

CONVERSATIONAL ARTIFICIAL INTELLIGENCE AND PATIENT GENERATED HEALTH DATA: TRANSITIONAL PATIENT APPLICATIONS TO IMPROVE OUTCOMES IN THE 30 DAY POST-DISCHARGE WINDOW

By

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A Dissertation Submitted to the Department of Health Informatics

Rutgers State University of New Jersey

School of Health Professions

in Partial Fulfillment of the Requirements for the Degree of

Doctor of Philosophy

January, 2020

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Final Dissertation Approval Form

Conversational Artificial Intelligence and Patient Generated Health Data: Transitional Patient Applications to Improve Outcomes in the 30-Day Post Discharge Window

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Abstract

Readmission within 30 days of hospital discharge and avoidable emergency room visits have been shown to result in substantial costs and increased risk to patients. Evolving payment models under the ACA are focused on reducing unnecessary costs and decreasing short-term readmissions and will eliminate or reduce payment for 30-day readmissions after treatment for specified conditions and procedures. Evolving communications technology can help providers and patients to exchange critical patient data in the vulnerable post-discharge period and can encourage a shift to shared responsibility and collaboration between patients and providers. However, many providers are not prepared to collect, analyze, or respond to PGHD in their existing workflows, to make it actionable at the point of care, and to establish best practices for the use of PGHD. This study considers the patient's outcomes of readmission and/or emergency department use in relation to the use of conversational artificial intelligence in the form of chatbots to gather structured PGHD which is integrated directly into the patient's EHR and into usual provider workflow, making it available in real time for the provider for use in treatment decisions. Additionally, the study describes characteristics of patients elect or decline to participate in the use of chatbots and their preferences for how they receive and send messages. This study may provide valuable insight into developing optimal models of chatbot use for PGHD sharing and for the establishment of best practices for future implementations of this emerging technology.

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ACKNOWLEDGEMENTS

Although writing a dissertation is rather a solitary process, no one achieves this goal alone, and there are several people whose contributions to this project have mattered greatly to me.

My committee, Dr. Frederick Coffman, Dr. Shankar Srinivisan, and Dr. Simita Mishra. You have all been incredibly supportive, providing your expertise when I needed it and your encouragement when that was the greater need. I have learned a great deal from each of you and will always be grateful for your help and for your many kindnesses.

Northwell Health and my many colleagues, in particular Zach Gardner and Abraham Saraya for their help in gathering data, and Dr. Amer Saati and Dr. Simita Mishra for their support. I'd also like to thank Dr. Phil Marshall and the team at Conversa Health for providing access to so many resources.

And my family, including my parents who encouraged a lifelong love of learning; my son, who is a constant role model of perseverance and curiosity; and especially my husband, who has supported me in achieving so much. You did everything possible to make this goal achievable for me – and this accomplishment is <u>ours</u>.

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List of Abbreviations

5 0	
5G	Fifth Generation (Wireless)
ACA	Patient Protection and Affordable Care Act
ADT	Admission, Discharge, Transfer
AI	Artificial Intelligence
APN	Advanced Practice Nurse
BPCI	Bundled Payment for Care Initiative
CABG	Coronary Artery Bypass Graft
CAI	Conversational Artificial Intelligence
CCFA	Crohn's and Colitis Foundation of America
CEHRT	Certified Electronic Health Record Technology
CHI	Consumer Health Informatics
CMS	Centers for Medicare and Medicaid Services
CN	Care Navigator
COPD	Chronic Obstructive Pulmonary Disease
CTI	Care Transitions Intervention
DRG	Diagnosis Related Group
ED	Emergency Department
EHR	Electronic Health Record
EMPOWER-	Empowering and Motivating Patients Online With Enhanced Resources -
Н	Hypertension
FFS	Fee-for-Service
GDP	Gross Domestic Product
HHS	Health and Human Sevices
HIPAA	Health Insurance Portability and Accountability Act
HIT	Health Information Technology
HRRP	Hospital Readmission Reduction Program
HVBP	Hospital Value-Based Purchasing
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
MedPAC	Medicare Payment Advisory Committee
mHealth	Mobile Health
MIPS	Merit-based Incentive Payment
ML	Machine Learning
MMA	Medicare Modernization Act
MSSP	Madiana Sharad Savin an Dua anan
MISSI	Medicare Shared Savings Program

NIA	National Institute on Aging
NIH	National Institutes of Health
NLM	National Library of Medicine
NP	Nurse Practitioner
P4P	Pay For Performance
PA	Physician Assistant
PGHD	Patient Generated Health Data
PHR	Personal Health Record
PPRN	Patient-Powered Research Network
PPS	Prospective Payment System
PRO	Patient-Reported Outcome
PROMIS	Patient-Reported Outcome Measurement Information System
RCT	Randomized Controlled Trial
ROI	Return On Investment
SCHIP	State Children's Health Insurance Program
SDOH	Social Determinants of Health
SDT	Self Determination Theory
SMS	Short Message Service
TCM	Transitional Care Management
TES	Technology-Enabled Self-Management
TMI	Text-Messaging Interventions

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CHAPTER I

INTRODUCTION

It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm.

-Florence Nightingale

1.1 Background of the problem

According to the Centers for Medicare and Medicaid Services (CMS), U.S health care costs represented 18 percent of the gross domestic product (GDP) in 2017 and are projected to reach 20 percent by 2020, increasing at a greater rate than the overall economy for 31 of 40 of the calendar years from 1970 to 2010 (CMS, 2018; Keehan et al., 2011). To put these cost increases into perspective, a dozen eggs would cost \$55 and a gallon of milk would cost \$48 if the cost of other goods had increased at the same rate since World War II (Institute of Medicine, 2013). Exacerbating the issue, the Institute of Medicine (IOM) has estimated that a large percentage of health care expenditures are wasted on unnecessary services, inefficient delivery of services, excessive prices for services, excessive administrative costs, preventable illnesses, and fraud. By their account, \$756 billion was wasted in 2009 alone, representing 30 percent of all health care spending for that year (Institute of Medicine, 2010). These wasted health care dollars totaled more than the entire \$666 billion budget for the United States Department of Defense for the same year (U.S. Department of Defense, 2019) and, by definition, added no value to patient care. It is widely acknowledged that healthcare spending diverts major resources from other national priorities, such as education and infrastructure, and that the current growth rate of healthcare spending is unsustainable (Berwick, Nolan, & Whittington, 2008; Chandra, Dalton, & Holmes, 2013; Dowling & Kenney, 2018; Institute of Medicine, 2010; Manchikanti, Helm Ii, Benyamin, & Hirsch, 2017).

Under traditional fee-for-service payment models health care providers are paid based on the volume of services they deliver, so that incentives are not aligned with reducing waste or preventing unnecessary care (Conrad, 2015; Dowling & Kenney, 2018; Institute of Medicine, 2010; Manchikanti et al., 2017). In such a fragmented fee-forservice system providers are rewarded for providing additional care, even if the potential benefit is small (Chandra et al., 2013). In addition to the financial consequences of wasted and unnecessary care on health care spending, the care poses significant physical, psychological, and social risk to patients and can result in decreased patient satisfaction and even harm from unnecessary testing and treatment (Carroll, 2017; Korenstein et al., 2018).

In 2008 researchers at the Institute for Healthcare Improvement (IHI) described the "Triple Aim" for health care delivery as simultaneously improving the individual experience of care, improving the health of populations, and decreasing the per-capita costs of care for populations (Berwick et al., 2008; Institute of Medicine, 2008). In 2014 Bodenheimer and Sinsky proposed expansion of the Triple Aim to the "Quadruple Aim," (Figure 1) acknowledging the rising prevalence of physician burnout and adding the goal of improving the clinician experience in the workplace, because burnout is associated

with poorer outcomes, lower patient satisfaction and increased costs (Bodenheimer & Sinsky, 2014; Fiscella & Carroll, 2019).

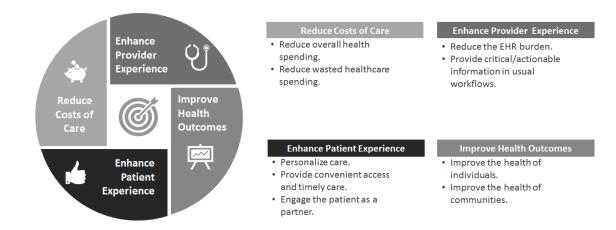


Figure 1. The goals of the Quadruple Aim

Despite consensus that the goals of the Quadruple Aim are worthy, health care organizations often choose to limit their focus on reducing per capita costs because their payment models do not reward them for decreasing the volume of care and sometimes even penalize them when improved health leads to less revenue (Whittington, Nolan, Lewis, & Torres, 2015). Both providers and patients have expressed concern about motives in cost-containment, so that framing overuse of services for these stakeholders in terms of patient outcomes, rather than strictly measuring overuse in dollars, may be more effective in achieving the overarching goals of reducing costs and improving outcomes (Korenstein et al., 2018).

Evolving reimbursement and care-delivery models increasingly focus on Value-Based Care and Pay-for-Performance (P4P) so that health care providers are paid based on the quality of the care they provide and on patient outcomes, rather than volume of service provided (CMS, 2019e; Conrad, 2015; Feder, 2013; Institute of Medicine, 2010). This is a paradigm shift that rewards providers who deliver effective and efficient care (Srinivasan & Desai, 2017). Under these models "value" is defined as achieving the optimal health benefit at the minimum cost, which translates to improved health outcomes, increased quality, enhanced patient satisfaction/experience, and reduced costs of care (Conrad, 2015). Under the 2010 Patient Protection and Affordable Care Act (ACA), CMS has expanded value-based payment for Medicare patients across various health care settings in an attempt to meet the Quadruple Aim. Some of the newer P4P models include both pay-for quality and pay-for-efficiency models, while Shared-Savings models return a portion of saved health care dollars to the provider of care, and Bundled-Payment-for-Care-Initiatives (BPCI) provide a single payment for an episode of care, regardless of the volume of services provided within the episode (CMS, 2019e; Damberg, 2014).

Under these new payment models there is increased scrutiny on hospital readmissions within 30 days of discharge from an inpatient facility because readmissions are seen as a measure of poor quality and because they result in increased costs (Ashton & Wray, 1996; Espinoza et al., 2016; Goldman, Sarkar, Kessell, & et al., 2014; Hannan et al., 2011; Joynt, 2016). In a 2008 report to Congress the Medicare Payment Advisory Committee (MedPAC) reported the as much as \$12 billion was spent on potentially preventable readmissions for Medicare patients in 2008 (MedPAC, 2008). Under the ACA, CMS introduced in 2012 a value-based purchasing program for inpatient care called the Hospital Readmission Reduction Program (HRRP) which financially penalizes hospitals for excess 30 day readmissions for patients initially admitted for specific high volume/high risk conditions (Boozary, Manchin, Iii, & Wicker, 2015; CMS, 2019d).

These conditions include heart failure, heart attack, pneumonia, chronic obstructive pulmonary disease (COPD), coronary artery bypass graft surgery (CABG) and elective hip and knee replacement (Srinivasan & Desai, 2017).

At the same time that reimbursement is redirecting health system priorities, concepts of patient engagement and consumerism are redefining provider-patient relationships and changing the way that care is delivered (Graffigna & Barello, 2018b; Hibbard & Greene, 2013; Lewis, Eysenbach, Kukafka, Stavri, & Jimison, 2005). Engaging patients and their families as active participants in the delivery of care has been identified as crucial to success in the transformed health care environment to reduce costs and promote wellness and disease self-management (Dowling, 2012). This focus on patient engagement and activation within the health care team, rather than only on their compliance with prescribed treatment, recognizes that patients play an important role in the ongoing management of their health (Hibbard & Greene, 2013). Patients are increasingly empowered, self-directing participants in their own care and a mutual awareness of shifting roles and responsibilities between patients and healthcare providers is the basis for collaboration and co-creation of a more sustainable and satisfactory health care model (Graffigna & Barello, 2018b).

Technology is also playing a role in health care transformation as telemedicine and telehealth replace traditional office visits (Chandak & Joshi, 2015; Kahn, 2015; Simblett et al., 2018; Watson, 2016). Telemedicine refers to the direct provision of clinical services when distance separates the patient and provider, while telehealth is a broader term for a wide range of health services, including monitoring and patient education (Schwamm, 2014). The broad adoption of mobile technology is facilitating

this transformation and a recent Pew Research Institute report indicated that almost 75% of Americans now own a smartphone and that 40% of those owners are over 64 years old (Smith, 2017). Although younger patients are more inclined to use a smartphone regularly, older adults are just as likely to use a smartphone for a specific purpose, such as the collection of health information or communication with a health care provider (Abelson et al., 2017).

Armed with these internet connected devices, more patients are using personal health apps and wearable devices to track health information or to monitor illness creating volumes of patient generated health data (PGHD) (Lai, Hsueh, Choi, & Austin, 2017; Reading & Merrill, 2018; Tiase, 2017). The Office of the National Coordinator for Health Information Technology defines PGHD as health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern (Office of the National Coordinator, 2013). Some of the key features of PGHD include that the data is captured by the patient, the data is collected outside of the usual clinical setting, and the data is longitudinal/capable of being captured frequently (Howie, Hirsch, Locklear, & Abernethy, 2014). Current evidence on the benefit of PGHD is sparse, but, advances in technology and policy changes are providing both means and motivation to incorporate the technology into practice. Recognizing that PGHD has the potential to improve the quality of care, CMS has initiated policy changes that incentivize and reimburse providers for reviewing and interpreting PGHD as of January, 2018 (Reading & Merrill, 2018).

PGHD is not itself a new phenomenon as patients have long recorded personal health information such as blood pressure and blood glucose levels manually and

reported results to providers at face-to-face visits (Basch, 2013). However, technology that allows patients to record large volumes of data and to share the information electronically presents both opportunities and obstacles (Basch, 2013; Cohen et al., 2016; Danis, 2016; Gollamudi SS, 2016). Innovators are exploring ways in which online tools available on internet-connected devices can support patients in achieving better health through patient/caregiver education, community involvement, and by facilitating communication between patients and providers (Frist, 2014). Health care systems are challenged to incorporate PGHD to actionable information within long-defined provider workflows (P. Y. Hsueh et al., 2017; Rosenbloom, 2016; Tiase, 2017). Patients who share PGHD with providers seek instruction and reassurance based on the data they share, while providers want to standardize/limit the scope of PGHD, to receive PGHD only from selected patient populations and to have clear clinical guidelines about how and when to respond to PGHD (Reading & Merrill, 2018). In addition to workflow challenges associated with PGHD, health systems will have to address concerns of device usability, security of personal health information, data storage and data reliability/usability (Lai et al., 2017; Sanger et al., 2016). We must also consider the ethical concerns associated with disparities in care for those who do not have access to the technology used to share PGHD with their provider (Lai et al., 2017; Nguyen, Mosadeghi, & Almario, 2017). Further research can also help us to better understand the reliability, validity and utility of PGHD to different potential stakeholders (Rosenbloom, 2016).

In response to growing demand for these services the user interface for many apps and wearable devices are becoming more patient-friendly, and electronic health record (EHR) interfaces have evolved to integrate PGHD in a format that can facilitate interpretation of results as well as alert providers to alarming results (Irizarry, DeVito Dabbs, & Curran, 2015; S. Waldren, Agresta, & Wilkes, 2017). In order to comply with stage 2 meaningful use requirements many EHRs are now also equipped with patientportals that have survey capability as well as the ability to capture data with sensors from wireless devices and even integrate PGHD into clinical decision-support solutions (Howie et al., 2014). Smartphones can leverage software apps to automatically upload and store data securely from multiple devices, including glucometers, scales, and blood pressure cuffs, thereby reducing the likelihood of user error in transcribing PGHD (S. Waldren et al., 2017). Further research can also help us to better understand the reliability, validity and utility of PGHD to different potential stakeholders (Rosenbloom, 2016).

Emerging communications technology that meets the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) offers potential to enhance patient-provider communication and increase efficiency in health care delivery (Sukyung, Panattoni, Chi, & Palaniappan, 2017; Sulieman et al., 2017; S. Waldren et al., 2017; S. E. Waldren & Solis, 2016). Electronic Health Records (EHRs) now have patient portals, allowing patients to view parts of their health record and to communicate with providers using secure web messaging (Sukyung, Panattoni, Chi, Palaniappan, & Chung, 2017). This messaging is different than traditional email in that it is used only for patient-provider or provider-provider electronic communications and it requires specific login procedures and user identification to maintain the security of highly-sensitive

patient data, such as lab results, diagnostic test results, prescription refills or referrals to other services (Franklin, 2013; Wakefield et al., 2010).

The use of secure web-messaging in health care has more recently evolved to include the use of "chatbots" to securely exchange conversational messages with patients and offers promise as an efficient and cost-effective model of communication (Arndt, 2018; Kowatsch et al., 2017; Pereira & Díaz, 2019). Some limits of the technology include patient and provider concerns about security of the exchanged information, credibility of the data exchanged, and the impersonal nature of technology assisted "conversation", with success of the model dependent upon the ability to reach a real human if the responses indicate that intervention is needed (Arndt, 2018). Despite limited research on patient outcomes, secure messaging and chatbots have shown positive results when used as a mobile health (mHealth) intervention for both physical and mental health issues (Inkster, Sarda, & Subramanian, 2018; Rathbone & Prescott, 2017).

Much of the research on secure messaging and chatbots in healthcare has focused on the technical facilitators and barriers to this type of information exchange, provider workload and workflows, and content of the actual messages, rather than on the effect on patient outcomes or efficiencies gained by the technology (Ho, Hancock, & Miner, 2018; Inkster et al., 2018). Little data is available on the cost-effectiveness of secure messaging and chatbots to exchange PGHD because most providers using the technology are so early in the implementation that they do not yet have data on cost savings (Arndt, 2018). In the 2012 "Empowering and Motivating Patients Online With Enhanced Resources – Hypertension" (EMPOWER-H) study, researchers used a web-based system of secure messaging integrated with the EHR to support patient-provider communication with

structured use of PGHD and a personalized care-plan to facilitate patient engagement and enhanced clinical management of hypertension patients, resulting in 86 percent of participants achieving a clinically meaningful reduction in blood pressure (Lv et al., 2017). It is acknowledged that the technology will be more widely adopted in health care if additional demonstration projects are shown to reduce costs or improve outcomes (Schwamm, 2014). Many studies of secure messaging and chatbots for exchange of PGHD have focused on chronic illness, such as hypertension and diabetes, with fewer researchers focusing on acute illness or post-operative patients (Abelson et al., 2017).

With increased scrutiny on readmissions, health systems are increasing their focus on identifying patients at higher risk (Auerbach et al., 2016a; Espinoza et al., 2016; Fanari, Elliott, Russo, Kolm, & Weintraub, 2017; Harvath, Hilu, Nemana, & Sairamesh, 2013; Kripalani, Theobald, Anctil, & Vasilevskis, 2014). Some of the patient risk factors associated with readmission include socioeconomic status, insurance status, and patient comorbidities, such as diabetes, dependency on dialysis, COPD or heart failure (Feng, White, Gaber-Baylis, Turnbull, & Rong, 2018; M. H. Hall et al., 2014). Family members also reported that they felt unprepared for the role of caregiver when patients were discharged soon after surgery, specifically regarding such things as symptom monitoring, medications, and mobility (Halm, 2016). By the time the patient is readmitted their symptoms have often advanced to the point where the readmission is urgent and necessary to address clinical deterioration of the patient (Jencks, 2010). This is often the result of a fragmented system that failed to identify the patient's developing issues and address them earlier in the transitional period from hospital to home (Callahan & Hartsell, 2015; Jencks, 2010). Most of the available research on readmissions has

focused on the identification of patients at risk for readmission and suggested potential interventions to prevent avoidable readmissions, however few of the researchers have actually implemented the suggested interventions or evaluated their effectiveness (Jones et al., 2016).

Some health systems have implemented transitional care programs, involving advanced practice Nurse Practitioners (NPs) and Physician Assistants (PAs) in the role of "Care Navigator" (CN) for the patient, in order to improve care continuity after patient discharge home with a goal of reducing 30-day readmissions (Coleman, Parry, Chalmers, & Min, 2006; M. H. Hall et al., 2014; Naylor et al., 2004). These programs include home visits, medication reconciliation, patient/caregiver education and assistance with coordinating follow-up care during the transitional period after discharge (Coleman et al., 2006; M. H. Hall et al., 2014; Naylor et al., 2004). Although these programs have demonstrated potential benefit to patients they have not been widely adopted because of high costs associated with implementing the model and the current culture of medical practice, which is characterized by care delivered in a disjointed fashion (i.e. Hospital, Physician Office, Home Care) with little integration to support patients throughout an entire episode of acute illness (Naylor et al., 2004). The advanced practice transitional care model has shown success at reducing readmissions and the costs of the programs were more than offset by the reduced spending on re-hospitalization (M. H. Hall et al., 2014; Nabagiez, Shariff, Molloy, Demissie, & McGinn, 2016). However, such personalized care management is expensive and the programs could be more scalable if CNs were able to use technology to identify patients whose condition is changing and who might benefit from timely intervention (Weintraub et al., 2018).

Providing a method for patients to securely exchange PGHD with providers in the post-acute discharge window may provide a more scalable model that allows providers to identify patients at greatest risk and respond proactively to changes in patient condition to improve patient outcomes and reduce unnecessary readmissions (Arlene E. Chung et al., 2016; P. Y. Hsueh et al., 2017; Reading & Merrill, 2018). Such a model can also assist patients in self-management, thereby reducing their reliance on health care personnel (Lv et al., 2017). Arndt (2018) reports that a major health system in the New York metropolitan area has implemented a web-based secure messaging chatbot system for recently discharged patients that returns PGHD to the patient's EHR and alerts the CN in real time to patient responses that are associated with increased risk of readmission. A link sent to the patient's smartphone or email launches a HIPAA compliant web-based messaging application where patients have a conversation with a text-based chatbot. Using this model the patient receives approximately a 3-fold increase in contacts, from 5 to about 15 during the 30-day post-discharge window and 96% of patients who enroll and complete at least one conversation report that it is helpful (Arndt, 2018).

1.2 Statement of the Problem

Readmission within 30 days of hospital discharge has been shown to result in substantial costs and increased risk to patients (Carroll, 2017; Hannan et al., 2011; Korenstein et al., 2018). Evolving payment models under the ACA are focused on reducing unnecessary costs and decreasing short-term readmissions and will eliminate or reduce payment for 30-day readmissions after treatment for specified conditions and procedures (Conrad, 2015; Hannan et al., 2011; NEJM, 2018). Evolving technology can help providers and patients to exchange critical patient data in the vulnerable post-

discharge period and can encourage a shift to shared responsibility and collaboration between patients and providers (Tiase, 2017). However, many providers are not prepared to collect, analyze, or respond to PGHD in their existing workflows (Cohen et al., 2016).

The specific problem is that health systems are challenged to integrate PGHD into provider workflow, to make it actionable at the point of care, and to establish best practices for the use of PGHD (Ingebrigtsen et al., 2014; Lv et al., 2017; Tiase, 2017). This study considers the patient's outcomes of readmission and/or emergency department use in relation to the use of chatbots to gather structured PGHD which is integrated directly into the patient's EHR and into usual provider workflow, making it available in real time for the provider for use in treatment decisions. Additionally, understanding which patients elect to participate in the use of chatbots and their preferences for how they receive and send messages may provide valuable insight into developing optimal models of chatbot use for PGHD sharing and for the establishment of best practices for future implementations of this emerging technology.

1.3 Purpose of the research

The purpose of this retrospective descriptive study is to explore the impact of sending structured PGHD to the EHR via chatbots on the rate of 30-day readmissions and ED visits for recently discharged transitional care management patients at a major health system in New York from 2018 to 2019.

1.4 The research hypotheses

Research Question 1:

Does providing structured patient generated health data to the electronic health record via chatbots result in fewer hospital readmissions for transitional care patients within the first thirty days following an index discharge?

(HA0): There is no significant difference in the number of readmissions between patients that provide structured patient generated health data to the electronic health record via chatbots versus those that don't within the first thirty days after an index discharge.

(HA1): There is a significant difference in the number of readmissions between patients that provide structured patient generated health data to the electronic health record via chatbots versus those that don't within the first thirty days after an index discharge.

Research Question 2:

Does providing structured patient generated health data to the electronic health record via chatbots result in fewer emergency room visits for transitional care patients within the first thirty days following an index discharge?

(HB0): There is no significant difference in the number of emergency room visits between patients that provide structured patient generated health data to the electronic health record via chatbots and those that don't within the first thirty days after an index discharge.

(HB1): There is a significant difference in the number of emergency room visits for patients who provide structured patient generated health data to the electronic health

record via chatbots and those that don't within the first thirty days after an index discharge.

Research Question 3: To what degree do discharged transitional care management patients elect to participate in providing structured patient generated health data to the electronic health record via chatbots by:

- a. Age;
- b. Gender;
- c. Mode of contact (text or email);
- d. Recipient of the message (patient or proxy);
- e. Chat Module (diagnosis).

1.5 Significance of the Research

1.5.1 Significance for Practice

As the use of technology to track health has grown, health care providers have expressed concern that the volume of PGHD received may overwhelm existing workflows (Sulieman et al., 2017). In this project we have integrated the structured PGHD directly to the EHR in near real time with associated color-coded levels of alert based on the patient's replies. This allows providers to more readily identify PGHD that may require their intervention, while minimizing the disruption of monitoring patients whose replies indicate that their condition is stable or improving.

Additionally, providers have asked us to identify how to make PGHD actionable at the point of care in accordance with clinical workflows for the greatest leverage of this valuable data (Tiase, 2017). By integrating PGHD directly into the EHR this project provides an opportunity to determine if providing PGHD in the existing health record used by providers at the point of care is associated with improved outcomes for patients discharged in the last thirty days. Alerts sent directly to the provider when a patient's replies are associated with increased risk of a poor outcome also provide real time support to clinicians in managing PGHD within their usual workflows.

Transitional care management by advanced practice nurse practitioners and physician assistants in the post-acute period following discharge has been shown to reduce readmissions (M. H. Hall et al., 2014; Naylor et al., 2004). Although they have been proven to be cost-effective, such programs are expensive to implement and may be difficult to scale in some settings due to issues of geographical distance in rural areas and availability of highly specialized and experienced staff to provide this intense level of care management (M. H. Hall et al., 2014). This study focuses on how technology may be able to quickly and effectively identify and engage those patients who are at highest risk, potentially allowing us to achieve overall cost reductions and improved outcomes for patients without additional human resources.

1.5.2 Significance for Research

There is very limited research available on the use of chatbots to capture PGHD in the EHR, and even less research about the impact of this emerging technology on patient outcomes. What research is available regarding PGHD is often focused on patients with chronic illnesses, rather than on patients in the transitional period following discharge from an acute care facility (Abelson et al., 2017). This study will offer an opportunity to

consider the impact of using the technology on an acute care population and may inform future care coordination standards development. Additionally, the study will add to the shallow body of knowledge regarding PGHD and mHealth (Lv et al., 2017) to determine how they might be applied to other clinical situations and populations . The study will also address additional concerns regarding PGHD that may help to establish best practices, including defining how to incorporate this information into provider workflow to make it actionable at the point-of-care (Ingebrigtsen et al., 2014; Tiase, 2017).

Chapter II

REVIEW OF THE RELATED LITERATURE

Were there none who were discontented with what they have, the world would never reach anything better.

-Florence Nightingale

2.1 The Evolution of Health Care Payment: The Shift to Value-Based Care

2.1.1 The Politics of Health Care Payment

Payment for health care in the U.S. has long been a topic of political debate and discord. At the start of the 20th century, in the wake of passage of the National Insurance Act of 1911 in the United Kingdom, efforts to implement universal health coverage in the United States were initiated by President Theodore Roosevelt (Manchikanti et al., 2017). In the 1930's President Franklin D. Roosevelt, while drafting provisions to Social Security legislation, put forth several plans to provide universal health care to all Americans under a national, compulsory health plan, an issue which some still consider the unfinished legacy of the New Deal (Blumenthal & Marone, 2009). Federal and state governments since then have grappled with the issues of health care access and payment for all Americans with liberal-leaning politicians historically supporting the safety net a nationalized system would provide and conservatives arguing that such a system represents the worst of government overreach and is the first step toward socialized medicine (Manchikanti et al., 2017).

In 1965 the opposing sides were able to agree on the provision of coverage for vulnerable populations, specifically the elderly and poor, and they enacted Medicare and Medicaid legislation, but still fell short of addressing coverage for all Americans (Blumenthal & Marone, 2009). In 1997, under the Clinton administration, the Children's Health Insurance Program was created as a joint state-federal partnership to provide health insurance to low income children (CMS, 2019f). Today, an estimated 140 million Americans rely on health care benefits through Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). These three major programs are administered by CMS, an agency of the U.S. Department of Health and Human Services (HHS), which is the single largest payer for health care in the United States (CMS, 2019b).

At its inception, traditional Medicare paid physicians on a fee-for-service basis, reimbursing their "customary, prevailing and reasonable" fees. Hospital charges were paid based on their costs with a 2% surcharge added to payments to help hospitals cover bad debts and to grow their facilities (Mayes, 2004, 2007). Under these models physicians and hospitals had no incentives to lower costs and were actually incentivized to provide more services, regardless of medical necessity. Health care spending increased dramatically, and by the 1970s rapidly increasing medical inflation forced those who paid for care, including employers, to intervene to control costs of health care (Mayes, 2004). President Carter had campaigned against waste, excess spending, and profits in the medical industry, arguing that because people were not directly involved in payment for health services the medical establishment was motivated to provide excessive services and gain enormous profits (Carter, 1982; Mayes, 2007). As President, Carter pledged to

address the issue with limits on all hospital payment rates. In an effort to avoid regulatory changes the hospital industry proposed voluntary efforts to contain spending, which had small initial success, but then failed and hospital cost inflation jumped to 13% in 1980 and 18% in 1981(Mayes, 2007).

Elected in 1980, President Reagan faced a deep recession, and even leading representatives of the hospital industry acknowledge that major reform of Medicare's payment system was inevitable (Mayes, 2007). Recognizing that the rate of growth in health care costs was unsustainable, an alternative hospital payment model was proposed based on a patient classification system using Diagnosis Related Groups (DRGs), a system which identified classes of patients with similar care needs and services for a single hospital stay (Fetter, Shin, Freeman, Averill, & Thompson, 1980). Under the DRG model hospitals received a standard prospective payment for a patient's hospitalization, regardless of length of stay or number of tests administered to the patient. If the hospital could improve efficiency and provide the patient's care for less than the standard DRG payment, it was able to keep the difference. If they provided excessive services they would not receive additional reimbursement. Medicare's Prospective Payment System (PPS) based on DRGs was implemented for hospitalized patients on October 1, 1983, representing a significant shift in power between the providers of care and those who paid for it, introducing dramatically shorter hospital stays and new limits on health care provider autonomy (Blumenthal & Marone, 2009; Mayes, 2007).

The shift in Medicare hospital payments based on DRGs also impacted private insurance throughout the 1990s as hospitals shifted costs to privately insured patients, driving up the cost of employer sponsored health insurance. Employers responded by switching more employees from fee-for-service to managed care policies, which restricted patients' access to more expensive medical care and limited physician autonomy. The growth of managed care plans in both public and private insurance initially helped to curb health care spending in the first half of the 1990s, but double-digit annual increase in health insurance premiums returned by the late 1990s (Mayes, 2004). President Clinton's attempts to reform health care and assure universal coverage were unsuccessful and the politicization of health care became even more entrenched along party lines in this period (Blumenthal & Marone, 2009).

President George W. Bush signed the Medicare Modernization Act of 2003 (MMA), providing optional prescription drug coverage for the elderly beginning in 2006 (Oliver, Lee, & Lipton, 2004). In a compromise with conservatives who resisted this expansion of Medicare coverage the bill also included several other provisions including experiments designed to improve the quality of care, reduce the costs of chronic illness, and require reporting data on quality of care by providers (Blumenthal & Marone, 2009). MMA also provided private health plans the ability to compete in order to foster innovation and flexibility in coverage and offered coverage for preventive services (CMS, 2015).

2.2 Emerging Payment Models

The Patient Protection and Affordable Care Act (ACA) enacted by the Obama administration in 2010 built on the quality measures in MMA, focusing on value-based care initiatives that placed greater emphasis on patient outcomes and satisfaction in addition to cost and efficiency (Srinivasan & Desai, 2017). The Center for Medicare and

Medicaid Innovation (also known as the Innovation Center) was created as part of the ACA with a goal of testing innovative payment and service delivery models that might reduce spending while improving quality for CMS covered patients (CMS, 2019a). Some of the newer pay-for-performance (P4P) models include both pay-for quality and pay-for-efficiency provisions, while Shared-Savings models return a portion of saved health care dollars to the provider of care, and Bundled-Payment-for-Care-Initiatives (BPCI) provide a single payment for an episode of care, regardless of the volume of services provided within the episode (Damberg, 2014). Under these models "value" is defined as achieving the optimal health benefit at the minimum cost, which translates to improved health outcomes, increased quality, enhanced patient satisfaction/experience, and reduced costs of care (Conrad, 2015; Tailor, 2015).

The Medicare Access and CHIP Reauthorization Act of 2015 replaced traditional fee-for-service, volume-based payments for Medicare covered services with models intended to reward improved quality and cost control (Dowling and Kenney 2018). The Bundled Payment for Care Initiative (BPCI) has four broadly defined models of care that link payments for the care received during an episode, which may include an extended period beyond the hospital discharge (CMS, 2019a). The Hospital Value Based Purchasing program (HVBP) rewards acute care hospital with incentive payments based on performance measures of quality in four domains: clinical care, efficiency and cost reduction, safety, and patient experience (Srinivasan & Desai, 2017). The Hospital Readmissions Reduction Program (HRRP) penalizes acute-care hospitals whose 30-day readmission rates are high relative to other facilities. The HRRP tracks readmissions for Medicare patients admitted initially for six targeted conditions: heart attack, heart failure, pneumonia, chronic obstructive pulmonary disease (COPD), coronary artery bypass graft (CABG) and elective hip and knee replacement (NEJM, 2018). Under these models, health care providers are increasingly paid based on the quality of the care they provide and on patient outcomes, a paradigm shift that rewards providers who deliver effective and efficient care (Srinivasan & Desai, 2017).

In 2016, 29% of health care payments were made through alternative payment models, including bundled payments, shared savings and shared risk programs, up from 23% in 2015 (Market Insider, 2017). As of 2017, more than 12 million Medicare and Medicaid beneficiaries received their care from more than 350,000 clinicians participating in alternative-payment models, all with the same higher quality/lower cost goal (CMS, 2017). The shift from payment for volume to payment for value will require a total restructuring of the industry (Coutre, 2017). Health care systems face new challenges as they navigate an environment where more and more of the care they deliver is based on these emerging payment models (Dowling, 2012).

2.2 Readmissions

2.2.1 Frequency and Cost of Readmissions

Under these evolving payment models there is increased scrutiny on hospital readmissions within 30 days of discharge from an inpatient facility, because readmissions are considered a surrogate measure of poor quality and because they result in increased costs (Ashton & Wray, 1996; Hannan et al., 2011; Jencks et al., 2009). In an analysis of 2003-2004 claims data it was reported that one in every five hospitalized Medicare fee-for-service beneficiaries had an inpatient readmission within thirty days of discharge and

more than one third were rehospitalized within 90 days (Callahan & Hartsell, 2015; Jencks et al., 2009). Of the \$102.6 billion spent on hospital payments for Medicare beneficiaries in the period from 2003 to 2004, an estimated \$17.4 billion was spent on unplanned readmissions (Jencks et al., 2009). Certainly not all readmissions are preventable, but in a report to Congress the Medicare Payment Advisory Committee (MedPAC) reported the as much as \$12 billion was spent on potentially preventable readmissions for Medicare patients in 2008 (MedPAC, 2008).

Readmissions carry more than financial risk, as rehospitalized patients are subjected to the damaging effects of immobility, nosocomial infections and other iatrogenic hazards every day they are hospitalized (Creditor, 1993; Schimmel, 2003). Avoidable readmissions put patients at unnecessary risk and are, by definition, an overuse of services. Korenstein et al have described an evidence-based conceptual map (Figure 2.1) that defines 6 domains of potential harm to patients by overuse of health care services, including:

- Physical, such as adverse drug reactions or procedural complications,
- Psychological, such as anxiety or depression associated with illness,
- Social, including loss of ability to participate in family/social networks,
- Financial burden, due to medical bills and lost wages,
- Treatment burden, defined as time spent managing illness and care, and
- Dissatisfaction with care, resulting from frustration or loss of faith in providers (Korenstein et al., 2018)

According to the map, an overused service can lead directly to short-term and/or longterm negative consequences for patients and negative consequences can also lead to additional downstream services, which themselves can lead to negative consequences.

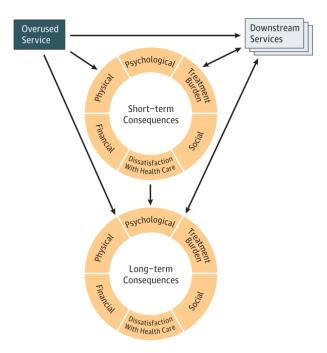


Figure 2. Conceptual Model of Overused Services and short-term and long-term negative consequences for patients across six domains. Overused services can also lead to downstream services that can have their own negative consequences. Korenstein, 2018 (Reprinted with permission)

2.2.2 Identification of Readmission Risk

Readmissions are considered to be multifactorial, a result of both patient-specific risks such as post-operative complications or medication adherence, and system-level risks such as poor access to follow-up care in a community or public transportation options (Jencks et al., 2009; Rumsfeld & Allen, 2011). Caregivers have also reported that they feel inadequately prepared for their role in the post-discharge period, citing medication management, dealing with symptoms, and navigating required follow-up care as sources of stress (Halm, 2016). Additionally, certain diagnoses, such as heart failure, chronic obstructive pulmonary disease (COPD) and dependence on dialysis have been identified as factors for higher readmission risk (M. H. Hall et al., 2014). Health systems

are increasingly focused on identifying the patient characteristics that are associated with costly readmissions and on identifying and managing patients at higher risk (Feng et al., 2018). Studies into the causes of readmission have identified race, age, length of hospital stay, previous admissions within a year, polypharmacy, and multiple comorbidities, in addition to several other factors for readmission with 30 days (Auerbach et al., 2016b; M. H. Hall et al., 2014; Kripalani et al., 2014; Robinson & Hudali, 2017).

Accurate identification of these patients is important to controlling cost and deploying resources where they might have the greatest impact. Providers use many standardized tools to identify their hospitalized patients at risk of readmission, such as LACE Index or HOSPITAL Score. LACE Index uses four variables to measure risk, including length of the index hospitalization (L), acuity, measured by whether the index hospitalization was planned or emergent (A), comorbidities of the patient (C) and emergency department use in the 6 months prior to admission (E) (Robinson & Hudali, 2017). The HOSPITAL score considers the patient's hemoglobin level (H), discharge from oncology service (O), serum sodium level (S), procedures during hospitalization (P), index admission type, whether planned or emergent (I and T), previous admissions in the last year (A), and length of hospital stay (L) (Donzé et al., 2016). These models of prediction may enable health systems to focus resources on those patients who are at greatest risk, but their focus on clinical factors is a limitation to the models because they do not address the socioeconomic factors that are known to be an important determinant of readmission risk (Lancey et al., 2015). Additionally, these models lack sensitivity and specificity, overestimating many patients' risk for readmission and missing others who do get readmitted (Harvath et al., 2013). Information technology is now facilitating the

identification of high-risk patients through the use of big data business intelligence and artificial intelligence (AI), which can use both coded clinical data and text analytics to mine patient records to identify high-risk patients while they are still hospitalized, to identify the disease-specific programs for which they might qualify, and to provide clinical decision support to providers who manage their care (Harvath et al., 2013; Topol, 2019). Using admissions, discharge and transfer (ADT) and claims data, combined with text data drawn from nursing and care management notes can improve the sensitivity and specificity of these models to near 90% (Harvath et al., 2013). As even greater volumes of data are captured in electronic health records these models may offer greater opportunities to improve outcomes (Bayati et al., 2014).

2.2.3 Emerging Payment Models and Readmissions

Under the ACA, CMS introduced in 2012 a value-based purchasing program for inpatient care called the Hospital Readmission Reduction Program (HRRP) which financially penalizes hospitals for excess 30 day readmissions for patients initially admitted for specific high volume/high risk conditions (Desai & Stevenson, 2012). These conditions include heart failure, heart attack, pneumonia, chronic obstructive pulmonary disease (COPD), coronary artery bypass graft surgery (CABG) and elective hip and knee replacement (Srinivasan & Desai, 2017). Under this program, hospitals with higher than average risk-adjusted readmission rates are penalized up to 3% for all Medicare admissions in the following year in proportion to their rate of excess rehospitalizations for the targeted diagnoses (CMS, 2019c). For the fiscal year 2016, three-quarters of U.S. hospitals faced financial penalties under HRRP for higher incidence of readmissions within 30-days, for a total of \$420 million in Medicare reimbursement (Shah et al., 2017; The Advisory Board, 2019).

2.2.4 Readmission Reduction Models

Health systems have developed several models of care to guide high-risk patients through the transitional period following discharge from the hospital through investments in such initiatives as post-discharge care coordination, telehealth, follow-up phone call programs, patient education and self-management support (Bayati et al., 2014; Harvath et al., 2013). Successful models share several core activities aimed at "bridging" the gap between hospital and home (Figure 2.2), including medication management, care coordination, outpatient follow-up, patient education in self-management, and communicating information across the patient's health care team (Burke, Kripalani, Vasilevskis, & Schnipper, 2013; Kripalani et al., 2014).

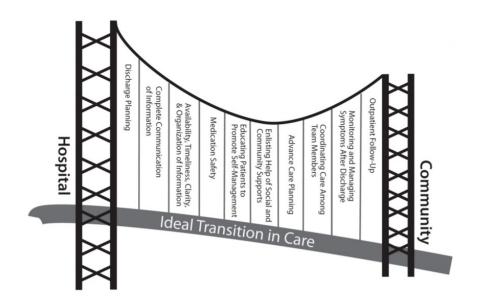


Figure 3. The Ideal Transition in Care. Burke, 2013 (Reprinted with permission)

Under Naylor's Transitional Care Model (TCM) it was shown that the introduction of an Advanced Practice Nurse (APN) collaborating with the patient's physician during and beyond hospitalization for ninety days increased the time to first readmission, reduced the total number of rehospitalizations for one year post discharge, reduced ED visits, and reduced hospital costs in three randomized controlled trials (Enderlin et al., 2013; Naylor et al., 2004). Under Coleman's Care Transitions Intervention (CTI) Model there is focus on four "pillars" of quality in transitional care management – medication self-management, a patient-owned health record, follow-up with a primary care provider or specialist, and awareness of red flags. In the CTI model an APN also acts as a patient advocate in the post-discharge period, with studies showing a 30% reduction in all cause readmissions for patients who participated in the program (Coleman et al., 2006). Other programs use community paramedics (CPs) who receive additional training in the role of physician extender to provide mobile evaluations and treatment of patients at home, with an MD available for telephonic or video consult, potentially avoiding unnecessary ED visits or readmissions (Abrashkin et al., 2019).

Despite the success of these transitional care models, they can be prohibitively expensive to implement for large patient populations, costing approximately \$348 per discharge in the New York metropolitan area (Chollet, Barrett, & Lake, 2011; M. H. Hall et al., 2014; Nabagiez et al., 2016). One of the principles of care management is that it should be selectively used, and these models can achieve net savings if the highest risk patients are identified and these interventions are applied selectively to those patients. (Bayati et al., 2014; Weintraub et al., 2018). Further research is needed to determine how to optimize transitional care management programs to assure that these expensive resources are effectively and efficiently used (Arndt, 2018; M. H. Hall et al., 2014; Nabagiez et al., 2016).

2.3 Consumerism

While reimbursement and quality initiatives are redirecting health system priorities, concepts of patient engagement and consumerism are redefining providerpatient relationships and also changing the way that care is delivered. The ACA acknowledges that reform will most successful if we engage patients in their own care and a growing body of evidence supports patient activation as important to health and cost outcomes (Graffigna & Barello, 2018b; Hibbard & Greene, 2013; Topol, 2015).

2.3.1 The Patient as a Partner in Their Own Health

Rising health care costs result in higher out-of-pocket costs for patients in the form of premiums and deductibles. In the ten years from 2006 to 2016, average out-of-pocket spending for health care in the U.S. rose by 54%, from \$525 in 2006 to \$806 in 2016, while wages only rose 29% in the same period (Claxton, Levitt, Rae, & Sawyer, 2018). Facing greater financial responsibility for managing their health, individuals are behaving like consumers when making health care decisions, expecting service on demand/ease of access, access to their own information, and cost-sensitivity/transparency and they are pushing back on providers who hoard health data (Butcher, 2015; Petersen, 2018). Today's patients expect the connectedness that they experience in other industries and feel that making a medical appointment or receiving routine results should be as simple as online banking, or buying an airline ticket (Frist, 2014). A new,

"democratized" model of medicine is taking hold in which patients generate their own health data, such as electrocardiograms or blood glucose levels on their own devices, or receive personal health data through access to patient portals (Topol, 2015).

All of this represents a tremendous shift from the longstanding model of paternalistic, provider-centered health care, in which only the physician had access to all patient information and could choose to tell the patient (or not) based on their personal perceptions of whether or not the information would be beneficial to the patient. The ancient Greek physician Hippocrates felt that knowledge should be compartmentalized to physicians and that medical information should be withheld from patients (Veatch, 2009). This paternalism pervaded medicine for thousands of years and as recently as 1961 a published study reported that 88% of physicians had a policy of not telling their patients they had cancer (Oken, 1961). Today it would be considered completely unacceptable for a physician to withhold any diagnosis from a patient, but a fundamental information asymmetry has persisted, and until recently only physicians had all of the data, information and knowledge (Topol, 2015). Certainly, there will always be a knowledge gap in health care as physicians and nurses undergo years of training to prepare them to provide patient care. However, patients are increasingly willing and able to take independent actions to learn about and manage their own care and improve their own health outcomes (Hibbard & Greene, 2013; Volpp, 2019). The relationship between providers and patients has become more reciprocal, with the provider considered the expert on the technical aspects of care and the patient considered the expert on the personal values and priorities that impact their subjective experience of illness and care (Graffigna & Barello, 2018a). This revolution is creating a model where patients are

recognized as a knowledge resource, too, helping professionals to improve the quality of the care they provide (Ferguson & Frydman, 2004).

The shift to defining quality of care from the physician's perspective to the patient's perspective has changed what is viewed as a "successful" outcome, with patientreported outcomes replacing more traditional medical/clinical measures of outcomes (Kirschenbaum, 2015). Patient-reported outcomes (PROs) are measures of a patient's symptoms, functioning, and quality of life in domains such as anxiety, fatigue, or the ability to participate in social roles and activities. They are designed to capture information that cannot be captured with objective medical testing and are being implemented more broadly to evaluate treatment outcomes, to help patients engage in shared decision-making, and to prioritize the focus of treatment (Broderick, DeWitt, Rothrock, Crane, & Forrest, 2013). For example, a surgeon might measure the degrees of range-of-motion for a postoperative knee replacement patient to measure the "success" of the surgery, but the patient might measure success by their ability to return to work or to play with grandchildren. Both are valid, but the focus on the patient's goals reflects a growing understanding that the patient is a partner in care and in outcomes. The National Institutes of Health (NIH) launched the Patient-Reported Outcome Measurement Information System (PROMIS) initiative in 2004 to develop standardized, state-of-the-art PROs to improve the use of these measures in clinical research to compare treatment effectiveness and improve clinical care (Cella et al., 2007). PROs are increasing in significance as the focus on the patient perspective in medical decision making and evaluation of treatment outcomes has grown (Broderick et al., 2013).

2.3.2 The Patient as Informaticist

Patient-consumers also have access to vast amounts of health information through the internet, changing the way they get information about health and illness and leading to newly defined roles of "patient-informatician" (Petersen, 2018) and "e-patient" (Ferguson & Frydman, 2004). Physicians are no longer the patient's only source of information about health, disease and treatment options as patients use the internet to gather information and to connect with others who face the same health challenges (Ferguson & Frydman, 2004). The quality of the information patients and caregivers find on the internet can be a challenge as they may find information that is unscientifically validated or have difficulty understanding what they find. Although the paternalistic model of medicine was unsustainable, it did allow physicians to ensure that patients received valid information at a level appropriate to their health literacy (Tonsaker, Bartlett, & Trpkov, 2014). One way to assure the validity of internet information available to patients and caregivers is to have that information verified by professional organizations (Ferguson & Frydman, 2004). Recognizing that there was a need for reliable, consumer-level health information online and that patients were frequent users of products developed to support health professionals, the National Library of Medicine (NLM) committed in 1997 to provide health resources directly to the consumer, prompting Vice-President Al Gore to state, "This development, by itself, may do more to reform and improve the quality of health care in the United States than anything we have done in a long time" (Backus & Lacroix, 2005). NLM added a "For the Public" link on its navigation bar to guide users looking for information on their MEDLINE database, including complementary and alternative medicine articles, as well as publications in

both English and Spanish (NLM, 2018). ClinicalTrials.gov was initiated in 2000 as a resource for patients and health providers to find both federal and privately funded clinical trials for serious or life-threatening conditions (McCray, 2000). NLM also worked with the National Institute on Aging (NIA) to develop NIHSenior-Health.gov platform to address the specific needs of older consumers, including such features as larger fonts and options to have screen text read aloud (Lewis et al., 2005). The internet has potential to enhance the evolving patient-provider health partnership and to improve health, but it will require that online health information is both accurate and appropriate to the patient's needs (Tonsaker et al., 2014).

Using the internet to gather medical information represents only one aspect of the e-patient experience. Patients and their caregivers are also using the internet to develop social networks with the specific purposes of gaining emotional support, tracking and sharing health data, asking questions of professionals, and to gain access to clinical trials (Ferguson & Frydman, 2004; Swan, 2009). In addition to providing socialization and support, these "personalized health networks" empower patients to contribute to the body of knowledge about specific health issues. PatientsLikeMe is the largest of these networks, and they have gathered more than 43 million data points from over 650,000 people living with almost 3,000 conditions, publishing more than one hundred research studies (PatientsLikeMe, 2019). The Crohn's and Colitis Foundation of America (CCFA) launched the Patient-Powered Research Network (PPRN) in 2014, partnering with more than 14,000 patients and with industry leaders to share information and to measure and study patient-reported exposures, health behaviors, and outcomes (Arlene E. Chung et al., 2016). Patients and their caregivers are recognizing that 'research' is not something done

to them by professionals, but instead that science and research are methods that they can also apply to their own health and illness (Wicks, 2018).

There is general agreement that engaging patients to participate actively in their care is essential to improving quality and outcomes (Hibbard, Stockard, Mahoney, & Tusler, 2004). Although the number of patients who have and understand their personal medical data is small, there is increasing information parity between patients and providers and emerging patient authority in decision making (Frist, 2014; Petersen, 2018; Topol, 2015).

2.4 Patient Generated Health Data

As patients take a more proactive role in health and wellness, new concepts of consumer health informatics (CHI) and patient-generated health data (PGHD) have emerged, building on concepts of participatory medicine and allowing patients to actively participate in creating and using their own data to promote health and manage illness (Petersen, 2018). PGHD is defined by the Office of the National Coordinator as health-related data created, recorded, or gathered by or from patients, family members, or caregivers to help address a health concern (Office of the National Coordinator, 2013; Tiase, 2017). PGHD generally falls into two categories: (1) data that is reported directly by patients as relevant to their health and (2) sensor data that is passively collected through devices (Kennell, Willig, & Cimino, 2017). PGHD is captured outside of the clinical setting, is longitudinal, and is capable of being captured at frequent intervals (Howie et al., 2014). The concept of PGHD is not completely new, as patients have long used logs, diaries and other methods to track and document symptoms and measurements,

such as weight or blood pressure, and then report them at the time of a provider visit, where the information was interpreted and documented by the clinician (Basch, 2013; Lai et al., 2017; Stone, Shiffman, Schwartz, Broderick, & Hufford, 2003). However, the proliferation of mobile devices and advances in wearables and sensor technology now allow patients to collect and monitor multiple physiologic signs electronically, while improvements in interoperability allow this data to be shared to the patient record, decreasing the documentation burden on the clinician. Patients expect that this data will be used to improve their health outcomes (Tiase, 2017).

2.4.1 Technology as a Facilitator of PGHD

The widespread adoption of personal computing technology and personal health records has facilitated greater interest in CHI and in the potential of PGHD (Lai et al., 2017). Empowered patients are using self-monitoring technology to create the "quantified self" movement, which involves tracking one's own health data to better understand trends and change behavior to achieve a health goal (Gollamudi SS, 2016; Swan, 2009). Data from such commercial grade devices as scales, glucometers and blood pressure cuffs can be automatically uploaded and securely stored (S. Waldren, MD, MS, Thomas Agresta MD, MBI and Theresa Wilkes MS, CPHI, CHTS-PW, 2017). When incorporated into the EHR, this patient- generated data can improve the completeness and accuracy of the patient record, allow providers to interact with patients between visits, direct timely changes to the plan of treatment, enhance patient engagement and partnership in care, and save the clinician time by removing the need to document patient-reported data at the time of a visit (Bell, 2017; A. E. Chung & Basch, 2015). Patients have expressed high levels of interest and satisfaction with reporting this data

electronically and are more inclined to participate when it is clear that the data they share will be used in planning their care (Jensen, Gummerson, & Chung, 2016). Providers acknowledge that PGHD can improve the patient's ability to self-manage health and illness, with potential to improve outcomes and patient satisfaction (Cohen et al., 2016; Sanger et al., 2016).

2.4.2 Overcoming Workflow Barriers to the Use of PGHD in Practice

However, health care providers are concerned that they will be exposed to large volumes of PGHD in their daily workflows and that they will not be able to verify and analyze PGHD or provide timely feedback (Gollamudi SS, 2016; Greenwood, Gee, Fatkin, & Peeples, 2017). Additional challenges to the widespread adoption of PGHD include limited capacity of EHRs to capture and display the data intuitively, concerns about the validity/reliability of devices used to capture data, and workflow barriers/staff burden associated with large volumes of incoming data (Lai et al., 2017; Lavallee, 2016). There are multiple potential sources of error in the data, such as incorrect use or placement of a sensor or low-quality devices, and physicians have expressed concern about making sense of the data (Hsueh, Dey, Das, & Wetter, 2017; Lai et al., 2017). It has been suggested that providers discuss with patients their needs and concerns regarding PGHD, in order to manage expectations and prevent miscommunication (Lee, Matthias, Menachemi, Frankel, & Weiner, 2018). Patients and payers will encourage the use of PGHD to shift health care from an episodic, visit-based model to one focused on continuous disease and wellness management (Kilbridge, 2018). Balancing the needs of patients and providers will be critical to the incorporation of PGHD in clinical practice

and implementing provider-friendly systems with capabilities to analyze the data will facilitate this adoption (Sanger et al., 2016).

Key concepts in the successful integration of PGHD into clinical practice include 2-way communication between patients and providers, analysis of the data by the health care team, patient-specific education, and a feedback loop between patients and the health care team (Greenwood et al., 2017; Jimison H, 2008). Greenwood et al studied the impact of technology-enabled self-management in diabetes and proposed the TES Feedback Loop model (Figure 2.3), which can inform PGHD implementation for many disease states and patient populations.

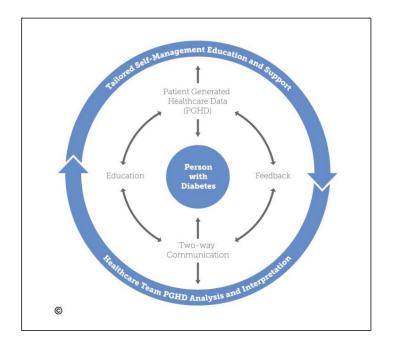


Figure 4. The Technology Enabled Self-Management Feedback Loop Greenwood (2017) (Reprinted with permission)

Professional organizations involved in the development of standardized protocols and guidelines for PGHD implementation can incorporate the TES feedback loop model in making recommendations (Greenwood et al., 2017).

2.4.3 PGHD as a Tool to Achieve the Quadruple Aim

The use of PGHD in patients with chronic diseases, such as diabetes, cancer and hypertension, has been studied more extensively than in populations experiencing acute illness and hospitalization (Abelson et al., 2017; Cohen et al., 2016; Lai et al., 2017; Lv et al., 2017). Chronic care models emphasize continuous care and monitoring and longitudinal care, placing them at odds with the episodic care model favored by health systems (Sands & Wald, 2014). Chronic diseases carry high costs and require the continuous and active involvement of both patients and providers and this technology can reduce the patient burden of self-reporting and the provider burden of documentation (Lai et al., 2017; Leventhal, 2015). Data collected from these patients between visits can be tracked to inform treatment decisions and may provide insights into patient behavior and health activity (Cohen et al., 2016). Although the chronically ill are a population that can likely benefit from this technology, clinicians will need to consider the number of devices implemented for these patient as device fatigue has been shown to be a significant challenge in as little as 4 weeks. Ultimately, fewer devices may be more effective in terms of device adherence (Shaw et al., 2016).

In the last decade there has also been a shift from a focus on disease, to an acknowledgment of the impact of patient lifestyle and patient behavior on health outcomes and costs (Frist, 2014; Graffigna & Barello, 2018a). Technology that can be used to track physiologic data such as activity or sleep is facilitating a deeper

understanding of personal health and performance. Fifty-eight percent of mobile phone users have downloaded a health app (Krebs & Duncan, 2016). Patients are using these apps, as well as sensors and devices, to track these physiologic functions and are compiling this personal data to find patterns in symptoms and to improve their communication with providers regarding their health (Petersen, 2018). The concept of "patient" in PGHD is evolving to consider the "person", as healthy people use technology to track health information, such as fitness activity, potentially allowing for secondary use of the large volumes of data to identify predictors of disease progression or to inform medical device development (P. Y. Hsueh et al., 2017).

Additionally, PGHD is not limited only to physiological or symptom data. Population Health initiatives have recently focused on Social Determinants of Health (SDOH) in achieving the Quadruple Aim, recognizing that those who are socioeconomically disadvantaged on measures such as employment, income and education can be expected to have poorer health, shorter life expectancies and less subjective well-being than those who have greater socioeconomic resources. (Chapman & Pelletier, 2004; Nash, 2014). Recognizing the critical importance of SDOH to health outcomes, the Stage 3 Meaningful Use requirements specify that certified EHRs must accept PGHD from multiple sources and incorporate the data, including data on social determinants of health, into the patient record (A. E. Chung & Basch, 2015; Hull, 2015; Tiase, 2017). As of January 1, 2018 CMS has also incentivized and reimbursed health care providers for reviewing and interpreting PGHD, which will likely accelerate the acceptance of this data in clinical practice (Reading & Merrill, 2018).

2.4.4 Future Research on PGHD

Despite some early positive study results that show how PGHD can impact care delivery, improve communication, and improve health outcomes there are still significant barriers to the use of this data in the clinical setting (Lai et al., 2017). As is true for much health information technology, standards for formatting, transmitting and integration of PGHD into the EHR are still evolving (Petersen, 2016). Under evolving payment models, as hospital stays shorten and patients spend more recovery time at home, capturing PGHD will become more critical to optimizing recovery and health (Abelson et al., 2017). The literature on the use of electronic communication in health care is still growing, and the technology associated with PGHD is not yet mature (Lee et al., 2018). Health care professionals and patients have reported that PGHD provides value, but additional research is needed to identify strategies for optimizing PGHD tools and for determining their impact on longitudinal clinical outcomes (Cohen et al., 2016; Lai et al., 2017). Although current evidence of the clinical benefit of PGHD is sparse, emerging technology and policy developments will necessitate that it be incorporated into practice (Reading & Merrill, 2018).

2.5 Evolving Technology in Patient-Provider Communication and Data Sharing

As financial incentives are shifting and patients are finding their voice as partners in their own health, advances in technology are facilitating information exchange between patients and providers, offering opportunities that can enhance communication and increase efficiencies (Institute of Medicine, 2001). Internet connected patients increasingly expect that their providers will communicate with them electronically, just

as banking and legal services professionals offer online services and email communication (Wakefield et al., 2010). Wireless networks are adopting fifth-generation (5G) broadband service, which will provide faster speed and greater bandwidth for data exchange, thereby providing the connectivity to also support the growing number of remote monitoring devices and sensors (Hossain & Hasan, 2015).

2.5.1 Patient Portals

In health care, the adoption of internet and mobile capabilities along with Meaning Use incentives for EHR optimization have facilitated access to "patient portals" in EHRs, allowing patients to view their medication list and test results, to request prescription refills, and to securely exchange messages with providers (Delbanco & Sands, 2004; Sukyung, Panattoni, Chi, Palaniappan, et al., 2017). Messages sent to patients from these portals include a web link that takes the patient to a secure login page for the web-based application, allowing the user to read or send messages and view documents without installing any software or plug-ins (Delbanco & Sands, 2004). These portals can provide a patients and caregivers a convenient way to communicate questions or concerns and can also improve patient care and satisfaction while overcoming some of the security and privacy concerns associated with regular email exchanges. Patient portals also offer the convenience of an asynchronous model of communication, allowing patients and providers to review and reply to messages at a time that works best for them (Patt, Houston, Jenckes, Sands, & Ford, 2003; Sands, 2005). As an added benefit, the messages that are exchanged become a permanent part of the patient record, with less risk of important information being lost in the translation of a phone message received by a staff member in the provider office (Franklin, 2013; Sands, 2005). Secure electronic

messaging via the patient portal offers an opportunity for savings of cost, time and effort in health care as a complement to in-person visits and can also create a more continuous record of the patient's lived experience of health and illness, rather than the fragmented model of patient data associated with episodic office visits and hospitalizations (Institute of Medicine, 2001). However, implementation of these systems requires sufficient planning on the part of health system leadership to assure the success of the project. It is not enough to provide the technology, leadership must consider the integration of retrieving and sending messages in provider workflow, assure compliance with HIPAA requirements, provide adequate training, assure that efforts are made to outreach and enroll patients to use the technology, and provide ongoing support once the project is launched (Wakefield et al., 2010).

2.5.2 Personal Health Records

The concept of electronic personal health records (PHRs) has evolved as another tool for patients to store and share their own health information. Using PHR apps patients are able to aggregate their health records from multiple providers and institutions along with their PGHD, creating a longitudinal, holistic view of their health and illness over a lifetime (Roehrs, da Costa, Righi, & de Oliveira, 2017). PHRs are especially helpful for patients with chronic illness and their caregivers, enabling them to track their condition and possibly prompting earlier intervention when a problem arises (Tang, Ash, Bates, Overhage, & Sands, 2006). Some of the models are "tethered," meaning they are linked to the provider EHR, and others are freestanding, also known as "untethered" PHRs (Lester, Boateng, Studeny, & Coustasse, 2016). Unlike the EHR, the content of the PHR is managed by the patient and the patient controls who has access to the information

(Wager, 2013). Meaningful Use Stage 2 requirements include a mandate for the inclusion of PHRs in any certified EHR and there is also growing research on the value of including provider clinical notes in the PHR to build stronger, more trusting relationships between patients and providers (Lai et al., 2017; Lester et al., 2016; OpenNotes Project, 2019). In our fragmented health system patients are often left with the responsibility of gathering and sharing health information with new providers and the PHR can provide a longitudinal record that is secure, accessible and portable (Tang et al., 2006; Tang & Lansky, 2005). Information entered in PHRs can be leveraged for patient self-management, care-management planning and at the point-of-care in the provider office (S. Waldren, MD, MS, Thomas Agresta MD, MBI and Theresa Wilkes MS, CPHI, CHTS-PW, 2017). However, issues of data privacy, data aggregation and resale, and interoperability remain. Further research is needed to determine the issues of patient health literacy and data transparency that still need to be addressed as PHRs are more widely adopted (Sunyaev, Dehling, Taylor, & Mandl, 2014).

2.5.3 Secure Messaging

Text messaging and short message services (SMS) have also gained acceptance in health care as patients and providers, equipped with expanding mobile technology, recognize that text-messaging interventions (TMIs) can supplement communication as part of an overall mobile health (mHealth) strategy (A. K. Hall, Cole-Lewis, & Bernhardt, 2015). Younger patients, in particular, expect the convenience of messaging instead of voice calls and email (Brenier, 2017). Messages can be sent, stored, and retrieved easily and at little cost, and this technology has been used to improve medication adherence, to collect patient information, to track events such as outbreaks,

and to support behavioral change such as smoking cessation or appointment adherence (Iribarren et al., 2017). However, traditional SMS messages are limited to 160 alphanumeric characters and may be shared over non-secure platforms, creating privacy concerns. Longer messages that are broken into multiple consecutive messages may potentially create changes in meaning that can result in miscommunication (Liu, Moosavinasab, Houston, & Yu, 2012). There are also workflow issues surrounding the use of SMS in provider-patient interaction, including patients who use these methods to convey urgent information, provider availability to monitor and reply to messages, and risks to patient privacy and security of the exchanges (Franklin, 2013). Although SMS is widely acknowledged as convenient by providers and perceived to improve communication when it is offered, there are challenges associated with this technology in practice, and identifying the best SMS platform for mHealth activities remains a challenge for health systems (Patel et al., 2016).

2.5.4 Emerging Models: Chatbots and Conversational AI

More recently, concepts of texting in health care have expanded to include the use of chatbots to exchange automated secure messages. The term chatbot is most often used in connection with written language or text applications, but advances in speech recognition and natural language processing are also facilitating the adoption of voice communication using this technology (Dale, 2016). Chatbot is derived from the words "chat" and "robot" and refers to computer programs that simulate human conversation, whether by text or voice communication (Petouhoff, 2019). In these models a computer program takes the user through varied algorithmic conversational pathways, based on the user's preformatted replies to questions provided by the chatbot (Inkster et al., 2018). The chatbot uses the algorithms to generate responses or additional questions from a predefined, finite collection of possible replies, in a model that simulates dynamic interaction with the user (Georgian Partners, 2019). In health care these platforms are "trained" with clinically validated content and questions that are controlled by health care providers (Rouger, 2019).

One of the earliest chatbot models was ELIZA, developed at Massachusetts Institute of Technology in 1965 by Joseph Weizenbaum as a tool to mimic a psychotherapy session (Topol, 2019). ELIZA used keywords and pattern matching to answer a user's questions with scripted, simple, open-ended replies (Petouhoff, 2019). This model inspired a community of interest in building chatbots that might one day pass the Turing Test, a test of a computer's ability to exhibit intelligent behavior indistinguishable from that of a human (Dale, 2016; Laranjo et al., 2018). Recognizing the potential of this technology, developers have since incorporated advances in computer science to build more sophisticated products that can better understand and reply in a more personal way to users. Over the last twenty years conversational agents have shown benefit in improving physical activity, increasing fruit and vegetable consumption, and providing accessibility to online health information, but have only allowed for restricted user input in the form of multiple-choice replies, without the capability for natural language processing (NLP) (Laranjo et al., 2018). Chatbots can also remember and learn from previous interactions with a user, allowing them to personalize future conversations even further. The use of this emerging technology is of great interest to both the medical and computing communities (Pereira & Díaz, 2019).

The use of messaging apps, speech-based assistants and chatbots to automate communication at scale while creating a natural, personalized experience for the individual user is part of a growing field known as Conversational Artificial Intelligence (AI) (Brenier, 2017). Companies use Conversational AI and chatbots in customer service to greet customers, to gather initial information prior to connecting the customer with an agent, to provide self-service when possible, and to provide guidance to agents for recommendations as they help customers (Georgian Partners, 2019). Fifty-three percent of service organizations expect to use chatbots by 2020, representing a growth rate of 136% from 2019 to 2020 (Salesforce Research, 2019). The use of conversational AI with chatbots can provide additional contextual information to the chatbot about the user, creating less work for the user and improving the personalization of the chatbot experience (Georgian Partners, 2019). The back-and-forth nature of the dialogue can also enable conversational AI to foster an ongoing, personal relationship with the user (Brenier, 2017).

This technology has tremendous potential application in health care, where the vast amounts of personal health data stored in patient records can be analyzed to steer the conversation to topics most relevant to optimizing the user's health (Rouger, 2019). This large and increasing volume of data will require sophisticated analytical resources, such as AI, in order for us to analyze it and turn it into info to drive health (Dowling, 2012). Early experiences in health care chatbot implementation began in 2014 with a focus on helping patients with symptom-based diagnosis in less time and for less money than it would take to see a medical provider (Pereira & Díaz, 2019). A 2017 study showed that medication adherence for 4,737 breast cancer patients was improved by over 20% when

using a chatbot for prescription reminders, and the overall patient satisfaction with the project was 94% (Rouger, 2019).

While this technology has been widely adopted in other industries, issues of privacy, security, and information accuracy are more critical in health care than for other industries and adoption has been tempered with caution that the user is always able to reach a human when needed (Arndt, 2018; Brenier, 2017; Inkster et al., 2018; Pereira & Díaz, 2019; Schueller, Tomasino, & Mohr, 2017). Health care conversations often cover very personal information and it is critical to the successful implementation of this technology that we understand the emotional, relational, and psychological outcomes of patients who disclose personal information when the partner is a computer, rather than a person (Ho et al., 2018). However, early studies have shown that people may actually disclose information more freely when they are communicating with a chatbot rather than a human, especially when the questions are considered embarrassing or the patient may fear judgment for their replies (Lucas, Gratch, King, & Morency, 2014). Additional research is needed to evaluate the social implications of chatbot use in health care, including the impact on patient-provider relationships and identification of potential biases in the algorithms that are developed to drive the conversations (Pereira & Díaz, 2019).

Most health care organizations that are using chatbots are in early phases and published reports are descriptive of the chatbot development and implementation process, rather than systematic, large scale data-driven studies on outcomes such as cost savings or improved health (Arndt, 2018; Laranjo et al., 2018; Pereira & Díaz, 2019). However, return on investment (ROI) for this type of technology can be measured in many ways

other than dollars, including increased patient engagement in care, efficiencies in communication, higher patient satisfaction, and increased patient loyalty and retention (Validec, 2018). The use of chatbot technology is in its infancy in health care, but supplemented with the growth of wearable sensors and enhanced natural language processing capabilities it offers great promise for monitoring and educating patients, and for preventing or detecting illnesses, ultimately improving care and outcomes (Inkster et al., 2018; Pereira & Díaz, 2019). Chatbots can offer a simple and convenient method for patients to communicate with providers, and can offer to providers improved connection to patients and increased productivity (Arndt, 2018). Patients can also use chatbots to get immediate answers on practical issues, such as medication side-effects or reimbursement concerns, and chatbots can reinforce answers provided during a consultation, potentially allowing the patient to avoid an additional office visit to get the information they need (Rouger, 2019).

Artificial Intelligence has the potential to scale care management programs by providing supplemental information that can be used to support patients and providers alike (Koh, 2019). In a 2017 randomized controlled trial (RCT) on the use of chatbots to support patients and providers in managing childhood obesity the chatbot was able to drive 99.5% of the conversational turns, underlining the scalability of the model (Kowatsch et al., 2017). Rules-based systems that triage the "chats" and allow health care providers to receive automated notifications for patient responses or questions that are associated with increased risk of poor outcomes also helps providers identify patients at risk without having to monitor or review every conversational turn between the patient and the chatbot (Greenwood et al., 2017; Kowatsch et al., 2017).

Given the changing health care environment and the rise of the consumer-patient, the optimal informatics solutions to improve health care will require the capability for patients and providers to work collaboratively, rather than in isolation (Reading & Merrill, 2018). Chatbots can provide many of the elements needed to streamline patientprovider communication, such as asynchronicity, personalization, scalability, security, and interoperability (Pereira & Díaz, 2019). As more and more data is stored in patient records and the volume of chats increases, advances in conversational AI and machine learning (ML) will facilitate even greater personalization and further adoption of the technology (Inkster et al., 2018).

2.5.5 The Conversa Model

The Conversa Conversation Platform[™] is a conversational AI chatbot model that is focused on the health care industry (Figure 2.4). Conversa has a library of validated clinical content, but can also work with providers to configure customized algorithms for clinical conversations, including threshold settings and paths for escalation when a patient's replies indicate intervention is needed. The platform uses a taxonomy-driven foundation to create a patient profile that considers data from the clinical EHR, insurance claims, and biometrics/devices as well as patient-generated health data to personalize and dynamically sequence both the content and sequence of questions, as well as the feedback sent to patients. The data is monitored to generate notifications to providers within the clinical workflow so that they may intervene in a timely manner to improve individual outcomes. The platform is also able to analyze data across populations to identify trends and use machine learning to gain insight that can be leveraged to improve the health of populations (Conversa Health, 2019).

CONVERSA CONVERSATION PLATFORM[®]

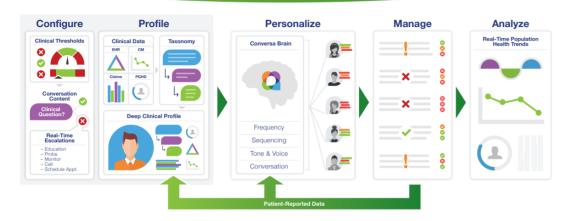


Figure 5. The Conversa Platform, ConversaHealth.com (2019) (Reprinted with permission)

The platform is structured on Self-Determination Theory (SDT) (Figure 2.5), which holds that behavioral change to support health is more effective and longer-lasting when patients have three basic psychological needs met:

- Autonomy a sense of control over behavioral choices,
- Competence a sense of mastery or ability to effect change, and
- Relatedness a feeling that they are understood and cared for (Ryan, Patrick, Deci, & Williams, 2007).

There are personal and contextual factors that can contribute to the needs satisfaction of the patient, including a health care environment that supports autonomy, recognizes personality differences in patients, and values the intrinsic and extrinsic life aspirations of the patient. An autonomy supportive health care environment respects patient choice, while a controlling environment exerts pressure on the patient to conform (Ng et al., 2012). Patients whose personality traits include a greater autonomy orientation are more highly motivated to make positive behavior changes to improve health, and those whose motivation is intrinsic, rather than based on extrinsic factors (such as fame) are also more likely to successfully change behavior to improve health (Ryan et al., 2007).

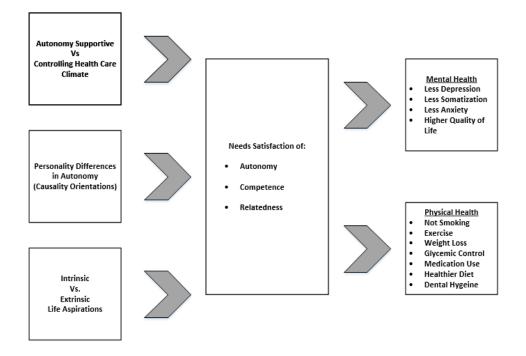


Figure 6. The Self Determination Theory (SDT) Model of Health Behavior Change adapted from Ryan, Patrick, Deci and Williams (2008).

SDT provides a useful framework for development of health care interventions that are more effective, as well as more cost-effective (Ng et al., 2012; Patrick & Williams, 2012; Ryan et al., 2007).

A 2018 report suggests that 98% of health care executives believe that automated healthcare technology, such as chatbots to gather PGHD, will be important to providing the continuous and collaborative patient experience that will close the gaps from episodic care to a more continuous model (WBR Insights, 2018). This technology is nascent in

health care delivery, and establishing best practices for the use of chatbots and consideration of its social and workflow implications will require further research to assure that it is optimally used to improve health outcomes, to reduce costs, and to enhance the shared experience of both patients and providers (Arndt, 2018; Ingebrigtsen et al., 2014; Inkster et al., 2018; Laranjo et al., 2018).

Chapter III

RESEARCH METHODOLOGY

I think one's feelings waste themselves in words. They ought to be distilled into actions, and into actions which bring results. -Florence Nightingale

3.1 Research Overview/Introduction:

In 2018 Northwell Health implemented a pilot project for an interactive, webbased chatbot system as a supplemental method for engaging recently discharged patients. The chatbot application was also integrated to store both the questions and the replies received from the patient as PGHD in the patient's EHR. The model was designed to support the patient's self-management in the post-acute 30-day transitional period, to document the patient's recovery in the EHR, and to provide real time feedback/alerts to the patient's care navigator who could then intervene if a patient's replies indicated the patient was at risk of a poor outcome. The goals of the program for this patient population were:

- to increase the engagement of patients and caregivers in self-care and wellness promotion,
- to prevent unnecessary emergency department visits,
- to decrease avoidable readmissions in the 30-day window immediately following discharge, and
- to better understand the workflow issues and technological issues surrounding the use of chatbots in transitional care management.

3.1.1 Purpose Statement

The purpose of this ex-post-facto descriptive study is to review characteristics of those who chose or decline to use chatbot technology and to explore the impact of chatbot use for gathering patient generated health data on readmissions and emergency room use in the 30-day post-discharge window for patients receiving traditional transitional care management at a major hospital system in New York and discharged from October 1, 2018 through March 31, 2019.

3.2 Research Questions and Hypotheses of the Research

3.2.1 Research Question 1: Does providing structured patient generated health data to the electronic health record via chatbots result in fewer hospital readmissions for transitional care patients within the first thirty days following an index discharge?

(HA0): There is no significant difference in the number of readmissions between patients that provide structured patient generated health data to the electronic health record via chatbots versus those that don't within the first thirty days after an index discharge.

(HA1): There is a significant difference in the number of readmissions between patients that provide structured patient generated health data to the electronic health record via chatbots versus those that don't within the first thirty days after an index discharge.

3.2.2 Research Question 2: Does providing structured patient generated health data to the electronic health record via chatbots result in fewer emergency room visits for transitional care patients within the first thirty days following an index discharge?

(HB0): There is no significant difference in the number of emergency room visits between patients that provide structured patient generated health data to the electronic health record via chatbots and those that don't within the first thirty days after an index discharge.

(HB1): There is a significant difference in the number of emergency room visits for patients who provide structured patient generated health data to the electronic health record via chatbots and those that don't within the first thirty days after an index discharge.

3.2.3 Research Question 3: To what degree do discharged transitional care management patients elect to participate in providing structured patient generated health data to the electronic health record via chatbots by:

- f. Age;
- g. Gender;
- h. Mode of contact (text or email); and
- i. Recipient of the message (patient or proxy)
- j. Chat module (diagnosis).

3.3 Research Method Selection

The quantitative method was selected for this study, as it provides a method to compare the variables using statistical analysis to determine if patients who engage with the chatbot have different outcomes than those who do not, and to describe the distribution of several variables for the population/sample. Researchers often use graphs to display the data distribution. Quantitative research focuses on testing objective theories by examining the relationship between variables, which can be analyzed using statistical methods. It differs from qualitative research, which is centered on better describing or understanding a social or human phenomenon, with the researcher drawing meaning from or explaining the complexity of the data. In a mixed-methods design the researcher integrates both quantitative and qualitative data to yield additional insight beyond what might be possible by providing quantitative or qualitative data alone (Creswell, 2018).

The comparison of outcomes for patients who consented to use the chatbot/declined to use the chatbot was completed using the Chi-Square coefficient, which is primarily used with one or two categorical variables. The coefficient is a measure of the difference between observed and expected outcomes and is used to determine if the variables are dependent upon or independent of each other. The observed frequency is the number of people that fall into each category (readmitted/not readmitted, ED visit/No ED visit) and the expected frequency is the number of people expected in each category if there is no difference in the sample and population. The term "residual" is used to describe the difference between the observed and expected values. If the residual is large then the chi square calculated is said to be "statistically significant". The Chi-Square is also known as the "goodness of fit" test, as it tests how closely the sample observations fit the hypothesis (Frey, 2016).

Specifically, the study is an ex-post facto descriptive study to describe the characteristics and preferences of patients who elected to participate in the project, and to determine if there is a change in the frequency of hospital readmissions or emergency department use for patients who agreed to use chatbots to gather PGHD and store it in

their electronic health record in the 30-day post-discharge period. Although prospective studies are often the preferred method of research, little research on the use of chatbots in health care has been done. A retrospective study such as this may significantly contribute to the field as it can be used to identify potential feasibility issues for planned prospective studies, to inform prospective study questions, to clarify future hypotheses, and to determine appropriate sample sizes for prospective studies in the same patient population (Hess, 2004).

3.4 The Pilot Sample

This pilot study was limited to the cohort of patients who had an acute care inpatient hospitalization in a Northwell Health system facility, and who were discharged between October 1, 2018 and March 31, 2019, and who qualified for and consented to enroll in Northwell's Health Solutions Transitional Care Management (TCM) program. Since the chatbot model sent alerts to the patient's Care Navigator (CN) when a patient's replies indicated that they were at increased risk, only patients who agreed to enroll in the existing TCM services model were considered for participation in the pilot.

The TCM model was implemented by Northwell in 2014 to manage qualifying patients in the post-discharge period. Hospitalized patients who qualified for TCM services were identified through a combination of clinical and payer data, such as highrisk ICD-10 codes or specific insurance, including multiple Medicare Value-Based care initiatives. Patients who qualified for TCM services were then assigned a CN, who was either a nurse practitioner (NP) or a physician assistant (PA). The CN generally met the patient in the hospital setting to introduce the program and to get consent for participation in TCM care-coordination for a period of thirty to ninety days following discharge. If the patient had already been discharged before consent was obtained this contact may have been completed by phone. Patients who gave consent to participate in the program were considered "Enrolled" in TCM for the 30 to 90-day period immediately following discharge. If a patient qualified for, but declined to enroll in the TCM program the CN kept the patient on their roster in a "Monitored" status for the duration of the postdischarge period, allowing the CN to receive real time notifications if the patient was seen in the ED or readmitted to an inpatient facility. Only patients in enrolled status were offered the chatbot program and those patients could then separately elect or decline to also use the chatbot.

3.5 The Chatbot Intervention as a Supplement to TCM Services

For those patients who were enrolled in the TCM program the chatbot was a supplement to the existing TCM care model in the first thirty days following discharge and did not replace any services offered to all enrolled patients. Under this existing care management model the CN collaborated with physicians and other health care providers of enrolled patients in the post-discharge window to optimize the patient's health through:

- scheduled phone interactions to provide support and education to patients and caregivers,
- comprehensive assessment of physical and psychosocial status to determine the patient's short and long-term needs,
- reconciliation of medications and patient/caregiver education on medication actions, side effects, self-monitoring and adherence,
- coordination and scheduling of all necessary follow-up appointments and confirmation that appointments are kept,

- patient and caregiver education in disease management and wellness promotion,
- home visits by an NP or PA as needed to assess or support the patient and caregiver,
- provision of the CN cell phone number for the patient/caregiver to reach their CN for questions or concerns, with after-hours coverage of that phone number by an RN-staffed call center, 24-hours/day,
- referral to other services, as indicated by patient need, including home care, long term care management, hospice, community resources, etc.,
- coordination and communication with all members of the patient's medical/surgical team to assure collaboration between providers during the vulnerable post-discharge period, and
- real-time notification when the patient was seen in the ED or readmitted, so that the CN could provide the ED/inpatient team information on availability of TCM services to the patient in the community.

3.5.1 The Chatbot Algorithms

Northwell Health selected a team of physician specialists who determined the questions to be used for each module and the algorithms to determine the order of questions based on patient replies from a multiple-choice menu. Algorithms were developed for specific high risk diagnoses, including COPD, CHF, CABG, Pneumonia, Stroke and Acute MI. Additionally, a General Discharge algorithm was developed for patients whose post-discharge needs were not tied to a specific diagnosis. No free text replies from patients were allowed during this pilot implementation. Each possible reply from a patient was categorized using the colors red (high risk), yellow (moderate risk) and green (low risk) to indicate the level of risk for a poor outcome associated with the reply. For example, patients were asked if they had filled their prescriptions following discharge. A patient reply of "yes" would be categorized as green, meaning that the reply

is associated with a good outcome, while a "no" reply would be categorized as "red", indicating that the patient might need intervention from the CN. Questions and replies from the chatbot application were dynamic and responsive to patient feedback, so that patients received different follow up questions and education based upon the PGHD they shared. In the example above a patient who replied that they had filled their prescriptions might next be asked about follow up appointments or symptoms, while a patient who replied that they had not filled the prescriptions would be asked to select from a list of reasons they'd not filled the prescription. While certain questions would be common to multiple modules, the patient's replies directed the order of questions and theoretically it is possible that no two patients would receive the same chat.

All the questions and replies that were generated by the chatbot were sent via API directly to the patient's record in Northwell's proprietary care management EHR, called the "Care Tool", with visual cues to the CN indicating the level of alarm associated with the reply (Figure 3.4).

Conversa	5 - 🤡 1 - 🔺 5 - 🛽	Patient
How would you rate your overall health since then?	Better	0
Are you having any shortness of breath?	Yes	
Since we last chatted, how would you describe your shortness of breath?	Better	0
Do you have a cough?	Yes	
Compared to when we last chatted, how would you describe your cough?	Better	0
Is your cough productive?	Yes	A
Are you coughing up anything that is green, yellow, bloody, or smelly?	Yes	×

Figure 7. The view of chatbot questions and replies in the EHR with associated color/risk.

Any time a patient sent a reply that was categorized as yellow or red the CN received a real time text alert indicating the patient might be at risk, and an email was

sent to a group distribution so that a centralized team of RNs could assist the CNs in reaching out to patients whose replies were yellow or red. Red replies triggered a phone call to a patient by an RN within 15 minutes of the notification, while yellow replies triggered a phone call from an RN within 4 hours. Replies that were categorized as green did not trigger any notification or email, although the questions and replies were still stored in the patient record.

3.6 Consent

Patients who qualified for transitional care management services provided consent to the Care Navigator for their participation in the care management program. Additional consent was requested to participate in the chatbot model and was obtained via a secure web-based link, where the patient acknowledged and accepted the terms of agreement (Appendix A). As this research is a retrospective chart review and no PHI was collected, no additional consent was obtained as deemed acceptable by the Northwell Health IRB (Appendix B).

For patients who declined to participate in the chatbot program the CN documented the "No" response in the EHR and no additional information was required to complete the consent form (Figure 3.1). For patients who elected to participate in the chatbot program the CN also documented the following information:

- who granted the consent to participate in the chatbot program,
- who would be the chat recipient (patients can receive the chats directly, or appoint a proxy to respond to chats),
- the chat language (English or Spanish were available),

• the chat module to be sent to the patient/proxy (Pilot options included chats targeting specific diagnoses of Heart Failure, COPD, CABG, Acute

MI, Pneumonia, and Stroke, as well as a General Discharge chat module).

Conversa, Testpat151 Male 1/1/2000 – 19y	CMS-STA
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Conversa Participant conversa Conversation Participant: Patient Proxy NameRetedenship E2EConversa, Testpat151 / Self SMS Phone Number Email Address	
Conversa Participant conversa Conversation Participant: Patient Proxy NameRetedenship EZEConversa, Testpat151 / Self SMS Phone Number Email Address referred Conversation Method: SMS Email	
Conversa Participant conversa Conversation Participant: Patient Proxy NameRetedenship E2EConversa, Testpat151 / Self SMS Phone Number Email Address	

Figure 8. The consent for chatbot documented in the EHR

This information documented in the Consent form was stored in the patient's record in the Care Tool. If the enrolled patient consented to receive chats then the data on the consent form was sent to the chatbot vendor via API upon patient discharge from the facility and triggered the chatbot conversations to start at 9am on the first day immediately following discharge.

At the time the first chat was sent the patient or proxy received a welcome message or email with a secure link to the Northwell Health Chats interface (Figure 3.2), where they were prompted to accept the terms of use, privacy policy and Northwell Communications policy.

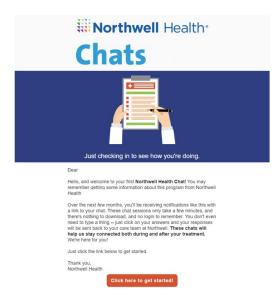


Figure 9. The welcome message sent to initiate chats

Patients were then given the option to Accept or Decline (Figure 3.3), and chats were initiated only for patients who clicked "Accept".



Figure 10. Prompt to Accept or Decline Terms of Use for chats

3.6.1 Research Subjects and Human Subjects Protection

In keeping with the US Department of Health and Human Services standards for compliance regarding de-identification of protected health information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) all cases studied in the project were de-identified using Safe-Harbor method. It is widely recognized that deidentified information created by this method is no longer protected by the Privacy Rule, as it is no longer PHI. It should be noted that de-identification may limit the usefulness of the data for future research. However the full patient records for this project remain available for future researchers who may request access to additional data through the Northwell Health Institutional Review Board (IRB).

Under the Safe Harbor method the following identifiers of the individual or of relatives, employers, or household members of the individual, are not included in the data set for this research:

- a. Name
- b. Geographic subdivisions smaller than a state
- c. All elements of dates (except year) for dates that are directly related to an individual, including birth date and admission/discharge dates. All patients age 90 and over are aggregated into a single category.
- d. Telephone numbers
- e. Vehicle Identification Numbers/License plates
- f. Fax numbers
- g. Device Identification and Serial Numbers
- h. Email addresses
- i. Web Universal Resource Locators (URLs)
- j. Social Security Numbers
- k. Medical Record Numbers
- I. Biometric identifiers, such as finger and voice prints
- m. Internet Protocol (IP) addresses
- n. Insurance ID numbers
- o. Full face photographs or comparable images
- p. Account numbers
- q. Any other unique identifying number, characteristic, or code
- r. Certificate/License numbers (HHS, 2015)

3.7 Data Sources and Variables

Data for the study was pulled from Northwell's proprietary Care Tool platform via query of the existing application database. The Care Tool is a homegrown software application used by Northwell Care Navigators to document care management activities and interactions with patients who qualify for transitional care management. It is also where the CNs document consent to participate in the Conversa project and where they can view each of the patient's questions and replies.

All study data were managed on Northwell Health PHI-secure servers and by using the REDCap (Research Electronic Data Capture) platform hosted at Northwell Health, a secure web application for building and managing online databases and surveys for research studies and applications. Northwell Health is part of the international REDCap Consortium, a network of 3449 non-profit and governmental institutional partners in over 130 countries who use REDCap to securely store and exchange research information. REDCap was created in 2004 at Vanderbilt University and then launched to the consortium in 2006 as a tool for clinical researchers who needed to store data in a way that met HIPAA compliance standards. It provides 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export; 3) automated export procedures for data downloads to common statistical packages; and 4) procedures for importing data from external sources. The platform is supported in part by the National Institutes of Health (Harris et al., 2009; VanderbiltUniversity, 2019). RedCAP is considered more secure than Microsoft Excel or Microsoft Access for data storage and can be accessed from any device with an Internet connection and web browser for users who have been granted access (Patridge & Bardyn, 2018).

The variables in the research data include (Table 3.1):

- 1. Age in Years (90 and over are placed in a single category of >=90, in accordance with Safe Harbor Privacy Protection standards)
- 2. Gender
- 3. Conversa Consent
- 4. Conversa Module (Typically the patient's primary diagnosis)
- 5. Participant in chatbot
- 6. Method of chatbot
- 7. Chat language
- 8. Readmission within 30 days of discharge
- 9. Emergency Department admission within 30 days of discharge

Table 1. Data/Variables of the Research

Study Variable	Variable Description		
Demographics			
Patient Age in Years (Label: AGE)	Categorical Variable – Eight Levels 1=Age 18-29 2= Age 30-39 3=Age 40-49 4=Age 50-59 5=Age 60-69 6=Age 70-79 7=Age 80-89 8=Age >=90		
Patient Gender (Label: GENDER)	Categorical value - Binary 1=Male 2=Female		
Chatbot Metrics			
Conversa Consent Granted (Label: CONSENT)	Categorical Variable – Binary 1=Yes 2=No		

Conversa Module (Label: MODULE)	Categorical Variable – Seven levels 1=Acute MI 2=CABG 3=COPD 4=Heart Failure 5=Pneumonia 6=Stroke 7=General Discharge
Recipient of Chat	7=General Discharge Categorical Variable – Binary
(Label: RECIPIENT)	1=Patient 2=Proxy

Method of Chat

(Label: METHOD)

Language of Chat

(Label: LANGUAGE)

Categorical Variable - Binary 1=English 2=Spanish

Categorical Variable - Binary 1=Text

2=Email

Outcome Metrics			
Inpatient Readmission	Categorical Variable - Binary		
within 30 Days of Discharge	1=Yes		
(Data Label: READMISSION)	2=No		
Emergency Department Admission	Categorical Value - Binary		
within 30 days of Discharge	1=Yes		
(Data Label: EDADMISSION)	2=No		

3.8 Limitations of the Research

A limitation of this research is that we cannot generalize the results of this chatbot implementation to other health systems because the chat algorithms/modules used in this project were developed by Northwell specialist physicians and are proprietary to Northwell Health. Although the vendor has off-the-shelf chat content developed and available to other users, we cannot assume that an implementation using the ready-made Conversa content would have the same results.

Additionally, the patients involved in the transitional care management program for this study were discharged from several different facilities, which may have different procedures for discharge planning that could also impact outcomes in the post-discharge window. We also cannot account for differing care management style/technique of the multiple care navigators who coordinated care for these patients. Additionally, because care coordination is an evolving practice in large health systems there may have been other changes made to the standard care coordination processes/procedures that may also have impacted outcomes for patients in the study during the pilot phase, making it difficult to generalize these results to patients who received care coordination at a different time.

Chapter IV

RESEARCH RESULTS

Statistics is the most important science in the whole world; for upon it depends the practical application of every other science and of every art. -Florence Nightingale

4.1 Descriptive Analysis

During the study period more than 3,000 patient conversations were recorded, adding 22,500 answered questions to patient records without any manual data entry. When asked "Did you find today's conversation helpful?" 96% of patients replied "Yes". Of the color-coded replies that were recorded, 81% were coded green, 6% were coded yellow, and 13% were coded red. It was observed that red replies were more frequently reported in the first 7 to 10 days immediately following discharge, while the number of green replies generally increased over the course of the 30-day post discharge window.

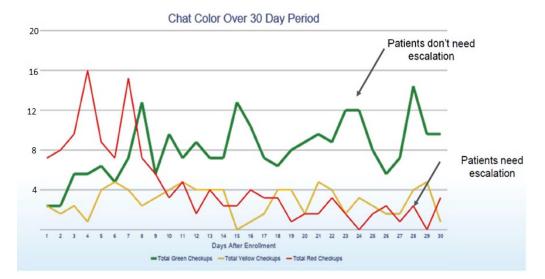


Figure 11. Chat Reply Color Over 30 Days

4.1.1 Consent Granted

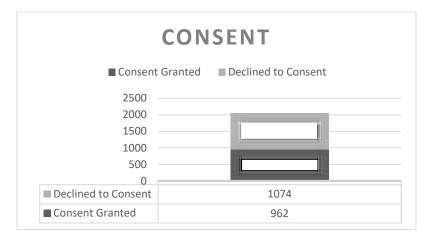
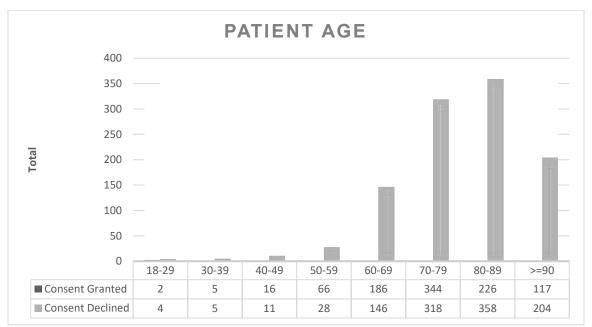


Figure 12. Consent Granted

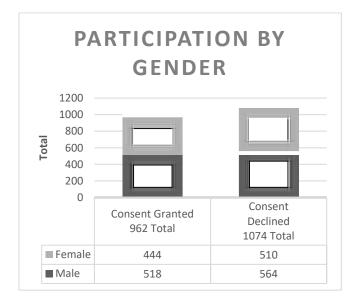
Of the 2036 asked to participate in the project to gather PGHD using chatbots during the study period, 962 patients/caregivers (47%) consented to participate and 1074 (53%) declined.



4.1.2 Patient Age in Years

Figure 13. Patient Age

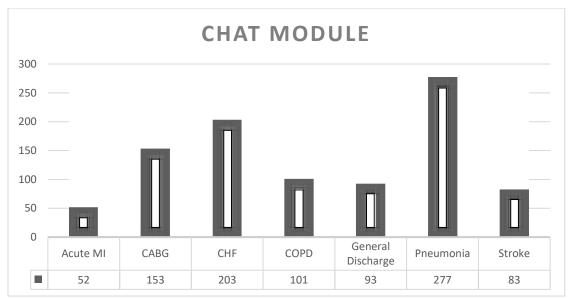
Age was a categorical variable with eight levels defined. In keeping with Safe Harbor privacy practices all patients over the age of 90 were included in a single category. The majority of the patients who were included in the sample fell into older age ranges as qualification for the project was based upon first qualifying for TCM based on specific combinations of payer and diagnoses. Since many of the diagnoses are largely diseases associated with aging and Medicare insurance is associated with many valuebased care initiatives, fewer patients overall fell into the younger age categories. However, when asked, younger patients consented at higher percentages than older patients. From age 18 through 79 more patients consented to participate than declined, but after age 80 more patients declined to participate than consented. Between the ages of 18-59 65% of patients consented, while only 53% of patients between the ages of 60-79 consented to participate. After the age of 80 the percentage of patients granting consent fell to 38%.



4.1.3 Patient Gender

Figure 14. Patient Gender

Of the 962 patients who consented to participate 46% were female and 54% were male (444 and 518 patients respectively). Of the 1074 who declined to participate 47% were female and 53% were male (510 and 564 patients respectively). A Chi-Square test of independence was performed to examine the relationship between gender and consent to participate. For the sample of 2036 patients with 1 degree of freedom the Chi Square statistic was 0.3617 and the p-value was .55. At a level of significance (alpha) of .05, there is not a significant relationship between gender and consent to participate.



4.1.4 Chatbot Module/Diagnosis

Figure 15. Chat Module

Of the modules used in the pilot, Pneumonia had the highest rate of participation, possibly because of the age of patients with that acute condition.

4.1.5 Chat Recipient

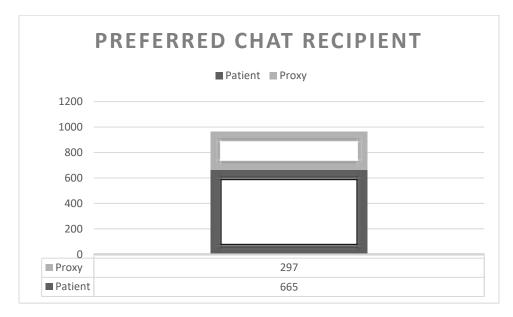
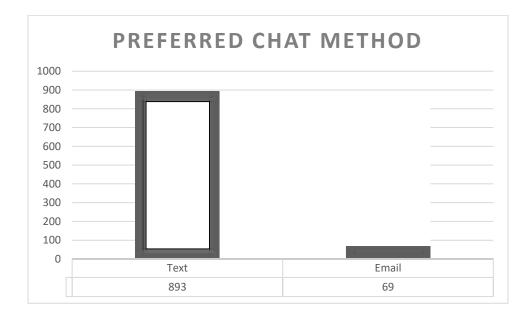


Figure 16. Chat Recipient

More patients elected to receive the chats themselves (69%), rather than appoint a

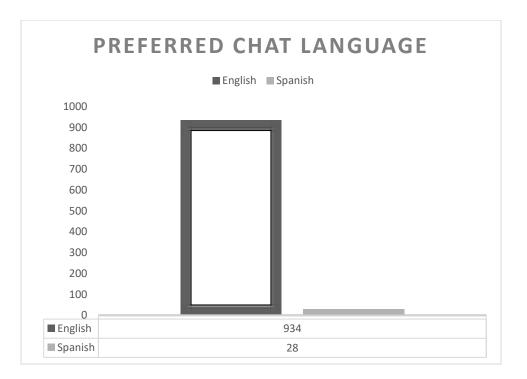
proxy (31%) to complete the chats on their behalf (665 and 297 patients respectively).



4.1.6 Chat Method

Figure 17. Chat Method

The vast majority (93%) of participating patients elected to receive the chats via text on a smartphone/tablet, rather than by email (7%).



4.1.7 Chat Language

Figure 18. Chat Language

The overwhelming majority of the patients who participated elected to receive the chats in English (97%), rather than Spanish (3%) (934 and 28 patients respectively).

4.2 Inferential Analysis - Outcome Metrics

Analysis of the outcome data on readmissions and emergency department visits was done using the Chi Square statistic. The Chi-Square test is intended to test how likely it is that an observed outcome is due to chance, rather than to the intervention (in this case, granting consent to the chatbot pilot). It is designed to measure categorical data, rather than continuous data. It is appropriate for this analysis because the sample is random, each outcome is categorical (that is, each outcome is mutually exclusive of other outcomes and there is no crossover), and we more than five in each cell in the distribution table used for calculating the Chi-Square formula:

$$X^{2} = \sum_{i=1}^{n} \frac{(O_{i} - E_{i})^{2}}{E_{i}}$$

 X^2 is the Chi-Square value, O is the observed value, E is the expected value if the outcomes are independent, n is the sample size and *i* is the degrees of freedom. The Chi Square value is used to calculate the p-value or level of significance, used to determine if the result suggests a relationship between variables.

Study Intervention		ervention		
		Consent For	Consent for	
		Chatbot	Chatbot	
		Granted	Declined	
Quitanama	Outcome #1 Within 30 Days	# of patients who consented and had outcome #1	# of patients who declined to consent and who had outcome #1	Total patients with outcome #1
Outcome	Outcome #2 Within 30 Days	# of patients who consented and had outcome #2	# of patients who declined to consent and who had outcome #2	Total patients with outcome #2
		Total patients who granted consent	Total patients who declined to consent	

Table 2. The Chi-Square table for two dimensions of categorization

4.2.1 30-Day Inpatient Readmission

Research Question 1:

Does providing structured patient generated health data to the electronic health record via chatbots result in fewer hospital readmissions for transitional care patients within the first thirty days following an index discharge?

		Study Intervention		
		Consent For	Consent for	Totals
		Chatbot Granted	Chatbot Declined	
	Readmission	139	198	337
Outcome	Within 30 Days			Readmitted
Outcome	No Readmission		077	1699
	Within 30 Days 822	822	877	Not Readmitted
Totals		961	1075	2036
		Granted Consent	Declined Consent	Total Patients

Table 3. The Chi-Square Table for Hospital Readmissions Data

The Null Hypothesis: **(HA0):** There is no significant difference in the number of readmissions between patients that provide structured patient generated health data to the electronic health record via chatbots versus those that don't within the first thirty days after an index discharge.

A Chi-Square test of independence was performed to examine the relation between chatbot consent and inpatient hospital readmission within 30 days of discharge. For a sample of 2036 patients with 1 degree of freedom the Chi-Square statistic was 5.74 and the p-value was .016538. At a level of significance of .05 we <u>reject the null</u> <u>hypothesis</u>. The alternative hypothesis is upheld **(HA1):** There is a significant difference in the number of readmissions between patients that provide structured patient generated health data to the electronic health record via chatbots versus those that don't within the first thirty days after an index discharge.

4.2.2 30-Day Emergency Room Admission

Research Question 2:

Does providing structured patient generated health data to the electronic health record via chatbots result in fewer emergency room visits for transitional care patients within the first thirty days following an index discharge?

Study Intervent		ervention		
		Consent For	Consent for	Totals
		Chatbot Granted	Chatbot Declined	
	ED Admission Within 30 Days	73	98	171
Outcome	Outcome ED Admission Within 30 Days	888	977	1865
Totals		961	1075	2036
		Granted Consent	Declined Consent	Total Patients

Table 4. The Chi-Square Table for Emergency Room Admissions Data

The Null Hypothesis: **(HB0):** There is no significant difference in the number of emergency room visits between patients that provide structured patient generated health data to the electronic health record via chatbots and those that don't within the first thirty days after an index discharge.

A Chi-Square test of independence was performed to examine the relation between chatbot consent and emergency department admissions within 30 days of discharge. For a sample of 2036 patients with 1 degree of freedom the Chi-Square statistic was 2.51 and the p-value was .113292. At a level of significance of .05 we <u>fail to</u> <u>reject the null hypothesis</u>. There is not a significant difference in the number of ED admissions between patients that consent to provide structured patient generated health data to the electronic health record versus those that don't within the first thirty days after an index discharge.

CHAPTER V

DISCUSSION AND CONCLUSIONS

A hundred struggle and drown in the breakers. One discovers the new world. But rather, ten times rather, die in the surf, heralding the way to the new world, than stand idly on the shore.

Florence Nightingale

5.1 Discussion

Although many studies have been done on the technical aspects of secure exchange and the data content of PGHD, research in the area of actual patient outcomes when PGHD is integrated into provider workflows is limited. This study also provides a novel model of collecting PGHD using chatbots, introducing another dimension of biomedical informatics that has not yet been well studied. The study shows that the use of this emerging technology to gather PGHD may enable providers to quickly identify and engage transitional care patients who are at risk of a poor outcome, specifically readmissions, potentially allowing us to achieve overall cost reductions and improved outcomes for patients without additional human resources.

Despite the success of the pilot, we still face challenges to the widespread adoption of the technology across the Northwell Health enterprise both at the systemwide and department levels. Under the existing project model each department must approve budget for the implementation of chatbots to gather PGHD. While the storage requirements are minimal for the text data we are currently collecting, the costs of data storage may climb significantly if images are included, such as photos of surgical

wounds. Additionally, the development of disease-specific chatbot algorithms along with custom user interfaces in our multiple EHRs results in considerable startup costs for each department, particularly for early adopters who cannot leverage previously developed functionality. These costs have created some reluctance to implement the technology in departments facing multiple competing priorities with constrained financial resources. Documentation of the return on investment for the project in transitional care through studies such as this one may facilitate the acceptance of the technology as an investment, rather than an expense, and break down some resistance. Enterprise sponsors of the chatbot project may be able to facilitate the system-wide adoption of the technology by budgeting to provide the technical and financial support to handle the data storage and implementation of the technology, thereby allowing departments to focus energy on learning to use the chatbot model and overcoming workflow barriers to the use of PGHD. Additionally, since poor patient outcomes like readmissions are a system wide issue, rather than an issue specific to a single facility or a department, assuring consistent and standardized implementation of the technology and workflows may benefit the enterprise in the long term. The PGHD gathered by the use of chatbots may be relevant for multiple initiatives within the enterprise, now and in the future, so that standardizing the algorithms early in the rollout process can facilitate the capture of standardized data for analytics. As the chatbot program grows the individual departments may be able to share in some of the implementation costs proportional to their use of the technology or the value gained from it. Additionally, as the project is scaled we may also be able to leverage successful patient outcomes in contract negotiations with insurance payers to support the further expansion of the project.

As departments implement the technology we will also have to address how to best share this valuable data across multiple facilities and divisions who use different EHRs to care for the same patients. Northwell has implemented s system-wide HIE that provides a "Clinical Viewer" link inside of our inpatient, emergency, ambulatory and care-management EHRs. By clicking on the Clinical Viewer link from within the EHR used in their usual workflow the provider can access patient notes, results, schedules, etc. from multiple Northwell sources, each connected to this internal HIE. This platform has been identified as the first level of integration of the Conversa PGHD into the patient record beyond the vendor dashboard and the Care Tool user interface that was developed for this pilot. The HIE team has an operational budget that allows for this integration to be undertaken this year and we are soliciting input from the CNs who participated in the pilot to see if any UI optimization is needed for that next phase. Conversations have been initiated to address how we will handle patients who qualify for multiple programs using the chatbot technology to assure we do not duplicate questions or frustrate patients with multiple messages daily. There is also consideration of the 24-hour RN staffed Clinical Call Center as a resource to support the entire enterprise in monitoring and responding to PGHD gathered by chatbots, with triage and escalation to the appropriate provider based on the patient's replies, as was done after-hours for patients participating in this pilot.

Our experience in this study has shown that younger patients consent to participate at a higher rate than older patients, with the majority of patients between 18 and 79 consenting to participate and only 38% of patients 80 years and older providing consent to exchange PGHD via chatbot in the pilot. This information may inform leadership decisions on next-steps in deciding where to invest in the technology. The

diagnoses covered under value-based care initiatives are largely diseases associated with advanced age, such as stroke or COPD. Future projects may be focused on patients who, based on age, may be more likely to use chatbots, such as high-risk pregnancy or orthopedics/sports injuries. Currently there is a project in development to implement the technology to provide education, support and follow-up for patients scheduled for colonoscopy, a patient population largely in their 50's and 60's. Recognizing the disparity in participation among older adults may also drive additional studies into the reasons for the decision to decline participation, perhaps enabling us to optimize the technology to target older patients through audio/visual enhancements or providing devices/internet access and technical support to advanced age patients in order to facilitate their participation.

We also observed that the majority of patients who elected to participate chose to receive the chats directly, rather than appoint a proxy to complete the chat questions for them (70% and 30% respectively). This information may be leveraged to determine what other types of questions, education modules and motivational materials could be shared using the chat technology to optimize patient outcomes. Knowing that we are reaching the patient directly we might be able to use the Self-Determination Model of Health Behavior Changes to develop additional questions and educational materials that support a patient's autonomy and competence in managing their illness, while building the relationship that allows them to feel that the exchange is personal and meaningful for them. This approach might have the added benefit of increasing their engagement with and loyalty to our system while improving their health outcomes.

The majority of patients (93%) who consented to exchange PGHD via chatbots elected to receive the chats by text, rather than by email. Although the literature reports that smartphone devices are gaining widespread acceptance, particularly by those under 70 years old, this overwhelming choice of text over email was still surprising. It tells us that we should focus our resources on features that are compatible with smart phone/texting capability, such as touch screen and scrolling enhancements, rather than on email capabilities as the project expands.

The CNs selected which patients to ask to participate in the chatbot pilot to gather PGHD, rather than a truly random sampling of patients, introducing the risk of selection bias for the entire study sample. As in any study where participants are allowed to consent or decline to participate there may also be a risk of self-selection bias to this study. However, the high level of participation and even distribution of participants consenting/declining may indicate that the selection of participants was adequately diverse to mitigate such risk of bias.

The study also revealed that the overwhelming majority of patients who participated in the pilot elected to receive the chats in English, rather than Spanish (97% and 3% respectively). It is possible that the CNs introduced bias in patient selection that excluded non-English speaking patients knowing that follow-up phone calls to manage these patients can already be challenging and the introduction of the technology might further complicate the care management and the pilot results. However, our health system is in Metropolitan NY, a very diverse area of the country with over 11 million people, 39% of whom speak a language other than English. Our Center for Health Diversity, Inclusion and Health Equity is focused on health literacy and community to improve

health outcomes. In addition to Spanish, the translation of chats has been discussed for Mandarin and Cantonese dialects of Chinese, as well as Russian. These languages present specific challenges of dialect, and we will also need to consider the cultural norms of these varied populations to assure that the questions are structured in a way that gets the most accurate and valuable information from the patient, taking into consideration such cultural factors as stoicism and acquiescence to authority. It is worth noting that the chat questions and replies display in the patient chart in English, regardless of the language used in the chat itself, so that the CNs are able to easily read the chats. However, as other languages are deployed we will need to assure that we have adequate translation services available to support the model when a patient's red or yellow replies trigger a phone call.

The graphing of replies by color over the 30-day window shows a consistent pattern of increased red replies in the first 7-10 days immediately following discharge and an overall trend of increasing green replies over the 30-day period. Clearly the first 7-10 days are a high risk period for recently discharged patients and this information may inform decisions about the frequency and pace of contact with patients over the course of the transitional care management episode, even for those who are not using the chatbot. For example, instead of making 2 calls each week for 4 weeks of TCM the CN might make 3 or 4 calls the first week followed by weekly calls during weeks 2 through 4 for patients who are stable. This pattern would still result in the same workload for the CN with 7 or 8 calls over the 30 days for each patient, but, would allow them to interact more frequently during that high risk window, potentially averting a poor outcome. Additionally, the study of the pattern of reply colors shows spikes in red replies at days 3 and 7 following discharge. We are currently undertaking a chart review to determine if there is a pattern to the reason for those spikes that might redirect CN activities or if the algorithms need review to reduce false positives in that window. The trend toward increasing green replies by days 15 to 30 following discharge may allow us to change the model to transition patients entirely to chatbot-only after multiple green conversations, thereby reducing workload on the CNs and leaving them available to manage other patients.

Northwell provides robust care management to transitional patients and our readmission rates for targeted value-based care cohorts are already below the national average. Even in the face of that previous success we were able to further reduce readmissions by using chatbots to gather PGHD. Health systems that do not have an existing TCM framework may be able to gain even greater reductions in readmissions by implementing this technology, but will be challenged to provide the rapid response to patient replies that indicate the patient is at risk. Those workflow issues will need to be addressed by any system seeking to implement a similar model.

Complicating the expansion of the project at Northwell is the fact that we also have many patients who are still covered under traditional fee-for-service payment models at the same time that value-based care is expanding in our population. This may inform some decisions about how to prioritize future projects to support the optimal balance between improving patient outcomes/engagement, improving provider experience and reducing overall health care costs to meet the goals of the Quadruple Aim, while still maintaining a healthy bottom line for the health system as we simultaneously navigate in these two very different worlds.

5.2 Future Research Recommendations

As often happens with a pilot project, we have gained great knowledge, but have raised even more questions about the technology and its implications for practice. There is general excitement in the organization about the potential of this technology to improve patient care and outcomes, but decisions about how best to implement and optimize the technology across a large enterprise system are many. Additional research and analytics will be needed to determine how best to redefine workflows and scale the program to cover larger populations across our enterprise system. Some of the possibilities for future research in the use of chatbots to gather PGHD in our enterprise (and others) include:

- Observation of TCM patient outcome results over a longer time frame, perhaps at 6 months and one year, may help to determine if the use of the chatbot to gather PGHD has any impact on admissions or ED visits for these patients beyond the 30-day window. Is the improvement in readmissions sustainable once the chatbot is removed? Is there a significant difference in the number of ED visits for patients who use chatbots to exchange data if the duration of the study period is longer? TCM is an emerging model and changes to practice are implemented regularly. Assessing the long term impact of the use of chatbots could mitigate the impact of other changes to the TCM model over the study period.
- How might we incorporate PGHD from devices connected wirelessly to the chatbot, such as scales for heart failure patients or glucometers for diabetic patients? Does the incorporation of devices reduce data transcription errors?
 Does it improve patient outcomes? How might the voluminous data

captured by devices be used in research to identify trends or to identify patients at risk of longer-term poor outcomes, allowing us to intervene in a timely manner to reduce risk?

- How can we address the ethical concerns associated with disparities in care for patients without devices or internet access? If the device/equipment is provided do larger numbers of patients participate? What type of technical support/Help Desk structure would be required to support patients in that model?
- What are the best practices for incorporating PGHD into the EHR? What IT practices can support the integration of the data into workflow? What methods of display in the UI are most intuitive? How can the data be made actionable at the point of care via task lists, alerts, reminders? What are the appropriate thresholds for alerts based on diagnosis, comorbidities, medications, past medical history, age, etc.?
- Patients have told us that they want the ability to use free text to ask questions or address issues not discussed in the chat algorithm. How can we incorporate and effectively respond to free text replies from patients? During the study period all replies were restricted to Red/Yellow/Green structured replies. Allowing patients to send us free text will require additional monitoring of replies to be sure that any urgent issues are addressed quickly. If a patient uses text to report a symptom that was not part of the algorithm a clinician would need to triage that reply and respond accordingly. Does the use of optical character recognition and

natural language processing to read and interpret free text replies provide adequate support to providers and patients?

- What types of patient support models could allow us to capture PGHD and provide the patient education chats beyond the 30-day TCM window, in the absence of the Care Navigator. Does providing access to the 24-hour RN Clinical Call Center adequately meet the needs of patients who are exchanging PGHD with our enterprise? Are there specific patient populations for whom that model would be more effective/less effective?
- We will need to review our algorithms and correct to improve sensitivity and specificity. How many patients with green replies have poor outcomes?
 What questions might have been asked differently or scored differently to catch those patients? Conversely, how many red replies are captured and trigger CN phone calls for patients they triage and deem not at risk?
- What other patient populations can benefit from this technology? Subacute care and nursing home patients historically have higher rates of readmission (Nabagiez et al., 2016), which is somewhat counterintuitive since these patients have nurses available to them around the clock. It is unclear if the higher rate of readmission is secondary to higher patient acuity in those settings, to greater vigilance on the part of those bedside nurses, or to lack of adequate support in the alternate settings. How might the technology be used to support clinicians in those alternate settings if they are able to use the chatbot to answer questions about their patients and receive validated feedback and advice about when to escalate care or

when to take a watchful waiting approach? Could such a model be used by our home care agency to supplement nursing visits?

- The PGHD gathered using chatbots is itself valuable to the organization. How can we mine that data to find patterns that are associated with higher risk? What patterns are associated with better outcomes? What are the issues identified with data integrity or validity? What data can be used to trigger additional outreach to engage patients? Can the data be compared to the patient's problem list or medication list in the EHR to identify gaps in care or to strengthen clinical decision support systems?
- Reducing unnecessary physician office visits can reduce costs and improve the patient's experience of illness and recovery. How might this technology be used to supplement or replace physician office-visits for chronic illness?
- Does providing PGHD via chatbot result in increased engagement or loyalty to the Northwell enterprise when additional services are needed by the patient? By a family member?

5.3 Conclusions

The use of chatbots to gather PGHD is a nascent field of study and there is great opportunity to study and learn more about the use of the technology and its impact on the experiences of patients and providers, as well as its impact on clinical and cost outcomes. Although barriers to widespread use exist, this study provides some insight into the preferences and outcomes of patients who elect or decline to use chatbots to share PGHD that can be leveraged to overcome those barriers. The study shows that the use of

chatbots to gather PGHD into the EHR along with integration into provider workflows can successfully reduce hospital readmissions in transitional care patients in the 30 days immediately following discharge. Questions remain about the scalability and economic impact of the technology and larger studies over a longer period of time are indicated. This technology has the potential to positively impact patient and provider experience, reduce costs, and improve the health outcomes of individuals and populations, meeting all four goals of the Quadruple Aim.

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APPENDIX A: Terms of Agreement

Welcome to the Conversa Health Automated Conversation System

Conversa Health ("Conversa") is a service that enables users to engage in automated digital conversation sessions with their doctors and other health care providers. These automated, interactive conversation (or "chat") sessions are referred to in our Privacy Policy and in these Terms of Agreement ("Terms") as our "Automated Conversation System" or the "Services".

The Services also include the website at www.conversahealth.com and any other service offered by us.

The Services are provided by Conversa Health, Inc. ("Conversa", "we" or "us") on behalf of your provider. Please read these Terms carefully because they govern your legal relationship with us and your use of the Services.

Agreement to Terms

If you wish to use the Services, you will be asked to agree to these Terms. If you do so and then proceed to use the Automated Conversation System or any other aspect of the Services, you are agreeing to be bound by these Terms.

If you visit or use our website, you are also agreeing to these Terms. If you don't agree with these Terms, you are not permitted to visit or use our website or Services.

No Medical Advice

You understand and agree that Conversa does not provide medical advice, diagnosis, treatment, or prescriptions, either through the Services or in any other way. We're here to help you to communicate with your provider, but we're not your doctor or provider. The Services are not a substitute for professional medical advice, diagnosis, treatment or prescriptions. Please seek medical advice and treatment only from a healthcare provider, and if you have any questions about any communications you received through the Services, call your healthcare provider or visit him or her in person. If you think you may have a medical emergency, call your healthcare provider or 911 immediately.

ANY HEALTH INFORMATION SERVICES, SUGGESTIONS, OR OTHER CONTENT PROVIDED VIA THE SERVICES ARE FOR INFORMATIONAL PURPOSES ONLY. YOU ASSUME FULL RESPONSIBILITY FOR THE USE OF ANY INFORMATION OBTAINED THROUGH THE SERVICES AND AGREE THAT WE'RE NOT RESPONSIBLE OR LIABLE FOR ANY CLAIMS, LOSSES, OR DAMAGES ARISING FROM USING THAT INFORMATION AND WE DISCLAIM ANY LIABILITY RELATING THERETO. IF YOU RELY ON ANY INFORMATION PROVIDED TO YOU VIA THE SERVICES, YOU DO SO AT YOUR OWN RISK. YOU AGREE THAT WE HAVE NO RESPONSIBILITY TO PROVIDE MEDICAL

ADVICE OR TAKE ANY MEDICALLY RELATED ACTION IN RESPONSE TO ANY INFORMATION YOU PROVIDE THROUGH THE SERVICES.

Definitions

"Conversa" includes Conversa Health, Inc. and its affiliates, subsidiaries, officers, directors, employees and agents.

"Patient" is used synonymously with "user" in these Terms and the Privacy Policy. In most cases, "patient" refers to a patient of a licensed health care provider, but it could also refer to a user for whom the Services are being provided by a personal service provider, such as a trainer, fitness coach, or lifestyle/health coach.

"Provider" means the person or company that asked us to offer you the Automated Conversation System, which could be your healthcare provider, such as a doctor, nurse, or physical therapist, or other personal service provider, such as a trainer, fitness coach, or lifestyle/health coach.

Changes to Terms or Services

We may modify these Terms at any time. If we make only minor, editorial changes, we'll let you know about the updated Terms when you access the Services, and the new Terms will apply to you. If, however, we make any material changes, we'll ask if you consent to the new Terms before you continue to use the Services, and if you decline to consent, the Services might not be available to you.

The current version of the Terms will be dated and posted here.

Because our Services are evolving over time, we may change all or any part of the Services, at any time and without notice, at our sole discretion. In addition, we will stop providing the Services if your provider asks us to.

Who May Use the Services

You may use the Services only if you are authorized to use the Services by your provider and you are 18 years or older and legally competent.

The Services are intended for residents of the United States. If you are not a U.S. resident and you register or submit personal information through the Services, you agree that we may collect, us, store, and disclose that information in the U.S. or any other country outside your country of residence. You understand that data protection laws outside of your jurisdiction may not be as protective as those in your jurisdiction. By providing your information to Conversa, you are consenting to the international transfer and processing of your information for the purposes explained in these Terms, the Privacy Policy , or elsewhere in the Services. You may use the Services solely for your personal purposes; you understand and agree that any commercial use is strictly prohibited.

Alerts and Notifications

As described in our Privacy Policy, we will contact about your use of the Services. Please refer to the Privacy Policy for an important message about the security of ordinary email or text messages, which are frequently used as a part of the Services.

You are responsible for any messaging or data fees you may be charged by your wireless carrier.

Intellectual Property Rights

Conversa and its licensors exclusively own all right, title and interest in and to the Services, including all associated intellectual property rights. Conversa Health, www.conversahealth.com, and our logo are trademarks belonging to us. You acknowledge that the Services are protected by copyright, trademark, and other laws of the United States and foreign countries. You agree not to remove, alter or obscure any copyright, trademark, service mark or other proprietary rights notices incorporated in or accompanying the Services.

You grant to us a non-exclusive, worldwide, perpetual, irrevocable, fully paid, royaltyfree, sublicensable, and transferrable license under any and all intellectual property rights that you own or control to use, copy, modify, or create derivative works based upon and otherwise exploit any information or content you submit through the Services. You also grant us the right to sub-license these rights and the right to bring an action for infringement of these rights. All intellectual property rights are reserved. Nothing in the license you grant us permits us to make any use or disclosure that is prohibited by our Privacy Policy or applicable law, including the Health Information Portability and Accountability Act ("HIPAA").

If you believe that your intellectual property has been copied or is accessible via the Services in a manner that constitutes copyright infringement, please contact us at<u>legal@conversahealth.com</u>. The requirements for what you must include in your notice are in the Digital Millennium Copyright Act, 17 U.S.C. § 512.

Prohibited Uses

You agree that you will not use the Services in any way prohibited by law or these Terms. These prohibitions include, but are not limited to, the following:

- You may not damage, overburden, or impair the Services or their availability.
- You may not use the Services in any way that is illegal, fraudulent, or harmful.
- You may not attempt to gain unauthorized access to the Services or other accounts, computers, or networks via the Services.

- You may not use the Services to copy, store, host, transmit, send, use, publish or distribute any malicious software or other harmful item.
- You may not copy, modify, distribute, sell, or lease any part of the Services or their content or software, nor may you reverse engineer or attempt to extract the source code of that software.
- You may not conduct any systematic or automated data collection activities without our specific, written pre-authorization (including, without limitation, any data mining, scraping, extraction, or harvesting.)
- You may not use the Services to send spam, surveys, or any commercial communications that are not an authorized part of Digital Checkups.

Links to Third Party Websites or Resources

The Services may contain links to third-party websites or resources. We are not responsible for the content, products or services on or available from those websites or resources or links displayed on such websites. You acknowledge sole responsibility for and assume all risk arising from your use of any third-party websites or resources (including those provided by your provider).

Termination

We may terminate your access to and use of the Services at any time and for any reason, including upon termination or expiration of our agreement with your provider or upon the request of your provider. You may stop using the Services at any time. Upon any termination, discontinuation or cancellation of Services, the following provisions will survive: the provisions entitled "No Medical Advice," "Information You Provide," "Feedback," "Links to Third Party Websites or Resources," "Termination," "Warranty Disclaimers," Limitation of Liability," "General," and any provisions that, by their nature, should survive termination.

Warranty Disclaimers

THE SERVICES ARE PROVIDED "AS IS," WITHOUT WARRANTY OF ANY KIND. WITHOUT LIMITING THE FOREGOING AND TO THE EXTENT PERMITTED BY LAW, WE EXPLICITLY DISCLAIM ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, QUIET ENJOYMENT OR NON-INFRINGEMENT, AND ANY WARRANTIES ARISING OUT OF COURSE OF DEALING OR USAGE OF TRADE. We make no warranty that the Services will meet your requirements or be available on an uninterrupted, secure, or error-free basis. We make no warranty regarding the quality, accuracy, timeliness, truthfulness, completeness or reliability of the Services or any information provided to you via the Services.

You assume total responsibility and risk for your use of the Services and communications made via the Services, including by internet and text message. You understand and agree that any uploads or transmissions through the Services could be intercepted and used by

an unauthorized third party and that all of the risk associated therewith is solely yours. You also agree that Conversa will have no liability whatsoever for any unavailability of the Services or loss or inadvertent unauthorized use or disclosure of data or misdelivery or nondelivery of communications caused by system outages or any third party acts or any other outages involving the Services, internet providers, the internet infrastructure, or any third parties.

Limitation of Liability

NEITHER CONVERSA NOR ANY OTHER PARTY INVOLVED IN CREATING, PRODUCING, OR DELIVERING THE SERVICES WILL BE LIABLE FOR ANY DIRECT, INCIDENTAL, SPECIAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS, LOSS OF DATA OR GOODWILL, SERVICE INTERRUPTION, COMPUTER DAMAGE OR SYSTEM FAILURE OR THE COST OF SUBSTITUTE SERVICES ARISING OUT OF OR IN CONNECTION WITH THESE TERMS OR FROM THE USE OF OR INABILITY TO USE THE SERVICES, WHETHER BASED ON WARRANTY, CONTRACT, TORT (INCLUDING NEGLIGENCE), PRODUCT LIABILITY OR ANY OTHER LEGAL THEORY, AND WHETHER OR NOT CONVERSA HAS BEEN INFORMED OF THE POSSIBILITY OF SUCH DAMAGE, EVEN IF A LIMITED REMEDY SET FORTH HEREIN IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE. SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF LIABILITY FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU.

YOUR SOLE REMEDY FOR ANY DISSATISFACTION WITH THE SERVICES IS TO STOP USING THE SERVICES.

IN NO EVENT WILL CONVERSA'S TOTAL LIABILITY ARISING OUT OF OR IN CONNECTION WITH THESE TERMS OR FROM THE USE OF OR INABILITY TO USE THE SERVICES EXCEED FIFTY DOLLARS (\$50).

THE EXCLUSIONS AND LIMITATIONS OF DAMAGES SET FORTH ABOVE ARE FUNDAMENTAL ELEMENTS OF THE BASIS OF THE BARGAIN BETWEEN CONVERSA AND YOU.

Dispute Resolution

Governing Law and Jurisdiction

Except for matters of United States federal law governing intellectual property, these Terms and any action related to the Terms or the Services will be governed by the laws of the State of Oregon without regard to conflict of laws provisions. If applicable, you consent to personal jurisdiction in Oregon courts and venue in Multnomah County, Oregon.

Time Limitation

You agree that, regardless of any law, any claim you may have against us must be brought within one year after the claim arises or is known or reasonably should have been known to you, or the claim will be forever barred.

Agreement to Arbitrate

If you have a complaint, question, claim, or dispute (collectively, "Dispute") regarding the Services, you are encouraged to bring it to our attention directly. Please email us at<u>legal@conversahealth.com</u>, and we will address your concerns.

If we are unable to resolve a Dispute ourselves, any Dispute relating in any way to the Terms or Services must be submitted to binding arbitration in Multnomah County, Oregon, except that to the extent you have in any manner violated or threatened to violate our intellectual property rights, we may seek injunctive or other appropriate relief in any federal or state court. Arbitration shall be conducted in accordance with these Terms and the prevailing rules and procedures of the American Arbitration Association. Each party shall be responsible for its own costs and fees, and the joint costs of arbitration shall be shared equally by the parties. The arbitrator's award shall be final and binding and may be entered as a judgment in any court of competent jurisdiction.

To the fullest extent permitted by applicable law, no arbitration or claim under these Terms may be joined to any other arbitration or claim, including any arbitration or other legal proceeding involving any other current or former user of the Site, and no class action proceedings will be permitted.

By agreeing to arbitration in these Terms, you understand and agree that you are giving up (i) any right to pursue claims or have Disputes resolved in a court of law, (ii) any right to compulsory discovery, and (iii) any right to the appeal of any adverse arbitration decision.

General

These Terms, including our Privacy Policy incorporated herein, constitute the entire and exclusive understanding and agreement between Conversa and you regarding the Services, and these Terms supersede and replace any and all prior oral or written understandings or agreements between Conversa and you regarding the Services. If we enter into an additional or separate written agreement with you, the terms of that agreement will supplement these Terms and will control to the extent they are contrary to these Terms.

If for any reason a court of competent jurisdiction finds any provision of these Terms invalid or unenforceable, that provision will be enforced to the maximum extent permissible and the other provisions of these Terms will remain in full force and effect.

You may not assign or transfer these Terms, by operation of law or otherwise, without Conversa's prior written consent. Any attempt by you to assign or transfer these Terms, without such consent, will be null. Conversa may freely assign or transfer these Terms without restriction. Subject to the foregoing, these Terms will bind and inure to the benefit of the parties, their successors and permitted assigns.

Headings in these Terms are solely for convenience.

The Services may use cookies to store information on your computer or device. By visiting the website or using the Services, you consent to the placement of these cookies.

Any notices or other communications provided by Conversa under these Terms, including those regarding modifications to these Terms, will be given via email, text or via the Services. For notices made by email or text, the date of receipt will be deemed the date on which such notice is transmitted. You consent to the use of these electronic methods of communication from us and agree that all communications, including Terms and agreements, that we provide electronically satisfy any legal requirement that such communications would satisfy if they were in writing.

Conversa's failure to enforce any right or provision of these Terms will not be considered a waiver of such right or provision. The waiver of any such right or provision will be effective only if in writing and signed by a duly authorized representative of Conversa. Except as expressly set forth in these Terms, the exercise by either party of any of its remedies under these Terms will be without prejudice to its other remedies under these Terms or otherwise.

Contact Information

If you have any questions about these Terms or the Services, please contact Conversa at <u>legal@conversahealth.com</u>.

We welcome feedback, comments, complaints and suggestions for improvements to the Services ("Feedback"). You can submit Feedback by emailing us at<u>feedback@conversahealth.com.</u>

Prior Versions

Prior versions of these Terms are available here.

Effective Date

The effective date of these Terms is September 1, 2017

APPENDIX B – IRB Determination

Home	🔗 Find Study (Ctrl+Q)					
Study 19-0500-OTH (IRB)				Help Kathl	een's Settings	Sign of
▼Study						
Study:	19-0500	Sponsor(s):				
Committee:		Sponsor Id:				
Category:		Grants:				
Department:	CORPH - OCIO					
Agent Types:	Data Collection -Retrospective	CRO:				
	Conversational AI in Transitional Care to Reduce Avoidable Re-admissions and ED Visits	Year:	2019			
External IRB:		PeopleSoft Fund Number:				
Protocol Version:		Risk Determination:				
Study-Site						
	OTH - Other NSLIJ Locations - Please indicate the location via note	PI:	Mazza, Kathleen			
Status:	Not Human Subjects Research	Additional:	N			
Approval:		Expiration:				
Initial Approval:		Other Expirations:				
Study-Site Attachme	ents (2)					
Name	\$	Туре	\$	Date 🔺	Ву	¢
Mazza Conversa Project Data Collection Sheet		Additional Documents		06/04/2019	kmazza@north	nwell.edu
athleen Mazza CV		CV		06/04/2019	kmazza@north	nwell.edu