2) relationship with healthcare provider, (3) supportive environments, and (4) feedback and guidance.

Neither study found evidence of moderating effects of age, gender, or experience with technology on the relationship between predictors and sustained engagement. This may reflect the underlying lack of variability in the iHEART trial subjects, who were similar in these

respects. Alternatively, demographic characteristics typically associated with technology use may be less relevant as mobile technology becomes ubiquitous in society across age, gender, race/ethnicity, socioeconomic, and geographic groups (Pew, 2018). Assumptions surrounding technology adoption and use may need to be revisited given the degree to which technology has permeated all aspects of society since the UTAUT model was constructed by Venkatesh et al. in 2003.

Recent studies have identified individual predictors of sustained engagement, including perceived ease of use, perceived usefulness, age, gender, and health-related characteristics (Hermsen et al., 2017; Park et al., 2018; Sharpe et al., 2017). However to our knowledge, only Jiang et al. (2016) have sought to validate a theoretical model (an adapted version of the UTAUT model) that can be broadly applied for future sustained engagement research. By using the adapted UTAUT model, we were able to understand the parameters of sustained engagement among adults with AF who are unique from individuals with other chronic conditions, as others have reported about adults with AF (Dagres et al., 2007; Kaiser et al., 2016; Lip et al., 2015). The adapted UTAUT model used in this dissertation was based on the work of Jiang et al. (2016), who condensed some aspects of the original UTAUT model when they adapted it for sustained engagement. However, we found evidence that, in our patient population, some factors present in the original UTAUT model (individuals' internal values and supportive environments as two additional facilitating conditions, "social influence" as an additional predictor) were related to sustained engagement. This led us to conclude that the UTAUT model always needs to be modified to the unique characteristics of a patient population.

Based on the findings of this dissertation, those seeking to adapt UTAUT to other populations should consult relevant clinical literature to identify any documented relationships

between variables in the UTAUT model (such as age, gender, and disease-specific characteristics) that may interact to influence sustained engagement together. In addition, both quantitative and qualitative methods are useful, as we were able to uncover nuances and additional factors associated with sustained engagement through qualitative interviews and focus groups that were not identifiable through quantitative analysis. Importantly, more accurate measurement of constructs from the adapted UTAUT model at the time of the most reliable data, which is likely at the time of mHealth use, should be explored due to limitations of secondary data analysis discussed in Chapter Three. Real-time data capture via smartphone application, such as ecological momentary assessment (EMA), is one feasible approach as smartphones become increasingly popular and prevalent (Pew, 2018). Through this approach, individuals' responses to questions of interest may have higher content validity and fewer limitations (missing data, recall bias) to allow for a more robust evaluation of the adapted UTAUT model in the context of sustained engagement (Hand & Perzynski, 2016; Shiffman et al., 2008).

Themes from the Findings of this Dissertation

Shift towards a collaborative patient-centered model. In recent decades, the model of patient care has shifted from one in which patients are deferential and providers have authority, towards one in which patients are considered active and valued members of the care team (Knorr-Cetina, 2003). In Chapter Two we found that patients and providers report that PGHD enhances the working patient-provider relationship by fostering communication and information exchange. In Chapter Four, our subjects reported that a collaborative patient-provider relationship could sustain patient engagement to collect PGHD. Others have anticipated that PGHD will be a major component of the paradigm shift towards collaborative, patient-centered healthcare (Hull, 2015; Van Doornik, 2013) and the findings of this dissertation provide early

evidence of that. At the same time, we also found that in most systems for collecting and using PGHD described in Chapter Two, only providers and not patients were the intended audience of PGHD. Therefore, our design implications (discussed later) recognize that the patient is an increasingly vital part of the care team and thus, consider the patient a user, not only a collector, of PGHD.

The importance of considering patients and providers together. By examining patients' and providers' perspectives together in Chapters Two and Four, we found inextricable links between these two stakeholders in the process of collecting and using PGHD. For instance, patients needed feedback and guidance from providers, while providers needed to set boundaries with patients to manage the flow of data into their practice. Each group was also aware of each other's needs even if it did not relate to their own, such as when providers acknowledged that patients need support regarding data collection to avoid becoming anxious. This suggests that systems that collect and display PGHD should be developed with both primary stakeholders in mind. While this approach may present challenges regarding the detail and complexity of data display, it has the potential to enhance transparency and mitigate many of the challenges described by patients and providers regarding communication and interoperability (Lavalley et al., 2016).

Revisiting the concept of engagement. By examining individual factors that contribute to sustained engagement, we conclude that it is a multifaceted concept. This dissertation uncovered three interconnected facets contributing sustained engagement with self-monitoring: *the patient, the provider, and the technology*. This conceptualization helps to explain why research that addressed these facets in isolation has demonstrated little success improving sustained engagement (King et al., 2013; Shimada, Allison, Rosen, Feng, & Houston, 2016).

Further, our findings suggest that all three facets should be incorporated into the design and evaluation of self-monitoring technologies that facilitate sustained engagement.

In this dissertation we found evidence that engagement is more complex than use or non-use of mHealth technology. For instance, those patients who appropriately discontinue self-monitoring when clinically stable may be less frequent users over time, but their independent interpretation of their self-monitoring data would deem them engaged in their overall self-management. However, there exists a lack of a clear definition of engagement with self-monitoring in the informatics community. Moreover, while usage may not be a measure of engagement that fully captures its dimensionality, usage data is the most common approach to understanding engagement in the absence of a standardized measurement of the phenomenon. Future work should seek to develop a standardized definition and measurement of engagement with self-monitoring that still accounts for nuances such as those described above.

Leveraging PGHD to sustain patient engagement. The findings of this dissertation highlight new opportunities to use PGHD to motivate this unique group of patients with AF to continue to collect PGHD. Specifically, we found that adults with AF who derive value from their self-monitoring data continue to collect it. They reportedly derive value from understanding their health data in the context of their personal as well as population norms, and from understanding the impact of their lifestyle and other behaviors on their health (quantified with PGHD). Similarly, ONC's practical guide states that highlighting the personal value of PGHD can be a tool for motivating individuals to continue to collect it (ONC, January 2018a). However, the possibility of using PGHD to motivate further data collection has been primarily explored among patients who are highly activated to collect these data in the first place, such as members of the "Quantified Self" movement, but is not well understood among patients for whom baseline

engagement is more variable (Braber, 2016; Miyamoto et al., 2016). Therefore, individuals who are not intrinsically motivated by their own data require a tailored approach to engagement based on their distinct motivations.

Limitations and Strengths

This dissertation has several limitations. The integrative review in Chapter Two is comprised of a heterogeneous sample of studies with respect to clinical focus, samples of subjects, and type and purpose of PGHD collected. This made generalization of findings across studies included in the review difficult. At the same time, the studies in Chapters Three and Four are limited by using data and participants from the ongoing iHEART trial, who were highly similar to one another and unique from other patient populations. This is especially true of the patients described in Chapter Four, who self-selected to participate in focus groups and interviews and are likely among the most engaged iHEART participants. Therefore, the results of these studies reflect a patient population that is not generalizable to others with chronic conditions. Additionally, the small number of subjects and use of secondary data that was prone to missing values and recall bias limited the quantitative study in Chapter Three.

Nonetheless, this dissertation has clear strengths. The study in Chapter Two contributes a synthesis of rich accounts of PGHD use in real-world settings from two primary stakeholders, patients and providers, to the literature. From these accounts we compiled a list of diverging and converging needs, which may inform future design of systems involving PGHD collection and use that accommodate the needs of both major stakeholders. The design of such systems is needed given major aligning initiatives to accelerate the integration of PGHD into clinical practice (CMS, 2017b; ONC, January 2018b). We also conducted a more thorough investigation of one barrier to PGHD collection in particular, sustained engagement, that has been well

documented but not thoroughly explored (Hermesen et al., 2017; Lai et al., 2017). Using a validated model of sustained engagement allowed us to clarify the parameters of sustained engagement in a unique patient population of adults with AF, and use these parameters to generate design options for engaging adults with AF to collect PGHD for a sustained period of time. These studies are also strengthened by the use of application usage data from patients self-monitoring in their daily lives over one year. This allowed for examination of more natural patient behaviors that are difficult to observe in health sciences research, in which app use is typically studied for shorter periods of time and in more controlled settings (Lai et al., 2017). Additionally, by interviewing a variety of stakeholders, including patients (engaged and unengaged), healthcare providers, and research coordinators, our understanding of sustained engagement in this population is multifaceted and the design options for optimizing patient sustained engagement are likely more comprehensive.

Implications

Implications at the Intersection of Clinical Practice and Health Policy

Much of healthcare reform stemming from the Affordable Care Act (ACA) and associated legislation, such as HITECH, MACRA, and 21st Century Cures, has emphasized and promoted health information technology (HIT) to support a transformed system ("21st Century Cures Act (Cures Act) ", 2016; "The Health Information Technology for Economic and Clinical Health (HITECH) Act," 2009; "Medicare Access and CHIP Reauthorization Act of 2015," 2015; "Patient Protection and Affordable Care Act," 2010). Each of these pieces of legislation contain significant provisions that have supported the development and adoption of HIT over the past eight years, creating an impetus for this technology in clinical practice through incentives, mandates, and laws (Van Doornik, 2013). Moreover these changes are occurring quickly, with

new policy related to PGHD having been proposed or passed even since the initial conception of this dissertation (CMS, 2017b, 2018a). Therefore we focus on the implications of our findings at the intersection of clinical practice and health policy, rather than considering each in isolation.

PGHD is poised to dramatically alter clinical practice in years to come (ONC, January 2018b). The findings of this dissertation support previous research reporting that PGHD produces information and knowledge to support clinical decision-making for providers, and also provides a context for those decisions (C. F. Chung et al., 2016; Shaw et al., 2015). In this way PGHD represents an opportunity to personalize care based on the unique characteristics of individual patients. By aggregating data from individuals to understand population-level relationships between determinants of health and health outcomes, PGHD also has the potential to improve population health (Bauer et al., 2014). PGHD may be especially beneficial for individuals and populations in the setting of chronic conditions, whose trajectory is influenced by the synergy of biology, environment, and lifestyle (Bell, 2017).

Policy initiatives surrounding PGHD continue to provide momentum for these data to be collected and used by healthcare providers and health sciences researchers. Recognizing PGHD as having the potential to advance patient engagement, care delivery, and research, ONC continues to support the integration of PGHD into the EHR (HealthIT.gov, 2016). The quality payment program initiated by MACRA includes a Merit-based Incentive Payment System (MIPS), which measures clinicians' performance based on quality measures (CMS, 2018c). Incorporation of PGHD into a certified EHR for at least one patient is a quality measure that advances care information through coordination of care and patient engagement (CMS, 2018b). Recently proposed changes would remove mandatory *reporting* on this measure due to the burden to providers (CMS, 2018a), and the informatics community will need to address the

complexity and burden of PGHD for providers in clinical practice. Nonetheless, CMS will continue to *reimburse* providers for the review of certain PGHD under the 2018 Physician Fee Schedule, which incentivizes integration of these data into clinical care (CMS, 2017).

In addition, the National Academy of Medicine (formerly the Institute of Medicine) has promoted the concept of the Learning Healthcare System, in which new knowledge is captured and integrated into the care delivery system in a seamless, cyclical process to support continuous improvement and innovation ("Background: Learning Healthcare System," 2018). PGHD has been acknowledged as an important source of information from outside of the clinical setting to be incorporated into the Learning Healthcare System (Foley & Fairmichael, 2015). Finally, funding and opportunities related to the Precision Medicine Initiative, including the National Institute of Health's "All of Us" Research Program, have been growing and include the use of PGHD to understand relationships between lifestyle, environment, and biology (NIH, 2018).

Although evidence demonstrating the health and cost benefits of PGHD is growing, it remains limited and inconclusive, which has hampered clinical adoption and research activity related to implemented PGHD use in real-world settings (Bloss et al., 2016; ONC, January 2018b). In fact, one recent review article found a growing number of pilot studies using mHealth to collect PGHD, but a lack of research on the use of these data by patients and providers (Lai et al., 2017). Providers and researchers will need to collaborate and capitalize on the aligning policy initiatives described above to generate an evidence base of best practices related to PGHD (ONC, January 2018b; Tiase, 2017).

Evidence on PGHD use in real-world settings will clarify its potential to improve patient-provider communication and proactively manage health, especially chronic conditions, which are the most common and costly health conditions in the U.S. (Buttorff, 2017; CDC, 2016).

Ultimately, the vision is that PGHD will improve the quality of both individual and population health, as well as the patient experience, while reducing costs (C. F. Chung et al., 2016; Hsueh, Dey, Das, & Wetter, 2017; Van Doornik, 2013). The Quadruple (formerly Triple) Aim of better care, better health, lower cost, and now *provider* satisfaction continues to drive the evolution of our healthcare system (Bodenheimer & Sinsky, 2014). Though PGHD may be instrumental to achieving the Quadruple Aim, the findings of this dissertation research highlight the need for rigorous implementation research to ensure PGHD is a catalyst, not a detriment, to these goals.

Implications for Design

Table 5.1 provides a summary of existing mHealth design options and system requirements that have the potential to address the needs expressed by patient and providers regarding PGHD.

Table 5.1: Summary of existing mHealth design options and system requirements with potential to address the needs expressed by patient and providers regarding PGHD

Design Option	Patient and Provider Expressed Needs (Chapter where documented)
Online Health Communities	<ul style="list-style-type: none"> • Patients have emotional needs that can be met by providing context and understanding with PGHD. (2,4) • Patient motivation to collect PGHD can increase with peer and provider support. (2,4)
Patient-Provider Messaging with Constraints <i>Examples of constraints include giving a window of response time, specifying data to which providers will and won't respond (e.g., abnormal values only), and clarifying content that is appropriate and inappropriate to include in messages.</i>	<ul style="list-style-type: none"> • PGHD needs to support the working relationship between patients and providers. (2,4) • Patients have emotional needs that can be met by providing context and understanding with PGHD. (2,4) • Patients may want providers to constantly monitor their PGHD and provide feedback to dispel their doubts. (2,4) • Providers need to manage patient expectations regarding the review process. Patients want a timely response (e.g., within 4 hours) while providers fear a requirement for rapid response may disrupt workflows and care of other patients. (2,4) • Patients want the option to electronically communicate with providers about their PGHD while providers fear it could compromise the professional relationship. (2)
Patient-facing decision-support	<ul style="list-style-type: none"> • Patients need clinical guidance on how to collect and interpret their own health data (related to knowledge about their disease and perceived usefulness). (2,3,4) • Patients need technical guidance on how to troubleshoot and overcome technology-based problems to increase perceived ease of use. (2,4) • Patients and providers may not trust automated data summaries and algorithm outputs. (2,4)

<p>Patient-facing InfoButtons</p> <p><i>In some cases, InfoButtons may only be helpful in reinforcing initial patient-provider conversations surrounding details of collection and use of PGHD.</i></p>	<ul style="list-style-type: none"> • Patients need clinical guidance on how to collect and interpret their own health data (related to knowledge about their disease and perceived usefulness). (2,3,4) • Providers can leverage PGHD for health education and counseling. (2,4) • Patients have concerns about how their data is used, re-used, and how extensively it might be shared. (2,4) • Patients may not trust automated data summaries and algorithm outputs. (2,4)
<p>Interactive data visualizations and other analytics-based data summaries (both patient- and provider-facing)</p>	<ul style="list-style-type: none"> • Providers can leverage PGHD for health education and counseling. (2,3,4) • Patient motivation to collect PGHD can wane if benefits from self-monitoring are not immediate or shared with the patient. (2,3,4) • Providers need methods to reduce the time burden and “information overload” for PGHD review. (2) • Patients and providers need visualizations to be customizable, including the ability to vary the amount of detail, view data in different ways, and mark-up visualizations with notes and color-coding, to save time. (2) • Patients can use visualizations to help them make lifestyle adjustments that improve their health condition. (2) • Patients and providers need a summary of the data that is rapidly understandable and cues them to action. (2,4) • Patients expect data summaries may answer their questions without having to contact their provider. (2,4)

<p>Goal setting feature</p> <p><i>If goals are clearly displayed after being discussed and agreed upon, they may focus users on the purpose of collecting and using PGHD. They may also guide providers in selecting a subset of patients on which to receive PGHD, and signal when the benefits of PGHD collection begin to outweigh risks (such as increased patient anxiety with no further clinical benefit).</i></p>	<ul style="list-style-type: none"> • Goals for collecting and using PGHD may be different between patients and providers. (2) • There may be an appropriate time to stop self-monitoring for some patients (after the clinical goal has been achieved). (4) • Patients may become overly anxious by their data, at which point the risk of continued self-monitoring outweighs any potential benefit. (4) • Providers may need to select a subset of patients from whom to receive PGHD based on certain criteria (e.g., only those patients who are not anxious, or those whose disease is least well controlled). (2)
<p>Systems Requirements</p>	<p>Patient and Provider Expressed Needs (Chapter where documented)</p>
<p>Customizable but standardized data entry</p> <p><i>For instance, selection from a list that is iteratively developed based on user feedback until it encompasses majority of response options needed.</i></p>	<ul style="list-style-type: none"> • Patients may need to customize data entry to capture additional relevant data and increase perceived ease of use and usefulness. (2,4) • Providers may need customized patient data entry to support clinical decision-making. (2) • Providers need standardized definitions of data types to reduce the time burden of sifting through PGHD, and concerns about data quality that stem from open-ended responses. (2)
<p>Interoperability with Caveats (maintain privacy of HPI and data provenance)</p>	<ul style="list-style-type: none"> • Patients and providers need PGHD integrated into existing systems to reduce confusion and frustration, and improve care coordination and communication across providers. (2) • PGHD not directly pertaining to a clinical problem, or “contextual metadata,” can be valuable for understanding the relevant PGHD, clinical decision-making, and in emergency situations. (2)

<p>(Interoperability continued)</p>	<ul style="list-style-type: none"> ● Additional data capture may improve understanding of specific disease processes and relationship to symptoms and lifestyle habits (related to knowledge about their disease and perceived usefulness). (2,3,4) ● Providers are concerned about privacy issues with PGHD, especially from minors. (2) ● Patients are confused about whether their PGHD collection is private and confidential. (2,4) ● Providers are concerned about the quality of PGHD. (2) ● Providers need to distinguish data recorded by patients versus family members and healthcare professionals in other settings. (2)
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These design options are comprised of existing informatics tools that have yet to be widely implemented for self-monitoring. Although we studied different patient and provider populations in the integrative review and in the iHEART trial, design implications were congruent across studies and with recommendations recently published by ONC (ONC, January 2018a). These design options are meant to be studied, adapted, and iterated upon based on the unique characteristics of other patient and provider populations.

While we offer options that focus on design as a means of addressing many of the needs expressed by patients and providers in this dissertation, some of the needs that center on workflow, reimbursement, time, and communication are best addressed through other approaches, such as health policy, institutional protocols, and face-to-face patient-provider communication. In fact, some of the solutions we propose rest on the assumption that these other approaches are also instituted, and that design is merely a reinforcing factor. Nonetheless, while policy and initiatives surrounding PGHD are, to a certain extent, out of the purview of researchers, design is a research-based approach for meeting the needs of patients and providers that is less contingent on political and social undercurrents.

Design and development of mHealth technologies that aim to address expressed needs of patients and providers regarding PGHD must also consider the changing role of the Food and Drug Administration (FDA) in regulating these technologies. The 21st Century Cures Act clarified the FDA's role in regulating digital health by amending the definition of "device" to clarify software functions that were included and excluded from its regulatory scope ("21st Century Cures Act (Cures Act) ", 2016). In response, the FDA published a series of guidance papers outlining changes to their policies and procedures as a result of the Cures Act. These include papers specifically addressing: (1) low risk general wellness products (e.g., weight

management and physical fitness tracking), (2) clinical and patient decision support, (3) medical devices, (4) medical software, and (5) Software as a Medical Device (SaMD) (FDA, 2018).

Not only will researchers seeking to design and develop mHealth have to comply with the FDA's evolving regulations, but they will also need to consider the safety implications of releasing technologies for use by patients and providers that are not regulated. Without thoughtful design, patients and providers may draw inaccurate conclusions from digital health data and take inappropriate, possibly unsafe actions as a result of these conclusions (Howie et al., 2014).

Implications for Nursing

As the providers on the front-line of patient care, nurses and advanced practice nurses are likely to be among those most affected by the deluge of PGHD into clinical practice (Hull, 2015). As a tool for patient empowerment allowing patients to proactively manage their health, PGHD aligns with the nurse's role of delivering patient-centered care and empowering the patient (Samples, Ni, & Shaw, 2014). Therefore, nurses will be in a position to voice not only their perspective, but also the perspective of their patients (Hull, 2015; Tiase, 2017). These voices are critical in the current environment in which systems that collect and display PGHD are now being designed, developed, and used in clinical practice and research.

In addition, nurses and nursing informatics researchers are uniquely positioned to develop data science approaches for creating meaning from PGHD, including visualizations. Nursing informatics research focuses on leading the development, design, and implementation of technologies for presenting and retrieving information to support patients, nurses, and other providers (AMIA, 2009; Gee et al., 2012). With regards to PGHD, key questions for nursing informatics research will include how PGHD can be optimally integrated into nursing practice

such that it can inform nursing knowledge, support shared decision-making, and improve nursing care of individuals and populations (Hull, 2015). Nurses and advanced practice nurses in clinical practice can provide insights on optimal use of these data that consider both patients' and providers' priorities and realities. This can inform the iterative development of visualizations and other techniques to support use of PGHD.

However, nurses remain underprepared to practice and collaborate with researchers in an increasingly technological clinical environment. A recent study demonstrated that nurse executives lack competency-based nursing informatics education and training, and are unaware of the competencies they should expect in their nursing graduates (Collins, Yen, Phillips, & Kennedy, 2017). At the same time, nursing graduates continued to be underprepared for informatics tools and concepts they will encounter in clinical practice because precise informatics competencies have yet to be well integrated into nursing curricula (Foster & Sethares, 2017). As new forms of data and technology increasingly pervade clinical practice, all clinical nurses, not just nursing informatics specialists (as was the case in years past), will need to be equipped with informatics training. With informatics training, nurses will gain awareness of how their knowledge of their nursing practice and of the patient can both inform and benefit from technology development (Foster & Sethares, 2017). The anticipated surge in PGHD in the near future places more urgency on the necessity that all nurses understand the informatics aspects of PGHD to ensure they are collected, managed, and presented appropriately (Hull, 2015; Tiase, 2017).

Moreover, in this dissertation, we found that the nurse's role and scope of practice relating to PGHD remain poorly defined, even in those settings that are more accustomed to receiving PGHD than most, such as electrophysiology (Turakhia & Kaiser, 2016). Nurses and

nurse practitioners are unsure how their current clinical practice will translate to reviewing and responding to PGHD. For instance, can they independently titrate patients' medications based on these data? Can they make diagnoses with it? As the role of nurses in the integrated care team evolves, the unique responsibilities and priorities of nursing practice surrounding PGHD will need to be well differentiated (Foster & Sethares, 2017; Lindroth, Isind, Steineck, & Lundin, 2018).

Implications for Future Research

As new approaches and technologies for collecting PGHD are developed and become interconnected, these data are likely to increase in size and complexity. Novel approaches for producing meaning and insights from the data are needed. PGHD is unlike “neat” experimental data that health sciences researchers typically work with (Hull, 2015; Shaw et al., 2015). Rather, it is heterogeneous, originates from a variety of sources, and often in free-text format. This presents new challenges for gathering, cleaning, and organizing the data. Current approaches for working with “big data” such as machine learning and natural language processing may provide solutions, but current applications are limited in their ability manage the heterogeneous nature of PGHD (Hsueh et al., 2017; Lai et al., 2017). As described in Chapters Two and Four, patients collecting these data, their caregivers, and their healthcare providers, are faced with the task of deriving insights to address a specific health concern, such as chronic disease management. This process can be time-consuming, confusing, and have myriad legal and social implications that have yet to be fully addressed. Therefore, novel methods are needed that translate and display PGHD into consumable knowledge that will support actions by patients and providers to improve health for individuals, and also for populations of individuals that face common problems.

In the integrative review in Chapter Two, both patients and providers indicated that they prefer visualizations as an approach to efficiently synthesize and act on the PGHD. However developing such visualizations can be challenging due to competing requirements. For instance, visualizations must balance adequate detail with simplicity. Patients and providers each have unique needs from the data, and even within each of these groups, levels of statistical literacy and specific questions asked of the data can vary. Moreover, visualizations must support rapid interpretation and insights given the potential for data to be overwhelming and time-consuming that we documented throughout this dissertation. Pilot testing of different visualizations that display complex PGHD has been conducted (Hohenstein et al., 2018; Lindroth, Islind, Steineck, & Lundin, 2018), but research on the use of these visualizations within clinical workflows or among patients in the community setting has yet to be established.

Collaborative research on PGHD between data science and other research domains is also warranted. Data science and healthcare delivery science intersect at the common aim of reducing the cognitive and logistic burden of these data in clinical practice (ONC, January 2018b). Additionally, data science work with PGHD carries myriad ethical questions as this space evolves. For instance, there exists a tension between the moral obligation to make population-level insights from PGHD equally accessible to all, and the need to protect personal health information (PHI), proprietary algorithms, and other intellectual property (Hsueh et al., 2017; Peterson et al., 2013). Moreover, the possibility that PGHD may worsen, rather than ameliorate, existing health disparities given evidence that individuals from medically underserved backgrounds are less likely to engage in self-monitoring (termed the “digital divide”) must be addressed (Dlugasch & Ugarriza, 2014; Lee, 2014; Lobelo et al., 2016). Finally, given close ties between a patient’s health data and health behaviors as they collect and use PGHD, data science

may benefit from behavior change theories as a means of understanding approaches for presenting data in a way that positively influences individual health behaviors (Michie, Yardley, West, Patrick, & Greaves, 2017).

Conclusion

PGHD holds both promise and pitfalls for healthcare. By offering understanding of the patient's daily experiences through data on lifestyle, mood, symptoms, and physiology, PGHD offers a more informative context for providers to make better healthcare decisions. As an increasingly valued member of the healthcare team, patients may also better understand their own health and, as a result, make better decisions about it. This is especially true for the 150 million individuals in the U.S. who are living with a chronic condition (Buttorff, 2017), for whom daily decisions made outside of clinical settings synergistically impact disease trajectories and health outcomes. Nonetheless, questions surrounding technical, logistical, and financial aspects of integration of these data into routine care remain unanswered. The complexity and volume of PGHD present new challenges for deriving meaning and insights that can be readily translated into actionable knowledge. Future research at the intersection of clinical practice, policy, and informatics is critically needed to design, develop, and implement solutions that address these challenges. Equipped with deep knowledge of the patient experience, nurses are uniquely positioned to collaborate across settings, stakeholders, and disciplines to optimize the process of PGHD collection and use. Therefore this work can and should involve nurses, but practice- and education-based competencies are needed to ensure they are equipped with the informatics knowledge necessary to actively participate in these processes.

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Review

Converging and diverging needs between patients and providers who are collecting and using patient-generated health data: an integrative review

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ABSTRACT

Objective: This integrative review identifies convergent and divergent areas of need for collecting and using patient-generated health data (PGHD) identified by patients and providers (i.e., physicians, nurses, advanced practice nurses, physician assistants, and dietitians).

Methods: A systematic search of 9 scholarly databases targeted peer-reviewed studies published after 2010 that reported patients' and/or providers' needs for incorporating PGHD in clinical care. The studies were assessed for quality and bias with the Mixed-Methods Appraisal Tool. The results section of each article was coded to themes inductively developed to categorize patient and provider needs. Distinct claims were extracted and areas of convergence and divergence identified.

Results: Eleven studies met inclusion criteria. All had moderate to low risk of bias. Three themes (clinical, logistic, and technological needs), and 13 subthemes emerged. Forty-eight claims were extracted. Four were divergent and twenty were convergent. The remainder was discussed by only patients or only providers.

Conclusion: As momentum gains for integrating PGHD into clinical care, this analysis of primary source data is critical to understanding the requirements of the 2 groups directly involved in collection and use of PGHD.

INTRODUCTION

As of January 1, 2018 the Centers for Medicare and Medicaid Services initiated policy changes that will incentivize and reimburse healthcare providers for reviewing and interpreting patient-generated health data (PGHD), which is expected to accelerate adoption and use of these data in clinical practice.^{1,2} PGHD is a term to describe "health-related data... created, recorded, gathered, or inferred by or from patients or their designees (e.g., care partners or those who assist them) to help address a health concern."³ Key features of PGHD are: (1) the patient, not the healthcare provider, captures the data; (2) the data are obtained outside of clinical settings; and (3) the data are both longitudinal and capable of being collected at high-frequency intervals. Patient-reported outcomes

(PROs) are considered a controlled form of PGHD, typically consisting of structured data elements captured at discrete intervals.⁴

Increasingly, PGHD are collected and stored digitally via ubiquitous smartphone applications (apps), connected devices, and cloud-based platforms.^{4–7} PGHD produces not only information and knowledge to support clinical decision-making for individual health care providers, but also a context for those decisions.^{6,7} For instance, knowledge of circumstances external to a patient's clinical situation may call for adjustments to therapeutic decisions made by any provider within a health care team (e.g., physicians, nurses, advanced practice nurses, physician assistants, or dietitians). Current evidence on the clinical benefit of PGHD is sparse but emerging as technology and policy provide the means to incorporate it into clinical practice.^{8–10}

On a policy level, digital PGHD may contribute to healthcare quality by augmenting the type, amount, and detail of health information exchanged between patients and providers.^{11,12} Healthcare costs associated with unnecessary office visits and hospitalizations may decrease when patients share PGHD by allowing the provider to proactively manage illnesses and prevent complications.⁴ Patients with previous barriers to healthcare for cost- or location-related reasons may now exchange health information more easily and affordably with providers because mobile device ownership is prevalent across diverse populations.^{4,5,11}

The US Office of the National Coordinator for Health Information Technology has identified the value and existing challenges for patients and providers regarding PHGD, and called for evidence-based strategies to facilitate its adoption and use.¹³ An understanding of PGHD from the patient and provider perspectives is needed to align concurrent federal initiatives that aim to incorporate PGHD into clinical care, such as the Medicare and Medicaid Electronic Health Record Incentive Programs Stage 3 and Modifications to Meaningful Use, and the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015 (MACRA).¹³

Objective

A synthesis of the evidence regarding patient and provider needs for information systems that incorporate PHGD can inform their optimal development.^{5,14} To our knowledge there is no review that examines empirical evidence on the needs of the 2 primary users of PGHD. Therefore, the aims of this integrative review are to (1) summarize needs of both healthcare providers and patients concerning the collection and use of digital PGHD and (2) identify areas of convergence and divergence between them. The review follows procedures and recommendations detailed by Whittemore and Knafl.¹⁵

METHODS

Information Sources and Search Strategy

Nine scholarly databases (Pubmed, Scopus, Applied Science, Medline, PsycINFO, Science Direct, CINAHL, Cochrane, and ACM Digital Library) were searched in November 2016 using the terms: "Patient generated health data," "Patient generated data," "Patient reported outcome(s) [AND] digital," "Patient reported data [AND] digital," and "Self-monitoring data." Search terms were determined in consultation with a biomedical librarian and 2 experts engaged in research involving PGHD, and iteratively by examining key words in retrieved publications. PROs are a type of patient-generated health data, which in some cases are recorded digitally; therefore, PROs were included in the search terms for thoroughness.^{4,16} No filters or additional search criteria were applied. Scopus was searched for grey literature using the same terms. An inspection of reference lists from retrieved articles identified relevant publications not obtained through the database search.

Eligibility Criteria

Publications were evaluated against the following criteria: (1) documented patients' or providers' needs; (2) PGHD was used in a "real world" rather than study setting; (3) addressed any type of digital PGHD collected for any health-related purpose (e.g., chronic disease management, post-operative monitoring, etc.), and (4) any study design (qualitative, quantitative, or mixed-methods). Exclusion criteria were: (1) published prior to 2011; (2) not a peer-reviewed article; (3) non-digital PGHD; (4) PGHD not used in "real world setting"

and clinical workflow; and (5) not reporting patients' and/or providers' perspectives. We define workflow as "a modular sequence of tasks, with a distinct beginning and end, performed for the specific purpose of delivering clinical care."¹⁷ Studies with samples of only patients or only providers were included provided they met other inclusion criteria.

The specification of "digital" data was thought to automatically exclude older studies, so publication year search filters were not initially applied. However, this approach retrieved several studies published between 1980 and 2010 reporting on now obsolete technology. The publication date criterion was added in acknowledgement of the rapid development of patient- and provider-facing health information technology within the past 5 years. Unlike non-electronic (e.g., verbal or written) information generated by patients, digital PGHD can be collected with greater frequency and detail and computationally summarized. These features present unique opportunities and challenges, which are the focus of this review.

Data Screening, Extraction, and Synthesis

Two reviewers used Covidence, a Cochrane technology platform, to select eligible studies from the pool of retrieved records.¹⁸ Covidence automatically removes most duplicate records. The reviewers removed any missed duplicate records. Then, the reviewers screened titles and abstracts against the inclusion/exclusion criteria. Full texts of the records included were rescreened using the same criteria. Any discrepancies between the reviewers were discussed and resolved.

Methodological Quality Assessment of Studies

Quality was evaluated with the Mixed Methods Appraisal Tool (MMAT),¹⁹ which is specifically designed for concomitantly appraising quantitative, qualitative, and mixed-methods research. MMAT was chosen for its ability to produce comparable scores across study designs,^{19,20} with highly reliable inter-class correlations ranging from 0.84 to 0.94.²¹⁻²³

The MMAT consists of 2 initial screening questions and subsequent question sets that are specific to the study design (quantitative; qualitative; or mixed-methods). The screening questions identify studies for which further appraisal may not be feasible or appropriate (e.g., no clear research question.) Studies failing either or both screening questions do not proceed to domain-specific appraisal. There are 4 domain-specific questions for qualitative studies and 4 questions for each of the 3 quantitative study designs (randomized controlled, non-randomized, or descriptive). Mixed-methods studies are evaluated using both the qualitative and appropriate quantitative study questions; there are 3 additional questions specific to mixed-methods studies. The quality appraisal score is determined by dividing *n* criteria met by *N* criteria in each applicable domain. Scores are typically converted to percentages for comparison across studies.^{19,20} Following this protocol, 2 reviewers (M.R., J.M.) independently appraised and calculated scores for each study. As in the earlier stage, discrepancies between the reviewers were discussed and resolved.

Data Extraction and Qualitative Synthesis

The goals of data analysis in integrative reviews are first, to provide an unbiased and complete interpretation of primary source data, and second, to critically synthesize this data.¹⁵ The primary author (M.R.) reviewed and extracted relevant characteristics from each study, including: sample characteristics, setting, context, PGHD collected, Health information technology (HIT) used, study design, data collection methods, data analysis methods, and study findings.

Both reviewers (M.R., J.M.) analyzed the quantitative and qualitative data using a general inductive approach to develop a unified response to the objectives of the integrative review. The steps include: (1) data reduction; (2) data display; (3) data comparison; (4) conclusion drawing and verification.¹⁵ During data reduction, text containing the qualitative and/or quantitative findings was excerpted from each article and combined into a single corpus. The primary author (M.R.) coded this text using a general inductive approach in which codes were developed, consolidated if warranted, and then organized into a hierarchy. From this process, a set of thematic axes emerged. The second reviewer (J.M.) independently coded 50% of the records using this preliminary schema with the freedom to identify new or alternative codes. Alternative codes were discussed until consensus was reached on a final coding schema, which was used for inter-rater reliability calculation. To further distill the findings for subsequent comparison, both reviewers revisited the coded text to identify distinct expressions of a need related to PGHD, which they extracted in the form of declarative statements, or “claims.” NVivo Version 11.4.1 (QSR International, Inc., Burlington, MA, USA) was used to code the data and calculate inter-rater reliability.

Second, a table of findings was created to display the data and visualize claims according to the coding theme/sub-theme and patient/provider perspectives on each claim. Third, the claims were reviewed and discussed to determine the presence of patterns and relationships. The perspectives of individual claims were reviewed and discussed to evaluate if the viewpoints expressed were convergent, divergent, or relevant only to patients or only to providers. Finally, each declarative claim was verified with primary source(s) to ensure accuracy. Specifically, the primary author (M.R.) mapped the claims back to the theme they were originally coded under, and both reviewers participated in reordering or consolidating claims if warranted.

RESULTS

Search Results

A total of 996 records were retrieved from 9 databases (Figure 1). Removal of duplicate records ($n = 274$) left 722 articles for the title/abstract screening. During title/abstract screening, 644 records were excluded for: publication date prior to 2011 ($n = 356$), not peer-reviewed ($n = 122$), not digital PGHD ($n = 86$), and not about integrating PGHD into the clinical workflow ($n = 80$). A full text screening of 78 remaining records excluded 67 for: reporting neither patient nor provider perspective ($n = 37$); not being a digital PGHD ($n = 17$); and not being about integrating PGHD into the clinical workflow ($n = 13$). A total of 11 records were accepted for review.^{24–34} The provider perspectives covered in these records included physicians, nurses, advanced practice nurses, physician assistants, and dietitians.

Risk of Bias

Quality appraisal results of the 4 qualitative and 7 mixed-methods studies are summarized in Table 1.

Qualitative studies received 5 to 6 of 6 possible points, and the mixed-methods studies received 8 to 11 of 13 possible points. When converted to percentages, studies scored from 62% to 100%. Studies lost points in the qualitative domain for claiming a specific method (e.g., grounded theory) but describing data analysis inconsistent with that method, or for failing to acknowledge, or

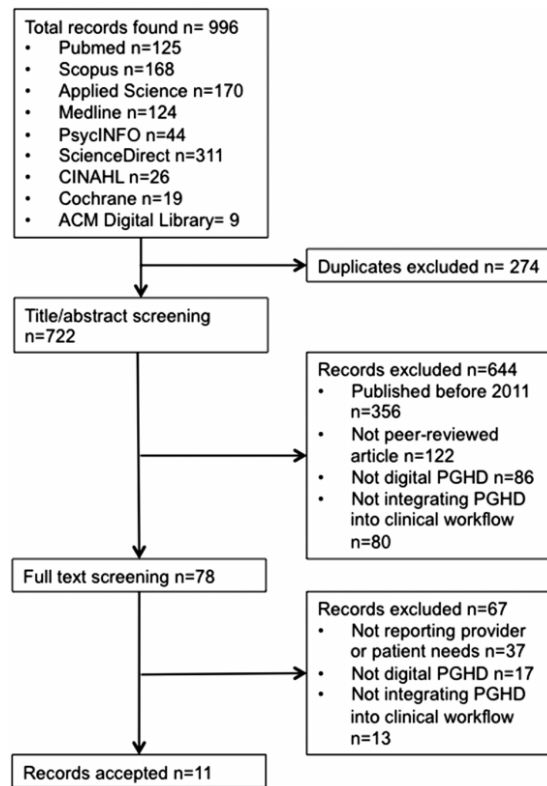


Figure 1. Flow diagram of study selection process.

“bracket,” their interaction with study participants as a potential source of bias. Studies lost points in the quantitative domain for sampling strategies that introduced bias, or surveys not psychometrically validated.

Characteristics of Included Studies

The characteristics of 11 studies are summarized in Table 2.

Six studies included both patients and provider participants.^{24–29} Two included participants who were not patients or providers but were closely involved with them during the study period and could speak to their perspectives.^{29,30}

Providers included physicians (surgeons, primary care physicians, specialists), nurses, advanced practice nurses, physician assistants, and dietitians. Their mean clinical experience ranged from 7 to 17 years. Patients’ mean ages ranged from 44 to 71 and gender breakdown ranged from 30% to 100% male. The study settings ranged from large, academic medical centers to outpatient clinics, and 8 of the 11 studies examined a specific tool to collect and use the PGHD being tested. Qualitative data collection involved individual semi-structured interviews, open-ended survey questions, and observations. Quantitative data was collected through surveys and application usage reports.

Characteristics of PGHD in Included Studies

The characteristics of PGHD in the 8 studies that were tested as an actual data tool are summarized in Table 2. PGHD included physiological, self-report, and passive sensor data targeting a wide range of

Table 1. Risk of Bias for 11 Studies Based on Criteria from the Mixed Methods Appraisal Tool³⁵

Domain	Criterion	Cheng et al. (2015) ^{24,a}	Chung et al. (2016) ²⁵	Cohen et al. (2016) ^{30,a}	Hartzler et al. (2016) ²⁶	Hochstenbach et al. (2016) ²⁷	Huba and Zhang (2012) ^{31,a}	Kummerow Broman et al. (2015) ²⁸	Lind et al. (2016) ³²	Nundy et al. (2014) ³³	Sanger et al. (2016) ^{29,a}	Thompson and Valdez (2015) ³⁴
Screening questions	Clear research questions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Data adequate to address research questions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Qualitative	Relevant data sources	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓
	Relevant data analysis methodology	✓	✗	✓	✗	✓	✓	✗	✗	✓	✗	✓
	Consideration of setting of data collection	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Consideration of researchers' influence	✗	✓	✗	✗	✗	✓	✗	✗	✓	✓	✓
Quantitative descriptive	Relevance of sampling strategy		✓		✓	✓		✗	✓	✓		✗
	Representative sample		✓		✗	✗		✓	✓	✗		✓
	Validated measures		✗		✓	✓		✗	✗	✗		✗
	Acceptable response rate (60% or above)		✗		✓	✓		✓	✓	✓		✓
Mixed- methods	Appropriateness of mixed-methods design		✓		✓	✓		✓	✓	✓		✓
	Adequate integration of quantitative and qualitative data		✓		✓	✓		✓	✓	✓		✓
	Consideration of divergent quantitative and qualitative findings		✓		✓	✓		✓	✓	✓		✓
	Total scores	5/6	10/13	5/6	10/13	11/13	6/6	8/13	10/13	11/13	5/6	11/13
	Percentages	83	77	83	77	85	100	62	77	85	83	85

^aThese studies had qualitative designs and were only evaluated with qualitative domain questions.

Table 2. Studies Reporting Evidence on Patient and Provider Needs Regarding Patient Generated Health Data

No.	References	Method and design	Participants	n	Setting/context	Focus	Tool	PGHD collected	PGHD user	Outcomes
1	Cheng et al. (2016) ²⁴	Qualitative; interviews observation	MDs, RNs, RDs Patients	15 35	Post discharge Neonatal Intensive Care Unit	Follow-up of clinically “high-risk” infants	Estrellita: a mobile and web-based system for monitoring and supporting development of high-risk infants	Infant diaper usage, weight, behaviors, milestones, complications, attendance at infant medical appointments	Providers	Provider experiences and reflections Actual provider use of PGHD
2	Chung et al. (2016) ²⁵	Mixed-Methods, descriptive; surveys interviews	MDs, APRNs, RDs Patients (mean age 44)	21 18 interview 211 survey	University health system and a health maintenance organization	Data sharing practices	Investigates general perspectives, no specific tool	Investigates general perspectives, no specific PGHD	Patients Providers	Expectations, concerns re: actual and potential PGHD collection and use
3	Cohen et al. (2016) ³⁰	Qualitative, semi-structured interviews	MDs, RNs Researchers ^a	12 13	Evaluation of 5 projects funded by Robert Wood Johnson Foundation Project Health Design	1. asthma 2. elders at risk for cognitive decline 3. overweight young adults 4. people living w/Crohn's disease 5. caregivers of premature infants	mHealth apps and passive sensors used to collect PGHD; Summary sheets and web-based portals used to share data with providers	Medications Physiological data (peak expiratory flow, weight) Passive sensor data (physical activity, task completion), Self-reports on mood, behavior, diet, symptoms	Patients Caregivers Providers	Challenges, benefits, and general experiences of using PGHD
4	Hartzler et al. (2016) ⁴⁶	Mixed-Methods, descriptive; Surveys Semi-structured interviews	MDs Male patients	50 50	Academic medical center	Prostate cancer; long-term follow-up of patient status post treatment	Web-based dashboard displaying PGHD over time compared to similar patients based on age and treatment plan	Health-related quality of life; urinary, bowel, sexual symptoms	Patients providers	Patient self-efficacy Satisfaction Communication Compliance w/ quality indicators Helpfulness of visualizations Experience using PGHD
5	Hochstenbach et al. (2016) ²⁷	Mixed-Methods, descriptive; Surveys Usage Data Semi-structured interviews	RNs Patients	3 11	Outpatient oncology clinic Feasibility study of PGHD-based intervention	Self-management of pain for home-dwelling cancer patients	Mobile and web-based application for collecting and reviewing PGHD, patient education, and messaging provider	Pain level, adverse effects, pain interference with sleep or activity, satisfaction with pain treatment, medication adherence	Providers	Learnability, usability, desire to use app to collect PGHD Adherence (usage data) General experiences using PGHD

(continued)

Table 2. continued

No.	References	Method and design	Participants	n	Setting/context	Focus	Tool	PGHD collected	PGHD user	Outcomes
6	Huba and Zhang (2012) ³¹	Qualitative; Semi-structured interviews	MDs, RNs	21	Large hospitals and outpatient clinics	Clinical practice	Investigates general perspectives (no specific tool)	Investigates general perspectives (no specific PGHD)	Providers	Current or theoretical use of PGHD
7	Kum-merow Bro-man et al. (2015) ²⁸	Mixed-Methods, descriptive; Surveys with open and close ended questions	MDs Patients	5 50	Surgical outpatient clinic Pilot study of PGHD-based intervention	Post-operative follow-up of patients post laparoscopy for cholecystectomy; hernia repair (ventricular, umbilical, or inguinal)	Patient portal for collecting and viewing PGHD, messaging provider	Symptoms survey, wound photos	Patients Providers	Acceptance of PGHD Use of PGHD Visit times of on-line (PGHD-based) versus in-person clinic visits
8	Lind et al. (2016) ³²	Mixed-Methods, descriptive; Surveys with open and close ended questions Usage data	Patients	14	Hospital-based home-care clinic at an academic hospital Pilot study of PGHD-based intervention	Home-based management of patients with severe heart failure	Anoto™ digital pen-and-paper technology linked to a web-based application for receiving and storage PGHD	Responses to health diary forms (symptoms and medications) and physiological measurements (blood pressure, heart rate, oxygen saturation, weight)	Providers	Experience using PGHD Actual usage of app to collect PGHD
9	Nundy et al. (2014) ³³	Mixed-Methods, descriptive Semi-structured interviews Surveys	MDs	12	Outpatient management program affiliated with an academic medical center Feasibility and utility study of PGHD-based intervention	Diabetes (type I or II) self-management	CareSmarts: automated text messaging, Text-back responses to record PGHD; viewed by providers in summary sheet	Medication adherence, glucose monitoring adherence, barriers to diabetes self-management, progress on CareSmarts educational modules	Providers	Usability Helpfulness Influence on care Willingness to use General experiences and reflections
10	Sanger et al. (2016) ²⁹	Qualitative Semi-structured interviews	MDs, APRNs, PAs, RNs Patient advocates ^a	11 13 6	Outpatient surgical clinic affiliated with an academic medical center Design of tool to collect and display PGHD	Post-operative surgical site infection monitoring in patients with a prior history of surgical site infections	mPOWER: mobile Post-Operative Wound Evaluation: application for collecting PGHD and viewing PGHD, and messaging	Longitudinal detailed symptom data, wound photos, miscellaneous free-text data entry	Patients and providers	General experience using PGHD Feedback on mockups of different systems to collect/display PGHD

(continued)

Table 2. continued

No.	References	Method and design	Participants	n	Setting/context	Focus	Tool	PGHD collected	PGHD user	Outcomes
11	Thompson and Valdez (2015) ³⁴	Mixed-Methods, descriptive	Patients	87	Web-based survey	Patient mHealth use	Investigates general perspectives (no specific tool)	Investigates general perspectives (no specific tool)	Patients	Preferences and experiences collecting/using PGHD for self and for provider

^aThese participants spoke about the patients' and/or providers' experiences collecting and using PGHD in the study
 Abbreviations: MD = physicians; RN = registered nurses; APRN = advanced practice registered nurses; PA = physician assistants; RD = registered dietitians.

clinical problems. PGHD was collected in a mobile format and/or through web-based platforms. Some tools allowed both patients and providers to visualize data, while others only had a provider view. PGHD collection included manual entry into an application, automated entry from connected devices, photographs taken with digital cameras or mobile phones, text messaging, and a proprietary pen-and-paper technology. In 5 studies providers were the only intended users of PGHD, even if patients or their caregivers could view the data; in these studies patients were reportedly not acting upon their data but deferring to the provider's interpretation of it.

Qualitative Synthesis

Qualitative synthesis results are provided in Tables 3 and 4.

Inter-rater reliability between the 2 coders was acceptable ($\kappa = 0.7280$). All coding discrepancies were discussed and resolved.

Three high-level themes emerged regarding patient/provider needs: clinical, logistic, and technological (Table 3). Thirteen sub-themes also emerged. Clinical sub-themes address patient-provider relationships; contextual metadata, and patient/provider needs for guidance. Logistic sub-themes address motivation and incentives; time; transparency; and provider preferences for patient selection. Technological sub-themes address customization; interoperability/EHR integration; data summaries; quality, security, confidentiality; and variation in features desired by the patient/provider. A total of 48 distinct claims were extracted. Claims were grouped under 1 of the 3 major themes (16 clinical, 14 logistic, and 18 technological) and appropriate sub-theme (Table 3). Each claim was classified as convergent, divergent, or relevant to only patients or providers (Table 4).

There are 20 convergent claims in which patients and providers both acknowledge a need and share similar views (8 clinical, 3 logistic, and 9 technological). This includes claims that pertain only to a patient or to a provider, but that both groups discuss. For instance, in a patient-provider relationship, emotional needs are directly pertinent to the patient, but providers acknowledge that patient emotional needs must be met.

There are 4 divergent claims that both groups discussed from opposing perspectives (0 clinical, 3 logistic, and 1 technological). For example, patients want a response to their PGHD within a few hours, while providers fear responding that quickly would disrupt their work.

There are 5 claims identified only by patients (2 clinical, 1 logistic, and 2 technological). There are 19 claims identified only by providers (6 clinical, 7 logistic, and 6 technological).

DISCUSSION

Convergence and Divergence of Perspectives

This integrative review identified 3 broad themes concerning patient and provider needs around collecting and using PGHD, from 11 primary sources of quantitative and qualitative data. Synthesis of the findings produced a set of 48 distinct claims. Half of the claims (24 of 48) were discussed by one group only, suggesting a mutual unawareness of each other's needs. There were several points of convergence on claims pertinent to one group, but acknowledged by the other. For example, patients acknowledged that providers need interoperability and EHR integration, and providers recognized that patients need education and guidance on PGHD collection. This suggests that collection and use of PGHD is a bi-directional relationship: patients and providers are cognizant of at least some of the other's needs and are inextricably linked in the PGHD process.

Table 3. Claims Generated from Qualitative Synthesis^a

Claim	Explanation (Source)
Clinical sub-theme: Effect of PGHD on the patient-provider relationship	
PGHD can enhance the working relationship between patients and providers	Patients reported PGHD involved them in their care, and informed providers of their day-to-day experience. ^{2,8}
PGHD can facilitate provider monitoring	A significant positive correlation ($r = 0.79$) was observed between frequency of abnormal PGHD and patient-provider communication. ⁸
Patient emotional needs can be met by providing PGHD	Examples of emotional needs include empathy for symptoms and praise for progress. ^{2,3}
PGHD can worsen the patient-provider relationships	Communication, thoroughness, and rapport were lost when review of PGHD was substituted for clinic visits; it is not a substitute for “face-to-face” with providers. ^{7,11}
Clinical sub-theme: contextual metadata is helpful for patients and providers	
PGHD not directly pertaining to a clinical problem, or “contextual metadata,” can be valuable for understanding the relevant PGHD	For patients, value was in provider understanding their daily life, comorbidities, and anxieties. ^{2,10}
Contextual metadata can be used for decision making to improve care	For providers, value was in decision making supported by contextual metadata: patient goals, moods, experiences, behaviors, perceptions, and quality of life. ^{1,6,9}
Providers may want access to PGHD collected for other purposes or for other providers	As in the case of a pediatrician who received images of babies on a scale to convey weight data, and incidentally noted signs and symptoms that prompted follow up. ¹
PGHD has value in emergency situations	Especially for conditions that are rare or that transcend specialties, such as psychiatric disorders, to facilitate referrals, and communication with colleagues. ^{1,6}
Clinical sub-theme: patients need guidance	
Patients need training and support before collecting PGHD	When no one can provide a medical history. One provider said, “Something’s better than nothing.” ⁶
Patients need help interpreting their data	Patients lack understanding of how to take health-related measurements and record them, leading them to incorrectly report their data. ⁵ One patient said, “I don’t trust myself. . . I don’t know what to look for.” ^{7,8}
Providers can leverage PGHD for health education and counseling	Patients need to identify trends and correlations in their data to interpret in context of average values. ^{2,4} Providers can guide patients on which data are/are not significant (with a goal of patient independence). ^{2,4,10}
Patients may want providers to constantly monitor their PGHD to dispel their doubts	For example, one provider noticed a patient nonadherence to calorie requirements and used the data to reinforce education on calorie counting and weight management. ²
Clinical sub-theme: providers need guidance	
PGHD is not customary in current provider work flows. Providers need protocols to guide their responses to PGHD	Patients may distrust their own ability and/or the ability of software algorithms to detect abnormal data. ^{4,10,11}
Providers may have questions about their role when responding to PGHD	Patients react positively to the idea of multiple providers monitoring (eg, nurse, physician, and pharmacist), e.g., “someone looking over your shoulder every day.” ⁵
Providers have legal and ethical concerns about receiving PGHD that is outside of their scope of practice	For instance, one nurse described an algorithm her group practice devised to categorize PGHD into acuity “zones” each with corresponding actions. ³
Providers may need to delegate data management	A nurse said, “At times I’m not sure. . . What is allowed? When do I intervene? . . . What does the treating physician want? When do I interfere and take over care?” ³
Logistic sub-theme: motivation and incentives	
Patients and providers can lose motivation to collect and use PGHD	Patients may not be aware of the scope of a provider’s expertise, both in terms of clinical specialty and provider type (RN, MD, etc.). Providers are concerned that once they receive the data, they are responsible for it. ^{1,2,10}
Patient motivation can wane if benefits from self-monitoring are not immediate	Providers delegate when they do not have the knowledge or experience to manage data themselves. ^{2,10}
Patient motivation to collect PGHD can increase with peer and provider support	They are motivated to collect and use PGHD when it saves time (eg, not missing work, fewer office visits) and is easy, but not when the process is distracting, time-consuming, or inconvenient. ^{7,9–11}
Provider motivation to review PGHD can improve with incentives	Providers recognized this and reported trying to help patients see value in collecting PGHD even if benefits were not immediate. ^{2,11}
Providers’ current clinical workflows and incentive structures reduce their motivation to review PGHD	However, fear of being “judged” by peers or providers can decrease motivation. ^{2,11}
	Examples of incentives include saved time and financial reimbursement. ^{2,7,10}
	Providers lost motivation because they felt the work that went unrecognized and was not billable. ^{2,10} One provider said the incentive structure “has a perverse, mixed message: collect the data but you don’t have time to do it.” ²

(continued)

Table 3. continued

Claim	Explanation (Source)
Logistic sub-theme: time	
Providers need to make time for PGHD data review	Practices varied greatly; some providers continuously monitored PGHD, some reviewed before a patient visit, and some only reviewed during the visit. Some providers resorted to evenings and weekends to catch up on data review. ^{1,2}
Providers need methods to reduce the time burden for PGHD review	Alerts when at-risk patients generate abnormal data, ^{1,10} and brief summary reports ^{9,10} were 2 reportedly successful methods to reduce the burden for providers
Providers have concerns about liability and the risk of “information overload”	They feel they need to negotiate with patients on data received. They saw this as a fluid process of negotiating data elements based on the patients’ evolving status ^{1,2,10}
Logistic sub-theme: transparency	
Patients have concerns about how their data is used, re-used, and how extensively it might be shared	This concern is exacerbated by use of mHealth apps for which privacy and confidentiality standards can vary enormously. ^{2,11}
Patients want a timely response (e.g., within 4 h) while providers fear a requirement for rapid response may disrupt workflows and care of other patients	When patients were unaware of the provider response process they are anxious: “Because sometimes you’re just sitting there waiting... and it’s like God, what am I supposed to do?” ¹⁰
Providers need to manage patient expectations regarding the review process	Providers wanted patients to have “realistic expectations of how available I am to them” ¹⁰
Goals for collecting and using PGHD may be different	Patients want to know who will review their data and if/when they will be contacted. ¹⁰ Many times providers felt communication was only warranted if the data was abnormal ^{1,10}
Logistic sub-theme: patient selection varies by provider	
Providers may need to select a subset of patients from whom to receive PGHD	Patients want to indefinitely monitor their health with their provider, while providers aim to empower the patient so that they will transition to more independently monitor ^{2,10}
Providers may need to encourage all of their patients to self-monitor.	Examples of patient subsets included: those whose disease is poorly controlled, ^{3,9} those who are poor historians, ⁹ and those who are at increased risk for complications per an objective risk measure ¹⁰
Technology sub-theme: customization	
Patients and providers need visualizations to be customizable	One provider said, “So anyone who has a phone and can text I think... let’s use it... offer this to anyone who wants to really” ⁹
Providers need to customize visualizations to save time	The need the ability to: <ul style="list-style-type: none"> • Vary amount of detail seen⁴ • View data in different ways (graphs, tables, etc.)^{3–5} • Mark-up visualizations with notes and color-coding^{4,5} One provider said, “Just going through this much data was going to be so time consuming. [would help if] we could see all the graphs at once, and see if anything correlated.” ³
Patients can use visualizations to help them make life style adjustments that improve their health condition	If the visualization didn’t facilitate this type of insight patients often stopped using them. General visualization preferences included charts and line graphs over data tables or pictographs, and data visualized in chronological order. ^{2,4,5}
Patients may need to customize data entry	A lack of customizable data entry can discourage patients from self-monitoring and cause nonuse, especially for patients who need to track multiple, specific data points, and can lead to errors in data entry. ^{2,5}
Providers may need customized patient data entry to support clinical decision-making	Some providers noted that data entry that is too open-ended could cause data to be unnecessarily complex and irrelevant, so they favored some form of structure to “nudge [the patient] in the right direction” ^{5,10}
Technology sub-theme: interoperability/EHR integration	
Patients and providers need PGHD integrated into existing systems	There was a strong preference for systems that integrate PGHD to “building on existing technical systems” so that the review process would be streamlined. ^{3,6,10}
PGHD integrated into existing systems may reduce confusion and frustration	Commonly, providers must use different systems and modes of communication to view and respond to PGHD. Providers become less willing to use PGHD and patient-provider communication about PGHD was increasingly complex when the provider workflow was not streamlined. ^{2,3,10}
PGHD integrated into existing EHRs could improve care coordination and communication across providers	Care plans and patient instructions generated by one provider can be viewed and taken into account by other providers caring for the same patient. ^{1,6}
Technology sub-theme: data summaries	
Patients and providers need a summary of the data that is rapidly understandable and cues them to action	PGHD can be complex, heterogeneous, and high frequency. Data summaries that help providers quickly make sense of large amounts of data could save time, inform decision-making, and improve patient care. ^{4–6}
Patients expect data summaries may answer their questions without having to contact their provider	For instance, longitudinal trends can answer their questions about their progress quickly. ^{2,4,10}
Patients and providers may not trust automated data summaries	They reported skepticism about the algorithms used to condense and present PGHD. ^{2,10,11}

(continued)

Table 3. continued

Claim	Explanation (Source)
Technology sub-theme: quality, security, confidentiality	
Patients are confused about whether their PGHD collection is private and confidential	Patients did not know if the mHealth apps they were using to collect and view PGHD fully complied with privacy and confidentiality regulations. ^{2,11} One study showed that over 20% of patients were concerned about the privacy and confidentiality of their PGHD ¹¹
Providers are concerned about privacy issues with PGHD from minors	One provider said, “There are some things that when they talk to us about sexually related issues, substance abuse, mental health, after age 12, they’re protected from us talking to their parents about it. There would be a selective bias... about what they enter” ³
Providers are concerned about the quality of PGHD	For instance, photographs in a post-operative wound monitoring study were poor quality or only show part of the wound. ⁷ In 1 study 76% of providers worried that patients could incorrectly measure or report PGHD ⁶
Providers need to distinguish data recorded by patients vs by healthcare professionals in other settings	Objective measurements can be more accurate when recorded by healthcare professionals. ^{7,9} However patient-reported data (e.g., medication adherence) can be more accurate because there is less pressure to “please the doctor” with answers as there is in face-to-face visits ⁹
Technology sub-theme: desired additional features vary by patient and provider	
Patients want the option to electronically communicate with providers about their PGHD, while providers fear it could compromise the professional relationship	Patients liked the ability to electronically communicate with their provider for nonurgent questions that would help them understand their health conditions ^{1,5} Providers felt text messages and other free-text data would be, “totally disruptive... I don’t want that kind of access with patients,” but in one study this perception was more common in physicians than nurses ¹⁰
Providers need standardized data summaries to reduce the time burden of sifting through PGHD	They acknowledged that some data types lend themselves to standardization (eg, blood glucose) while varied and complex data do not (e.g., nutrition data) ^{2,10}
Providers need standardized definitions of data types	For instance, “physical activity” can mean any movement or vigorous exercise ²

^aSources refer to the numbered studies listed in Table 2.

Thus well-designed informatics solutions must include capability for patients and providers to work with PGHD collaboratively, not in isolation.

Unsurprisingly, there were many more instances of providers noticing a patient need than vice versa. This may reflect providers’ awareness of patient needs as a clinical skill, and of patients limited knowledge of provider workflows and clinical practices. For instance, all 3 claims that referred to time limitations were provider-generated; patients did not specify time as an issue in these 11 studies.

An analysis of points of convergence and divergence found that patients and providers agree more about clinical and technological needs than they do about logistic needs. Our analysis suggests a general tension between patients needing more: more support, more guidance, more feedback on data, and providers needing less: less time burden, less data to review, less liability. There is also a suggestion that underlying anxieties surrounding PGHD and the health problems for which it is collected are also at odds: patients are anxious to understand their health status, while providers are anxious about the implications of PGHD for their clinical practice, including liability, reimbursement, and time. Finally, the findings suggest that while patients want more flexibility with the data (which providers supported in some cases), providers still need methods for standardizing and limiting the data received.

Sustained patient engagement as a major barrier

Patients indicated that if the data and/or the tools to collect and view it did not meet their needs or produce some immediate benefit, their participation would be dampened or discontinued altogether. This corroborates recent evidence suggesting that sustained engagement with self-monitoring is a critical problem.^{36–38} There is evidence that certain subsets of patients only collect data because providers ask them, rather than out of a natural curiosity or desire to learn.^{39,40} In 5 of the 8 studies that evaluated a tool, the PGHD

was intended for provider use only (Table 2). As healthcare shifts to a patient-provider collaboration model,^{7,41,42} research is needed on factors that contribute to sustained patient engagement with the process of collecting and using PGHD.

Significance of This Review

Our analysis draws upon prior research that compared the perspectives of patients and providers on PGHD,^{24–29} and extends that work by generating an integrated set of requirements substantiated by multiple primary sources. The findings of this review substantiate findings from a federally-commissioned report, which relied on expert opinion,¹³ with an analysis of primary source data from the 2 groups directly involved in collection and use of PGHD. Rich primary data from patients and providers offers increased validity and depth of understanding of the technical challenges, policy and reimbursement issues, the need for clinical guidelines, and the lack of sustained engagement by patients recording PGHD. Furthermore, by analyzing patient and provider needs in relation to each other, points of convergence and divergence emerged. This information may be applied to developing systems to improve the collection and use of PGHD through accommodating the needs of both user groups, thereby potentially increasing the likelihood of success.

Implications for Policy and Design

Overall, the findings suggest that expectations should be set between patients, providers, and other relevant stakeholders (e.g., administrators, reimbursing agencies, and technology vendors) from the very beginning of the process – including identifying and reconciling differences in those expectations. Transparency in this process may be an approach to avoid frustration and confusion. Goals for collecting and using PGHD need to be explicit, as our findings illustrate

Table 4. Synthesis of Claims According to Theme and User Group

Theme	Convergence: patients and providers identified a need and shared similar perspectives	Divergence: patients and providers identified a need and held opposite perspectives	Patient identified need	Provider identified need
Clinical	<p>PGHD can enhance the working relationship between patients and providers</p> <p>PGHD can facilitate provider monitoring</p> <p>Patient emotional needs can be met by providing PGHD</p> <p>PGHD can worsen the patient-provider relationships</p> <p>PGHD not directly pertaining to a clinical problem, or “contextual metadata,” can be valuable for understanding the relevant PGHD</p> <p>Contextual metadata can be used for decision making to improve care</p> <p>Patients need help interpreting their data</p> <p>Providers can leverage PGHD for health education and counseling</p>		<p>Need training and support before collecting PGHD</p> <p>May want providers to constantly monitor their PGHD to dispel their doubts</p>	<p>May want access to PGHD collected for other purposes or for other providers</p> <p>PGHD has value in emergency situations</p> <p>PGHD is not customary in current provider workflows. Need protocols to guide responses to PGHD</p> <p>May have questions about their role when responding to PGHD</p> <p>Legal and ethical concerns about receiving PGHD that is outside of their scope of practice</p> <p>May need to delegate data management</p>
Logistic	<p>Patients and providers can lose motivation to collect and use PGHD</p> <p>Patient motivation can wane if benefits from self-monitoring are not immediate</p> <p>Patient motivation to collect PGHD can increase with peer and provider support</p>	<p>Patients want a timely response (e.g., within 4 h) while providers fear a requirement for rapid response may disrupt workflows and care of other patients</p> <p>Providers need to manage patient expectations regarding the review process</p> <p>Goals for collecting and using PGHD may be different</p>	<p>Concerns about how their data is used, re-used, and how extensively it might be shared</p>	<p>Motivation to review PGHD can improve with incentives.</p> <p>Current clinical workflows and incentive structures reduce motivation to review PGHD</p> <p>Need to make time for PGHD data review</p> <p>Need methods to reduce the time burden for PGHD review</p> <p>Concerns about liability and the risk of “information overload”</p> <p>May select a subset of patients from whom to receive PGHD</p> <p>May encourage all of their patients to self-monitor</p>
Technology	<p>Patients and providers need visualizations to be customizable</p> <p>Patients can use visualizations to help them make lifestyle adjustments that improve their health condition</p> <p>Patients may need to customize data entry</p> <p>Providers may need customized patient data entry to support clinical decision-making</p> <p>Patients and providers need PGHD integrated into existing systems</p> <p>PGHD integrated into existing systems may reduce confusion and frustration</p> <p>PGHD integrated into existing EHRs could improve care coordination and communication across providers</p> <p>Patients and providers need a summary of the data that is rapidly understandable and cues them to action</p> <p>Patients and providers may not trust automated data summaries</p>	<p>Patients want the option to electronically communicate with providers about their PGHD while providers fear it could compromise the professional relationship</p>	<p>Expect that data summaries may answer their questions without having to contact provider</p> <p>Confusion about whether their PGHD collection is private and confidential</p>	<p>Need to customize visualizations to save time.</p> <p>Uncertain about privacy issues with PGHD from minors</p> <p>Providers are uncertain about the quality of PGHD.</p> <p>Need to distinguish data recorded by patients versus by healthcare professionals in other settings</p> <p>Need standardized data summaries to reduce the time burden of sifting through PGHD</p> <p>Need standardized definitions of data types</p>

that these can be different. Before implementing a tool, technology vendors are advised to follow best practices for engaging patients and providers in specifying system requirements for flexibility, standardization, visualizations, messaging, data summarization, and integration.^{43,44} Administrators can identify and seek to mitigate workflow barriers such as scheduling, role delegation, and scope of practice. Policymakers should analyze current incentive structures for patients and reimbursement for providers. Future research that examines the health outcomes and the cost-benefit of PGHD compared to standard care can produce the evidence to drive policy towards incentivizing the collection and use of PGHD.

CONCLUSION

Patients and providers share many common needs when collecting and using PGHD in practice. These needs are clinical (maintain a relationship, data interpretation, contextual metadata), logistic (motivation, negotiation, convenience/usability, and transparent provider roles), and technological (customizable visualizations, flexible data input, electronic integration, simple actionable data summaries, and management of data quality and security concerns). Differences between patients and providers arose in these 3 main categories as well, mainly centering on patients' needs for reassurance, instruction, and communication with providers, as compared to providers' needs to limit scope of PGHD, standardize it, receive it from only certain patients (in many cases), and have clear clinical guidelines to follow in responding to it.

Patients and providers are the 2 primary stakeholders directly involved with PGHD collection and use, and their needs in this process are inextricably linked. As momentum gains for PGHD to become fully integrated into the healthcare system, these perspectives are critical to ensure their needs are concurrently being met.

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CONTRIBUTORS

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Appendix B: Table of Variables from the Adapted UTAUT Model used in the study in Chapter Three

Variable/Concept	Operational Definition	Data Source	Measurement	Binary variable used in analysis
Outcome: Use of ECG mHealth technology	Type of use of ECG mHealth technology over 6 months (voluntary versus prompted)	Dated and time-stamped ECG transmissions	Continuous; count of transmissions per 30 day period	N/A- this variable was not converted into a binary variable
Perceived Usefulness	The degree to which an individual believes that using the technology will improve his or her health	Perceived benefit question; iHEART Patient Experience Survey	Binary; yes/no response	N/A- already binary
Perceived Ease of Use	The degree of ease associated with the use of the technology	Perceived ease of use questions; iHEART Patient Experience Survey	1-5 with 1 being poor and 5 being great	PEU ≤ 3 = low PEU; PEU > 3 = high PEU
Facilitating Condition: Severity of AF Symptoms	Presence or absence of symptoms and association with therapies, functional status, and quality of life	Canadian Cardiovascular Society Severity in Atrial Fibrillation (CCS-SAF) score	0-4 with 0 being asymptomatic and 4 being severe symptoms	Score ≤ 1 = low severity; Score > 1 = high severity
Facilitating Condition: Frequency of AF episodes	Frequency of confirmed episodes of AF	Dated and time-stamped ECG transmissions diagnosed as AF	Continuous; average number of episodes per week	≤ 1 episode = low frequency; > 1 episode = high frequency
Facilitating Condition: AF Knowledge	Patient's reported knowledge about AF	AF Knowledge Survey score	Continuous; raw score out of 11 possible points	Score ≤ 7 = low knowledge; Score > 7 = high knowledge
Age	Patient's age per medical record	Patient's medical record	Continuous; calculated using birthday	Age ≤ 62 = younger age; Age > 62 = older age
Gender	Patient's reported gender	Stated gender on demographic data	Binary; male/female	N/A- already binary
Experience with Technology	Patient's reported experience with technology prior to the start of the study	Baseline experience with technology questionnaire consisting of ten "yes/no" questions	Continuous; number of "yes" answers each indicating experience with technology (out of ten)	< 8 "yes" answers = low experience; ≥ 8 "yes" answers = high experience

Appendix C: iPhone® Helping Evaluate Atrial Fibrillation Rhythm through Technology (iHEART) Trial Surveys providing data for the study in Chapter Three

1. The Canadian Cardiovascular Society Severity of Atrial Fibrillation (SAF) Scale

Supplemental Material

Canadian Cardiovascular Society Severity of Atrial Fibrillation (SAF) Scale

Step 1 – Symptoms

Identify the presence of the following symptoms:

- Palpitation
- Dyspnea
- Dizziness, presyncope, or syncope
- Chest pain
- Weakness or fatigue

Step 2 – Association

Is AF, when present, associated with the above-listed symptoms (A-E)?

For example: Ascertain if any of the above symptoms are present during AF and likely caused by AF (as opposed to some other cause).

Step 3 – Functionality

Determine if the symptoms associated with AF (or the treatment of AF) affect the patient's functionality (subjective quality of life).

CCS-SAF Class Definitions

Class 0

Asymptomatic with respect to AF

Class 1

Symptoms attributable to AF have **minimal** effect on patient's general QOL.

- ☐ minimal and/or infrequent symptoms, or
- ☐ single episode of AF without syncope or heart failure

Class 2

Symptoms attributable to AF have a **minor** effect on patient's general QOL.

- ☐ mild awareness of symptoms in patients with persistent/permanent AF, or
- ☐ rare episodes (e.g. less than a few per year) in patients with paroxysmal or intermittent AF

Class 3

Symptoms attributable to AF have a **moderate** effect on patient's general QOL.

- ☐ moderate awareness of symptoms on most days in patients with persistent/permanent AF, or
- ☐ more common episodes (e.g. more than every few months) or more severe symptoms, or both, in patients with paroxysmal or intermittent AF

Class 4

Symptoms attributable to AF have a **severe** effect on patient's general QOL.

- ☐ very unpleasant symptoms in patients with persistent/paroxysmal AF and/or
- ☐ frequent and highly symptomatic episodes in patients with paroxysmal or intermittent AF and/or
- ☐ syncope thought to be due to AF and/or
- ☐ congestive heart failure secondary to AF

2. The Atrial Fibrillation Knowledge Scale

The Atrial Fibrillation Knowledge Scale (AFKS)

1. What are the trigger factors for Atrial Fibrillation?
 - Allergy to grass, animals or house dust
 - Alcohol, coffee, or spicy food
 - Noise or loud sounds
2. Why is it important to take my medication for Atrial Fibrillation properly?
 - Because the doctor wants me to
 - To prevent severe consequences of the arrhythmia
 - To prevent the possibility of a heart attack or sudden death
3. If Atrial Fibrillation is identified without the patient experiencing any complaints, the patient should immediately visit the hospital.
 - True
 - False
 - Don't know
4. What is Atrial Fibrillation?
 - A heart disease in which the heart is not able to pump a sufficient amount of blood through the body
 - A blood disorder causing blood clots in the heart
 - An electric disorder in the atria of the heart which results in the heart contracting too fast and irregularly
5. Why is oral anticoagulation medication prescribed in certain patients with Atrial Fibrillation?
 - To prevent the risk of blood clots which can cause a stroke
 - To make the blood flow more easily through the body
 - To prevent fluid retention in the body
6. Why should a person using anticoagulation medication be careful with the use of alcohol?
 - Alcohol increase the retention of fluid in the body resulting in the blood becoming too thin
 - Alcohol causes blockage of the blood vessels which in turn, slows blood flow to the heart
 - Alcohol influences the effect of the medication and this effects the clotting ability of the blood
7. Atrial Fibrillation is a rare condition.
 - True
 - False
 - Don't know
8. It is particularly risky if a person does not feel his/her Atrial Fibrillation.
 - True
 - False
 - Don't know

9. Which statement with regard to physical exercise is true of patients with Atrial Fibrillation?

- It is important for patients to rest in order to maintain normal heart activity
- Patients with chronic Atrial Fibrillation cannot work fulltime
- It is important to exercise normally within personal limitations

10. Which statement is true?

- Atrial Fibrillation is life-endangering because it can result in a heart attack
- Atrial Fibrillation is completely harmless
- Atrial Fibrillation is harmless if the right medication is taken

11. What is the function of the thrombosis center?

- To monitor blood clotting and the number of tablets taken each day
- To determine if the arrhythmia is present
- To determine if the patient needs to continue taking oral anticoagulation

Reference:

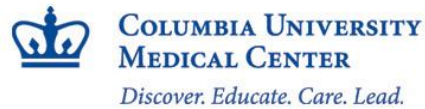
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3. Baseline Experience with Technology Questions

iHEART: Baseline Comfort/Experience with Technology Interview Questions

1. Do you currently own a cell phone?	YES	NO
2. Do you currently own a smartphone (iPhone, Android, etc.)?	YES	NO
2a. Do you use your smartphone to browse the internet?	YES	NO
2b. Do you use your smartphone for email?	YES	NO
2c. Have you ever downloaded an application on your smartphone without any outside assistance?	YES	NO
3. Do you currently send or receive text messages?	YES	NO
3a. Have you ever received and followed a link to a website from a text message?	YES	NO
4. Do you have access to and use a computer/laptop or tablet at home?	YES	NO
4a. Do you have highspeed/wireless internet access?	YES	NO
4b. Do you feel comfortable using your computer to browse the internet?	YES	NO
5. Which of the following statements best describes your use and adoption of new technologies? A. You tend to try new technologies when they are new, before others B. You wait a little to see that the new technology has been tested, but adopt them more quickly than the average person C. You tend to wait until a technology is widely used before trying it D. When it comes to adopting new technologies, you tend to wait and are one of the last to try		
6. Have you done any of the following to obtain information about your health? (CIRCLE ALL THAT APPLY) A. Searched for health related information on the internet B. Used an electronic organizer or other electronic method to keep track of doctor appointments C. Used an electronic organizer or other electronic method to keep track of medications D. Used technological devices or systems to assist with your healthcare needs		
7. Do you feel you will face challenges using the iHEART technologies (smartphone, AliveCor ECG monitoring, text messaging) if randomized to the iHEART group?	YES	NO
7a. If YES, tell me some details about what challenges you may face with any of the iHEART technologies:		

4. iHEART Patient Satisfaction Survey



iHEART Patient Satisfaction Survey

The purpose of this survey is to collect information regarding how you felt participating in this study. All contents of this survey have been approved by the Columbia University Institutional Review Board (IRB). Your responses will be kept confidential and anonymous. Thank you for your time.

Age: _____ Race/Ethnicity: _____ Asian
 _____ Pacific Islander
 Gender: _____ Black/African American
 _____ American Indian/Alaska Native
 _____ White (Not Hispanic or Latino)
 _____ Hispanic or Latino
 Female _____



Please circle how you felt in each category:	GREAT 5	GOOD 4	OK 3	FAIR 2	POOR 1
1. Ease of using the device:					
With your fingertips	5	4	3	2	1
On your chest wall	5	4	3	2	1
Overall convenience of the device	5	4	3	2	1
Overall portability of the device	5	4	3	2	1
2. Using AliveCor™ application on iPhone:					
Layout of the application	5	4	3	2	1
Ease of using the application	5	4	3	2	1
Collecting the ECG with the application	5	4	3	2	1
Saving ECG readings using the application	5	4	3	2	1
3. Initial device training with the study team:					
Explanation of the device and how it works	5	4	3	2	1
Showed methods of obtaining an ECG reading with the device	5	4	3	2	1
Answered your questions in a way you could understand	5	4	3	2	1
4. Follow-up sessions with the study team:					
Explained your ECG results in an understandable way	5	4	3	2	1
Answered any questions you had about ECG results	5	4	3	2	1
Overall quality of the follow-up sessions	5	4	3	2	1



Please circle how you felt in each category:	GREAT 5	GOOD 4	OK 3	FAIR 2	POOR 1
5. Behavioral Altering Motivational (BAM) Messaging:					
Ease of understanding the text messages	5	4	3	2	1
Usefulness of BAM messages in guiding healthy choices	5	4	3	2	1
Usefulness of BAM messages to change your health behavior	5	4	3	2	1
Quantity of text messages received	5	4	3	2	1
6. Overall Satisfaction:					
Using the device once daily	5	4	3	2	1
With the device in general	5	4	3	2	1

7. What made it EASY to use the AliveCor™ device?

(PLACE CHECK MARK NEXT TO ALL THAT APPLY)

- ☐ Simple device
☐ Technical support from the study team
☐ Help from my family/friends
☐ I'm comfortable with electronics
☐ Text message reminders from the study team
☐ I felt good knowing someone was looking at my ECGs daily
☐ Other (please list) _____

8. What made it DIFFICULT to use the AliveCor™ device?

(PLACE CHECK MARK NEXT TO ALL THAT APPLY)

- ☐ I had to change my regular routine
☐ I had too many other things on my mind
☐ New electronic equipment is hard for me to get used to
☐ I didn't have anyone help me
☐ I didn't have reminders
☐ Other (please list) _____

9. Did the reminder texts help you to remember to send your ECGs daily?

- ☐ Yes
☐ No

10. How easy was it for you to incorporate daily ECG recordings into your routine?

11. Did you have trouble using your device? If “yes,” how so?

12. Do you feel the device is beneficial?

13. Do you feel more health-conscious after participating in the study using technology?

14. What do you like best about using the device?

15. What do you like least about using the device?

16. Suggestions for improvement?

Appendix D: Interview/ Focus Group Guides used in data collection in the study in Chapter Four

Guide used in Interviews/Focus Groups with Patients

Question	Probes	Guiding Concept(s) from Adapted UTAUT Model
Tell us about your experience using AliveCor™ while you were participating in the iHEART trial.	➤ What did you like about using AliveCor™? What didn't you like?	Perceived usefulness, perceived ease of use
	➤ What was easy to use about AliveCor™? What was difficult to use?	Potentially modifying factors (age, gender) if brought up by participant
	➤ Did you think AliveCor™ was useful? Why or why not?	
Did your experience using AliveCor™ change throughout the six months?	➤ Did your perception of how easy it was to use change?	Perceived usefulness, perceived ease of use, actual use of ECG mHealth technology
	➤ Did you perception of how useful it was change?	
	➤ Did you need to be reminded more (e.g., "prompts") to use AliveCor over the six months? Less? About the same?	
Do you have any previous experience using other health applications (apps) or devices?	➤ If no, was it hard getting used to using AliveCor™ in the iHEART trial? Explain.	Experience with technology
	➤ If yes, tell us about these experiences. Do you think they helped you use AliveCor™ in the iHEART trial? Why or why not?	
How did you remember to use AliveCor™ for the whole six months? Explain.	➤ Research coordinators?	Facilitating conditions, Actual use of ECG mHealth technology
	➤ Symptoms?	
	➤ Other cues (for example, time of day)?	
During the iHEART trial, how much did you pay attention to the data you were collecting with AliveCor™?	➤ Did you spend time looking at the data you were collecting and trying to make sense of it?	Facilitating conditions; Actual use of ECG mHealth technology/ high level engagement
	➤ Do you think its your job to try to make sense of the data you collect, or your healthcare providers? Or both? Explain.	
Do you think you would use AliveCor™ voluntarily if you weren't enrolled in a study?	➤ Why or why not?	Actual use of ECG mHealth technology/ high level engagement
	➤ If not, what do you think would encourage you to use AliveCor voluntarily?	

Guide used in Interviews/Focus Groups with Healthcare Providers and Research Coordinators

Question	Probes	Guiding Concept(s) from Adapted UTAUT Model
Tell us about your experience using data collected from your patients who were using AliveCor™ in the iHEART trial.	<ul style="list-style-type: none"> ➤ What did you like about the data from AliveCor™? What didn't you like? ➤ What was easy to use about the data from AliveCor™? What was difficult to use? ➤ Did you think the data from AliveCor™ was useful? Why or why not? 	<p>Perceived usefulness, perceived ease of use</p> <p>Potentially modifying factors (age, gender) if brought up by participant</p>
Did your experience using data from AliveCor™ change throughout the six months?	<ul style="list-style-type: none"> ➤ Did your perception of how easy it was to use change? ➤ Did your perception of how useful it was change? ➤ Did your actual use of the data change (used it more, less, or the same) in your clinical practice? 	<p>Perceived usefulness, perceived ease of use, actual use of ECG mHealth technology</p>
Do you have any previous experience using data that patients have collected from other health applications (apps) or devices?	<ul style="list-style-type: none"> ➤ If no, was it hard to get used to using data from AliveCor™ in the iHEART trial? Explain. ➤ If yes, tell us about these experiences. Do you think they helped you use data from AliveCor™ in the iHEART trial? Why or why not? 	<p>Experience with technology</p>
Now let's talk about your patients. Do you think your patients were engaged with self-monitoring with AliveCor™ for the whole six months? Explain.	<ul style="list-style-type: none"> ➤ If yes, what do you think kept them engaged? ➤ If no, what do you think were possible reasons for them not remaining engaged? ➤ Were there differences in your patient population in terms of engagement? If so, describe the different groups (engaged versus not-engaged). 	<p>Facilitating conditions, Actual use of ECG mHealth technology</p>
During the iHEART trial, how much do you think your patients paid attention to the data they were collecting with AliveCor™?	<ul style="list-style-type: none"> ➤ In your experience, did they spend time looking at the data you were collecting and trying to make sense of it? ➤ Do you think it is primarily their job to try to make sense of the data they collect, or yours as a healthcare provider? Or both? Explain. 	<p>Facilitating conditions, Actual use of ECG mHealth technology/ high level engagement</p>
Do you think your patients would use AliveCor™ voluntarily if you weren't enrolled in a study?	<ul style="list-style-type: none"> ➤ Why or why not? ➤ If not, what do you think would encourage them to use AliveCor voluntarily? 	<p>Actual use of ECG mHealth technology/ high level engagement</p>

Appendix E: Illustrative Quotes from Participants in the study in Chapter Four

1. Ease of Use

1.1 Similarities in Ease of Use

“I think it’s pretty user-friendly... Three fingers on each side and it saves automatically. And for the patients in our research study that are connected to our patient portal, so then they don’t even have to do anything further.” –Provider 3

“It’s very handy. It’s small. If I’m travelling I can bring it with me and not worry about the size and stuff. I remember when they first let me out of the hospital they attached me device that measure my heart rate and stuff like that. It was very cumbersome and this is just terrific.” –Patient 13 (engaged)

“It was easy at the beginning, it was easy at the end.” –Patient 1 (unengaged)

“For the most part, most patients do not document symptoms. Most patients just transmit, in our study.” –Research coordinator 1

1.2 Differences in Responses to Technical Issues

“Sometimes...if there was a microwave or something going on in the area, it gave a false reading... I’ll wait maybe like 30 or 40 seconds or something, maybe clean my fingers, and redo the test. And usually it shows up as normal.” –Patient 3 (engaged)

“I’ve been working out quite a bit. I can walk in about seven to eight miles a day. I figured maybe the EKG isn’t reading correctly or it’s just coming up unclassified because [the heart rate is] so low. I wasn’t concerned at all.” –Patient 4 (engaged)

“I didn’t feel safe in my ability to get accurate readings. You’re really talking about sitting in your own body and getting scary information...I’m sitting here panicking whether or not, I mean, I feel okay but this machine is telling me that I’m not okay.” –Patient 1 (unengaged)

1.3 Differences in Healthcare Provider Feedback

“I did have several false readings...those would at first bother me a little bit but after I saw the doctor the first time he said don’t pay attention to those...He took that off the table for me to worry about and we spend more time on other things.” –Patient 9 (engaged)

“I stopped because it said unclassified and...nothing was happening. And I was going insane. What was going on? I wanted feedback.” –Patient 11 (unengaged)

“It would’ve been nice in the early days to have some sort of positive recognition that, you know, “received” or something...Because it was just... Is this really going somewhere?” –Patient 2 (unengaged)

“If you hear from someone who is supposedly a human being to look at it and check it, then you’ll feel more confident that it’s probably right.” –Patient 1 (unengaged)

“Some of the patients have a misconception about it...someone’s sitting there and watching it and then they’ll give feedback right away. But unless somebody opens the email and loads it in, and downloads all the different tracings, then there’s no intervention right away. So that’s the only downside of it.” –Provider 4

2. Usefulness of the technology

2.1 Similar Usefulness of Identifying Rhythm

“With this I get affirmation each day that there’s normal heartbeat, no abnormalities” – Patient 2 (unengaged)

“My life would be much, much different without it, just because of the stress that not knowing causes...that lack of assurance that I’m in rhythm in itself causes stress. So, having that AliveCor device...it just reassures me.” –Patient 13 (engaged)

“For the first time it allows patients to record their own EKG with a very high quality device that they can keep with them indefinitely. So that is a major shift in the way we’ve been able to monitor patient’s EKG’s for arrhythmia.” –Provider 6

2.2 Differences in Insights and Perceived Value of the Data

“If I went for a walk or something, then again when I got home from the walk I would do it. Just to find out, for my own information, if there was any kind of effect from any outside activities.” –Patient 3 (engaged)

“Sometimes I’ll forget to take the medication but I never forget [Alivecor]...I know why. Because I value the feedback that it gives me tremendously.” –Patient 13 (engaged)

“I guess if I went into A fib and believed the readings, it would definitely help me to contact my cardiologist and discuss our options. So to that end it would be useful, but when you think something’s not working it’s just worse.” –Patient 1 (unengaged)

“You guys know if it’s a weird reading, but I don’t know that it’s a weird reading...I mean, I feel okay but this machine is telling me that I’m not okay.” –Patient 1 (unengaged)

“AliveCor creates too many false positive readings where it says atrial fibrillation or possible atrial fibrillation. It seems like it needs more work because then it creates when it’s false positive it’s creates anxiety and unnecessary phone calls and emails just because the computer said it was atrial fibrillation.” – Provider 6

“You just told me something I never noticed. That I can go back and see it all. I didn’t know that. I never looked at it.” –Patient 10 (unengaged)

“I’m blissfully unaware of other stuff that I should want to know... I don’t know if there’s any other data that would be meaningful to me.” –Patient 2 (unengaged)

2.3 Differences in Healthcare Provider Feedback

“AliveCor was an improved process for both me and for the physician because they had something that they could read...that was not a patient testimonial.” –Patient 9 (engaged)

“It’s potentially a long-term commitment... to stay engaged as we can to try to sort out why they’re having this rhythm problem and identify any triggers. Often there are not identifiable triggers. Sometimes there are. But again, most of the patients are willing to do that.” –Provider 5

“So, I was using it for quite a while... When I stopped, and I think part of it was getting the message unclassified kind of made wonder what the utility of this thing was. It was unclassified. What does that mean? And nobody guided me... I originally joined this study because I wanted to know what was going on.” –Patient 10 (unengaged)

“I, in fact, encourage them to not check it as often... We have a treatment plan, there’s really not much else that we can glean from the data, and so for them to persevere on it – it just doesn’t serve any purpose besides potentially causing more anxiety about it.” –Provider 5

3. Facilitating Conditions

3.1 AF Severity: Long AF Histories but Varying Proactive Behaviors

“The first time I didn’t take it seriously and then by the third I said enough is enough. Like I said I switched my diet. I started working out and I’m hoping not to have that again because I really don’t want to have an ablation.” –Patient 4 (engaged)

“I tried to use it every morning right after the ablation and pretty much through the first six months, I was probably pretty religious about it... As my rhythm returned to just a bunch of more normal kind of activity it became something I checked less.” –Patient 9 (engaged)

“After I had the ablation and it went back that quick, you know, a few hours later, that was, yeah, that was a disappointment.” –Patient 2 (unengaged)

“I’m no longer in [AF], at least, each time that I’ve been checked since the [intervention]... I go in about every six weeks, just to be checked.” –Patient 1 (unengaged)

“It’s not that they lost interest. The issue is that for the clinical part... treatment is achieved and the patients are doing well... They’re not less engaged, they’re appropriately using it.” –Provider 1

“These [engaged] people they know if they’re out of rhythm, because that’s the only time they’re using it. If they’re less using it, they’re doing great, the ablation worked. The only issue will be the asymptomatic one. Those are the ones, they’re going to miss it.” –Provider 2

3.2 AF Knowledge: Differences in Uncovering Self-knowledge

“[This] patient population happens to be in general very sophisticated and educated so I can’t say this is generalizable to all patient populations. Almost all the patients have smart phones and so that says something.” –Provider 6

“I think that what changed was my sense of how this problem was affecting my day to day life...the one doctor that I had since I was using [AliveCor] was pretty aware of what was going on with my body as a result of it. I don’t think that the AliveCor affected his knowledge of what was going on with me. I think it was my own understanding of what was going on.” –Patient 13 (engaged)

“[My doctor] had told me that relatively speaking [caffeine is] the least effective trigger for me. He said alcohol is the worst and it definitely is, there’s no question.” –Provider 7 (unengaged)

3.3 AF Symptoms: Driving Use for Unengaged Patients

“It’s like...Atrial Fibrillation hiding out on you” –Patient 10 (unengaged)

“Without the device, no other way to do it... it’s not I can feel [my symptoms] in my body necessarily, but I can certainly feel them in my energy level, if I’m in AFib or not. So the Kardia device sort of corroborates my AFib symptoms because I’m thinking I’m having it because of my energy level being up or down.” –Patient 6 (engaged)

“When I feel fine, I’m not gonna use it.” – Patient 5 (unengaged)

“I probably use it too much because every time I have chest pain, I just pull it out. And after a while, I just stop that...Because I can’t be doing it all the time.” –Patient 5 (unengaged)

“Well, I guess it’s how you feel...I’ve been on a six or eight week cycle of seeing my cardiologist. And I’m more comfortable with that.” –Patient 1 (unengaged)

“Most patients... are not always out of rhythm when they do document symptoms, and not always an A fib when they do document symptoms... they might feel light-headed or something at that particular time. So a lot of the time, what they perceive to be something is not always the case.” –Research Coordinator 1

“[My symptoms are] not at all predictive anymore, it seems.”

4. Moderators: Age, Gender, and Experience with Technology

4.1 Age

“I have a mother who has AFib, she’s 85, she’s not using any technology because she’s 85. It took me three years to convince her to get a laptop. So she can read email and still doesn’t know how to open attachments so she is never going to use something like the device.” –Patient 7 (unengaged)

“I’ve been surprised by how easily patients even in their 60’s, 70’s and 80’s have adopted using this. Not a lot of pushback. Patients find this empowering and patients like having this.” –Provider 6

4.2 Experience with Technology

“I know my way around the computers” – Patient 4 (engaged)

“I picked it up very easily. It was simple. And I’m not very good—I can’t even program a remote control.” –Patient 5 (unengaged)

“I found a free app that’s called heart rate something... this was before Kardia. It takes the pulse through your thumb... I could see where I was heart rate wise.” –Patient 8 (engaged)

“I did a diary for my cardiologist. It was more about how much medication I should take and how I was feeling within the first couple of hours after I take it.” –Patient 1 (unengaged)

“It’s not always the most cognitive or the most savvy individual. Our first patient in the trial would comply with sending his transmissions, and he wasn’t the most tech savvy person. But his enthusiasm for his care was there.” –Research Coordinator 1

5. New Factors

5.1 Personality traits and behavioral tendencies

“I’d like to live a long healthy life and being 50 years old, it’s time to make a change. I’m hoping...I can continue to have a quality of life as I grow older.” –Patient 4 (engaged)

“I would want to know if there’s something wrong. I’m worried about not doing OK and not knowing about it.” –Patient 11 (unengaged)

“There are patients who, psychologically, just want to reassure themselves...once they see something unusual from the baseline...they panic. Once they panic, or they just see something different, they call right away.” –Provider 1

5.2 Relationship with Healthcare Provider

“With the AliveCor™ device at Columbia, I feel like I am, you know, 99% in tune with them, or they with me, because it just gives them such important information.” –Patient 6 (engaged)

“Oftentimes the physician’s assistant will get it and she will refer to it and talk it over with the doctor, so he always knows what’s going on too, and then by email, she’ll write me back and say, you know, I think that you should continue with a certain medication and maybe stop this one, et cetera, but keep sending this to us because they’re very helpful.” –Patient 6 (engaged)

“There should be some way to use this equipment to my advantage beyond supporting the efforts of someone like Dr. X or collecting data for medical research...I’m happy to share my information but it seemed like a one-way street where you guys were just taking my information and I’m out there on my own. Without a contact in the event of something like the machine not working correctly.” –Patient 1 (unengaged)

“Anybody in the medical system needs an advocate, and you’ve got to be an advocate person foremost yourself...we all know that there’s an awful lot of stuff that we can do to impact that care and impact our general well-being and so forth...we’ve got to be involved.” –Patient 2 (unengaged)

5.3 Creating Supportive Environments

“It’s just part of my daily ritual...first thing I do when I wake up, it’s right by my nightstand. Just pick it up, check my messages of course, see my EKG 30 seconds and in the shower and get the day started.” –Patient 4 (engaged)

“Wallet, dollar bills, glucose tablets. Everything goes in my pockets, along with that [AliveCor] device, so I carry with me all the time.” –Patient 7 (unengaged)

“If I’ve missed the night I know to do it early in the morning and then just do twice the next day. It’s rare...If I’m traveling I’ll take it with me.” –Patient 8 (engaged)

“Remembering was difficult but my wife was very helpful in the evenings and in the mornings.” – Patient 13 (engaged)

“I’m still using it right now. And I’m planning to sign up to use it after the trial period...it’s a big help for me! At least I would know, and then if I did have a problem, I could go into the hospital and get it attended to before it turns into some sort of dangerous issue.” –Patient 3 (engaged).

“On weekends I didn’t do it...from the beginning I wasn’t doing it every day. I guess, I just forgot it. I don’t take it to work.” –Patient 11 (unengaged).

“I find that most of my patients after the study is over stop doing it every day, or they stop doing it at all. Other people lose the device or they don’t replace the battery.” –Provider 6