

**PUSHING THE BOUNDARIES OF CONSUMER GRADE WEARABLE DEVICES IN
HEALTH CARE FOR OLDER ADULTS**

by

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Author's Declaration

This thesis consists of material all of which I authored or co-authored: see Statement of Contributions included in the thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

I understand that my thesis may be electronically available to the public.

Statement of Contributions

The manuscript and studies presented in this thesis, including four that have been published, submitted for publication, prepared for publication in peer-reviewed academic journals, or presented at an academic conference are the work of Ben Kim, in collaboration with his co-authors and committee members. The authorship for each thesis chapter (and the corresponding manuscripts) is shown below.

Chapter	Description	Reference	Status
3.0	White Paper	Kim, B., Lee, J. (2018, October). <i>Mobile & Sensor Technology, Big Data and Artificial Intelligence for Healthy Aging</i> . Paper presented at the AGE-WELL's 4 th Annual Conference: Innovation in Action, Vancouver, BC	Presented
4.0	Study 1	Kim, B., McKay, S., Lee, J. (Accepted). Predicting frailty with a consumer-grade wearable device in Canadian home care clients: A proof-of-concept study. <i>Journal of Medical Internet Research</i> #19732	Accepted
5.0	Study 2	Kim, B., Hunt, M., Muscedere, J., Maslove, D. M., Lee, J. (<i>under review</i>). Using consumer-grade wearable devices to measure frailty transitions in critical care survivors: An exploratory observational study. <i>JMIR mHealth and uHealth</i> #19589	Submitted
6.0	Study 3	Kim, B., Stolee, P., Lee, J. Comparing and contrasting clinicians and older adults' perceptions of patient-generated health data: a mixed-method study	Prepared

As lead author of the three main studies, I was responsible for conceptualizing study design, data collection and analysis, and drafting and submitting manuscripts. My co-authors provided methodological guidance and feedback on draft manuscripts, with full knowledge that the publication would be included in the doctoral thesis of Ben Kim.

Abstract

Background: The proliferation of wearable and mobile devices in recent years has led to the generation of unprecedented amounts of health-related data. Together with the growing population of older adults in Canada, the increasing adoption of these technologies created a momentous opportunity to improve the way we deliver, access, and interact with the health care system. Many have recognized the opportunity, yet there is a lack of evidence on how these devices and the growing size of health data can be used to transform health care and benefit us.

In Chapter 2, a review of the literature was presented to identify the current evidence of wearable technology and gaps that exist in aging research. Based on the literature review, one promising way to use wearable devices is to assess frailty, which can contribute to improving care and enhancing aging-in-place. Chapter 3 summarizes key concepts related to wearable devices including mobile health, patient-generated health data, big data, predictive algorithms, machine learning, and artificial intelligence. While in-depth mathematical representation of these big data analytics is outside the scope of this dissertation, this chapter provides foundational information along with examples found in health care settings.

Objective: The overall aim of this dissertation was to investigate possible use of consumer-grade wearable devices and the patient-generated health data to improve the health of older adults.

Methods: This thesis is presented as three individual studies included in Chapters 4 to 6. **Study 1** aimed to investigate use of wearable devices to predict and find associations with frailty for community-dwelling older adults receiving home care service. Participants were asked to wear

wearable device for 8 days in their home environment and no supervision was provided. Frailty level was assessed using the Fried Frailty Index. Other variables were collected including Charlson Comorbidity Index, independence using the Katz Index, and home care service utilization level. A sequential stepwise feature selection method was used to determine variables that are fitted in multiple variable logistic regression model to predict frailty. **Study 2** extended the investigation of possible use of wearable devices for understanding frailty by examining the relationship between wearable device data and frailty progression among critical illness survivors from an intensive care unit at Kingston General Hospital. Participants were assessed for frailty using the Clinical Frailty Scale three times; at admission, at hospital discharge, and at 4-weeks post-hospital discharge. The changes in frailty level between the three time points were used to identify association with wearable device data that was collected for 4 weeks post-hospital discharge. Demonstrating evidence for wearable devices and patient-generated health data in research does not guarantee its use in real life. In **Study 3**, a mixed method study was conducted to explore clinicians' and older adults' perceptions of patient-generated health data. Focus group interviews were conducted with older adults and health care providers from the Greater Toronto Area and the Kitchener-Waterloo region. A questionnaire that aimed to explore perceived usefulness of a range of different patient-generated health data was embedded in the study design. Focus group interviews were transcribed verbatim. Line by line coding was conducted on all interviews followed by thematic analysis.

Results: Results from **Study 1** indicate data generated from wearable devices are closely linked to frailty level. Results showed a significant difference between frail and non-frail participants in age ($p<0.01$), home care service utilization ($p=0.012$), daily step count ($p=0.04$), total sleep time

($p=0.010$), and deep sleep time ($p<0.01$). Total sleep time ($r=0.41$, $p=0.012$) and deep sleep time ($r=0.53$, $p<0.01$) were associated with frailty level. A receiver operating characteristics area under the curve of 0.90 was achieved using deep sleep time, sleep quality, age, and education level (Hosmer-Lemeshow $p=0.88$), demonstrating that data from wearable devices can augment the demographic and conventional clinical data in predicting frailty status.

Results from **Study 2** demonstrated that frailty level increases significantly following a critical illness ($p=0.02$). Frail survivors had significantly lower daily step counts ($p=0.02$). Daily step count ($r=-0.72$, $p=0.04$) and mean heart rate ($r=-0.72$, $p=0.046$) were strongly correlated with frailty level at admission and discharge. Mean standard deviation of heart rate was correlated with the change in frailty status from admission to 4-week follow-up ($r=0.78$, $p<0.05$). The results demonstrated a relationship between the worsening of frailty due to critical illness and the pattern of increasing step count ($r=0.65$, $p=0.03$) and heart rate ($r=0.62$, $p=0.03$) over the 4-week observation period.

Results from **Study 3** provided an understanding of what older adults and clinicians considered barriers to using patient-generated health data in their care and clinical settings. Four main themes were identified from the focus group interviews: influence of patient-generated health data on patient-provider trust; reliability of patient-generated health data; meaningful use of patient-generated health data and decision support system; and perceived clinical benefits and intrusiveness of patient-generated health data. Results from the questionnaire and focus group interviews demonstrated that older adults and clinicians perceived blood glucose, step count,

physical activity, sleep, blood pressure, and stress level as the most useful data for managing their health and delivering high quality care.

Discussion: This dissertation provides evidence for using consumer-grade wearable device to assess, monitor, and predict frailty for older adults who receive home care or survived critical illness. The possibility of using a wearable device to assess frailty can enable health care providers to obtain frailty information in a timely manner, which is challenging to acquire otherwise due to a lack of appropriate tools in primary care, ambulatory care, home and community care, critical illness care, and other sectors. There was a distinct relationship between failure to recover frailty level from critical illness and the pattern of daily step count and heart rate. This can enable early detection of critical illness survivors who may not return to pre-critical illness level. It can provide guidance to identify those who may benefit the most from follow-up visits and elevated treatment. To ensure the benefits of patient-generated health data are realized, it must be integrated into health care. There are technical challenges that prevent such integration and discussion around policies and regulations must begin to make progress.

Conclusion: This dissertation demonstrated use of wearable devices to assess frailty and identified factors that can hinder the integration of patient-generated health data into health care. It opened a possibility of assessing frailty, expanding the boundaries of current use of consumer-grade wearable devices.

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Table of Contents

Examining Committee Membership	ii
Author’s Declaration.....	iii
Statement of Contributions	iv
Abstract	vi
Acknowledgements.....	x
List of Figures	xvi
List of Tables	xvii
List of Abbreviations	xviii
Chapter 1. Introduction and Overview	1
1.1. Introduction	1
1.2. Philosophical Worldview	2
1.3. Research Rationale	3
1.4. Dissertation Overview	4
1.5. Overarching Purpose and Objectives.....	5
Chapter 2. Literature Review.....	8
2.1. Aging in Canada	8
2.2. Aging and Technology	9
2.3. Wearable Devices	10
2.4. Patient-Generated Health Data	12
2.5. Frailty	13
2.5.1. Definition of Frailty.....	13
2.5.2. Theoretical Frameworks	13
2.5.3. Challenges with Assessing Frailty	17
2.5.4. Transitions in Frailty States	18
2.6. Wearable Devices for Assessing Frailty.....	19
2.6.1. Physical Activity and Frailty	19
2.6.2. Heart Rate and Frailty.....	19
2.6.3. Sleep Quality and Frailty	20
Chapter 3. White Paper: Mobile & Sensor Technology, Big Data and Artificial Intelligence for Healthy Aging	22
3.1. Introduction	24
3.2. Mobile Health.....	24
3.3. Personal Sensing.....	26
3.4. Data to Knowledge	27

3.5.	Artificial Intelligence, Machine Learning, Deep Learning, and Big Data in Healthcare	29
3.6.	Machine Learning and Wearable Devices	31
3.7.	Machine Learning in Current and Future Health Care	32
3.7.1.	Example 1: Predicting patient outcomes in ICU	32
3.7.2.	Example 2: A.I. – Making diagnosis	33
3.7.3.	Example 3: Finding effective drugs just for you with machine learning	33
3.8.	Conclusion	34
Chapter 4. Predicting frailty with a consumer-grade wearable device in Canadian home care clients: A proof-of-concept study		35
4.1.	Chapter Overview	35
4.2.	Introduction	36
4.3.	Methods	39
4.3.1.	Study Design	39
4.3.2.	Recruitment	40
4.3.3.	Wearable Device	40
4.3.4.	Frailty Assessment	41
4.3.5.	Other Variables	42
4.3.6.	Statistical Analysis	42
4.3.7.	Ethics, Consent, and Permissions	44
4.4.	Results	44
4.4.1.	Recruitment	44
4.4.2.	Participant Characteristics	44
4.4.3.	Frailty and Wearable Device Data	45
4.4.4.	Factors Correlated with Frailty	46
4.4.5.	Frailty Prediction	47
4.5.	Discussion	50
4.5.1.	Principal Findings	50
4.5.2.	Limitations	55
4.6.	Conclusions	56
4.7.	Funding Statement	56
4.8.	Conflicts of Interest	56
Chapter 5. Using consumer-grade wearable devices to measure frailty transitions in critical care survivors: An exploratory observational study		57
5.1.	Chapter Overview	57
5.2.	Introduction	59
5.3.	Methods	60
5.3.1.	Study Design and Settings	60
5.3.2.	Data Collection and Instrumentation	61
5.3.3.	Procedure	63
5.3.4.	Data Analyses and Interpretation	65
5.3.5.	Ethics, Consent, and Permissions	66
5.3.6.	Patient and Public Involvement	66
5.4.	Results	66

5.4.1.	Recruitment	66
5.4.2.	Clinical Frailty Scale	67
5.4.3.	Frailty and Wearable Device Data	69
5.4.4.	Frailty and Wearable Device Data Trends over Time	71
5.5.	Discussion.....	72
5.6.	Limitations.....	76
5.7.	Conclusions	76
5.8.	Funding Statement.....	77
5.9.	Competing Interests.....	77
5.10.	Author’s Contribution.....	77
Chapter 6. Comparing and contrasting clinicians and older adults’ perceptions of patient-generated health data: A mixed-method study.....		78
6.1.	Background.....	78
6.2.	Research Objective	80
6.3.	Methods	81
6.3.1.	Study Design.....	81
6.3.2.	Procedures	81
6.3.3.	Recruitment	82
6.3.4.	Data Collection and Analysis	82
6.3.5.	Analysis	83
6.4.	Results	84
6.4.1.	Participant Characteristics	84
6.4.2.	Participants’ Exposure to Patient-Generated Health Data	85
6.5.	Thematic Analysis	85
6.5.1.	Theme 1: Influence of patient-generated health data on patient-provider trust	85
6.5.2.	Theme 2: Reliability of patient-generated health data	87
6.5.3.	Theme 3: Meaningful use of patient-generated health data and decision support system	90
6.5.4.	Theme 4: Perceived clinical benefits and intrusiveness of patient-generated health data.....	92
6.5.5.	Perceived usefulness of patient-generated health data.....	94
6.6.	Discussion.....	98
6.6.1.	Principal Findings.....	98
6.6.2.	Limitations.....	104
6.7.	Conclusion.....	104
Chapter 7. Discussion and Key Contributions.....		106
7.1.	Implications for Health Care Practice.....	106
7.2.	Implications for Technology Development and Policy	108
7.3.	Implications for Consumer Health Informatics Research.....	109
7.4.	Future Research	110
7.5.	Limitations.....	111
Chapter 8. Conclusion		113

Bibliography	114
Appendices.....	138
Appendix A.....	138
Appendix B.....	139
Appendix C.....	140
Appendix D.....	143
Appendix E.....	145
Appendix F.....	146

List of Figures

Figure 2.1. The cycle of phenotypic characteristics of frailty	15
Figure 3.1. Data to knowledge sensemaking framework with examples of personal sensing.....	28
Figure 4.1. The receiver operating characteristics curves for all Models fitted to predict frailty	50
Figure 5.1. Study procedure and time points of assessment and measurement tools	64
Figure 5.2. A spaghetti plot of the CFS score at T1, T2, and T3 (n=12).....	68
Figure 5.3. Example of the slope of linear regression line for daily step count, total sleep time, and heart rate. The slope of linear regression line represents the changes over D2	71
Figure 6.1. Bar graph showing the distribution of the Data Rating Questionnaire answers.....	98

List of Tables

Table 1.1. The overall aim of the dissertation and the objectives for each study	7
Table 3.1. Sources and types of data potentially useful for research and clinical practice	27
Table 4.1. Baseline sociodemographic and patient characteristics stratified by frailty status (n=37).....	45
Table 4.2. Difference in the data collected from the wearable device between frail and non-frail participants(n=37).....	46
Table 4.3. Correlations between wearable device data, patient characteristics and frailty	46
Table 4.4. Three frailty prediction models and the variables selected by the stepwise feature selection method	48
Table 4.5. Multiple logistic regression of factors associated with frailty	48
Table 4.6. Summary of model performance in predicting frailty status.	50
Table 5.1. Baseline characteristics, frailty, disability, and co-morbidity scores	67
Table 5.2. Changes in CFS score over D3.....	68
Table 5.3. Data collected from the wearable device (n=9).....	69
Table 5.4. Correlations between the data collected from the wearable devices and the frailty level and its change (n=9).....	70
Table 5.5. Correlation between the slope of daily step count and the CFS scores at T1, T2, and T3 and changes in CFS over D1, D2, and D3.....	71
Table 6.1. Participant characteristics	84
Table 6.2. Frequency of patient-generated health data mentioned in focus group interviews	94
Table 6.3. Average rating of patient-generated health data by older adults and clinicians	96

List of Abbreviations

ADL – Activities of Daily Living

AI – Artificial Intelligence

APACHE II – Acute Physiology and Chronic Health Evaluation II

AUC – (receiver operating) Area Under the Curve

BMI – Body Mass Index

CAM-ICU – Confusion Assessment Method – Intensive Care Unit

CCI – Charlson Comorbidity Index

CFS – Clinical Frailty Scale

CGA – Comprehensive Geriatric Assessment

COPD – Chronic Obstructive Pulmonary Disease

ECG – Electrocardiogram

EHR – Electronic Health Record

EMA – Ecological Momentary Assessment

EMR – Electronic Medical Record

GPS – Global Positioning System

HRV – Heart Rate Variability

ICU – Intensive Care Unit

ICU LOS – Intensive Care Unit Length of Stay

LOS – Length of Stay

mHealth – mobile Health

MLTAQ – Minnesota Leisure Time Activity Questionnaire

PROM – Patient Reported Outcome Measure

PSG – Polysomnography

SD – Standard Deviation

TST – Total Sleep Time

Chapter 1. Introduction and Overview

1.1. Introduction

In medicine, technology has always played a key role. The invention of a microscope in the 1500s led to the birth of cellular and microcellular biology (Poppick, 2017). Refinement of the stethoscope from the early- to mid-1800s enabled direct observation of acoustic signals of the human body, shifting the paradigm of the definition of disease as a combination of symptoms that were externally observed to issues with internal components of a human body without visible symptoms (Duffin, 2012). In modern medicine, technology has established a symbiotic relationship where its importance cannot be overstated. We can now see and track a single protein in a cell through a fluorescence microscope and see inside the body non-invasively clearer than ever using magnetic resonance imaging (Poppick, 2017).

In the last couple of decades, medicine and health care have faced the new challenges of organizing and sharing information more effectively through the use of computers and via the internet. A host of health information tools, including electronic health records (EHR), were introduced to collect and merge health information in a centralized way. It has contributed to the improved efficiency in managing health information, which brought benefits to patient care (The Office of the National Coordinator for Health Information Technology, 2019). It has also led to an accumulation of health information in the size we have never seen before. Big health data has opened new opportunities to analyze the data using advanced mathematical approaches, leading to the birth of new concepts such as precision medicine and personalized medicine (Joon Lee, Maslove, & Dubin, 2015; Sharafoddini, Dubin, & Lee, 2017). In recent years, we observed an

unprecedented advancement in sensor technology. Sensors found their way into many mobile phones and wearable devices that most of us use daily to collect data in hopes of improving our health and behaviours (Paré, Leaver, & Bourget, 2018). It has led to an explosion of patient generated health-related data, collected and shared from mobile and wearable devices.

The accumulation of patient-generated health data from mobile and wearable devices has earned the interest from a range of stakeholders of the health care system including patients, care providers, funders, governments and policy-makers, and technology developers (Accenture, 2016; Chung et al., 2016; Kelsey & Cavendish, 2014; Piwek, Ellis, Andrews, & Joinson, 2016; Swan, 2009). Many envision a future where deeper insights into the health of individuals and personalized care plans are procured from patient-generated health data to advance patient care. Yet, gaps remain in our understanding of what we can do with such data, how we can use the information, and how we can best implement it in the health care system.

1.2. Philosophical Worldview

For the work included in this dissertation, I espoused a pragmatic worldview (Creswell, 2013). The pragmatic view of the world enabled me to focus on problems while allowing me to choose research methods freely (Creswell, 2013). This pragmatic approach recognizes that research is not independent of the social, historical, political and other contexts it is situated in. Aligned with this view, the methodology of this dissertation was selected to best answer the research questions given the context of the research topic. I am a male researcher with a primary background in health information system projects. I am primarily a quantitative researcher and have appreciation and experience with qualitative research. My initial interest in this topic originated

from the experience of mobile device-based health information system implementation. The focus of my dissertation solidified as my interest evolved with my recognition and interest in wearable devices as their adoption among general populations increased exponentially along with a need to better understand ways to harness the patient-generated health data. I position myself as an explorer of the new ways of using patient-generated health data to improve its integration into health care and ultimately improve patient care.

1.3. Research Rationale

The population of Canada is aging and an unprecedented demand for health care is expected (Statistics Canada, 2016a). Of particular concern is the increasing prevalence of frailty among the aging population and the current ill-prepared health care system to treat frailty effectively (Muscedere et al., 2016). Technology has demonstrated its role in bridging this gap by supporting older adults to stay independent and healthy longer in the community (Reeder et al., 2013).

Frailty is linked to adverse health outcomes especially for older adults (Heyland et al., 2015). Improving frailty gets exponentially less likely as frailty status worsens and identifying at risk persons is paramount to preventing further deterioration (Gill, Gahbauer, Allore, & Han, 2006). Identifying at-risk populations is difficult among community-dwelling older adults as the implementation of routine frailty screening has been hampered by the lack of consensus on tools and questionable feasibility in different health care settings (Lee, Heckman, & Molnar, 2015).

There is evidence that frailty can be assessed with measures that have not been examined previously but are now possible with new technologies. Gait analysis, step count, physical activity level, and sedentariness have demonstrated their high correlation with frailty level (Dasenbrock, Heinks, Schwenk, & Bauer, 2016). Data generated from wearable devices such as continuously measured heart rate have been shown to improve the understanding of frailty status when analyzed together with physical activity level (Theou, Jakobi, Vandervoort, & Jones, 2012). Sleep quality measures from wearable devices including total sleep time and nocturnal awakenings were associated with frailty (Ensrud et al., 2009; M. Kim, Yoshida, Sasai, Kojima, & Kim, 2015). However, these studies were conducted in a laboratory setting with medical- and research-grade devices. This limits their generalizability and there is a need for evidence for consumer-grade wearable devices used in-situ for assessing frailty. There is growing evidence for the reliability of data generated from consumer-grade wearable devices for the measures demonstrated in these previous studies (Evenson, Goto, & Furberg, 2015; Shcherbina et al., 2017; Wang et al., 2016). Furthermore, the quality of data is only expected to improve as the sensor technology advances. Coupled with the increase in interest for such devices and anticipation of added clinical value from the data, this momentous opportunity provides a new avenue for researchers and clinicians to further investigate frailty.

1.4. Dissertation Overview

This dissertation begins with the introduction to background information and a review of the literature in Chapter 2. The literature review focuses on the current evidence on the need for improved care for older adults of Canada, the impact of frailty on health outcomes of older adults, and the demonstrated ways of using mobile and wearable devices to augment care in

home and community healthcare and critical illness care settings. In Chapter 3, a portion of a white paper presented at the 2018 AGE-WELL conference is included. This white paper summarizes the key concepts related to mobile health, wearable devices, and patient-generated health data including big data, machine learning and artificial intelligence. In-depth review of these concepts is beyond the scope of this dissertation, but they are imperative to understanding the current state of the patient-generated health data. The purpose of this white paper was to unpackage these concepts in a manner that can be understood by the conference attendees, consisting of older adults, caregivers, clinicians, researchers, and industry representatives. This white paper was a product of knowledge translation of this thesis. This work is included in this thesis to be informative for the readers who are not familiar with such concepts. Chapters 4-6 have been written for publication and present the three primary research studies conducted. Chapters 4 and 5 have been submitted for publication and Chapter 4 has been accepted for publication and Chapter 5 is currently under review. Chapter 6 will be prepared to be submitted. Chapter 7 connects all three primary studies and discusses the implications of this dissertation and future research studies. The concluding remark is presented in Chapter 8.

1.5. Overarching Purpose and Objectives

The overall aim of the dissertation was to investigate the possible uses of patient-generated health data collected from mobile and wearable devices to improve the health of older adults. This dissertation examined what we can do with such data, how we can use the information, and how best we can integrate it into the current health care system. Each study included in this thesis had its own objectives that provided evidence for this purpose. Table 1.1 illustrates the

relationship between the studies and how they collectively support the purpose of this dissertation.

Study 1: Predicting frailty with a consumer-grade wearable device in Canadian home care clients: A proof-of-concept study

Objectives

1. To investigate the relationship between the data from consumer-grade wearable devices and frailty
2. To identify key wearable device measures that can predict the status of frailty

Study 2: Using a consumer-grade wearable device to assess frailty transitions in critical care survivors: An exploratory observational study

Objective

1. To examine the data generated from wearable devices for their relationship with the progression of frailty for the critical illness survivors.

Study 3: Comparing and contrasting clinicians' and older adults' perceptions of patient-generated health data: A mixed-method study

Objectives

1. To explore the perceptions of older adults and clinicians on patient-generated health data.
2. To compare the perceived usefulness of a range of patient-generated health data by older adults and clinicians.

Table 1.1. The overall aim of the dissertation and the objectives for each study

What is the problem?	Potential opportunity	How can we begin to address the problem?	How is the patient-generated health data perceived by clinicians and older adults?	What are some next steps?
<p>LITERATURE REVIEW:</p> <ul style="list-style-type: none"> • Assessing frailty in community-dwelling older adults • Understanding frailty transitions among critical illness survivors 	<p>LITERATURE REVIEW:</p> <p>Patient-generated health data from wearable and mobile devices:</p> <ul style="list-style-type: none"> • Highly adopted and accepted • Affordable • Measures physiological and kinematic data that are independently associated with frailty • Generates big data for advanced statistical approaches such as machine learning 	<p>STUDY ONE: To predict frailty among community-dwelling older adults using wearable devices</p> <p>STUDY TWO: To investigate frailty transition among critical illness survivors using wearable devices</p>	<p>STUDY THREE: To explore the perception of older adults and clinicians toward using patient-generated health data; and to identify perceived usefulness of different types of patient-generated health data</p>	<p>DISCUSSION & CONCLUSIONS:</p> <ul style="list-style-type: none"> • Identification of contributions to current knowledge gaps • Recommendations for the focus of future research

Chapter 2. Literature Review

2.1. Aging in Canada

As of 2017, Canada has a larger population of persons aged 65 and older than of persons aged 15 and younger (Statistics Canada, 2016a). Almost 18% of Canadians are 65 years of age and older, while 16% are 14 years of age and younger (Statistics Canada, 2020). The number of Canadians who are 85 and older grew almost 20% from 2011 to 2016, which is four times the overall population growth (Statistics Canada, 2017). The rapid growth of this population of Canadians is expected to continue; by 2051, one in 4 seniors will be 85 and older (Statistics Canada, 2017).

The aging Canadian population provides many opportunities and poses new challenges. One of the major challenges associated with aging populations is the increasing demand on the health care system (Denton & Spencer, 2010). Chronic conditions are much more prevalent among Canadians aged 65 and over compared to those aged 45 to 64, while over 80% of those 71 years old and over have at least one chronic condition (Statistics Canada, 2016b). Population aging is followed by a significant rise in the prevalence of chronic diseases and it shifted the paradigm of healthcare that traditionally focused on acute and episodic treatment to prevention and chronic care (Canadian Institute for Health Information, 2011). The shifting needs for health care resources introduced challenging demands and many innovative solutions are pursued. In particular, technology is at the core of the strategic transformation of the health care system to improve the efficiency of health care and to deliver high-quality care to older adults.

2.2. Aging and Technology

Aging-in-place emphasizes the continuation of living at home and maximizing the independence and dignity of older adults (Bacsu et al., 2012). Encouraging aging-in-place has multiple benefits including physical and mental health (Chappell, Dlott, Hollander, Miller, & McWilliam, 2004; Graybill, McMeekin, & Wildman, 2014; Hollander & Chappell, 2010), quality of life (Bacsu et al., 2012; Chapin & Dobbs-Kepper, 2001; Wiles, Leibing, Guberman, Reeve, & Allen, 2012), and cost-effectiveness of health care (Graybill et al., 2014; Marek, Stetzer, Adams, Popejoy, & Rantz, 2012). Older adults also prefer aging-in-place over institutions or nursing homes as it is closely linked to sense of identity, independence, autonomy, and security (Wiles et al., 2012).

Technology can support aging-in-place by improving and maintaining the independence of older adults at home. Telehealth technologies demonstrated the potential to remotely monitor and provide healthcare services to manage chronic diseases (Paré, Jaana, & Sicotte, 2007). Sensor technologies support physiological and functional monitoring such as blood pressure and falls, home environment control such as automatic lights, and social interaction and cognitive memory aids (Demiris & Hensel, 2008; Peek et al., 2014; Reeder et al., 2013). These technologies utilize an array of sensors such as thermometers and infrared detectors placed in the home environment, embedded in furniture such as mattresses, or worn by older adults (Demiris & Hensel, 2008; Reeder et al., 2013). The benefits of technology-supported aging-in-place interventions include increased physical activity level, higher cognitive function level, improved quality of life, reduced hospital admission, and enhanced perceived security (Reeder et al., 2013).

2.3. Wearable Devices

A ubiquitous health system is a collection of wearable sensors that monitors health (Pantelopoulos & Bourbakis, 2010). This idea of on-body sensors is more commonly referred to as wearable devices for the general public. Wearable devices, however, are different from ubiquitous health systems in that they are frequently used to refer to consumer-grade off-the-shelf devices (Motti & Caine, 2016). Although many terms loosely define varying types of sensor technologies, for the purpose of this dissertation, they will be referred to as wearable devices. Wearable devices are defined as portable integrated electronic and computing technologies that are wearable or attachable on the body or clothes and collect some form of data (Office of the Privacy Commissioner of Canada, 2014).

Wearable devices can be categorized into medical-grade devices and consumer-grade off-the-shelf devices. Medical-grade wearable devices, according to the Food and Drug Administration of the U.S under the Food, Drug and Cosmetic Act, are the devices that received government approval for their accuracy and validity, and for their use for diagnosis and treatment (U.S. Food and Drug Administration, 2015). On the other hand, consumer level wearable devices can be used for weight management, physical fitness, stress management, mental acuity, sleep management and other general wellness (U.S. Food and Drug Administration, 2015). In 2019, Health Canada announced the guiding document for software for medical devices, where a similar distinction is made for wearable devices based on the purpose of the software (Health Canada, 2019).

Medical-grade and consumer-grade wearable devices differ tremendously in their price range, availability, accuracy and purpose. Medical-grade wearable devices have been commonly used in human kinesiology and kinematic research to analyze gait characteristics (Schwenk et al., 2013) and for physical rehabilitation (Jovanov, Milenkovic, Otto, & Groen, 2005). In recent years, use of sensor technologies has expanded its capability to detect stress level (Martinez-Rodrigo, Roberto Zangroniz, Pastor, & Fernandez-Caballero, 2015; Muaremi, Bexheti, Gravenhorst, Arnrich, & Troster, 2014; Sano & Picard, 2013), mood state (Lanata, Valenza, Nardelli, Gentili, & Scilingo, 2014; Valenza et al., 2014) and convulsive seizure (Poh et al., 2012). These new technologies promise continuous monitoring and early detection for deteriorating mental health and epileptic activities. On the other hand, consumer-grade wearable devices are easily accessible and affordable. Their main purpose is to enhance general wellness, often through increasing self-awareness by monitoring step count, physical activity level, energy expenditure, heart rate, and sleep patterns. In recent years, the line between medical- and consumer-grade wearable devices has blurred. A number of wearable devices that are intended for consumers received the U.S. Food and Drug Administration's *De Novo* clearance for Class II medical device for their capability to monitor blood pressure and to diagnose atrial fibrillation through the built-in electrocardiogram (ECG) sensors (U.S. Food and Drug Administration, 2018a, 2018b).

Consumer-grade off-the-shelf wearable devices have been increasingly adopted by the general public and older adults alike in recent years (Salah, MacIntosh, & Rajakulendran, 2014). It is estimated that one in six U.S. consumers wears a wearable device on a daily basis (Piwek et al., 2016). The greater adoption of wearable devices has also increased their use for research and

clinical uses (Zhu, Colgan, Reddy, & Choe, 2016). Research studies have begun to establish the validity and reliability of data from consumer-grade wearable devices (Evenson et al., 2015; Shcherbina et al., 2017). These studies have reported comparable reliability to gold standard measures that are frequently used in the laboratory and the clinical settings for measuring step count, sleep quality, and heart rate (Evenson et al., 2015; Shcherbina et al., 2017; Wang et al., 2016). Further validation studies demonstrated a high agreement between consumer-grade and medical-grade devices among specific populations including chronic obstructive pulmonary disease (COPD) patients (Vooijs et al., 2014), pediatric patients (Gardner, Voss, Dean, & Harris, 2016), intensive care unit (ICU) patients (Kroll, Boyd, & Maslove, 2016), and cardiac rehabilitation patients (Alharbi, Bauman, Neubeck, & Gallagher, 2016). Furthermore, consumer-grade wearable devices demonstrated high acceptability among older adults (McMahon et al., 2016) and chronic disease patients (Mercer et al., 2016).

2.4. Patient-Generated Health Data

Logging information to address a health concern is not a new phenomenon. Patients have always participated in self-care and logging information such as weight, blood pressure, and blood glucose meter. With the introduction of mobile and wearable devices, the number of people engaged in tracking health-related data via such devices also increased. A recent national survey reported almost 40% of older adults who are 55 years and older self-track health-related data digitally using mobile health (mHealth) apps, consumer-grade wearable devices, and smart medical devices (Paré et al., 2018). As the number of people using such devices has increased in recent years, the volume of data generated and collected has also increased exponentially. These data are termed patient-generated health data with the definition of “*data created, recorded,*

gathered or inferred by or from patients or their designees to help address a health concern” (Shapiro, Johnston, Wald, & Mon, 2012). The potential clinical benefits of patient-generated health data for improving health outcomes and efficiency of health care systems stimulated many actors to initiate foundational work (Kelsey & Cavendish, 2014; Piwek et al., 2016; Shapiro et al., 2012; Swan, 2009).

2.5. Frailty

2.5.1. Definition of Frailty

Frailty is a concept that captures the variability in health status given the same age among individuals (Rockwood, Fox, Stolee, Robertson, & Beattie, 1994). This disassociation between biological and chronological age is observable even when there is no distinguishable physical illness. Reflecting on this phenomenon, frailty is defined as a clinically recognizable biological state of increased vulnerability that puts an individual at higher risk for adverse health outcomes (Clegg, Young, Iliffe, Olde Rikkert, & Rockwood, 2013; Xue, 2011).

2.5.2. Theoretical Frameworks

Frailty can be viewed from different perspectives. One approach to view frailty focuses on physiologic and phenotypic characteristics. This theoretical approach, known as the *phenotype model*, defines frailty as a biologic syndrome where there is a decline of the physiologic reserve due to the accumulation of stressors across multiple physiological systems (Fried et al., 2001). The phenotype model allows the identification of biological and physiological markers of frailty. This view is more compatible with the idea that frailty is a clinical concept (Fried et al., 2001). Figure 2.1 depicts the cycle of frailty, which consists of core clinical signs, including sarcopenia,

strength, walking speed, exhaustion, and low energy expenditure (Fried et al., 2001). This cycle highlights the impact of aging, disease, and undernutrition on sarcopenia, which decreases resting metabolic rate, strength and power, and maximal oxygen uptake volume. They can negatively affect walking speed, which subsequently lead to a decreased activity level. These factors cause a decrease in total energy expenditure. Decreased total energy expenditure, along with the aging-related reduction in caloric intake, can lead to chronic undernutrition. The cycle completes as chronic undernutrition instigates further sarcopenia. From this model, the Fried Frailty Scale was developed (Fried et al., 2001). The phenotype model and the Fried Frailty Scale have been validated to successfully capture the relationship between frailty and increased mortality, hospitalization, and disabilities among frail older adults (Fried et al., 2001). Other independent studies further validated the phenotype model (Guilley et al., 2008; Sourial et al., 2010). This model is significant in that it provides an easy and feasible method to screen for frailty in routine care (Clegg et al., 2013). However, this theoretical model has been criticized for neglecting other potential factors for frailty such as cognitive and social aspects (Rothman, Leo-Summers, & Gill, 2008).

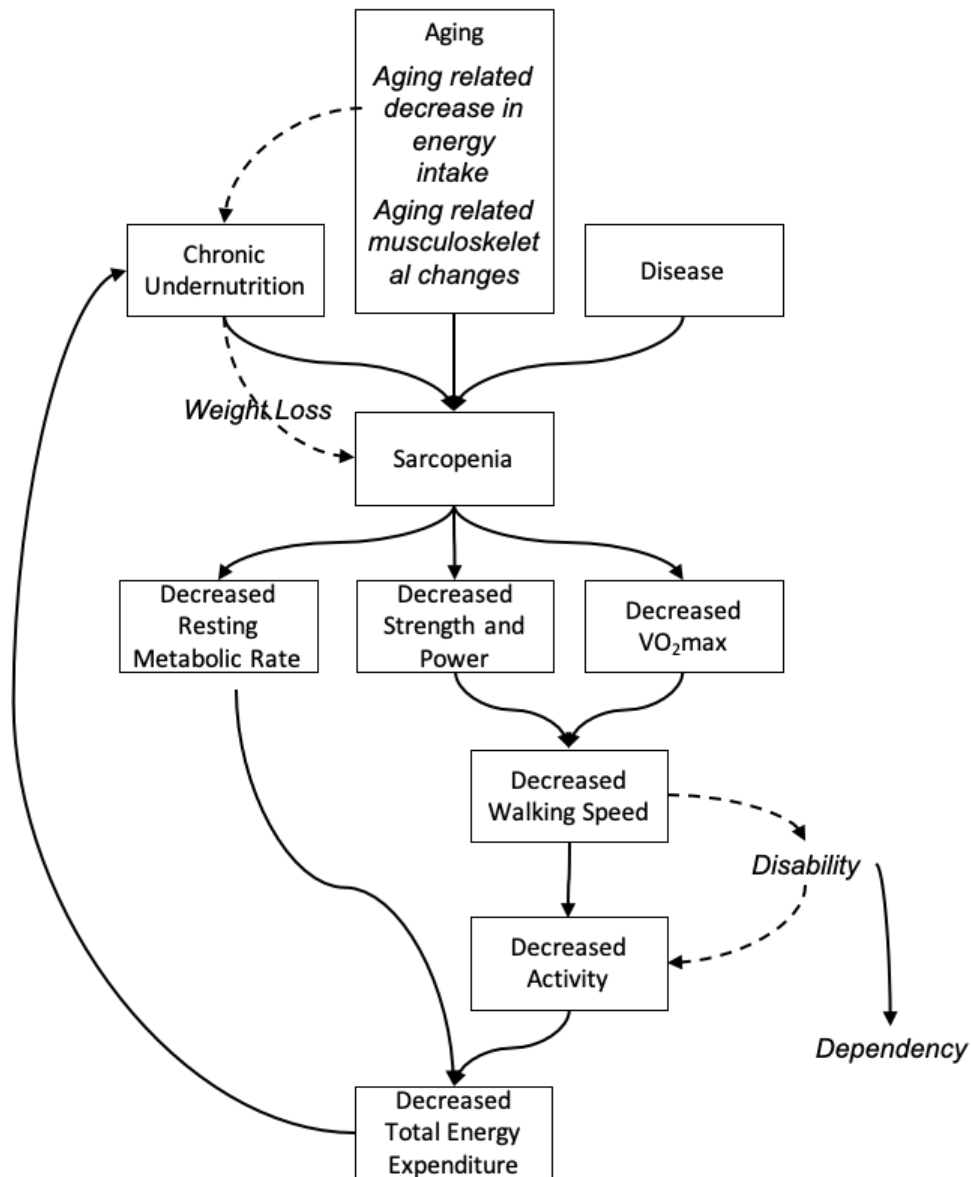


Figure 2.1. The cycle of phenotypic characteristics of frailty

The accumulation of deficits model is another model of frailty (Mitnitski, Mogilner, & Rockwood, 2001). It defines frailty as an accumulation of deficits, but rather than examining the core clinical markers, it statistically analyzes the proportion of deficits that an individual can have out of the total variables assessed. The concept of deficit was derived from the view of frailty that emphasizes the dynamic balancing between assets and deficits (Rockwood et al.,

1994). Health deficits should be associated with health status, increase with age but not suffer from a ceiling effect with age, and are inclusive of multiple aspects of health (Searle, Mitnitski, Gahbauer, Gill, & Rockwood, 2008). To calculate the frailty index, one divides the number of deficits observed by the total number of deficit variables. For example, if an individual has 40 out of 92 deficit variables, the score would be $40/92=0.43$. The number of deficits varies between studies, but 30 to 40 variables are considered sufficient to estimate adverse health outcomes (Searle et al., 2008). Moreover, the maximum frailty index score is not 1.0, but rather around 0.65 as demonstrated in a study that used 40-item frailty index (Rockwood & Mitnitski, 2006). This study showed that 99% of the study population is accounted for when the frailty index of 0.65 is reached. The main advantage of this model is that it can express frailty in gradation with a mathematical basis, which aligns with the theoretical perspective that frailty is a progressive accumulation of deficits. This model can also better identify, in mathematical form, the precarious threshold where an individual can no longer sustain additional deficits (Rockwood & Mitnitski, 2006). Its mathematical nature often cause unpopularity among clinicians (Dent, Kowal, & Hoogendijk, 2016). This is changing in recent years as the tool is being integrated into EMR systems, making it time-efficient (Clegg et al., 2016). Another limitation of this model is its heavy reliance on deficit information that are often not available readily in settings such as critical care (Pugh et al., 2018). It increases the reliance on proxy for obtaining information and a lack of proxy often results in the incomplete frailty assessment (Pugh et al., 2018). To overcome this challenge, a tool that solely relies on the clinical judgment was developed and has demonstrated its validity against the frailty index (Rockwood et al., 2005).

2.5.3. Challenges with Assessing Frailty

Assessing frailty and implementing a routine screening practice have been lagging in the Canadian health care system. The challenges of incorporating frailty assessments are complex and multifaceted. In primary care settings, frailty screening is difficult as the manifestation of frailty is frequently dismissed as normal aging due to the high resemblance to normal aging, subtle onset, and slow progress (L. Lee et al., 2015). Family physicians mostly have closest relationships with patients and should be best equipped to identify frailty. A challenge that is not unique to primary care is the lack of appropriate or feasible tools. Frailty assessment tools that rely on performance such as the Fried scale requires walking and hand gripping; tools that rely on self-report are not feasible for people with functional or cognitive impairments (Muscedere et al., 2016). Similarly, the comprehensive geriatric assessment (CGA) is an accepted and validated tool to measure frailty in long-term care facilities but the limited number of specialists hinders its feasibility for widespread use (Muscedere et al., 2016). Assessing frailty in critical care settings has its own challenges. Pre-critical illness frailty level is important information to determine and direct tailored medical treatments, but this has not been studied (Muscedere et al., 2016). Available tools such as the frailty index are too resource-intensive and performance-based tools are often not feasible in this setting and with this population. Furthermore, there is a knowledge gap in what specialized care is appropriate for frail patients, which further hampers incentivizing frailty assessment. These challenges with frailty assessment are well-acknowledged within the scientific communities of many disciplines and efforts have been made to find consensus on tools and standards to use (Kelaiditi et al., 2013; Rodríguez-Mañas et al., 2013). It is also recognized that no single tool can be used across all healthcare sectors (Muscedere et al., 2016), and, hence, novel ways to assess frailty need further exploration.

2.5.4. Transitions in Frailty States

The challenges with assessing frailty and the lack of tools that are sensitive to detect changes in frailty status have slowed down the study of frailty transitions. Gill and colleagues (Gill et al., 2006) monitored community-dwelling older adults for 54 months with frailty assessed every 18 months. This study reported that frailty improves extremely infrequently once an individual progresses into the most-frail state while transitions between non-frail and pre-frail state were frequent occurrences. Another study that monitored community-dwelling older adults for 48 months with 24-month frailty screening intervals examined the factors associated with the transitions of frailty states (J Lee, Auyeung, Leung, Kwok, & Woo, 2014). This study identified that men are more likely to decline in frailty status than women. Hospitalization, older age, previous stroke, lower cognitive function, diabetes, and osteoarthritis were associated with a negative transition of frailty status while high socioeconomic status was protective (Lee et al., 2014). However, evidence suggests a transition of frailty status may occur more frequently among pre-frail patients (Gill et al., 2006). Studies that examined the state of disability and independence reported frequent transitions occur at as short as monthly intervals (Gill & Kurland, 2003; Hardy, Dubin, Holford, & Gill, 2005). However, it is unknown whether the currently available frailty assessment tools are sensitive enough to detect changes in shorter intervals (de Vries et al., 2011).

2.6. Wearable Devices for Assessing Frailty

2.6.1. *Physical Activity and Frailty*

Technologies have been explored to objectively measure criteria for frailty including gait characteristics, physical activity level and step count (Chang, Lin, Chen, & Lee, 2011; Chen et al., 2015; Dasenbrock et al., 2016; Schwenk et al., 2013, 2015; Song et al., 2015; Theou et al., 2012). Technologies involved in these studies varied. Sensors such as electronic walkways, camera systems, and force plates were used to analyze gait characteristics (Schwenk et al., 2013, 2015). Tri-axial accelerometers were used in a research study to measure physical activity levels, step count, and sedentariness in free-living environments (Chen et al., 2015; Schwenk et al., 2015; Song et al., 2015; Theou et al., 2012). Gait parameters such as gait speed, variability, stride lengths, and cadence demonstrated a high discrimination power between frailty levels. Frailty level was highly correlated with the level of physical activity measures including step count, walking bout duration, and energy expenditure for community-dwelling older adults (Theou et al., 2012) and critical illness survivors (McNelly et al., 2016). A sedentary lifestyle was reported to be a risk factor for frailty for older adults (Song et al., 2015).

2.6.2. *Heart Rate and Frailty*

Heart rate variability (HRV) is a measure of fluctuations in the interval between regular heartbeats. Having a diminished fluctuation in heart rate may indicate a disrupted homeostatic balance among complex regulatory systems, which may be a surrogate marker for frailty (Chaves et al., 2008). Chaves and colleagues (2008) examined this hypothesis using a two-channel ECG and reported community-dwelling older adults with a lower HRV had a high likelihood of being frail. Another study that examined older women also reported a high correlation between frailty

and HRV (Varadhan et al., 2009). However, long-term continuous ECG monitoring is often not feasible as ECG monitors are too bulky and uncomfortable for long-term wear. Moreover, no consumer wearable devices could monitor ECG up until very recently.

Monitoring HRV was not possible but wearable devices are capable of measuring heart rate. No study to date has examined the relationship between wearable device-measured longitudinal heart rate data and frailty. However, one study that examined 10-second recordings of heart rate of older adults identified that higher resting heart rate was associated with a higher body mass index (BMI), a higher prevalence of diabetes, and current smoking (Ogliari et al., 2015). Frailty and disability as measured by an activities of daily living (ADL) score are closely related concepts and highly associated with each other (Fried, Ferrucci, Darer, Williamson, & Anderson, 2004). Another way to use heart rate data is to supplement the accelerometry data to better understand the physical activity level and sedentariness. Theou and colleagues (2012) used a research-grade wearable device to capture heart rate among community-dwelling older adults and defined sedentariness as the bottom 20% of heart rate reserve. Unfortunately, this approach to measure physical activity and sedentariness levels was not correlated with the physical activity level measured by electromyography, global positioning system (GPS), and the Minnesota Leisure Time Activity Questionnaire (MLTAQ) (Theou et al., 2012). To date, this is the only study that utilized heart rate measured by a wearable device to assess frailty.

2.6.3. Sleep Quality and Frailty

Sleep quality is a measure that is not included in many frailty assessment tools but the relationship between poor subjective sleep quality and frailty has been reported to be significant

(Del Brutto et al., 2016; Ensrud et al., 2012; Nobrega, Maciel, de Almeida Holanda, Oliveira Guerra, & Araujo, 2014). Such a significant relationship was found for institutionalized older adults (Nobrega et al., 2014) and community-dwelling older adults (Del Brutto et al., 2016; Ensrud et al., 2012). In recent years, polysomnography and actigraphy have been used to objectively measure sleep quality and confirmed the association with frailty (Ensrud et al., 2009; Kim et al., 2015). Using such technologies to measure sleep quality resulted in a detailed breakdown of sleep quality measures including total sleep time, nocturnal awakenings, sleep efficiency, and sleep latency (Kim et al., 2015). These sleep quality measures identified more granular details of the relationship between sleep and frailty. While poor sleep efficiency and frequent and long duration of nocturnal awakenings have been associated with frailty, short total sleep time and prolonged sleep latency were not (Ensrud et al., 2012; M. Kim et al., 2015). Only a few research studies have examined the relationship between frailty and sleep quality, requiring cautious interpretation and more research to validate these findings.

Chapter 3. White Paper: Mobile & Sensor Technology, Big Data and Artificial Intelligence for Healthy Aging

Kim, B. & Lee, J. (2018, October). White Paper: Mobile & Sensor Technology, Big Data and Artificial Intelligence for Healthy Aging. Paper presented at the AGE-WELL's 4th Annual Conference: Innovation in Action. Vancouver, Canada. Retrieved from <https://bit.ly/3heSDBv>

This chapter includes a white paper submitted and presented at the AGE-WELL's 4th Annual Conference: Innovation in Action. This white paper was developed with the audience in mind, consisting of older adults, caregivers, clinicians, researchers, and industry representatives. The white paper summarizes the important concepts associated with mobile health, wearable devices, and patient-generated health data including big data, machine learning, and artificial intelligence. As the purpose of the white paper was to convey these scientific terms to non-domain experts, they were supplemented by real-life examples both in and outside of health care. These examples highlight the underlying technology and mathematical approaches.

Since the white paper was presented, the understanding and the reception of the term personal sensing and patient-generated health data have evolved. The term personal sensing was used to encompass all data captured by sensor technology as well as health-related data (white paper page 5; Table 3.1). Correction should be made to have patient-generated health data as the umbrella term that encompasses sensor data as well as patient recorded data. The evolved understanding of these concepts is based on the definition of patient-generated health data as inclusive of all data created by patients or family members to address a health concern (Shapiro et al., 2012). It was decided to present the original white paper presented at the conference

without revising these terms to reflect the rapidly evolving nature of the topic of patient-generated health data.

3.1. Introduction

We live in a world where more people own a mobile device than own a toothbrush. Mobile devices such as smartphones and wearable devices are packed with sensors as simple as a compass to state-of-the-art biometric scanners such as fingerprint and iris scanners. The ubiquitous nature of mobile devices and rapid advancements in sensor technology have shifted their primary use from communication to information gathering and sharing. Various sensors on mobile devices can collect data on location, orientation and direction, altitude, and many more. These powerful and abundant tools are changing how researchers observe and conduct research studies, how clinicians deliver healthcare, and how we come to understand our health and well-being. In this report, we provide you with the latest development amongst researchers and clinicians on mHealth, big data, and artificial intelligence. We will give examples of what is currently possible and what the future holds for the health of older adults and aging, in particular.

3.2. Mobile Health

mHealth is a term that describes the use of mobile devices to support medical and health practice (World Health Organization, 2011). mHealth is a very broad concept. mHealth systems can be as simple as an app on smartphones for educational purposes and it can also be a complex system where doctors monitor vital signs and symptoms in real time to update prescription medications. We habitually link mHealth and smartphones, tablets, and laptops, but it is not limited to these devices.

Wearable devices are devices that are designed to be worn and equipped with multiple sensors (Mohr, Zhang, & Schueller, 2017). They are made small and discrete, and used for health and

fitness. Many of us are familiar with wearable devices such as activity trackers and smart watches but there are also smart clothes, smart shoes, smart glasses and so on. The term wearables is most frequently used to refer to consumer-level devices such as Fitbit and Apple Watch, but they are sometimes used to refer to medical devices. We will be referring to them as consumer-grade wearable devices.

Smartphones and wearable devices are closely integrated to each other. Most wearable devices are developed to work together with smartphones to show graphs of, for example, physical activity level over a week. Wearable device data can be viewed through ‘apps’ in most cases.

Sometimes, the apps ask for additional information. For example, they ask to record how we felt when we woke up on the phone. It asks to record blood pressure in the morning, blood sugar level before and after a meal, or symptoms of chronic conditions. Such health data is collected by patients. They are called patient-generated health data (Wood, Bennett, & Basch, 2015). They need us to measure and record the data on a smartphone, which are often shared with doctors and clinicians.

Combination of multiple data – one measured automatically by sensors on wearable devices and the other reported by you, patient-generated health data, can tell clinicians a more complete picture of your health than either one alone.

mHealth and wearable devices open new possibilities for researchers. They are minimally obtrusive and can be worn for a long period of time. They can collect data continuously,

repeatedly over time, and frequently. Researchers can use wearable devices to measure participants and their behaviours outside laboratory settings. Researchers can observe patterns of human behaviours in real world with the level of details that was never possible. This is different from how human research studies are commonly conducted. Conventionally, researchers relied on participants' memory and honesty to understand behaviour patterns such as their physical activity level. Researchers could only assess participants periodically.

mHealth and wearable devices offer a new way of measuring human behaviours and individual health and wellbeing with unprecedented level of details. As such, we need a new way of making sense of the vast amount of data and information to understand what its implications to healthy aging.

3.3. Personal Sensing

Making sense of vast amount of data from smartphones and services, sensors on wearable devices, and other sources to evaluate human behaviours is called personal sensing (Mohr et al., 2017). It is often called reality mining, personal informatics or digital phenotyping.

Personal sensing is, in a way, a method to make sense of a large amount of data from mHealth and wearable devices. Personal sensing is unique in that it can use both health and non-health-related data to provide insight into human behaviours. These health and non-health data include a variety of sensor data, patient-generated health data, and other data from different sources (Table 3.1).

Table 3.1. Sources and types of data potentially useful for research and clinical practice

Data sources	Data type
Sensor – passive	Accelerometry Heart rate Temperature UV exposure Geolocation Noise level
Sensor – active	Weight Blood pressure Blood glucose level
Patient-generated health data	Diet Mood/stress level Symptoms Medications Behaviours – Tobacco/alcohol consumption
Others	Social connectedness – Phone logs, texts, social media Financial data

3.4. Data to Knowledge

A data to knowledge sensemaking framework is a visual representation of the data, information, and knowledge cycle (Figure 3.1). It shows how raw data is processed to information, then to knowledge that can be used by researchers and clinicians.

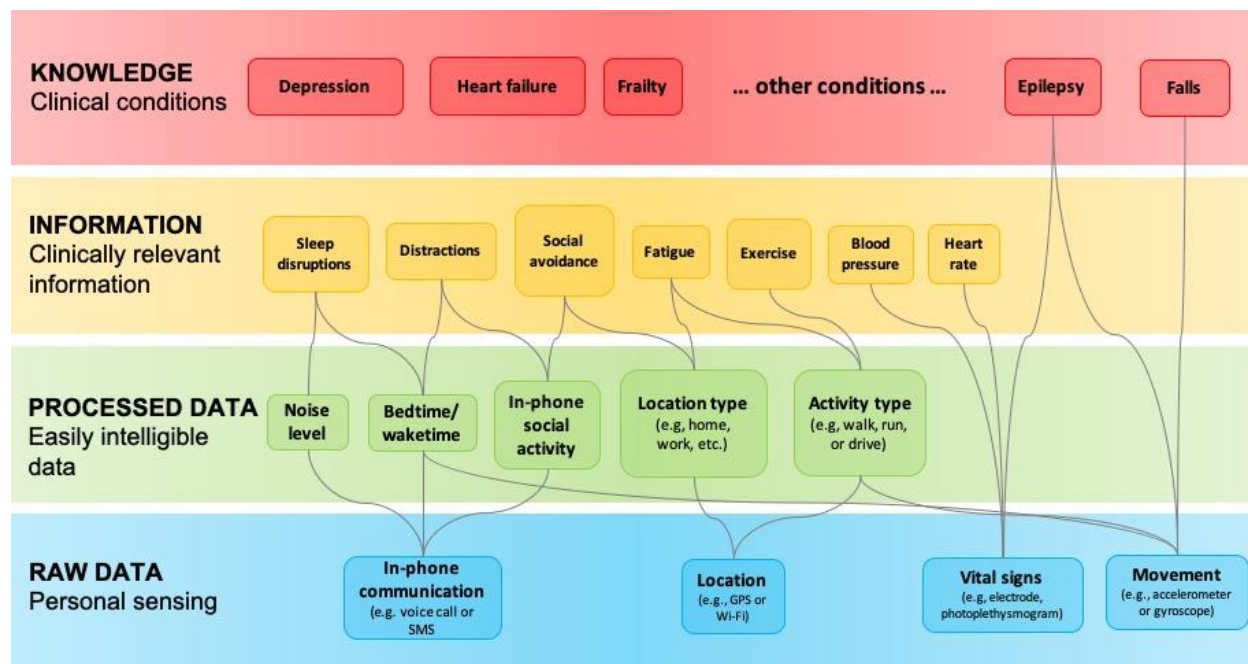


Figure 3.1. Data to knowledge sensemaking framework with examples of personal sensing

The cycle of data to knowledge begins with raw data. Raw data is generated by sensors on mobile phones and wearable device. Sensor data are often incomprehensible and meaningless. For example, GPS on the phone gets latitudinal and longitudinal coordinates. They are simply two numbers that are not clinically relevant.

Raw data is processed to become understandable information. This initial processing is often done by applying mathematical algorithms or by combining with other data. For example, GPS coordinates can be put on a map which can tell us information about the location.

Processed data are often not clinically meaningful. They require further processing to become clinically relevant information. For example, processed GPS can tell us whether the person was at home, work, gym, restaurant, and so on. Accelerometer sensor data measures physical activity

level. Combining two information sources more accurately distinguishes between gym exercise and other physical activities outside the gym for example.

Clinically relevant information can help clinicians identify and evaluate clinical conditions. For example, sleep duration, disturbances, social avoidance, depressed mood, and stress level may be able to tell the severity of depression. Such information can help clinicians design treatment plans that are customized and personalized.

Sense-making framework helps us visualize the journey of raw data that gets processed to become clinically meaningful information, which can be used by clinicians to evaluate and understand clinical conditions. Next, we will describe how data are processed to become meaningful information.

3.5. Artificial Intelligence, Machine Learning, Deep Learning, and Big Data in Healthcare

Artificial intelligence, machine learning, deep learning, big data; we will briefly describe each, current uses in our lives and in healthcare, and the future they hold.

We have seen examples of artificial intelligence (AI) in movies: C3PO and R2D2 in Star Wars. They are fictional examples of general AI. General AI possess human like characteristics such as senses, cognition, and intelligence. We have yet to achieve this level of AI in the modern world.

However, we have developed very good narrow AI. Narrow AI is an intelligence in a very focused topic. One example is handwriting recognition on letters by postal offices. How does a

computer read handwriting when everyone has different writing patterns and penmanship? What happens when they are very poorly written and illegible? Where does this intelligence come from?

Machine learning and deep learning are the answers to the question. They can examine a set of data, learn patterns, and make predictions. It is different from traditional programs, which operate based on explicit rules and defined parameters. For the example of mailing address, a machine learning algorithm examines a set of handwritten mailing addresses, learns different ways people write letters, and makes a very accurate prediction of each letter of handwritten mailing address. Machines need hundred thousands, if not millions, of examples of different hand writings before it can almost always correctly identify mailing addresses. A large dataset that has millions of examples, often called big data, is an essential ingredient for successful artificial intelligence.

Big data is defined as a vast amount of data that is ever increasing in its size, very complex, and most importantly, adds value to the intended use (Demchenko, Grosso, De Laat, & Membrey, 2013). Wearable device data is one example. Wearable devices generate enormous amounts of data. The data are increasing in their size at a very fast rate. Wearable devices data are getting more complex as more sensors are used. In recent years, the term big data analytics is frequently used to imply machine learning and deep learning methods that help us process a large amount of data into meaningful information. These terms are increasingly used interchangeably, blurring the original definitions.

3.6. Machine Learning and Wearable Devices

In a very similar way a postal office system can learn hand writings from millions of examples and read mailing addresses automatically, wearable devices recognize when you walk, run, sleep, swim, golf, and so on (Kamada, Shiroma, Harris, & Lee, 2016).

An accelerometer is a sensor embedded in wearable devices that measures movements in three directions: up and down, backwards and forward, and side by side. An accelerometer records your wrist movements in different directions every second. Imagine the pattern of your wrist movement when you walk. It creates a similar pattern for every cadence. A machine learning algorithm is used on a large dataset collected from people's wrist movement while they walk. A machine learning algorithm will learn the pattern and when next time a similar pattern is made, it will know that you took a step.

Similarly, machine learning is used to measure sleep duration and quality. Our nerve systems go through different phases while we sleep, which creates unique patterns of body movements. Certain patterns of body movements are associated with deep sleep stage. Machine learning algorithms learn body movement patterns and are able to determine your sleep quality.

Machine learning, coupled with wearable devices have opened a wide array of new possibilities for clinicians and researchers. A few examples that are currently available and being researched include detecting fall incidents (Chaudhuri, Thompson, & Demiris, 2014), detecting seizure episodes (Johansson, Malmgren, & Alt Murphy, 2018), emotional arousal (i.e. stress level and

mood swings) (Di Lascio, Gashi, & Santini, 2018), and nutritional intake (Vu, Lin, Alshurafa, & Xu, 2017).

mHealth is a source of big health and wellness data. Research studies have only begun to scratch the surface of its potential uses with powerful machine learning algorithms. It can drastically change how we access health care at home and in the community. It also holds unimaginable promise for future of health care.

3.7. Machine Learning in Current and Future Health Care

Artificial intelligence is embedded in many aspects of health care and it holds enormous potential for future. It is not immediately clear to most of us where in health care and how machine learning and artificial intelligence are currently used. They are used in a very broad range of health care services and research areas such as medical imaging, critical care, oncology, and many others. We will provide examples of current uses as well as the most cutting-edge research studies that hold great promise.

3.7.1. Example 1: Predicting patient outcomes in ICU

One area where machine learning plays a large role is in ICUs (Sharafoddini et al., 2017). ICU physicians are faced with difficult clinical decisions such as which patients require longer ICU stay or can they be moved to regular hospital beds; which patients can tolerate and benefit from invasive treatments; which patients will develop complications from treatments and so on.

Predicting these outcomes are very important to patients and family members to make informed decisions for their treatments. ICU stays are extremely expensive and accurate predictions on

medical outcomes can help manage resource efficiently. These medical outcome predictions can be made based on thousands of patient records using machine learning and such information guides physicians, patients and family, and hospital administrators to make accurate decisions.

3.7.2. Example 2: A.I. – Making diagnosis

One research study examined close to 100,000 images of retinas (i.e. eyes) of diabetic patients who suffer from retinopathy which can lead to blindness (Gulshan et al., 2016). Using deep learning methods, the program learned the patterns within the images of retinas. When it was tested with new images, it was able to determine retinopathy at 99% accuracy.

Using a neural network - a type of machine learning method – a system learned over 120,000 images of skin cancer (Esteva et al., 2017). This system could tell differences between the most common type of skin cancer from the deadliest form of skin cancer. This system can make a diagnosis as accurate as 21 trained dermatologists. This study is especially remarkable as the service can be provided to the public, using smartphone apps.

3.7.3. Example 3: Finding effective drugs just for you with machine learning

Drugs are developed meticulously and they go through rigorous testing for their safety and effectiveness. One downside of this is that many times, they are only tested on a group of people who are very similar biologically and physiologically. This raises a question: how will a drug work for a 90-year-old individual when it was only tested for, for example, 40 to 65-year-old individuals? With machine learning, we can examine previous effects of the drug on patients who have very similar characteristics as you. In this case, machine learning determines the group

of individuals who have similar characteristics as you (Ding, Takigawa, Mamitsuka, & Zhu, 2013).

3.8. Conclusion

We have summarized the current state of mobile and wearable technology, big data, machine learning and artificial intelligence for healthy aging. The field of mHealth is undergoing a revolutionary change. Sensor technology has greatly advanced recently, and it has introduced wearable devices as a new tool to collect a large amount of patient-generated health data. Machine learning and deep learning enable the interpretation of big data generated from them, allowing us to understand human behaviours in a whole different way. We have also examined the current research studies that attempt to bridge these new technologies into healthy aging. The potential for technology is immense but unrealized. Collaborative efforts by all stakeholders, including patients, caregivers, clinicians, researchers, and policymakers are warranted to reach a future where we can fully leverage the benefits of these technologies for healthy aging.

Chapter 4. Predicting frailty with a consumer-grade wearable device in

Canadian home care clients: A proof-of-concept study

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4.1. Chapter Overview

Background: Frailty has detrimental health impacts on older home care clients and is associated with increased hospitalization and long-term care admission. The prevalence of frailty among home care clients is poorly understood and ranges from 4.0% to 59.1%. Although frailty screening tools exist, their inconsistent use in practice calls for more innovative and easier-to-use tools. Owing to increases in the capacity of wearable devices, as well as in technology literacy and adoption in Canadian older adults, wearable devices are emerging as a viable tool to assess frailty in this population.

Objective: The objective of this study is to prove the concept of using a wearable device for assessing frailty for older home care clients.

Methods: We recruited home care clients from June 2018 to September 2019 aged 55 years and older to be monitored over a minimum of 8 days using a wearable device. Detailed sociodemographic information, and patient assessments including degree of comorbidity and

activities of daily living were collected. Frailty was measured using the Fried Frailty Index. Data collected from the wearable device was used to derive variables including daily step count, total sleep time, deep sleep time, light sleep time, awake time, sleep quality, heart rate, and heart rate standard deviation. Using both wearable and conventional assessment data, multiple logistic regression models were fitted via a sequential stepwise feature selection method to predict frailty.

Results: A total of 37 older home care clients completed the study. The mean age was 82.27 (SD: 10.84) years and 75.68% were female. Thirteen participants were frail, significantly older ($p < 0.01$), utilized more homecare service ($p = 0.012$), walked less ($p = 0.04$), slept longer ($p = 0.01$) and had longer deep sleep time ($p < 0.01$). Total sleep time ($r = 0.41$, $p = 0.012$) and deep sleep time ($r = 0.53$, $p < 0.01$) were moderately correlated with the frailty. The logistic regression model fitted with deep sleep time, step count, age, and education level yielded the best predictive performance with an AUC of 0.90 (Hosmer-Lemeshow $p = 0.88$).

Conclusions: We proved the concept of using a wearable device to assess frailty for older home care clients. Wearable data complemented the existing assessments and enhanced predictive power. Wearable technology can be used to identify vulnerable older adults who may benefit from additional home care services.

Keywords: frailty, wearable device, home care

4.2. Introduction

Frailty has detrimental health impacts among community-dwelling older adults. Frailty is associated with higher mortality (Campitelli et al., 2016; Fried et al., 2001; Shamliyan, Talley,

Ramakrishnan, & Kane, 2013), functional impairment (Fried et al., 2004; Vermeulen, Neyens, van Rossum, Spreeuwenberg, & de Witte, 2011), hospitalization (Campitelli et al., 2016; Shamliyan et al., 2013), long term care facility admission (Campitelli et al., 2016) and disability in activities of daily living (ADL) (Vermeulen et al., 2011). Frailty also increases the demand on formal and informal caregivers including home and community care services and family members (Sinha, 2012). A recent study identified that caregiver burden can be predicted based on the physical frailty level of geriatric patients (Ringer et al., 2016). Due to its significant impact on health outcomes and its burden on healthcare systems, improved screening and monitoring of frailty for community-dwelling older adults is deemed vital (Muscedere et al., 2016).

The prevalence of frailty among community-dwelling older adults is poorly understood. A systematic review reported that frailty prevalence ranges between 4.0% and 59.1% (Collard, Boter, Schoevers, & Oude Voshaar, 2012). Varying operational definitions and the heterogeneity of tools used in the studies resulted in a wide range of estimates. However, the prevalence range narrows to 4.0% to 17.0% when only the prevalence of physical phenotype frailty is aggregated, excluding social or cognitive deficits (Collard et al., 2012).

Home and community healthcare is challenged with increased demand, primarily due to the aging population and emphasis on aging-in-place (Keefe, 2011). The demand for home and community healthcare service is expected to continue to rise in an effort to keep patients in their community to reduce health care costs (Canadian Home Care Association, 2008). Screening and monitoring frailty in this population can benefit the home and community healthcare sector in

multiple ways. Effective frailty intervention programs involve lifestyle changes including improving nutritional status, increasing physical activity, and home environment modifications (Puts et al., 2017). Home and community healthcare clinicians are uniquely situated to deliver and monitor such interventions in a longitudinal manner, which can contribute to successful lifestyle changes. Screening for frailty at the community level can also help the home and community healthcare sector to identify vulnerable groups and allocate resources more efficiently.

Tools to screen community-dwelling older adults for frailty exist, but they have been used inconsistently and are often impractical or invalidated (Dwyer, Gahche, Weiler, & Arensberg, 2019). Wearable devices have been suggested as a potential tool to monitor frailty and a few research studies have explored this possibility (Mohler, Wendel, Taylor-Piliae, Toosizadeh, & Najafi, 2016; Parvaneh, Mohler, Toosizadeh, Grewal, & Najafi, 2017; Razjouyan et al., 2018; Rumer, Saraswathula, & Melcher, 2016). These studies explored the feasibility of using research-grade wearable devices such as ActiGraph or independently developed wearable devices. These studies provide evidence for the internal construct validity of research-grade wearable devices to screen for frailty (Chen et al., 2015), as well as a strong association between varying sleep quality parameters and frailty (Ensrud et al., 2009; Nobrega et al., 2014; Vaz Fragoso, Gahbauer, Van Ness, & Gill, 2009). Consumer-grade wearable devices are a promising tool to monitor frailty as they have become smaller, cheaper, and ever more accessible in recent years (Baig, Afifi, GholamHosseini, & Mirza, 2019), with older adults being the fastest growing group of wearable device users (“Older Americans Drive Growth of Wearables,” 2018). Research studies have demonstrated the reliability of these devices for measuring step count,

sleep quality, and heart rate compared to gold standard measures that are frequently used in laboratory and clinical settings (Evenson et al., 2015; Shcherbina et al., 2017; Wang et al., 2016). Further validation studies demonstrated a high agreement between consumer-grade and medical-grade devices among specific populations, including chronic obstructive pulmonary disease patients (Vooijs et al., 2014), pediatric patients (Gardner et al., 2016), intensive care unit patients (Kroll et al., 2016), and cardiac rehabilitation patients (Alharbi et al., 2016).

Recognizing the need for an innovative solution to measure frailty for community-dwelling older adults, we set out to investigate the possibility of using consumer-grade wearable devices. We examined the data generated from a wearable device worn by home care clients to identify associations with frailty. We also aimed to identify key wearable device measures that can predict the status of frailty. In the following Methods section, a description of the study procedure, tools, and statistical analysis used are described. The results of the study are presented, followed by the Discussion section where new findings are interpreted and compared to existing knowledge. Discussions are made about the implications on frailty research studies, wearable device research studies, and home and community health care sector, and the limitations of the study are presented.

4.3. Methods

4.3.1. Study Design

A prospective observational study was conducted to meet the study objectives. Participants were asked to wear a wearable device for a minimum of 8 days with details of the device described in

Section 4.3.3. At the end of the study, participants were assessed for frailty, ADL, and the level of comorbidity.

4.3.2. Recruitment

Home care clients in the Greater Toronto Area were recruited through VHA Home Healthcare from August 2018 to September 2019. VHA Home Healthcare is a home care agency that serves over 3,000 clients throughout the Greater Toronto Area and other metropolitan areas in Ontario, Canada. Patients 55 years or older who had been receiving personal support service for more than 3 months were eligible for the study. Patients who were diagnosed with primary neuromuscular pathology, dependent on wheelchair, in an end-of-life program, or had cognitive impairments that could interfere with the use of wearable devices were excluded. Eligible home care patients were identified using VHA's electronic medical record (EMR) system.

4.3.3. Wearable Device

The Xiaomi Mi Band Pulse 1S (Mi Band hereafter) is a commercially available wearable device that is worn on the wrist. It uses a tri-axial accelerometer to monitor motions to approximate step counts and sleep events. It is equipped with an optical heart rate sensor (i.e. photoplethysmography) to measure minute-by-minute heart rate. While the Mi Band can be worn on either the wrist or neck as a pendant, the placement was limited to the wrist for the study. The reliability and internal consistency of Mi Band's performance for measuring step counts over walking and jogging has been validated (Paradiso, Colino, & Liu, 2020; Ricchio, Lyter-Antonneau, & M. Palao, 2018). Wrist worn wearable devices displayed systematically lower

heart rate during exercise but the Mi band demonstrated the highest accuracy (Ricchio et al., 2018).

We collected daily step count, light sleep time, deep sleep time, total sleep time, awake time, sleep quality, mean heart rate, and heart rate standard deviation (SD). Sleep quality was calculated as the percentage of sleep duration over total sleep time; sleep duration was determined by subtracting awake time from total sleep time (Duncan et al., 2016; Kroll et al., 2017). Minute-by-minute heart rate measurements throughout the study period were used to calculate the mean and standard deviation. A pool of 10 devices were used and sanitized in rotation throughout the study. The compliance to wearing the device was defined as 10 hours or more of wear time per day (Tudor-Locke et al., 2015).

4.3.4. Frailty Assessment

Frailty was assessed using the Fried Frailty Index, a tool that has been built and used widely for community-dwelling older adults (Fried et al., 2001). The Fried Frailty Index assesses phenotypic frailty based on five criteria: weight loss, exhaustion, slowness, weakness, and low physical activity. The index categorizes frailty into three stages based on the number of criteria that has been fulfilled: non-frail, pre-frail, and frail corresponding to scores of 0, 1-2, and 3-5, respectively (Fried et al., 2001). We dichotomized the Fried Frailty Index into a frail group with a score of 3 or higher and a non-frail group with a score of 2 or lower (Fried et al., 2001).

4.3.5. *Other Variables*

Sociodemographic variables were collected using a short background questionnaire and review of the patient's medical chart. Collected information included age, sex, weight, height, ethnicity, level of education, income, and marital status. The degree of comorbidity was assessed using the Charlson Comorbidity Index (CCI) (J. N. Katz et al., 1996). The ADL level was assessed with the Katz index of independence (S. Katz, Downs, Cash, & Grotz, 1970). The number of hours of service received per week was collected from reviewing the patient's medical chart.

4.3.6. *Statistical Analysis*

Descriptive statistics and univariate comparisons of means, medians, and proportions were performed to describe the sociodemographic information and patient assessments according to their frailty status. The level of education was condensed into two levels; high school or below, and post-secondary or higher. Household income was categorized into a lower income group for those earned \$30,000 per year or less, and a higher income group who earned \$30,000 or higher per year. Ethnicity was categorized into two levels: Caucasian and others. Wearable device data were examined for their compliance level and days with less than 10 hours of wear time were excluded. Heart rate measurements of zero were generated when the device failed to have good skin contact. Such measurements were treated as missing and removed from the analyses.

The Shapiro-Wilk normality test was performed to check for normality. When the assumption of normal distribution was met, student's T test was performed while the Mann-Whitney U test was performed otherwise to check for significant differences between frail and non-frail patients. The chi-square test was performed for categorical variables. The post-hoc chi-square test was

performed when more than two levels were present in the chi-square test and a significance was observed.

Pearson and Spearman correlation statistics were used to examine the relationship between frailty, sociodemographic information, patient assessments, and the data collected from the wearable devices.

Multiple variable logistic regression models were generated to predict frailty status. A sequential stepwise feature selection method was used to select the variables to be fitted into the models. The feature selection was used on the pool of sociodemographic and patient assessment variables to determine the features to be included in Model 1. Model 2 was built by applying feature selection to the variables derived from the wearable device data. Models 3 used all available variables for the feature selection method and the selected variables were used to build the logistic regression model. The Hosmer-Lemeshow test was performed to test the goodness-of-fit for each model. The predictive performance of each model was evaluated and compared using the area under the receiver operating characteristic curve (AUC).

Statistical significance was set at $\alpha=0.05$ for all statistical results. The significance level for post-hoc tests were corrected using the Bonferroni method. All statistical analyses were performed using R in the R studio environment (R version 3.6.0, R Studio version 1.2.1335, R Studio, Inc., Boston, MA). Stepwise feature selection method was performed using the stepAIC function from the MASS package (Version 7.3-51.4) (Venables & Ripley, 2002).

4.3.7. Ethics, Consent, and Permissions

This study received ethics clearance from the Office of Research Ethics at the University of Waterloo (ORE22842).

4.4. Results

4.4.1. Recruitment

A total of 72 older adults responded to the mailed recruitment brochure. All 72 older adults were contacted, and 45 of the total contacted older adults agreed to participate in the study. Four participants withdrew before the completion of the 8-day study period. Study suffered data attrition due to technical issues for four participants. In total, 37 older home care clients were included in the study.

4.4.2. Participant Characteristics

Participants were 57 to 96 years of age, with a mean age of 82.23 ± 10.84 years and 75.68% (28/37) were female. The prevalence of frailty among the study population was 35.13% (13/37). On average, participants were observed for 9.43 (1.99) days. Frail participants were significantly older than their non-frail counterparts (mean ages: 83.92 vs. 80.61, $p < 0.01$). The chi-square test identified a significant difference in the income level between frail and non-frail older adults. Post-hoc comparisons within each of the three income levels showed no statistical significance after correcting the alpha level with the Bonferroni method. Frail patients received significantly greater hours of homecare services per week compared to non-frail patients (Table 4.1). The resulting p-values of the Shapiro-Wilk normality tests are presented in Appendix A. The results of group difference tests are presented in Appendix B.

Table 4.1. Baseline sociodemographic and patient characteristics stratified by frailty status (n=37)

	Frail, n=13	Non-frail, n=24	p-value
Age, years (SD)	83.92 (9.66)	80.61 (13.96)	<0.01*
Sex (female), n	10	18	>0.99
BMI, kg/m ² (SD)	26.96 (6.70)	28.54 (5.43)	0.44
ADL score (SD)	4.62 (1.45)	5.08 (0.88)	0.43
CCI score (SD)	1.92 (1.26)	1.25 (1.11)	0.11
Marital status			0.29
Single, n (%)	1 (7.69)	7 (29.17)	
Divorced or separated, n (%)	2 (15.38)	5 (20.83)	
Widowed, n (%)	4 (30.77)	7 (29.17)	
Currently married, n (%)	6 (14.15)	5 (20.83)	
Education			0.12
High school or less, n (%)	8 (61.54)	7 (29.17)	
Post-secondary or higher, n (%)	5 (38.46)	17 (70.83)	
Income			0.025*
Income - Prefer not to answer, n (%)	7 (53.85)	3 (12.50)	0.06 ^a
Low income, n (%)	4 (30.77)	13 (54.17)	0.93 ^a
Mid to high income, n (%)	2 (15.38)	8 (33.33)	>0.99 ^a
Ethnicity			0.71
White, n (%)	10 (76.92)	21 (87.50)	
Others, n (%)	3 (23.08)	3 (12.50)	
Homecare Utilization			
Personal support service, hours per week	5.15 (3.51)	2.77 (1.85)	0.01*

*p<0.05

^a Post-hoc chi-square test

4.4.3. Frailty and Wearable Device Data

The Mann-Whitney U-test and T-test were conducted to find the difference between wearable device data between frail and non-frail participants. On average, older adults wore the device for 20.03 (1.64) hours per day. Home care clients who were living with frailty reported significantly

lower daily step counts than their non-frail counterparts (mean steps per day: 367.11 vs. 1023.95, $p=0.04$). Total sleep time and deep sleep time were significantly longer for frail older adults, but no difference was found for light sleep time (Table 4.2). No difference was found for heart rate measures. Box plots corresponding to Table 4.2 are presented in Appendix C.

Table 4.2. Difference in the data collected from the wearable device between frail and non-frail participants($n=37$)

	Frail (SD), n=13	Not frail (SD), n=24	p-value
Worn time, hours per day	20.66 (1.03)	19.69 (1.82)	0.16
Daily step count, n	367.11 (272.63)	1023.95 (863.83)	0.04*
Deep sleep time, min	138.90 (64.00)	75.65 (39.12)	<0.01*
Light sleep time, min	350.88 (130.56)	312.78 (82.32)	0.35
Total sleep time, min	489.78 (139.54)	388.44 (93.28)	0.01*
Awake time, min	36.03 (24.27)	65.05 (57.97)	0.17
Sleep quality, %	92.48 (5.62)	78.95 (26.53)	0.08
Heart rate, bpm ^a	82.77 (10.25)	77.43 (8.66)	0.13
Heart rate SD, bpm ^a	22.12 (7.61)	18.78 (4.54)	0.17

* $p<0.05$

^a beats per minute

4.4.4. Factors Correlated with Frailty

The correlation between wearable data and frailty is summarized in Table 4.3. Daily step count was negatively correlated with frailty level ($r=-0.52$, $p<0.01$). All five sleep measures were moderately correlated with frailty. Education level was moderately correlated with the frailty status ($r=-0.40$, $p=0.02$). No relationship was found between heart rate measures and the frailty status.

Table 4.3. Correlations between wearable device data, patient characteristics and frailty

	Frailty	
	Correlation coefficient	p-value
Physical activity		
Daily step count	-0.52	<0.01*
Sleep measures		
Total sleep time	0.52	<0.01*
Deep sleep time	0.47	<0.01*
Light sleep time	0.35	0.03*
Sleep quality	0.56	<0.06*
Awake time	-0.54	<0.01*
Heart rate measures		
Average heart rate	0.11	0.54
Heart rate SD	-0.25	0.16
Sociodemographic		
Age	0.29	0.08
Sex	0.074	0.66
BMI	-0.068	0.69
Income level	-0.066	0.74
Education level	-0.40	0.02*
Patient assessments		
ADL score	-0.18	0.27
CCI score	0.16	0.33
Service utilization		
Personal support hours	0.23	0.17

* p<0.05

4.4.5. Frailty Prediction

4.4.5.1. Model description

A total of three multiple logistic regression models were fitted to predict frailty with the sociodemographic variables, patient assessments, and wearable data (Table 4.4). Income was excluded from the feature selection method since a high number of participants declined to answer. Model 1 formulation began by fitting the sociodemographic variables and patient assessments. The feature selection method resulted in a model that contains CCI and education level. Model 2 used variables derived from the wearable device data only. The resulting model

contained step count, deep sleep time, awake time, and heart rate SD. Model 3 used all available variables and the final model ultimately contained deep sleep time, step count, age, and education level.

Table 4.4. Three frailty prediction models and the variables selected by the stepwise feature selection method

Models	Variable pool	Selected variables
Model 1	Sociodemographic and patient assessment variables	CCI +education level
Model 2	Wearable device derived variables	Step count + Deep sleep time + light sleep time + heart rate SD
Model 3	Sociodemographic, patient assessment, and wearable device derived variables	Deep sleep time + step count + age + education level

4.4.5.2. Frailty prediction model evaluation

Table 4.5 shows the results of multiple logistic regression analyses and the factors predictive of frailty. Model 1 showed no significant association. For Model 2, deep sleep time was a significant predictor of frailty ($p < 0.01$). Increasing deep sleep time was significantly associated with increased odds of frailty (AOR 1.02, 95% CI 1.01-1.05, $p < 0.01$). For Model 3, deep sleep time ($p = 0.02$) and age ($p = 0.03$) were two significant predictors. Increasing deep sleep time was associated with an increase in the odds of frailty (AOR 1.03, 95% CI 1.01 – 1.07, $p = 0.02$), whereas increasing age was associated with a decrease in the odds of frailty (AOR 0.90, 95% CI 0.80 – 0.99, $p = 0.03$).

Table 4.5. Multiple logistic regression of factors associated with frailty

Model	Variable	Adjusted OR	Lower 95 % CI	Upper 95% CI	p-value
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Model 1					
	CCI	1.78	0.95	3.66	0.09
	Education level – High school or below (reference)	-	-	-	-
	Education level – Post-secondary education or higher	0.22	0.04	0.96	0.05
Model 2					
	Step count	1.00	1.00	1.00	0.17
	Deep sleep time	1.02	1.01	1.05	0.02*
	Awake time	0.97	0.93	1.01	0.18
	Heart rate SD	1.17	0.99	1.46	0.10
Model 3					
	Deep sleep time	1.03	1.01	1.07	0.04*
	Step count	1.00	1.00	1.00	0.06
	Age	0.90	0.80	0.99	0.04*
	Education level – High school or less (reference)	-	-	-	-
	Education level – Post-secondary education or higher	0.11	0.01	0.94	0.06

* $p < 0.05$

All three models were evaluated for their goodness of fit using the Hosmer-Lemeshow statistic.

Overall, no model showed statistical significance on this test, indicating they had acceptable goodness-of-fit and the predicted frailty matched the observed frailty status (Table 4.6).

When the predictive performance was evaluated by AUC, all three models showed medium to high AUCs. Model 1, based on sociodemographic and patient assessment variables, was outperformed by the Model 2, which was fitted with wearable device variables (AUC 0.77 vs.

0.88). Model 3 had the best predictive performance with an AUC of 0.90 (Table 4.6). The receiver operating characteristic curves are shown in Figure 1 for each Model.

Table 4.6. Summary of model performance in predicting frailty status.

Models	Accuracy	Sensitivity	Specificity	AUC	Hosmer-Lemeshow Test p-value
Model 1. Sociodemographic and patient assessment variables	0.76	0.46	0.92	0.77	0.73
Model 2. Wearable device derived variables	0.81	0.69	0.88	0.88	0.95
Model 3. All variables from Models 1 and 2	0.81	0.69	0.88	0.90	0.85

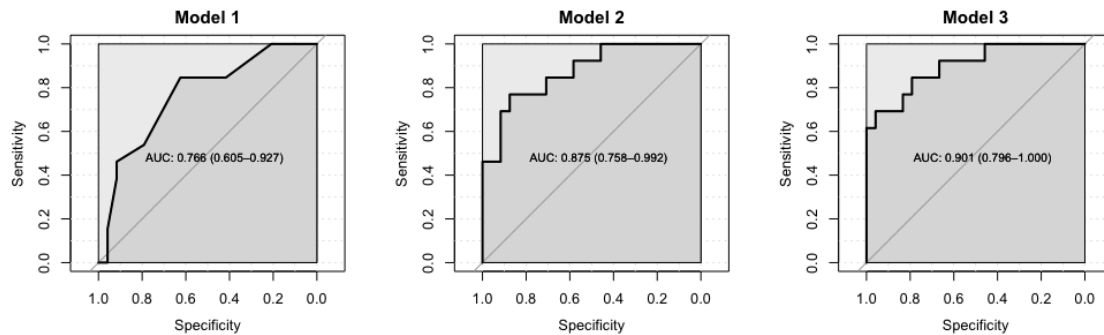


Figure 4.1. The receiver operating characteristics curves for all Models fitted to predict frailty

4.5. Discussion

4.5.1. Principal Findings

The growing aging population in Canada and the emphasis on aging-in-place call for innovative ways to improve efficiency in the home and community healthcare sector. There is an increasing

interest in integrating information and communication technology such as consumer-grade wearable devices into healthcare delivery due to their rising popularity, ease-of-use, and the potential usefulness of continuously collected data (Kelsey & Cavendish, 2014). The aim of this study was to investigate the possibility of assessing and predicting frailty using a wearable device.

We observed 37 older home care clients for a minimum of 8 days. The prevalence of frailty in the study sample, 35.13%, was similar to other research studies that examined home care clients (Campitelli et al., 2016; Kelly, O'Brien, Smuts, O'Sullivan, & Warters, 2017). Many research studies (Ávila-Funes et al., 2008; Collard et al., 2012) reported a significantly higher prevalence rate of frailty in older female adults compared to males, but this was not observed in our study sample. However, another study that examined the same population did not find any significant difference between the sexes (Campitelli et al., 2016). Overall, the study sample seemed reasonably representative of the home care population. Previous research studies reported an association between income and education level and frailty (Fried et al., 2001; St. John, Montgomery, & Tyas, 2013). Our study sample had a significant difference in income level between the two frailty groups. However, the post-hoc chi-square analysis results did not reach statistical significance. Education level was moderately correlated with frailty level. Overall, our study sample displayed the general characteristics of frail populations (Fried et al., 2001; St. John et al., 2013).

Our study found a significantly higher utilization of home care service by frail older adults compared to non-frail older adults (mean hours per week: 5.15 vs 2.77). Unfortunately, the

current system fails to meet all care needs of home care clients as indicated by the increased hours of informal care and caregiver distress for the home care client's with the more severe frailty (Maxwell et al., 2018). Resulting adverse health outcomes and increased healthcare utilization (Campitelli et al., 2016) highlight the need for a better allocation of home care service to those who stand to benefit the most.

In our study sample, non-frail older adults walked significantly more than the frail older adults. This result is in line with the findings of previous research studies where reduced daily step count and physical activity were observed for frail community-dwelling older adults (Cavanaugh, Coleman, Gaines, Laing, & Morey, 2007) and ICU patients (McNelly et al., 2016). In a previous study, daily step count was significantly related to frailty (Theou et al., 2012). Our study extended this evidence outside the controlled settings and beyond 24-hour monitoring period (Cook, Thompson, Prinsen, Dearani, & Deschamps, 2013; Schwenk et al., 2015), and demonstrated the relationship in an unsupervised setting.

Sleep measures including longer total sleep, deep sleep and light sleep durations, awake time and sleep quality were shown to be related to more severe frailty. This is contrary to the common knowledge of deterioration of sleep quality and quantity with aging (Espiritu, 2008). However, in epidemiological studies, a longer sleep duration was associated with an increased risk of heart disease and all-cause mortality (Gallicchio & Kalesan, 2009). The lowest mortality risk was found for those who sleep about 7 hours a night (Tamakoshi & Ohno, 2004), while men who slept more than 8 hours per day had a tripled risk of heart disease (Burazeri, Gofin, & Kark, 2003). This relationship was shown in our study sample where non-frail and frail older adults

had significantly different total sleep durations. Non-frail older adults had a mean total sleep duration of 6.48 hours (close to 7 hours), while their frail counterparts slept for 8.16 hours. These findings demonstrate the additional information wearable devices provide over conventional sleep quality assessments.

In this study, we built logistic regression models using a sequential stepwise feature selection method. Feature selection in general can help improve predictive performance (Kassambara, 2018). It minimizes the number of features needed in a model, which was critical given the small sample size of this study. While manual feature selection based on expert knowledge could have been a feasible alternative, our goal was to maximize frailty prediction performance in our data set by utilizing an empirical feature selection method. The analysis of multiple logistic regression models showed that wearable device data were a superior source of information for predicting frailty than sociodemographic information and patient assessments. However, the highest AUC of 0.90 was achieved with the model that used wearable device data, sociodemographic, and patient assessment information. Previously, a similar study that used a neck-worn wearable device to obtain step count and physical activity-related variables achieved an AUC of 0.88 in discriminating the pre-frail subgroup from the frail and non-frail subgroups (Razjouyan et al., 2018). Another study used two research-grade wearable devices concurrently and achieved an AUC of 0.86 in discriminating three frailty states, using stride length (Schwenk et al., 2015). Both studies were limited due to their short 48-hour observational period and being conducted in a laboratory setting. Our study demonstrated that unsupervised monitoring of frailty at home using a wearable device is possible. Our results corroborate that wearable technology should complement, rather than replace, the existing practice (Fasano & Mancini, 2020).

Many mobile health and telehealth applications have been successful at delivering healthcare while improving its efficiency (Iribarren, Cato, Falzon, & Stone, 2017). A study that examined telehealth for frail older adults found the most cost-effective telehealth program uses automated monitoring of vital signs to reduce health service use and facilitate remote follow-up (Barlow, Singh, Bayer, & Curry, 2007). Wearable devices are becoming increasingly affordable and are capable of offering a similar use-case as telehealth applications with their automated monitoring of physical activities, sleep and heart rate. The range of information collected from wearable devices are also increasing with the advancement of sensor technology such as electrocardiogram, blood glucose level, oxygen saturation level, and electrodermal activity. When coupled with well-calibrated algorithms that enable early detection of health deteriorations such as frailty, cost savings can be further increased. The added value of wearable devices in assessing frailty for home care clients and community-dwelling older adults should be carefully evaluated for their feasibility in real-life settings. Each home and community healthcare system is unique, including but not limited to the target population, geographical area, and funding structure. Future research should consider these factors when evaluating the clinical value and cost savings of wearable devices.

Future research should confirm the predictive power of data derived from wearable devices and extend it beyond the home and community care sector. Our results indicated that wearable devices are a valid tool when an adequate analytical process is used. We recommend future home care research studies to leverage the potential of consumer-grade wearable devices and help

identify vulnerable and frail subgroups who may benefit from additional home care services and increased access to healthcare.

4.5.2. Limitations

Our study has several limitations. First, the small study sample prevented us from stratifying patients into non-frail, pre-frail, and frail subgroups. A third frailty state could have helped us demonstrate gradient measures of wearable data. The small sample size also limited the number of variables that could be used in developing multiple logistic regression models. The three logistic regression models were fitted with two to four features. They have exceeded the common rule of one-in-ten and may have increased the risk of overfitting (Peduzzi, Concato, Kemper, Holford, & Feinstein, 1996). The small sample size precluded partitioning our data into training and test sets. As a result, the reported predictive performance overestimated the true performance on a different sample of older adults. A further caution should be taken when interpreting the results of the Hosmer-Lemeshow test due to the small sample size.

Our research adopted an 8-day observation period. While this was longer than the observation periods of most other studies using wearable devices, an even longer observational period may be required to reveal new patterns that are not observable within 8 days such as weekdays versus weekends and seasonal differences. Lastly, the validation studies that examined the Mi Band (Paradiso et al., 2020; Ricchio et al., 2018) were conducted in younger participants, limiting their generalizability to older adults of this study.

4.6. Conclusions

In this study, we proved the concept of using a wrist-worn consumer-grade wearable device to assess frailty among older home care clients. Data collected from the wearable device, such as total sleep time and deep sleep time, were associated with frailty. The frailty prediction model based on variables selected from wearable devices, sociodemographic, and patient assessments achieved the highest AUC of 0.90, compared to other predictive models using either only sociodemographic and assessment variables, or only wearable device derived variables.

4.7. Funding Statement

This work was supported by a Core Research Project Grant from the AGE-WELL Network of Centres of Excellence (WP7.3).

4.8. Conflicts of Interest

None declared.

Chapter 5. Using consumer-grade wearable devices to measure frailty transitions in critical care survivors: An exploratory observational study

This chapter is currently under review with JMIR mHealth and uHealth. The full citation of the manuscript is:

Kim B, Hunt M, Muscedere J, Maslove DM, Lee J. (under review). Using consumer-grade wearable devices to measure frailty transitions in critical care survivors: A proof-of-concept study. *JMIR mHealth and uHealth* #19859

5.1. Chapter Overview

Background: Critical illness has been suggested as a sentinel event for frailty development for at-risk older adults. Frail critical illness survivors suffer increased adverse health outcomes but monitoring the recovery post-ICU is challenging. Wearable devices offer a possibility of measuring frailty.

Objectives: To examine the data collected from wearable devices for the progression of frailty among the critical illness survivors.

Methods: A prospective observational study was conducted with 12 critical illness survivors from Kingston General Hospital in Canada. Frailty was measured by Clinical Frailty Scale (CFS) at ICU admission (AD), hospital discharge (DC), and 4-week follow-up (FU). Wearable device was worn between DC and FU. The wearable device collected data on steps, physical activity, sleep and heart rate.

Results: The CFS increased significantly following critical illness compared to pre-ICU frailty level ($p=0.02$, $d=-0.53$). Frail survivors over the 4-week follow-up period had significantly lower daily step counts than non-frail survivors ($p=0.02$, $d=1.81$). There was no difference in sleep and heart rate measures. Daily step count was strongly correlated with the CFS at FU ($r=-0.72$, $p=0.04$). Average heart rate was strongly correlated with the CFS at DC ($r=-0.72$, $p=0.046$). Heart rate SD was strongly correlated ($r=0.78$, $p<0.05$) with the CFS change from AD to FU. No relationship was found between the CFS and sleep measures. The pattern of increasing step count over the FU period was correlated with the worsening of frailty ($r=0.65$, $p=0.03$). The trend of increasing heart rate over this period was correlated with the worsening of frailty ($r=0.62$, $p=0.03$).

Conclusions: This study demonstrated a possibility of monitoring frailty and physical recovery using a consumer-grade wearable device. Daily step count and heart rate showed strong relationships with the frailty progression of critical illness survivors over time. Understanding this relationship could unlock a new avenue for clinicians to monitor and identify a vulnerable subset of the population that might benefit from an early intervention.

Keywords: frailty progression, step counts, heart rate, sleep quality, wearable devices

Strength and limitations of the study

- This study evaluates the possibility of using data collected from a consumer-grade wearable device to understand the frailty level of critical illness survivors.
- One of the first studies that examined frailty progression among critical care survivors.
- Exploratory nature of the study resulted in a restrictive sample size from a single intensive care unit, which likely limits generalizability to other populations.

5.2. Introduction

Frailty is a state of increased vulnerability to adverse health outcomes due to the loss of physiological and cognitive reserves (Rockwood et al., 2005). While the term frailty often overlaps with terms such as disability and comorbidity, it has been well described that frailty is an independent concept that can be quantitatively separated (Fried et al., 2004). Frailty is recognized as a dynamic state and recent studies have highlighted the need to quantify changes between the stages of frailty to better inform clinicians with the development of tailored treatments (McDermid, Stelfox, & Bagshaw, 2011).

Critical illness has been suggested as a sentinel event for the development of frailty, especially for at-risk older adults (Muscedere et al., 2016). Frailty is frequently evaluated as a prognostic tool in critical care settings to better guide decision making by clinicians and to manage expectations of patients and families of health outcomes (Bagshaw et al., 2014). Critical illness survivors who were frail before the illness, in comparison to non-frail survivors, have a significantly higher mortality rate (Bagshaw et al., 2014, 2015; Zeng et al., 2015), and are more likely to acquire functional dependence (Bagshaw et al., 2014; Ehlenbach et al., 2010), suffer from lower quality of life (Bagshaw et al., 2014), and are more frequently re-hospitalized within 12 months (Zeng et al., 2015). However, no studies have examined the progression of frailty throughout and beyond critical illness and how physical and functional recovery is related to the changes in frailty.

Monitoring critical illness survivors' functional recovery in clinical settings is challenging logistically and financially for patients, care providers, and healthcare organizations. New studies

have used wearable devices as a tool to objectively measure physical activity level (Baldwin, Johnston, Rowlands, & Williams, 2018; McNelly et al., 2016), sedentary behaviours (Baldwin, Johnston, Rowlands, Fraysse, & Williams, 2019), mobility (Cook et al., 2013), and to screen for frailty (Chen et al., 2015). We leveraged a consumer-grade wearable device to monitor physical recovery of critical illness survivors.

We examined the data generated from the wearable device for their relationship with the progression of frailty post-hospital discharge. We hypothesized that frail survivors would have lower physical activity, diminished sleep quality, and impaired heart rate control compared to non-frail survivors. We also hypothesized the survivors whose frailty returns to the pre-critical illness level would have a higher physical activity level, better sleep quality, and tighter heart rate control than those who have a persistent increase in frailty level after hospital discharge.

5.3. Methods

5.3.1. Study Design and Settings

This prospective observational study was conducted at Kingston General Hospital in Kingston, Ontario, Canada. Patients were recruited from the Frailty, Outcomes, Recovery and Care Steps of Critically Ill Patients (FORECAST) study, which assessed an array of clinical measurements and frailty. For the current study, patients were recruited at admission to the ICU from July 2017 to August 2018. Participants were followed up at 4-weeks post-hospital discharge.

A convenience sampling method was used to recruit patients aged 55 years and older. They were included in this study if they lived within or close to the hospital to ensure feasibility of attending

the 4-week follow-up session. Patients were excluded if shared decision makers were not available to collect collateral history. We also excluded patients who had medical conditions that may interfere with proper use of the wearable devices including those admitted to the ICU with catastrophic neurological illness that is not likely to be altered by ICU care (e.g., massive stroke requiring ICU care, spinal cord injury with neurological deficit), those diagnosed with primary neuromuscular pathology or atrial fibrillation, or those dependent on a wheelchair for mobility. Patients were further excluded if they had an expected survival of less than 1 month.

5.3.2. Data Collection and Instrumentation

5.3.2.1. Determination of frailty

Frailty was assessed using the CFS, a tool that has been widely used in critical care settings (Rockwood et al., 2005). The CFS has been shown to outperform other frailty assessment tools in the geriatric population in correctly differentiating major health outcomes such as hospital admission and fall incidents (Ritt et al., 2015). The CFS ranges from 1 to 9 where 1 denotes very fit and 9 represents terminally ill. The CFS score of 1 to 3 are considered not frail, the score of 4 is considered pre-frail, and 5 or higher is considered frail. A CFS score of 4 or higher was considered frail in this study. Frailty was assessed by one of the three experienced research coordinators.

5.3.2.2. Wearable device

Fitbit Charge HR (Fitbit, San Francisco, CA, USA) (Hereafter: Fitbit) is a commercially available wearable device that is worn on the wrist. It uses a tri-axial accelerometer to measure

motion. These data are used to estimate physical activity, sedentariness, and sleep quality. Fitbit also measures the changes in elevation using an altimeter. Fitbit uses an optical heart-rate sensor (i.e., photoplethysmography) to measure heart rate between 30 to 220 beats per minute.

In this study, we collected physical activity level including daily step count, active time, and sedentary time. Fitbit automatically deems active time to be when a physical activity of at least 3 metabolic equivalents is performed. Sleep related information is generated including total time in bed, total sleep time (TST), awake time, and awake count. Sleep quality was calculated as the percentage of the sleep time over the TST. The sleep time was determined by subtracting awake time from the TST. Heart rate was measured every minute. Heart rate data were used to assess average daily heart rate, average daily heart rate SD, and average nocturnal heart rate. The average nocturnal heart rate was calculated by only using the heart rate recorded during sleep as classified by the TST.

5.3.2.3. Other variables

The research coordinators reviewed the patients' medical charts and collected demographic information including age, sex, height and weight. The degree of comorbidity and ability to perform activities of daily living (ADL) were calculated using the Charlson Comorbidity Index (CCI) (Charlson, Pompei, Ales, & MacKenzie, 1987) and the Katz index (S. Katz, Ford, Moskowitz, Jackson, & Jaffe, 1963), respectively. The severity of illness and delirium were collected and calculated using the Acute Physiology and Chronic Health Evaluation II (APACHE II) (Knaus, Draper, Wagner, & Zimmerman, 1985) and the Confusion Assessment

Method-ICU (CAM-ICU) (Ely et al., 2001), respectively. The major critical care treatments received during the ICU stay including invasive mechanical ventilation, non-invasive ventilation, vasopressor use, corticosteroid use, continuous renal replacement therapy and intermittent hemodialysis were collected. The ICU length of stay (ICU LOS) and hospital LOS were calculated from chart review.

5.3.3. Procedure

Three trained research coordinators interviewed patients at three different time points: ICU admission (T1), hospital discharge (T2), and 4-week follow-up (T3). The assessment conducted at T1 was used to establish the baseline information (i.e., pre-ICU admission). Figure 5.1 outlines the study procedure and time points for assessments and measurement tools. All participants received a wearable device at ICU discharge and were trained on its use during the hospital ward stay prior to hospital discharge. Participants were encouraged to wear the device during the ward stay but only the post-hospital discharge data were used for analyses. Time between T1 and T2 is referred to as D1; T2 and T3 as D2; and T1 and T3 as D3, hereafter.

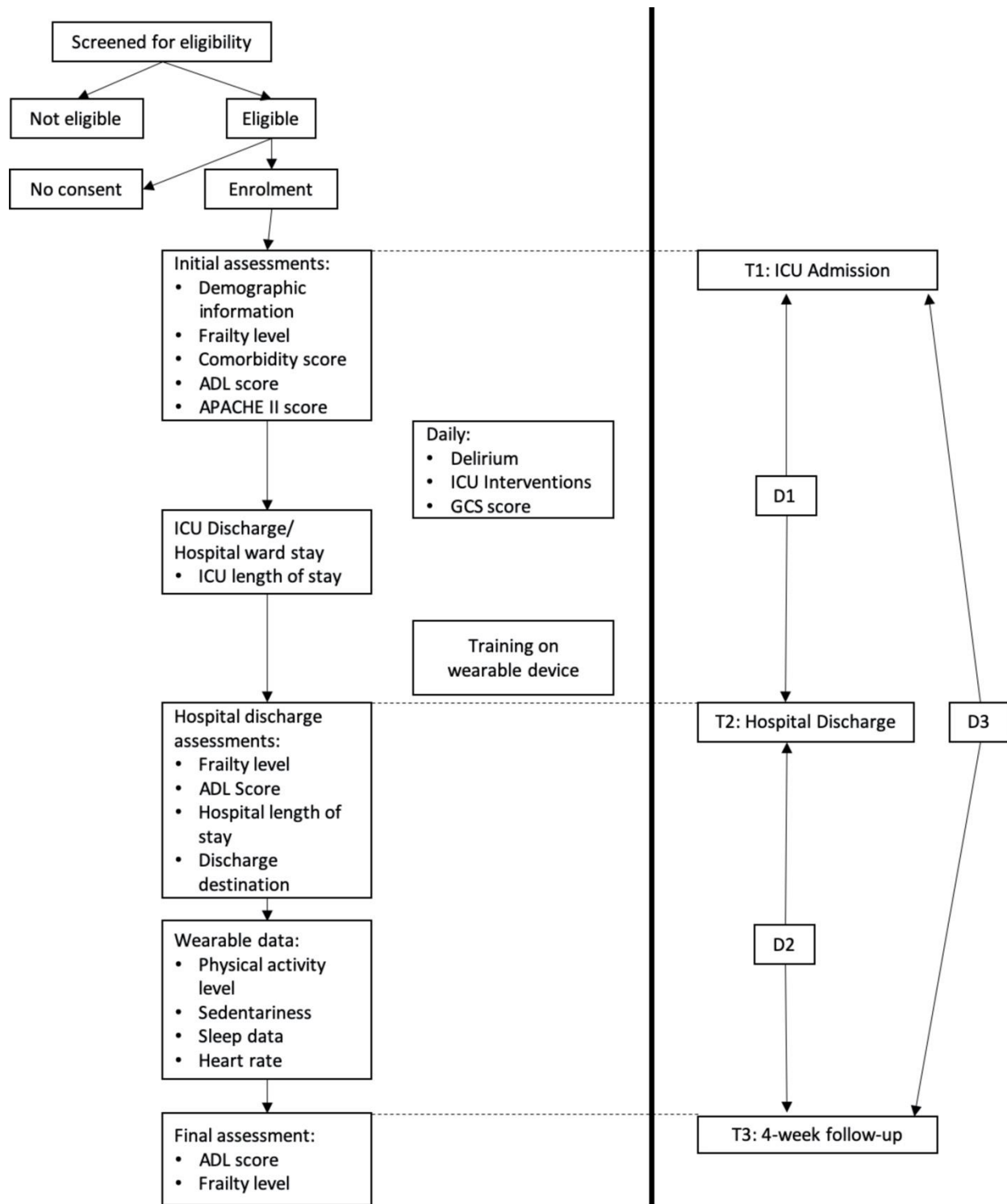


Figure 5.1. Study procedure and time points of assessment and measurement tools

5.3.4. Data Analyses and Interpretation

Descriptive statistics and univariate comparisons of means, medians, and proportions were performed to describe the demographic information and patient characteristics according to frailty status. The Shapiro-Wilk normality test was performed to check for normality. Student's t test, Mann-Whitney U test, or Chi-square test was performed to check for independence between frail and non-frail survivors at T3. Cohens' D was used to evaluate the effect size when a statistically significant difference was found.

The Pearson correlation coefficient and Spearman's rank correlation coefficient were calculated to analyze the correlation between the data collected from the wearable devices and the changes in the CFS score over D1, D2, and D3. Their relationships with the patient demographic information and medical data were further examined.

A linear regression was performed for individual patients' daily step count, daily total sleep time, daily awake duration, and heart rate over D2. The slope of the regression line (hereafter: slope) was examined for its relationship with the changes in the CFS score over D1, D2, and D3 by performing Spearman's rank correlation analysis. Patients with fewer than five days of the wearable device data were excluded from this analysis.

Statistical significance was set at $\alpha=0.05$ for all statistical results. Statistical analysis was performed using R in the R studio environment (R version 3.6.0, R Studio version 1.2.1335, R Studio, Inc., Boston, MA).

5.3.5. Ethics, Consent, and Permissions

This study received ethics clearance from the Office of Research Ethics at the University of Waterloo (ORE22219) and the Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics (ROME0/TRAQ 6020644).

5.3.6. Patient and Public Involvement

No patient was involved in the development of the research questions, design, and outcome measures of this study.

5.4. Results

5.4.1. Recruitment

A total of 16 patients admitted to the ICU were recruited and provided informed consent between July 2017 and August 2018. Two patients withdrew from the study and two patients' data were lost due to technical issues. In total, we had 12 patients with wearable device data successfully collected (Table 5.1).

Patients were 55 to 77 years of age, with a mean age (SD) of 66.75 (6.80) years and 7 were female. The mean ICU LOS was 14.50 days and hospital LOS was 22.92 days. The mean APACHE II score (SD) at T1 was 27.67 (5.25). Overall, 7 out of 12 patients were classified as frail at T3. There was no major difference in baseline characteristics between frail and non-frail patients at T3.

Table 5.1. Baseline characteristics, frailty, disability, and co-morbidity scores

	Frail at T3	Non-frail at T3	p-value
Demographics			
Patients, <i>n</i>	7	5	
Age, years (SD)	66 (8.12)	67.8 (5.07)	0.81
Sex, female	6	1	0.09
BMI, kg m ⁻²	30.22 (8.36)	26.34 (16.01)	0.21
Type of admission			
Medical, <i>n</i>	1	10	N/A ^a
Surgical, <i>n</i>	0	1	
ICU LOS	15.29 (5.19)	13.40 (9.63)	0.67
Hospital LOS	24.57 (10.49)	20.60 (16.32)	0.62
APACHE II	26.71 (6.63)	29.00 (2.45)	0.81
Glasgow coma scale	7.43 (4.54)	5.20 (2.28)	0.56
Charlson comorbidity index	1.57 (2.07)	1.00 (1.22)	0.21
Katz score at T1	5.00 (1.29)	5.60 (0.55)	0.59
Katz score at T3	5.71 (0.76)	6.00 (0.00)	0.50

^a p-value cannot be computed

5.4.2. Clinical Frailty Scale

Critical illness had a profound effect on patient's frailty level (Figure 5.2). Compared to the baseline CFS score at T1, the CFS score at T2 increased significantly ($p < 0.01$, $d = -1.13$). A general trend of the improvement in the frailty level was observed over D2 but the difference was not statistically significant ($p = 0.10$, $d = 0.59$). At T3, the frailty level returned to the baseline for 6 patients while it worsened for 6 patients. Overall, the CFS score increased significantly over D3 ($p = 0.02$, $d = -0.53$). The changes in the frailty level at different time points are summarized in Table 5.2.

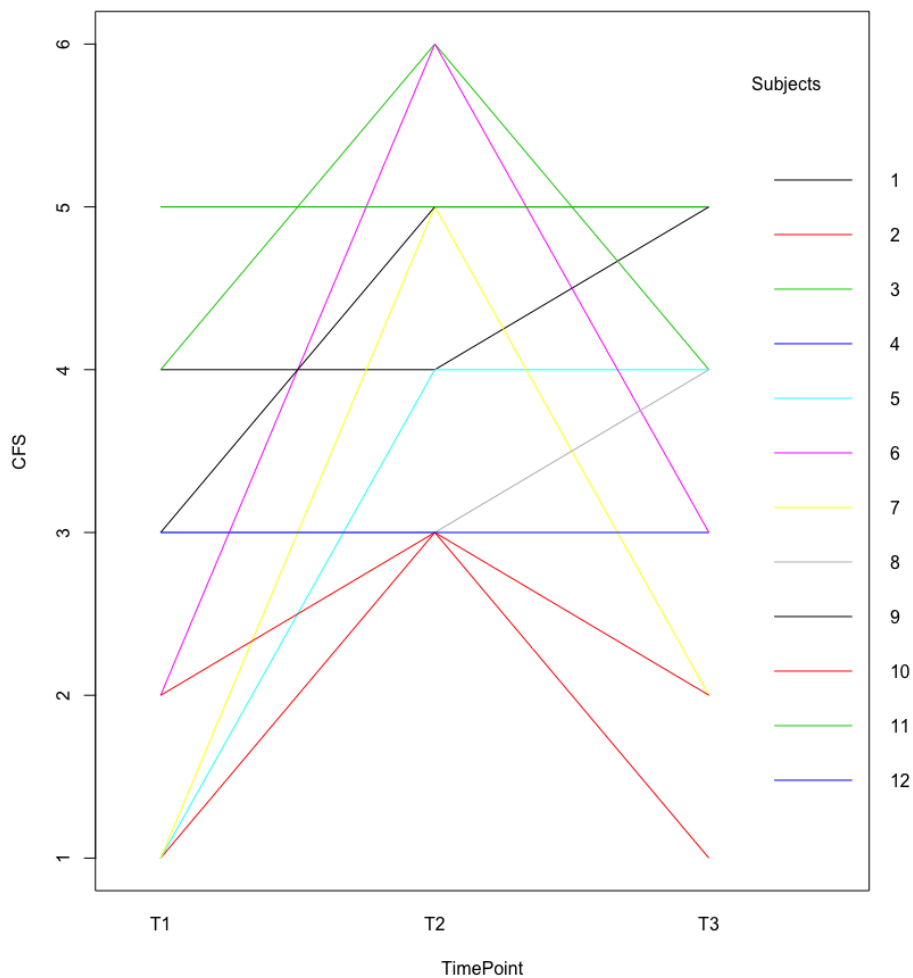


Figure 5.2. A spaghetti plot of the CFS score at T1, T2, and T3 (n=12)

Table 5.2. Changes in CFS score over D3

Frailty changes	D1: Pre-hospitalized to Hospital Discharge, <i>n</i>	D2: Hospital Discharge to 4-week follow-up, <i>n</i>	D3: Pre-hospitalized to 4-week follow-up, <i>n</i>
Improved	0	2	0
No change	5	4	6
Worsened	7	6	6

5.4.3. Frailty and Wearable Device Data

Of the 12 patients, 3 patients wore the wearable devices for fewer than 5 days over D3 (Table 5.3). On average, patients wore the wearable devices for 26.33 days. Frail patients at T3 had significantly lower daily step counts than non-frail patients (1336.40 vs 3781.04 steps, $p=0.02$, $d=1.81$). They engaged in daily physical activity for lesser amount than their counterparts (2.02 vs 16.34 minutes per day, $p=0.04$, $d=0.94$). There was no difference in sleep and heart rate measures between frail and non-frail.

Table 5.3. Data collected from the wearable device (n=9)

Wearable device measures	Frail at T3	Non-frail at T3	p-value
Patients, n	5	4	
Days worn, days (SD)	30.20 (8.73)	21.50 (8.27)	0.17
Physical activity variables			
Daily step count (SD)	1336.40 (1091.07)	3781.04 (1389.37)	0.02*
Sedentary time, minutes per day (SD)	84.11 (55.75)	104.95 (49.78)	0.58
Active duration, minutes per day (SD)	2.02 (3.83)	16.34 (10.66)	0.04*
Sleep measures			
Total sleep time, minutes per night (SD)	419.71 (166.62)	336.25 (134.07)	0.81
Total time in bed, minutes per night (SD)	456.31 (182.49)	362.16 (144.88)	0.84
Awake time, minutes per night (SD)	24.427 (11.20)	21.30 (11.33)	0.69
Awake count, times per night (SD)	1.65 (0.62)	1.54 (1.10)	0.85
Sleep quality, % (SD)	91.72 (2.35)	92.70 (2.00)	0.53
Heart rate measures			
Average heart rate, bpm (SD)	86.93 (7.10)	80.38 (13.18)	0.38
Heart Rate SD, bpm (SD)	8.81 (1.97)	10.66 (3.16)	0.32
Average nocturnal heart rate	86.42 (5.87)	74.10 (20.27)	0.27

* $p < 0.05$

The correlation between the wearable device data and frailty is summarized in Table 5.4. Daily step count was strongly correlated with the baseline CFS score at T1 ($r=-0.76$, $p=0.03$) and the

CFS score at T3 ($r=-0.72$, $p=0.006$). Sedentary time was strongly correlated with the CFS score at T1, but did not reach statistical significance ($r=-0.66$, $p=0.07$). Average heart rate was strongly correlated ($r=-0.72$, $p=0.046$) with the CFS score at T2, and heart rate SD was also strongly correlated ($r=0.78$, $p=0.02$) with the CFS change over D3. No relationship was found between sleep measures and the CFS scores. No patient characteristics had significant relationship with the CFS score (See Appendix D for the exact p-values for observed).

Table 5.4. Correlations between the data collected from the wearable devices and the frailty level and its change (n=9)

	Frailty at T1	Frailty at T2	Frailty at T3	Frailty change over D1	Frailty change over D2	Frailty change over D3
Physical activity data						
Daily step count	-0.76*	-0.35	-0.72*	0.55	-0.46	0.14
Active time, minutes per day	-0.62	0.03	-0.53	0.63	-0.56	0.18
Sedentary time, minutes per day	-0.66+	-0.39	-0.53	0.41	-0.24	0.25
Sleep data						
In bed, minutes per night	0.10	0.13	0.42	-0.01	0.32	0.45
Total sleep time, minutes per night	0.08	0.13	0.40	0.01	0.31	0.46
Awake time, minutes per night	-0.26	-0.07	0.07	0.22	0.13	0.50
Awake count, times per night	-0.31	0.06	-0.10	0.37	-0.15	0.33
Sleep quality	0.23	-0.10	0.12	-0.32	0.20	-0.19
Heart rate data						
Average heart rate	-0.24	-0.72*	-0.16	-0.28	0.37	0.13
Heart rate SD	-0.55	-0.05	-0.05	0.54	-0.01	0.78*
Average nocturnal heart rate	0.06	-0.21	-0.19	-0.22	-0.04	-0.37
Patient characteristics						
Age	0.18	0.56+	<0.01	0.24	-0.45	-0.27
BMI	0.42	0.38	0.47	-0.11	0.15	0.04
ICU LOS	-0.01	0.21	<0.01	0.17	-0.17	0.02
Hospital LOS	0.15	0.15	0.05	-0.03	-0.07	-0.14

Charlson Comorbidity Index	0.56	0.12	0.29	-0.44	0.19+	-0.44+
Glasgow Coma Scale	0.24	-0.06	0.15	-0.27	0.19	-0.16
Changes in ADL	0.06	0.34	0.05	0.20	-0.23	-0.02
APACHE II score	0.19	0.47	-0.12	0.17	-0.50	-0.47+

* p<0.05

+ p<0.10

5.4.4. Frailty and Wearable Device Data Trends over Time

The slope of the linear regression line for daily step count, TST and heart rate was calculated to investigate the relationship between frailty and wearable device data trends over time (Figure 5.3). The slope of daily step count demonstrated strong correlations with the CFS change over D1 ($r=0.71$, $p=0.01$) and D3 ($r=0.65$, $p=0.03$) (Table 5.5). The slope of heart rate was strongly correlated with frailty change over D3 ($r=0.62$, $p=0.03$).

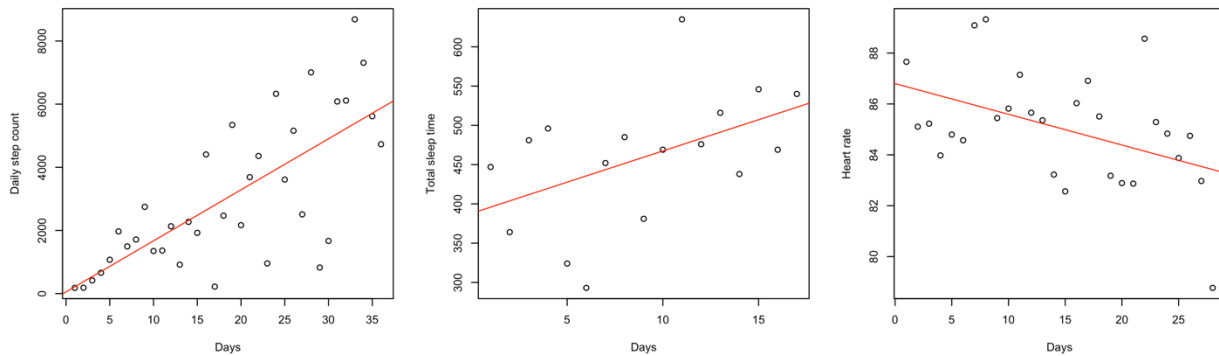


Figure 5.3. Example of the slope of linear regression line for daily step count, total sleep time, and heart rate. The slope of linear regression line represents the changes over D2

Table 5.5. Correlation between the slope of daily step count and the CFS scores at T1, T2, and T3 and changes in CFS over D1, D2, and D3

	Slope		
	Step count (p-value)	Total sleep time (p-value)	HR (p-value)
CFS score at T1	-0.55+ (0.08)	0.59+ (0.07)	-0.31 (0.32)

CFS score at T2	0.27 (0.43)	0.12 (0.74)	-0.12 (0.72)
CFS score at T3	-0.18 (0.60)	0.32 (0.36)	0.10 (0.75)
CFS change over D1	0.71* (0.01)	-0.49 (0.15)	0.21 (0.52)
CFS change over D2	-0.38 (0.25)	0.21 (0.56)	0.20 (0.54)
CFS change over D3	0.65* (0.03)	-0.52 (0.13)	0.62* (0.03)

* p<0.05

+ p<0.10

5.5. Discussion

In this exploratory observational study, we observed 12 elderly survivors of critical illness from the time of their admission to the ICU until 4-weeks after their hospital discharge. Physical recovery was monitored through the use of a wearable device. Frailty was assessed at multiple time points throughout their ICU and hospital stay and 4-weeks after discharge. Six patients became more frail after critical illness, while the frailty of the other six returned to their pre-critical illness levels. No participant's frailty improved above their pre-ICU baseline state. Incidence rate for the moderate level of frailty over three years is reported to be around 6.2% and 12.8% for men and women, respectively (Peterson et al., 2009). A systematic review of 16 studies that investigated frailty among community-dwelling older adults reported that 29.1% worsened over the average of 3.9 years. A noticeably higher rate of worsening frailty in the study sample confirms the notion that critical illness is a triggering event in the transition to a frail state (Muscedere et al., 2016).

We demonstrated the relationship between a lower physical activity level and an increased frailty level. This was evident in a significantly lower daily step count and active time by the frail survivors compared to their non-frail counterparts. This finding is consistent with a previous study that used a wearable device worn on the upper arm and reported a significantly reduced

step count by frail survivors compared to a healthy control group (McNelly et al., 2016). Our results suggest the rate at which an individual increases daily step count following critical illness may be an important indicator for the recovery of frailty back to pre-critical illness level. Those whose frailty worsened showed a significantly higher rate of increase in their daily step counts ($p=0.03$). We initially suspected the magnitude of the positive slope was amplified due to lower step counts among those whose frailty worsened. However, the average step count was not significantly different between those whose frailty worsened and those whose frailty did not change ($p=0.63$). We further speculated the difference in baseline frailty level may be contributing to this finding but there was no significant difference in the baseline frailty between two groups ($p=0.49$). Another possible explanation may be an increase in frailty is due to non-physical characteristics such as impaired cognitive function. Future research should confirm the relationship and investigate possible explanations. Understanding this relationship may help clinicians to accurately identify patients who will benefit from strengthened transitional care.

The pattern of increasing heart rate and the standard deviation of the heart rate was shown to relate to the worsening of frailty following critical illness. These findings are in line with the theoretical understanding of frailty as a concept of impaired homeostasis (Rockwood et al., 1994). These patterns may be caused by the inability to evoke dynamic physiologic processes to restore equilibrium. Studies that examined heart rate variability concluded that frailty is associated with impaired cardiac autonomic control (Chaves et al., 2008; Varadhan et al., 2009). However, the empirical evidence for the relationship between heart rate and frailty is lacking. Increased resting heart rate was found to be associated with the functional decline of older adults

(Ogliari et al., 2015), increased inflammatory markers (Sajadieh et al., 2004), and an increased mortality rate among trauma patients (Curtis, Romanowski, Sen, Hill, & Cocanour, 2018).

To the best of our knowledge, this is the first study to investigate frailty by collecting and analyzing longitudinal heart rate data from a consumer-grade wearable device. Use of consumer-grade wearable devices to monitor heart rate has garnered the interest of many researchers in recent years. Its feasibility and accuracy have been researched in different populations, including critically ill patients (Kroll et al., 2017). Many studies have demonstrated its feasibility and acceptable compliance level, but its capacity to measure heart rate accurately has been questioned, especially for the detection of non-sinus rhythms such as atrial fibrillation (Kroll et al., 2017; Shcherbina et al., 2017). Despite this, our study used longitudinal heart rate data to successfully confirm the relationship between frailty, heart rate, and its standard deviation. Future studies should expand on this relationship and its potential use as a screening and monitoring tool for frailty and detection of early signs of clinical deterioration amongst critical illness survivors.

Poor sleep quality, particularly night time disturbances, was reported to be associated with an increased risk of frailty among community-dwelling older adults (Ensrud et al., 2012; Vaz Fragoso et al., 2009). Frequent perturbed sleep in hospitals adversely impacts patient recovery (Young, Bougeois, Hilty, & Hardin, 2008). However, we found no significant relationship between sleep measures and change in frailty. This may be explained by inaccurate measures of sleep quality by wearable devices. The exact model of the device used in this study has been validated against polysomnography (PSG) for healthy adolescents and the same device brand

among young adults (Mantua, Gravel, & Spencer, 2016; de Zambotti et al., 2016). However, it was noted that the performance of these devices may be poor in populations with low sleep quality or a high number of motionless wake episodes. Continued efforts to use consumer-grade wearable devices for routine sleep monitoring should be encouraged since current methods such as PSG and sleep journals are not feasible due to their high cost and inaccuracy amongst critically ill patients (Kroll et al., 2017).

Our study explored the possibility of using a consumer-grade wearable device to monitor changes in frailty from critical illness survivors and identified the relationship between them. Critical illness survivors are uniquely situated as their physiological and cognitive reserve (i.e. frailty) have been disturbed from the critical illness. The successful recovery of the frailty back to pre-critical illness level is crucial for the protection from subsequent critical illness. Unsuccessful recovery of frailty puts the individual at a vulnerable state where a lesser illness may lead to amplified adverse health outcomes, thereby requiring greater healthcare resources (McIsaac, Beaulé, Bryson, & Van Walraven, 2016; Zampieri et al., 2018). Our study demonstrated the possibility of early detection of unsuccessful frailty recovery in the first 4 weeks of post-ICU discharge using a wearable device. Identifying such a vulnerable subset of critical illness survivors warrants timely delivery of frailty interventional programs that have been shown to improve frailty as well as various functional capabilities for community-dwelling older adults (Puts et al., 2017). Furthermore, wearable devices have the potential to enhance monitoring of the physical activities in ecological settings, which can guide clinicians and researchers further by complementing the supervised data acquired in the traditional settings (Fasano & Mancini, 2020).

5.6. Limitations

Our study has several limitations. The study sample likely is not representative of the entire critically ill population due to its small sample size and that the sample came from a single hospital. Other research studies reported significant differences in the age and sex between frail and non-frail patients, but our study sample did not. The small sample size prevented us from stratifying patients into non-frail, at risk, and frail groups. The addition of another level of frailty may have helped us interpret the slope of linear regression in more detail for daily step count, sleep time and heart rate. Furthermore, critically ill patients were discharged from the ICU to a hospital ward before being discharged, which led to varied hospital ward LOS. This may have impacted the assessment of frailty at the 4-week follow-up session. However, the hospital ward LOS was not statistically different between frail and non-frail patients (13.4 vs. 7.0 days, $p=0.20$). We chose 4-week follow-up to investigate the early recovery process immediately following the critical illness. A longer observation period of critical illness survivors will benefit future studies as full functional and physical recovery is achieved over 6 to 12 month periods for 25 to 50% of older critical illness survivors (Ferrante et al., 2016; Heyland et al., 2015).

5.7. Conclusions

In this study, we observed the physical recovery of ICU survivors using a wearable device. Monitoring physical activity, heart rate, and sleep through the wearable devices was feasible and participants showed a high compliance level. Unsuccessful recovery of frailty to pre-critical illness level was related to a significantly high rate of increase of daily step count during the 4-week follow-up period. This unsuccessful recovery was also related to increase in heart rate over

the same period of time. Sleep measures were not correlated with frailty. Our study demonstrated the possibility of using consumer-grade wearable devices as a tool to understand frailty progression for critical illness survivors. We also demonstrated the added value of longitudinal wearable device data. Consumer-grade wearable devices evolve rapidly and future research should focus on leveraging new features such as electrocardiogram, and more accurate measures of physical activity, sleep, and heart rate.

5.8. Funding Statement

This work was supported by a grant from the AGE-WELL Network of Centres of Excellence.

5.9. Competing Interests

None declared.

5.10. Author's Contribution

BK, DM, and JL formulated and designed the research. MH carried out the data collection under the supervision of DM and JM. BK and JL conducted analyses and BK prepared manuscript under the supervision of JL. DM contributed to the development and refinement of the manuscript.

Chapter 6. Comparing and contrasting clinicians and older adults' perceptions of patient-generated health data: A mixed-method study

6.1. Background

A recent national survey showed that Canadians who are 55 years and older have the highest rate of self-tracking of health data at 62.9% while 38.7% track the data digitally using mHealth apps, consumer wearable devices, and smart medical devices (Paré et al., 2018). Many self-trackers are motivated to track their health out of concern and to optimize their wellbeing including physical activity and sleep quality (Swan, 2013). The diversity and complexity of collected data evolved over time with the advancement of sensors. Self-tracking of health data began with a collection of simple measurements such as weight, step counts, hours slept, and exercise logs, has now demonstrated successful tracking of qualitative and subjective assessments such as mood and emotion (Swan, 2013). The added complexity of self-tracked health data demonstrates the level of motivation and interest of the general population and desire to improve one's health and well-being.

Self-tracking of health data results in a large amount of data and it is often referred to as patient-generated health data. Patient-generated health data is defined as data created and managed by patients or shared decision makers to help address a health concern (Shapiro et al., 2012). A key characteristic of patient-generated health data is the fact that its management and sharing are directed by patients. Similar concepts about collecting data from patients in natural settings exist such as patient reported outcome measures (PROM) and ecological momentary assessment

(EMA). PROMs are a standardized data collection method that is initiated by healthcare providers with the aim of evaluating the effectiveness of care (Canadian Institute for Health Information, 2015). Patient-generated health data differs from PROMs in its use of consumer technologies and that the collection and sharing are patient-directed. EMAs are a research-driven data collection method that allows participants to report the occurrence of research interest phenomena in the natural environment at the moment such as symptoms, behaviours, or cognitive processes (Stone & Shiffman, 1994). As with the PROMs, the EMAs are not patient-driven and its purpose is to provide data for research studies.

Patients, healthcare providers, researchers, private industry and governments share a similar vision of future healthcare where patient-generated health data plays an important and significant role (Accenture, 2016; Chung et al., 2016; Kelsey & Cavendish, 2014; Piwek et al., 2016; Swan, 2009). In the United Kingdom, patient-generated health data is envisioned to be one of the foundations to improving the quality of care and decreasing healthcare costs under the *Personalised Health and Care 2020* policy (Kelsey & Cavendish, 2014). The plan to integrate patient-generated health data into healthcare practice has been also shared by the United States government where patient-generated health data will provide a holistic and longitudinal view on patients' health (The Office of the National Coordinator for Health Information Technology, n.d.). While the increased interest in using patient-generated health data is evident in strong commitment by governments, successful adoption of health information system implementation hinges on the buy-in from the providers and users.

Despite the increased interest in patient-generated health data, little is known about clinicians' opinions and patients' opinions, even more scarcely. Common barriers to using patient-generated health data by clinicians include unfamiliarity with the data, insufficient expertise in interpreting the data, and concerns around data completeness, reliability, and relevance (West, Van Kleek, Giordano, Weal, & Shadbolt, 2018). Furthermore, the lack of time for any task outside of the routine clinical practice, technical challenges including incompatibility between patient-generated health data and EMR systems, and uncertainty around privacy regulatory practice hampered the clinicians' willingness to work with patient-generated health data (Kim et al., 2016; West, Giordano, Van Kleek, & Shadbolt, 2016; Zhu et al., 2016). While these factors hinder clinicians from utilizing patient-generated health data, little is known about older patients' opinion and common barriers to adopting patient-generated health data. Understanding the factors associated with the use of patient-generated health data by older adults can inform policy makers, healthcare providers, software developers and other stakeholders about the patient-generated health data and provide necessary guidance.

6.2. Research Objective

In this study, we set out to investigate the similarities and differences in the perceptions older adults and clinicians have on patient-generated health data. We compared and contrasted the attitudes toward different types of patient-generated health data. This study extends the current literature by investigating the opinions of older adults on the key factors that facilitate and hinder the use of patient-generated health data.

6.3. Methods

6.3.1. Study Design

An embedded mixed-method design was used with the one-phase QUAL(quan) approach (Creswell, 2013) to explore the study objective. To introduce the topic of patient-generated health data to the participants and set the scope of the focus group, we presented a case study that described an older patient asked to collect patient-generated health data to manage multiple chronic conditions (Yarborough, 2003). The quantitative data collection was nested within the overall research design and it was collected after reviewing the case study through a questionnaire. Focus group interviews were conducted immediately following the completion of the questionnaire to probe the perceived barriers and key factors related to using patient-generated health data.

Research ethics clearance for this study was received from the University of Waterloo Office of Research Ethics (ORE# 40803). All participants gave written informed consent.

6.3.2. Procedures

A Data Rating Questionnaire, created specifically for this study, was administered to measure participants' perceived usefulness of patient-generated health data. Demographic information and information regarding previous experience with mHealth apps and wearable technologies were also collected. Two focus group interviews were conducted at the University of Waterloo and at a conference room of a health care organization. A set of questions were prepared and used as a guide to probe into the participants' perceived factors that facilitate and hinder the use of patient-generated health data.

6.3.3. Recruitment

A convenience sample and a snowball recruitment strategies were used to recruit 5 older adults and 4 clinicians. They were recruited from the Greater Toronto Area and the Waterloo-Wellington region in Ontario, Canada. An invitation email was sent out to local clinicians and a research support group comprised of over 60 older adults. Recruitment started in October 2019 and focus group interviews were conducted in December 2019.

6.3.4. Data Collection and Analysis

6.3.4.1. Case study

The case study described a 77-year old male patient newly diagnosed with congestive heart failure with pre-existing type 2 diabetes, hypertension, and hyperlipidemia (Appendix E). The case study highlights the new responsibility given to the patient to monitor a plethora of patient-generated health data including weight, blood pressure, blood glucose level, dietary intake and medication log using a mix of digital tools and traditional paper journal. Participants reviewed the case study and were encouraged to ask questions about the types of patient-generated health data presented and the role of information technology in collecting the data. The case study was used as an anchor for the focus group as some participants were unfamiliar with the topic.

6.3.4.2. Data Rating Questionnaire

A 26-item, 5-point Likert scale questionnaire was developed based on the literature review (Nittas, Lun, Ehrler, Puhan, & Mütsch, 2019) and the outlined definition of patient-generated

health data (The Office of the National Coordinator for Health Information Technology, 2020). The questionnaire categorized patient-generated health data based on the mode of data collection as either passively collected data or actively collected data. Passively collected data are generated without a user input such as step count, sleep quality, and location information. Actively collected data are manually captured by patients and it is performed on-demand. Participants were asked to rate the perceived usefulness of each patient-generated health data based on the case study. The Data Rating Questionnaire is provided in Appendix F.

6.3.4.3. Focus group interviews

Two 30-minute long focus group interviews were conducted and audio recorded. We interviewed six participants in the first session and three participants in the second session. The first group was comprised of five older adults and one physiotherapist, while the second group had two nurses and one family physician. The composition of each session was based on geographical and logistical convenience and the division between clinicians and older adults were unintentional.

6.3.5. Analysis

Descriptive statistics were performed to analyze the demographic information, previous experience with mHealth app, wearable devices and collecting patient-generated health data, and the Data Rating Questionnaire results. Cases with missing data occurred as some participants declined answering and they were excluded from the quantitative analyses.

Focus group interviews were transcribed and read in their entirety. A constant comparative analysis strategy was used to code and categorize them into themes (Krueger & Casey, 2000). This inductive approach involves an iterative cycle of comparing the data to existing codes and themes, providing researchers a sense of the frequency of a theme. This approach further allows researchers to investigate other aspects of themes including its extensiveness, intensity, internal consistency, and perceived importance (Krueger & Casey, 2000). All quantitative analyses were performed using R in the R studio environment (R version 3.6.0, R Studio version 1.2.1335, R Studio, Inc., Boston, MA) and the qualitative analyses were performed using QSR NVivo 12.

6.4. Results

6.4.1. Participant Characteristics

Four of the nine participants (44.4%) identified themselves as clinicians including one primary care physician, one registered nurse, one clinical educator and registered nurse, and one registered physiotherapist. The mean age of the clinicians was 38.3 years and three of the four were female. The remainder of participants identified themselves as healthcare users. The mean age of this group was 81 years and four of the five older adults were female (Table 6.1).

Table 6.1. Participant characteristics

Participants	Age in years	Gender
Older adults		
P1	82	Female
P2	78	Female
P3	94	Male
P4	78	Female
P5	69	Female
Clinicians		

C1 - Physiotherapist	47	Female
C2 - Physician	39	Female
C3 – Registered Nurse	30	Male
C4 - Registered Nurse/ Educator	37	Female

6.4.2. Participants’ Exposure to Patient-Generated Health Data

When clinicians were asked about the previous use of mHealth apps, three of the four reported to have used them to track dietary intake and calories, monitor weight changes, and improve exercise and training. The same three clinicians were using a wearable device. Wearable devices were used to monitor step counts, physical activity level, exercise intensity, sleep quality, and heart rate. Three of the five older adults were using either an mHealth app or a wearable device to monitor step counts only in spite of the understanding that their wearable devices offered monitoring of other patient-generated health data.

6.5. Thematic Analysis

6.5.1. Theme 1: Influence of patient-generated health data on patient-provider trust

Older adults and clinicians had conflicting views on the impact of patient-generated health data on patient compliance. Older adults understood that monitoring of patient-generated health data increases the transparency of their (lack of) engagement in healthy behaviours. It was understood by older adults that the increased transparency encourages and motivates compliance although this was not explicitly stated.

... he just sits in that chair and watching TV and he can say “Oh I walk” but you didn’t. from here to the washroom to the kitchen; that’s not enough. - P1

... [clinicians will] see whether they have done this. And that goes for the exercise programs too and not just say it but follow through. – P3

I think the device would help the clinician know when somebody is sneaking a candy bar or somebody says that they go for a walk everyday but they really only go twice a week. – C1

Clinicians expressed concerns about the increased transparency via patient-generated health data and how it can lead to non-compliance to the use of the system and selective disclosure of the patient-generated health data by patients. Clinicians also perceived that older adults were afraid of the negative impact that non-compliance might have on the patient-provider relationship and in turn, on the quality of care they receive from the providers.

The biggest one I have seen as a doctor, is the fact that you've not been following your diet or your exercise plan so I'm not going to show you because now you know. – C2

So, [patients] are like, okay I'm not going to, I'm just going to skip it this day, because having no data is better than showing that I wasn't following directions or doing it properly. – C3

... the perception of, you know, how much they want to help me, because of things like, you know, well I can only help if you help yourself and then the perception of, well you don't want to help yourself, so how could that impact that relationship with the provider. – C3

Not all older adults agreed with the tendency towards selective disclosure of patient-generated health data. Two older adults expressed that they are less likely to share patient-generated health

data when they were non-compliant and inclined to share only the compliant information. However, one participant was comfortable sharing their patient-generated health data regardless of the results.

if you're underperforming, you're a little more likely not to want to tell everything that you do – P2

But if I walk everyday in the good weather – not this weather – I want him to know about it and I wouldn't tell him I did if I didn't do it. – P3

I would tell him. If I walk only 5000 or 6000 I will tell him too. – P1

Older adults and clinicians generally agreed on the benefit that increased transparency have on the care they provide and receive by sharing patient-generated health data. Ultimately, clinicians viewed the non-compliance to collecting patient-generated health data as an issue they can help prevent by gaining the buy-in from patients. Patients also raised the need for additional education that may improve the understanding of the need for patient-generated health data.

6.5.2. Theme 2: Reliability of patient-generated health data

Clinicians recognized the issue of accuracy of the patient-generated health data from mHealth apps and wearable devices and understood that they may not be perfect. Despite the inaccuracies, the perceived clinical value outweighed the alternative of no data. However, clinicians' concerns for the reliability of patient-generated health data stemmed from the perceived lack of trust in patients' ability to capture the data or share the data reliably.

You have to assume that the patient is wearing it for the majority of the time. – C1

Not remembering to do it ... I was told I was supposed to track this and I've forgotten so many times – C3

Older adults and clinicians perceived that lack of clinical knowledge by patients leads to collection of irrelevant patient-generated health data and decreases the usefulness of information. On the other hand, older adults viewed education on self-management as a key component to understanding what data to collect and monitor.

I guess it depends on who is looking at the data and if the person entering it can also appreciate or have some clinical background, because then they can say, okay I'll use it and I'll enter it, because it has usefulness for my clinical provider. – C3

they really are there to teach him, make sure that he understands what – he needs to understand that he needs to take his blood pressure medication everyday and they need to monitor that and see whether it's working – P4

Manipulating mHealth app and wearable devices by patients to gain favourable data was viewed as a threat to the reliability. Clinicians acknowledged that this issue is not unique to the patient-generated health data and it can happen to any self-reported information.

And how accurate is the data when it comes, so like if you learn to game the system, you can choose to, you know ... in the case of like blood sugars, you know, take it later on, so that way it looks like it's a better reading than it actually is. – C3

Shake your hand as though you're walking. – C2

They could be lying about writing down their values, right or they could be lying about the weight that they measure at their home scale or whatever, right. – C4

The threat to the reliability of patient-generated health data through manipulation of mHealth and wearable devices was given an intense emphasis by clinicians. It was because clinicians were aware of the advancement in sensor technology that enabled previously actively collected patient-generated health data to become passive data collection such as for blood glucose level. The passive data collection increased the trust clinicians put in the quality of the data as it prevented data manipulation by the patients.

Like blood glucose right now, like right now it's under actively sensed data ... because I guess you would have to do like a finger prick and then we do reading and then enter it in, but now there is technology that exists where you, you know, you attach, and all you have to do is put the device. – C3

I mean after having worked with patients and now having parents that are dealing with chronic conditions themselves, I really hope that at some point a lot of that data collection is passive. – C2

Overall, the reliability and accuracy of patient-generated health data was disproportionately perceived as an issue by clinicians than older adults. Clinicians also alluded to old age as a potential challenge as the older generation may not be as fluent with mHealth apps and wearable devices.

6.5.3. Theme 3: Meaningful use of patient-generated health data and decision support system

Uncertainty around the meaningful use of patient-generated health data was expressed by both older adults and clinicians. Older adults were reluctant to share the patient-generated health data with their clinicians as they were uncertain of the use of them by their clinicians and if the clinicians had adequate skills to use them.

That's the thing; check up are they really doing this? – P4

he is not going to absorb it any more than we would. – P3

A large amount of data was viewed as a major hindrance to use the data by both older adults and clinicians. Older adults felt 'overwhelmed' when trying to review and understand the data. Older adults also felt discouraged to share the data as they perceived that reviewing patient-generated health data is a time-consuming task and clinicians would not have enough time.

And you want to know what's important for you and I think people can do these things but you have to do it in little steps too. This is kind of overwhelming, the whole thing. – P2

... the doctor is just simply too busy, he'll never look at all this information that we're talking about here. He won't have the time. – P4

However, clinicians did not express the lack of skills as a barrier to using patient-generated health data. Instead, clinicians reiterated the issue of the volume of patient-generated health data

and acknowledged the lack of time to review and discuss the patient-generated health data before or during consultations.

... as a provider, like I wouldn't want to be the one going through like excel sheets of data – C2

If I'm looking at all of the data that's available across like 20 different measures, how long do I have for a consult even, or how long do I have allocated for a meeting for this patient. – C3

Despite the issues of large amounts of data and lack of time, clinicians saw clinical value in collecting more patient-generated health data. Clinicians envisioned that patient-generated health data can provide additional information they need when investigating the effectiveness of the treatment such as newly prescribed medication or behaviour changes.

I would say if it wasn't a technological or a financial cost constraint to have, at least the passive data stuff all included and made available to the clinician, because then you can correlate things like, all right well ... you know, they had a blood pressure issue, right. What were they doing at the time, what was your physical activity at the time or did they get a good night's sleep before, you may not see that directly, but having that data wouldn't hurt – C3

... from a clinician perspective, but when you asked about the clinician versus patients, I think it'd be nice to have all this data – C2

Clinicians had an extensive view on decision support system as an essential part of the patient-generated health data to effectively use it in clinical context. Decision support systems were

perceived as a tool that can highlight the most relevant information and reduce the time it takes to interpret the data. It was also viewed as an early warning system for patients that showed deteriorating health.

From the provider perspective, how is the data presented to me, is it a whole set of charts and numbers I have to go find and find trends? Or is it, is there a dashboard that comes up that easily [find] trends for you, because then I can look at it, I'm going, oh okay, I see a positive trend, here's what I can, it's actionable like you said, I can do something with it and provide guidance. If it's just a whole bunch of numbers and I have to see well how close is it and how much time will that take, then I may be less, I may be more hesitant to ask for this data or use this data. – C3

... with maybe mental health issues or support issues, like depression, with their consent I think that would be great ... if suddenly their social media usage or their call, texting has dropped then, you know, it should set off an alarm. – C2

Older adults perceived the patient-generated health data as difficult to use as it is too large and time consuming to gain understanding of their health and effectiveness of care. Clinicians expressed the significance of decision support system to be able to take action on patient-generated health data.

6.5.4. Theme 4: Perceived clinical benefits and intrusiveness of patient-generated health data

The monitoring aspect of patient-generated health data disturbed older adults to varying degrees. One older participant expressed emotionally charged negativity repeatedly towards the data collection and sharing with clinicians. It was further perceived as a threat to autonomy.

Clinicians acknowledged the tension between the clinical benefits and the intrusiveness of patient-generated health data systems. Clinicians also made themselves accountable to gain buy-in from patients.

It just seems to me very intrusive. Every little thing, every little step you take and so on... you get to a point where "I don't want so much of you in my life." I like the act that my doctor doesn't overdo it. You thought about not wearing it and then you don't get all the information. – P2

And I guess I'm afraid I'm going to be told "You shouldn't be doing this, you shouldn't be doing this, you shouldn't be doing that." That's hard to live with. – P2

... gaining that buy-in and helping people understand that this data is going to help them in the long run. – C2

Clinicians also had heightened sensitivity to the patient-generated health data that may intrude on the privacy of patients. One clinician perceived monitoring of social media usage for tracking mental health and GPS information for Alzheimer's and dementia patients to be intrusive. The internal conflict between clinical benefits and intrusiveness of patient-generated health data was evident for one clinician.

Yeah, the social media and the communication, I can see how that's useful, but I know there's been, there's been kind of pushback from geriatric lines, even with the GPS coordinates, because they feel monitored – C2

When asked about the current protective regulations for patient privacy and confidentiality, clinicians viewed them as a necessary barrier and as a facilitator for integrating patient-generated health data into existing health information systems safely and securely.

... talking now between patient and provider, like that definitely needs to be given the most security that we can... so if you want to take information from a wearable device and throw it to an EMR or a hospital system, there's sometimes a lot of challenges in being able to do that. – C2

the privacy laws are necessary ... I would say it's a, it's definitely a barrier what between like healthcare provider sharing, so yeah, it is a, it's a necessary barrier - C3

6.5.5. Perceived usefulness of patient-generated health data

When the frequency of the different patient-generated health data mentioned during the focus group was examined, clinicians engaged in more diverse types of patient-generated health data and more frequently than older adults. Table 6.2 summarizes the patient-generated health data asked in the Data Rating Questionnaire and the frequency they were discussed. Blood glucose level, step count, physical activity, sleep, and blood pressure were most frequently discussed.

Table 6.2. Frequency of patient-generated health data mentioned in focus group interviews

Patient-generated health data	Frequency – how often was a concept mentioned?		
	Clinicians	Older adults	Total
Blood glucose	6	3	9
Step count	3	4	7
Physical activity	5	2	7
Sleep	3	4	7
Blood pressure	2	4	6
Gait	4	-	4

Heart rate	2	2	4
Communication activity	3	-	3
Social media usage	3	-	3
Stress level	-	3	3
Dietary intake	2	1	3
Body temperature	2	-	2
Body weight	1	1	2
GPS	1	-	1
Air quality	1	-	1
Ambient light	1	-	1
Air pressure	1	-	1
Body fat percentage	1	-	1
Mood	-	1	1
Typing pattern	1	-	1
Wound pictures	1	-	1
Sedentariness	-	-	-
EDA	-	-	-
PEF	-	-	-
Inhaler usage	-	-	-
Total	45	24	69

In addition to the frequency, the extensiveness (i.e. how many people said something) of a topic was examined. Stress level was discussed only by older adults and it was portrayed with a significant importance for overall well-being. Older adults also made a distinction between acute stress and chronic stress.

If you have high stress and you have, what we would call a bad day, that affects your whole being, your whole body and your mind more. – P3

We get to this stage and many people have lost their spouse and it seems to take a really long – well, it never goes away. But to deal with stress is a high component. – P2

The Data Rating Questionnaire results showed that on average, participants rated the usefulness of patient-generated health data at 3.35 in between Moderately Useful and Very Useful. The five

most frequently mentioned patient-generated health data including blood pressure, step count, physical activity, sleep, and blood pressure had the higher average score of 3.83. The questionnaire results were significantly correlated with the frequency of patient-generated health data mentioned in the focus group interviews ($r=0.42$, $p=0.034$). Table 6.3 describes the average rating of patient-generated health data for older adults and clinicians. Figure 6.1 shows the overall distribution of ratings for each patient-generated health data.

Clinicians tended to rate patient-generated health data higher than older adults (mean 3.55 vs. 3.18, $p<0.01$). The actively collected patient-generated health data was rated significantly higher than passively collected patient-generated health data (mean 3.80 vs. 3.05, $p<0.049$). Clinicians perceived passively collected patient-generated health data as more trustworthy as it prevented data manipulation by patients. However, the clinicians' ratings for actively and passively collected patient-generated health data were not statistically different ($p=0.15$).

Table 6.3. Average rating of patient-generated health data by older adults and clinicians

Patient-generated health data	Average rating (1 = Not at all useful and 5 = Extremely useful)		
	Older adults	Clinicians	Both older adults and clinicians
Passively collected patient-generated health data			
Step count	2.8	4	3.33
Gait	2.75	3.25	3.00
Physical activity	3.8	4.5	4.11
Sleep	2.9	3.38	4.44
Heart rate	4	5	3.63
Sedentariness	3.75	3.5	3.56
Body temperature	3.2	4	4.00
EDA	3.6	4.5	3.11

GPS	2.8	3.5	2.67
Air quality	2.8	2.5	2.56
Ambient light	2.8	2.25	1.75
Air pressure	2	1.5	2.38
Communication activity	2.25	2.5	1.71
Social media usage	1.67	1.75	2.38
Typing pattern	1.75	3	3.11
Actively collected patient-generated health data			
Body weight	4.2	4.75	4.44
Body fat percentage	4.2	4.5	4.33
Blood glucose	4.4	5	4.67
Blood pressure	4.2	4.75	4.44
PEF	3.75	3.5	3.63
Inhaler usage	3.2	1.75	2.56
Wound pictures	2.25	2	2.13
ECG	4	5	4.44
Mood	2.4	3.75	3.00
Dietary intake	4	4.75	4.33
Mean	3.18	3.56	3.35

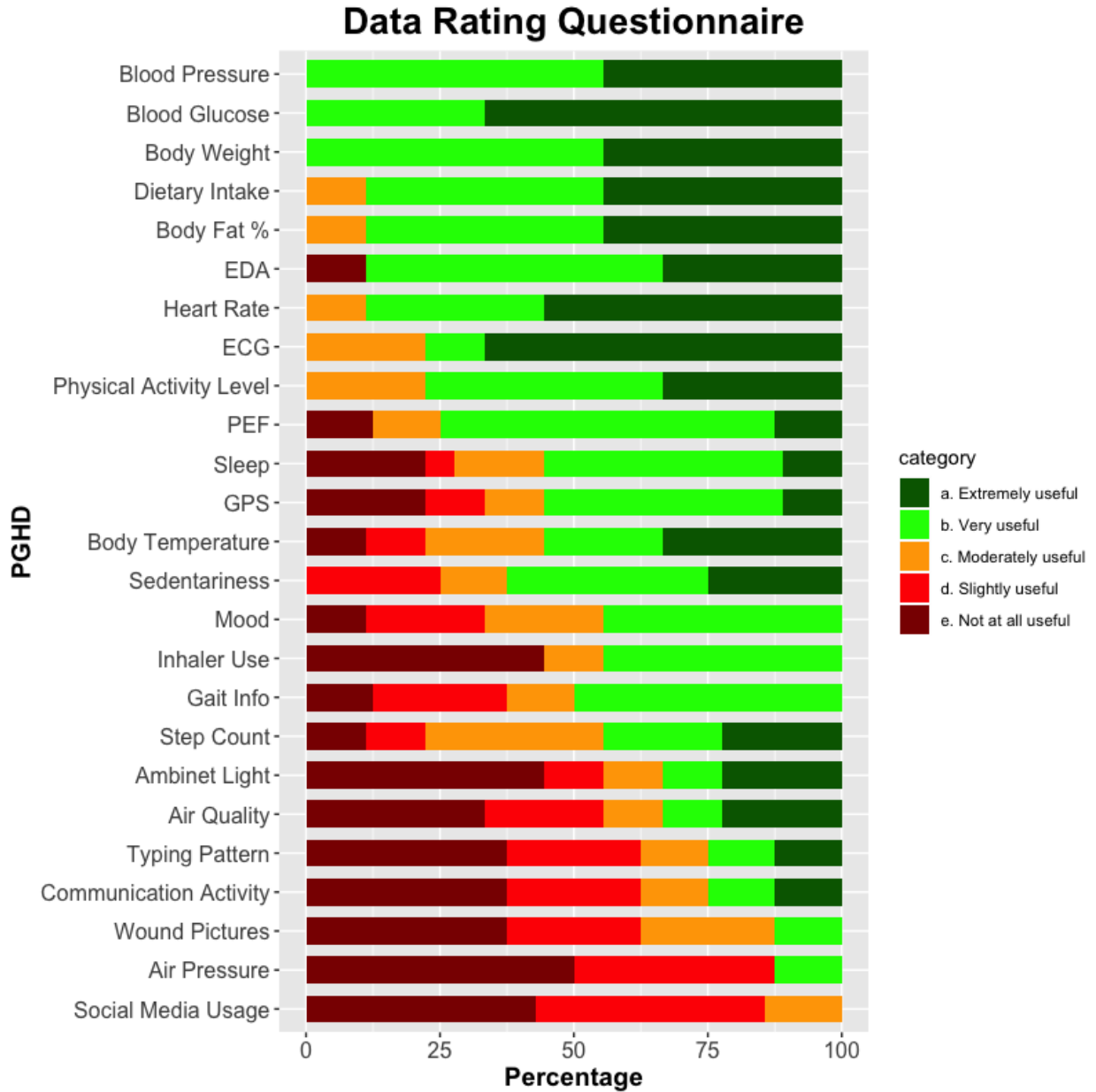


Figure 6.1. Bar graph showing the distribution of the Data Rating Questionnaire answers

6.6. Discussion

6.6.1. Principal Findings

In this study, we aimed to explore the perceptions of older adults and clinicians on patient-generated health data and their perceived usefulness. The embedded mixed method design

allowed us to investigate the viewpoints of participants qualitatively and added specificity by quantitatively measuring the perceived usefulness for patient-generated health data. This approach augmented the findings from the focus group interviews with the quantitative results by examining additional aspect of patient-generated health data while testing for the convergence of results from two data sources.

Overall, we identified four major themes that older adults and clinicians perceive to influence the use and sharing of patient-generated health data. Participants perceived that the objective nature of patient-generated health data provided transparency to the patient and provider relationship. From clinicians' experience, patients tended to react negatively to the added transparency by stopping collecting patient-generated health data, selectively disclosing favourable data, and manipulating the system. This view was reiterated by the patients. In general, people seek positive social interaction and the patient-provider relationship is not an exception (Klitzman, 2007). Patients display natural tendency to "please the doctor" and the older adults expressed the fear and anxiety around the patient-generated health data's capacity to highlight the non-compliance to care plan. As a result, it was perceived to have negative impacts on the patient-provider relationship. This finding expanded a recent interview study that called for exploration of unintended consequences of patient-generated health data which may include a feeling of failure or inadequacy by healthcare consumers (Lavalley et al., 2020). However, our study finding directly contradicts previous studies (Reading & Merrill, 2018). Previously, patient-generated health data was mainly viewed as a facilitator to enhancing patient-provider relationship with evidence for engaging patients in their care and increasing timely communication (Lai, Hsueh, Choi, & Austin, 2017). The difference in findings may be due to the

fact that previous studies focused on the effectiveness of patient-generated health data from the perspective of system implementation and evaluation with a limited insight into the patients' perception. Additionally, our study sample showed contradicting views on their comfort level around disclosing non-compliant patient-generated health data. This indicates the need for careful consideration on the user preferences for data sharing and the need for flexibility of system design.

The accuracy, reliability and validity of mHealth and wearable device-based patient-generated health data has been previously identified as a common barrier for clinical use (West et al., 2018). Our analyses identified the reliability of data to be a barrier, but the root cause for concern was the perceived lack of patient self-efficacy to carry out the collection of patient-generated health data rather than technical inaccuracies with the tools. Clinicians also voiced the concern around the perceived lack of understanding on the clinical relevance of patient-generated health data collected by patients. Inadequate levels of trust on mHealth and wearable systems were identified where clinicians expressed the issue of inaccurate self-reported data with an intensity. This theme highlighted the overall need for training as well as uncertainty around who is accountable for training the users. The need for patient training on collecting and recording patient-generated health data has been a repeating theme in the literature review (Reading & Merrill, 2018). Proper education may alleviate the issue but the responsibility of educating patients becomes unclear when the tracking of patient-generated health data is patient-initiated rather than clinician-initiated. Transferring the responsibility of educating patients about the proper use of patient-generated health data systems to clinicians may not be an efficient use of resources as the lack of expertise in patient-generated health data is a commonly reported barrier

for clinicians (West et al., 2018). This highlights the need for strong technical support for patients from healthcare organizations and for a higher standard for user-friendly interfaces especially for older adults from system developers.

Clinicians and older adults alike expressed their uncertainty around efficient ways to interpret patient-generated health data. Older adults had concerns about how the data are used by clinicians to benefit the care they receive. Clinicians voiced their lack of expertise in managing data to extract relevant information. This was perceived as the main barrier for the realizing of added clinical values of patient-generated health data. As a result, a decision support system was viewed as an essential component of patient-generated health data systems. This is in line with the recommendation that prioritizes decision support systems that can readily summarize the patient-generated health data and present the most relevant information as a key to integration into EHR (Cresswell, McKinstry, Wolters, Shah, & Sheikh, 2018). The need for decision support systems also extends to patients' use of patient-generated health data. It can help them easily extract the most relevant and helpful information. However, only a handful of mHealth and wearable device systems have integrated decision support that can guide users to effectively interpret information into meaningful actions (Kim & Lee, 2017; Lai et al., 2017). Future studies should investigate the types of decision support that can be effectively delivered via mHealth.

Protecting patient privacy and confidentiality goes beyond complying with the bare minimum requirements of local regulations. Some older adults perceived the monitoring of patient-generated health data to be intrusive and perceived it as a risk to their autonomy. Similar sentiments were shared by clinicians and a particular sensitivity was displayed towards GPS

information, communication tracking, and social media usage. Although concerned about its intrusiveness, clinicians saw the clinical benefits and the role of privacy regulations in enabling collection of such information safely and securely. Furthermore, clinicians perceived that privacy regulations can facilitate safe and secure integration of patient-generated health data into health information systems. This view from clinicians contradicted findings from the literature where many stakeholders view privacy concerns as a hindrance to successful use of patient-generated health data in clinical settings (Reading & Merrill, 2018; West et al., 2018; Zhu et al., 2016). For example, patients were often unsure of the privacy and confidentiality standards and regulations (Reading & Merrill, 2018). Patient-generated health data was sometimes shared with clinicians in non-compliant ways, further hindering the use by clinicians (Zhu et al., 2016). Privacy regulations are localized and each system faces unique challenges. There exists knowledge and expertise in health care for the integration of electronic medical record systems and parallels can be drawn with the integrating of patient-generated health data to EHR. Future studies should draw on this expertise to find efficient solutions.

Older adults and clinicians tended to discuss familiar patient-generated health data and they were rated higher and more useful than other unfamiliar patient-generated health data. The diversity in the patient-generated health data discussed differed significantly. Clinicians adventured into the discussion of patient-generated health data that were new to them more frequently than older adults and also explored how they may add clinical value. This result was different from a previous study that tracked a range of patient-generated health data collected by healthcare consumers and healthcare providers (Lavalley et al., 2020). They found healthcare consumers tracked a larger number of patient-generated health data and clinicians focused on patient-

generated health data related to their clinical specialty. The authors of this study did not identify the detailed information of the healthcare consumers, but we suspect the difference may be due to differences in the study population. This was suggested when the most commonly tracked patient-generated health data were wellness-focused such as dietary intake, physical activity, and heart rate while more clinical patient-generated health data including blood pressure and blood glucose were less frequently mentioned. However, we noted the similarity in the overall type of patient-generated health data tracked.

Clinicians carried out more extensive and detailed discussions around clinical use for a range of patient-generated health data than older adults. Significantly higher average ratings of patient-generated health data by clinicians supports this finding. Clinicians indicated increased trustworthiness of passively collected data over actively collected data as they prevent patients from incorrectly reporting the value. However, passively collected data were not rated more useful by clinicians. This may be because the most highly rated patient-generated health data including blood glucose, blood pressure, body weight, and dietary intake were classified as actively collected data. This represents the unmet technology requirements by mHealth and wearable devices to the need of patients and clinicians. It was explicitly mentioned that they hoped an advancement in sensor technology would lead to the expansion of passively collected data such as blood pressure and blood test results. This finding provides evidence to medical technology developers of the data needs of clinicians.

6.6.2. Limitations

Several limitations are present in this study. The small number of focus group interviews limited the concepts from reaching its saturation. This limitation was partly alleviated since more than 80% of all themes are discovered within two to three focus group sessions (Guest, Namey, & McKenna, 2017) and partly through the collection of quantitative data to augment the qualitative results. The composition of the focus group sessions between older adults and clinicians was uneven. This may have influenced the dynamic of discussion to be narrower in scope as one group of participants may have not been able to express their opinions freely. The analyses of the study results were conducted by a single reviewer, which may have introduced biases and personal views in the coding process and in synthesizing themes. The older participants were a member of a research support group and it may have presented a representative bias. Very limited information about the topic was provided prior to the focus group and some participants were unfamiliar with the topic of patient-generated health data. The lack of understanding of patient-generated health data may have limited the breadth and depth of discussion. However, this was intentional to capture the true perceptions of older adults and clinicians.

6.7. Conclusion

This embedded mixed method designed study generated several important findings about older adults and clinicians' perception and perceived usefulness on a range of patient-generated health data. The increasing popularity and adoption of consumer wearable devices and health-oriented mHealth apps, especially among older adults, will continue to put the demand for better integration of patient-generated health data into healthcare systems. The size and complexity of patient-generated health data will also continue to rise with the advancement of sensor

technologies and it has already begun to blur the line between consumer and medical devices. It presents new opportunities to improve the care clinicians provide and to increase the efficiencies of the healthcare system. Such momentous opportunity has been recognized by governments around the world and the foundational work has begun. Nevertheless, there exists a need for more evidence for identifying obstacles for healthcare users, providers, organizations and funders. Greater insight into these barriers can inform users, providers, developers, and other stakeholders of the priorities for effective integration of patient-generated health data into healthcare.

Chapter 7. Discussion and Key Contributions

7.1. Implications for Health Care Practice

The first two studies of this dissertation were designed to investigate the use of wearable device data to assess frailty with older adults receiving home care services and recovering from critical illness. Assessing and predicting frailty from data generated from consumer-grade wearable devices have implications on multiple sectors of the health care system.

In primary and ambulatory care settings, screening for frailty is faced with challenges of finding the right assessment tool. Undeniably, the comprehensive geriatric assessment is viewed as the most extensive tool to assess the health of an older adult, identify risk factors, and develop a management plan (Lacas & Rockwood, 2012). However, it is generally perceived as infeasible in primary care due to its resource intensiveness. The right tools must have the sensitivity to overcome the subtle onset and slow progression that mimics normal aging (Lee et al., 2015), yet it must also be efficient with time it takes. The results from Chapter 4 demonstrated that wearable device driven frailty assessment has the potential to fulfill these requirements. The evaluation of wearable device data can be seamlessly and instantaneously carried out. Many discussions in primary and ambulatory care settings are concerned with preventive measures, such as lifestyle changes, screening tests, or other medical investigations. Identifying frailty levels in primary care settings can bring a host of benefits. Frailty adds prognostic value and facilitates open dialogue with patients that can help make informed decisions for both patients and clinicians (Singh et al., 2008). It can guide clinicians in making decisions around how aggressively to seek further screening tests. It provides clinicians an opportunity to manage

conditions that underlie frailty to prevent adverse health outcomes (Lee et al., 2015). Interventions for frailty range from behavioural changes such as exercise and nutrition to pharmaceuticals such as angiotensin converting enzyme (ACE) inhibitors (Clegg et al., 2013) and Vitamin D supplements (Wicherts et al., 2007). Moreover, many interventions have demonstrated their effectiveness in improving independence, preventing falls, enhancing physical function, and reducing mortality (Beswick et al., 2008). They require the involvement of home care providers to deliver the intervention such as home-based rehabilitation programs (Crotty, Whitehead, Miller, & Gray, 2003; Cunliffe et al., 2004).

Critical care settings suffer from the same issues as the primary and ambulatory care settings, where they lack appropriate frailty assessment tools (Muscedere et al., 2016). Some tools are too time-consuming to be feasible for clinicians to conduct and the others are dependent on patient performance which limits their feasibility for critically ill patients. For patients who are too critically ill to obtain some necessary information, frailty was often estimated using available data that may indicate an elevated risk of frailty (Muscedere et al., 2016) or by asking a surrogate decision-maker (Flaatten et al., 2017; Hope et al., 2017). Estimation of frailty levels from wearable devices provides exciting opportunities for critical care settings. More accurate estimation of frailty can provide more precise prognoses (Bagshaw et al., 2015). Unfortunately, the current evidence for specialized treatments for frail patients is weak and many interventions such as early rehabilitation programs have failed to produce a meaningful impact on health outcomes (Wright et al., 2018). It may be due to failure to identify the population that can benefit the most (Muscedere et al., 2016), highlighting the potential benefit of wearable devices to estimate the pre-critical illness frailty level. Assessing frailty using wearable devices has another

implication to critical illness survivors. The results from Chapter 5 demonstrated the potential for wearable devices to act as an early detection tool for delayed recovery. In particular, the pattern of increasing step count and average heart rate over the 4-week period following the hospital discharge were correlated with failure to recover to pre-critical illness level. Some critical care teams provide follow up consultations to critical survivors. The results from the wearable devices can guide targeted follow-up visits to those who are failing to recover to the pre-critical illness level. Noting the limitations of Chapter 5, this finding should be confirmed and replicated by future research studies.

7.2. Implications for Technology Development and Policy

The potential benefits of patient-generated health data including wearable and mobile devices are unrealized in the current health care system. As discussed previously, timely evaluation of patient-generated health data can have positive implications in various health care sectors. The results from Chapter 6 also demonstrated the need for a carefully designed system that can transform patient-generated health data into clinically relevant information. However, this is only possible when patient-generated health data is integrated with existing health information systems.

There are complex and multi-faceted technical challenges that prevent integration at a larger scale including lack of standards in data definitions, data analytics, and interoperability between multiple systems (Cortez, Hsii, Mitchell, Riehl, & Smith, 2018; Shapiro et al., 2012). As it was found in Chapter 6, one of the major concerns is the reliability and accuracy of the data.

Consumer-grade wearable devices are not subject to the Food, Drug, and Cosmetic Act in the US

(U.S. Food and Drug Administration, 2015) or the Food and Drugs Act in Canada (Health Canada, 2019). This raises challenging questions around accountability and liability despite research studies reporting high validity and inter-device reliability for data quality (Evenson et al., 2015). Another issue revolves around the interoperability of patient-generated health data and existing health information systems. There is a lack of a standardized definition of patient-generated health data and it is preventing the merger of data from multiple sources for clinical and research use (Cortez et al., 2018). To overcome these issues, professional associations are developing wearable activity tracker performance standards (Cortez et al., 2018). Moreover, key industry players of wearable devices such as Apple, Google, and Samsung have made accommodations and released platforms to enable the sharing of patient-generated health data in a standardized way (Farshchian & Vilarinho, 2017). These initiatives shine positive light into the future of patient-generated health data but they also raise concerns for the need for regulatory oversight over these platforms for clinical and research use. Future discussions must focus on the need for regulatory oversight over the design and use of these platforms to share patient-generated health data that can potentially be used to inform clinical decisions.

7.3. Implications for Consumer Health Informatics Research

Researchers of diverse backgrounds recognized a good fit between the needs of older adults for healthy aging and the offers of wearable devices (Kim & Lee, 2017; Lewy, 2015; Majumder, Mondal, & Deen, 2017). To date, the majority of wearable device research effort in health has focused on investigating validity (Alharbi et al., 2016; Bai, Hibbing, Mantis, & Welk, 2018; de Bruin, Hartmann, Uebelhart, Murer, & Zijlstra, 2010; Evenson et al., 2015; Shcherbina et al., 2017) and acceptability (Mercer et al., 2016; Puri et al., 2017; Zhang & Li, 2017). There are

fewer intervention studies (de Bruin et al., 2010). Most studies employed the use of a device as an intervention in itself and examined the processed data such as step count and physical activity level (Allet, Knols, Shirato, & de Bruin, 2010; de Bruin et al., 2010; Stephenson, McDonough, Murphy, Nugent, & Mair, 2017). There are only a handful of examples of using wearable devices to assess clinical conditions. Examples include Parkinson's disease (Hubble, Naughton, Silburn, & Cole, 2015), epilepsy, and stroke (Johansson et al., 2018), where accelerometer-driven information is used to assess the severity of episodic events. The results from this dissertation add to the list of clinical conditions that can be assessed and expands the boundaries of the current use of wearable devices for clinical purposes. There are plentiful topics where patient-generated health data showed promising evidence. Assessment of mental health conditions and symptoms is one area that is also quickly gaining traction (Mohr et al., 2017; Seppälä et al., 2019). Advancing sensor technology and innovative use of the data and analytics should be focused in future research to expand this list further.

7.4. Future Research

Technology is present in frailty research. It is used to prevent, assess, and treat frailty (Mugueta-Aguinaga & Garcia-Zapirain, 2017, 2019). Previously, many frailty research studies used technologies to automate assessments of gait, balance, sit-to-stand and stand-to-sit performance, and other kinematic characteristics (Dasenbrock et al., 2016). Research studies that used an accelerometry data begun to emerge in recent years and indicated evidence for frailty assessment using this technology although refined to controlled laboratory settings (Fontecha, Navarro, Hervás, & Bravo, 2013; Theou et al., 2012). The results of Chapter 4 extended these studies and demonstrated that frailty could be predicted using wearable device data and easily obtainable, if

not already exist, health assessments for comorbidity and independence among community-dwelling older adults. One of the key issues of wearable and mobile research studies is the abundance of pilot studies, while there is a lack of larger-scale studies (Brickwood, Watson, O'Brien, & Williams, 2019; B. Kim & Lee, 2017). In order to progress research beyond the pilot phase, there should be an effort to develop a research purpose wearable device database that can scale-up the research activities. It can support innovative research studies using big data analytics. A recent study that used an administrative health database containing information from over a million older adults demonstrated the powerful predictive performance of an array of machine learning techniques (Tarekegn, Ricceri, Costa, Ferracin, & Giacobini, 2020). Such analytic performance can be improved by using data from wearable devices, as demonstrated in Chapter 4. Developing such research infrastructure for patient-generated health data requires funding, commitment, and most importantly, evidence. The evidence generated from this dissertation may be small but is an essential step in the right direction.

7.5. Limitations

Limitations for specific studies are included within each chapter. The purpose of this dissertation was to push the boundaries of the current practices with wearable devices and patient-generated health data in health care for older adults. This topic has gained much attention in health care research. Yet the topic has only begun and this dissertation carried out much needed exploratory investigation. As a result, the sample sizes for the studies were small. This limited the range of statistical analyses that could be used and made the results vulnerable to statistical assumptions. Despite the small sample sizes, evidence was successfully generated to prove the concept and it

warrants future work. Future research should build on the evidence from this dissertation, scale-up the research effort with larger sample size and also extend the findings in other populations.

Wearable technology is advancing continually, including since the beginning of the work for this dissertation. Two different wearable devices were used but they have been replaced with their successors from their manufacturers. New types of sensors such as ECG, blood pressure monitors and glucometers have entered the consumer market. This adds complexity to the patient-generated health data but opens new research opportunities. While this demonstrates wearable technologies are evolving very quickly and may threaten the specific results of Chapters 4 and 5 by making the devices used obsolete, the evidence it generated here can contribute to guiding future research studies on new wearable technologies.

Participants of the research studies were recruited from the Greater Toronto Area, the city of Kingston and its surrounding areas, and the Kitchener-Waterloo region, which are all urban areas of Ontario. Hence, the results may not be generalizable to older adults in rural settings. Future research is recommended to validate the generalizability to other populations of interest.

Chapter 8. Conclusion

Today, more health data are being generated than ever through wearable devices and mobile apps. As the technology advances, patient-generated health data will increase in size, the number of types and complexity. When these data are integrated with electronic health records, connected with strong data analytics and facilitated by sound regulatory policies, they can lead to innovative changes to the ways we access and interact with health care. The three studies of this dissertation collectively demonstrate a new way of using wearable device data to assess, monitor and predict frailty, and identified opportunities and challenges of patient-generated health data from the perspectives of healthcare professionals and older adults. The evidence generated by this dissertation work contributes to building a new way of health care. Integration of patient-generated health data will be difficult and face many challenges, but it is possible. As many of us witnessed the uptake of electronic health records in health care systems, successful implementation requires a shared vision across all stakeholders, strong commitment from government and leadership, and most importantly, guidance based on evidence from rigorous research and science.

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Appendices

Appendix A.

The results of Shapiro-Wilk normality tests for all continuous variables

	W statistic value (p-value)		Selected statistical test
	Non-frail	Frail	
Age	0.94 (0.17)	0.84 (0.02*)	Mann-Whitney U
BMI	0.98 (0.90)	0.92 (0.24)	t-test
ADL	0.77 (<0.01*)	0.85 (0.03*)	Mann-Whitney U
CCI	0.88 (0.01*)	0.93 (0.30)	Mann-Whitney U
Home care utilization	0.88 (<0.01*)	0.79 (<0.01*)	Mann-Whitney U
Worn time, hours per day	0.89 (0.01*)	0.92 (0.26)	Mann-Whitney U
Daily step count, n	0.90 (0.02*)	0.87 (0.06)	Mann-Whitney U
Deep sleep time, min	0.84 (<0.01*)	0.94 (0.43)	Mann-Whitney U
Light sleep time, min	0.97 (0.78)	0.90 (0.16)	t-test
Total sleep time, min	0.95 (0.29)	0.77 (<0.01*)	Mann-Whitney U
Awake time, min	0.86 (<0.01*)	0.87 (0.06)	Mann-Whitney U
Sleep quality, %	0.69 (<0.01*)	0.81 (0.01*)	Mann-Whitney U
Heart rate, bpm	0.97 (0.65)	0.95 (0.53)	t-test
Heart rate SD, bpm	0.96 (0.49)	0.91 (0.16)	t-test

* p<0.05

Appendix B.

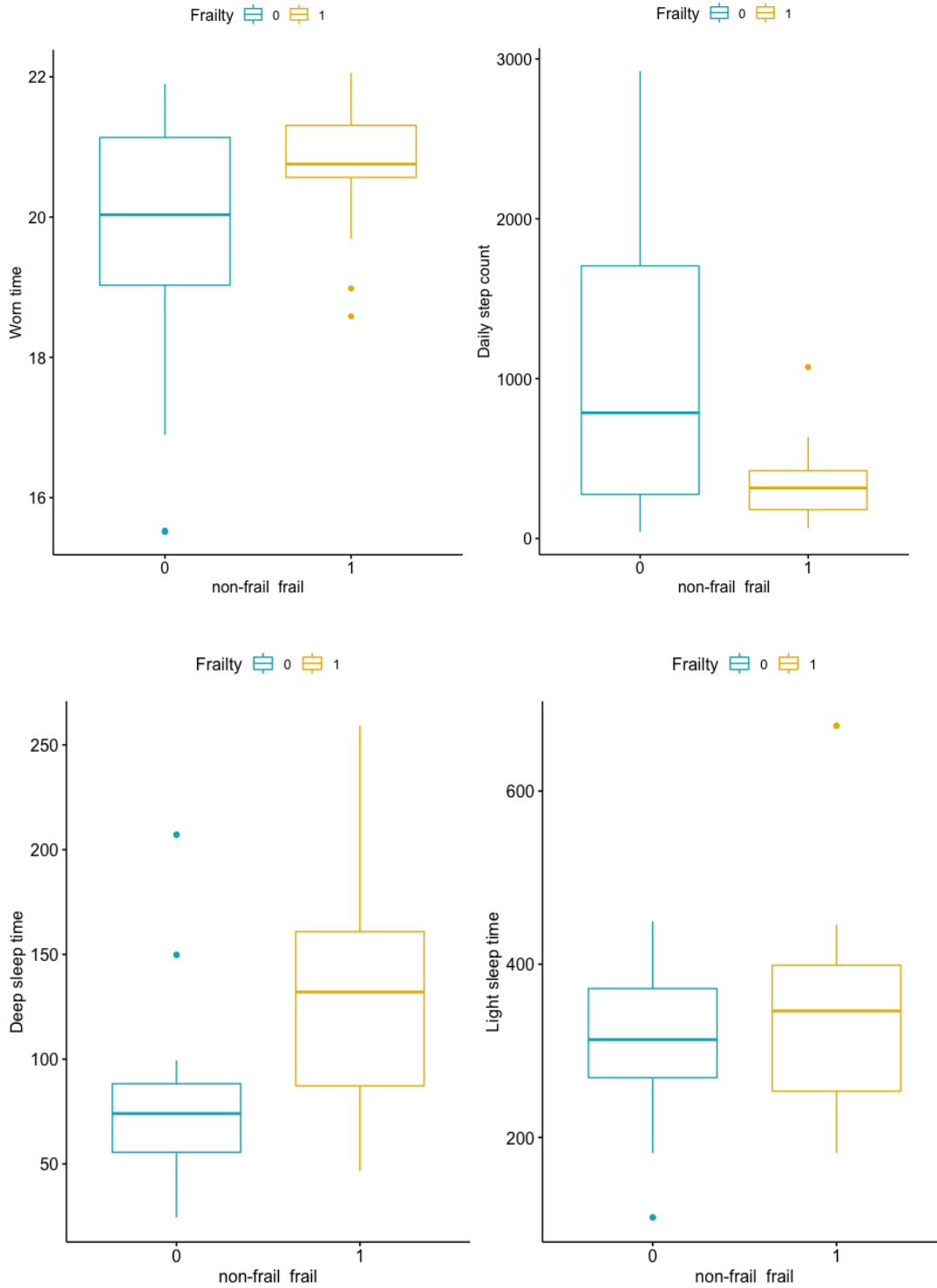
T-statistics and chi-square statistics for comparisons between the frail and non-frail participants with respect to baseline sociodemographic and patient characteristics (n=37)

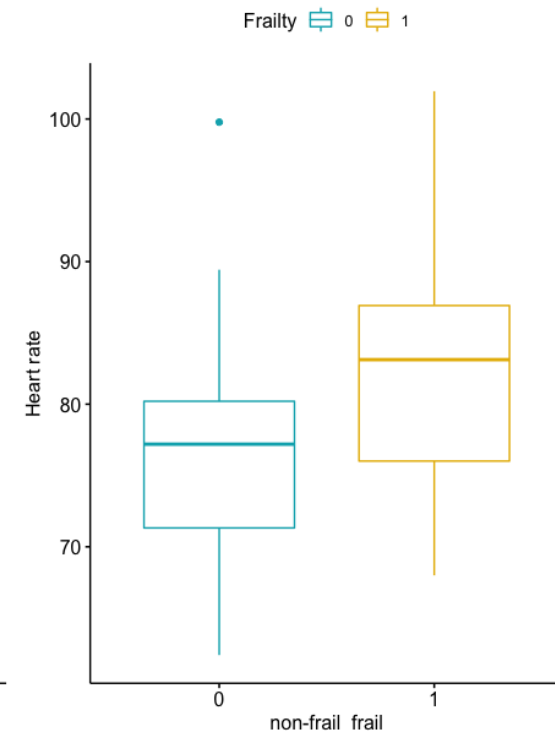
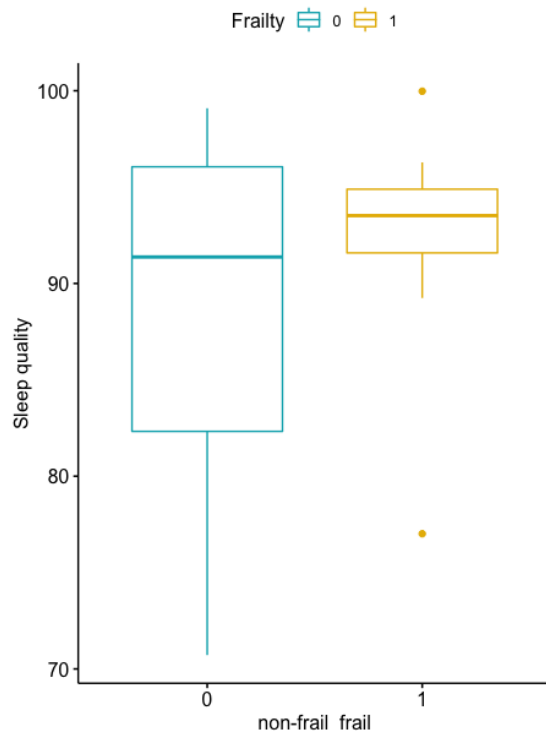
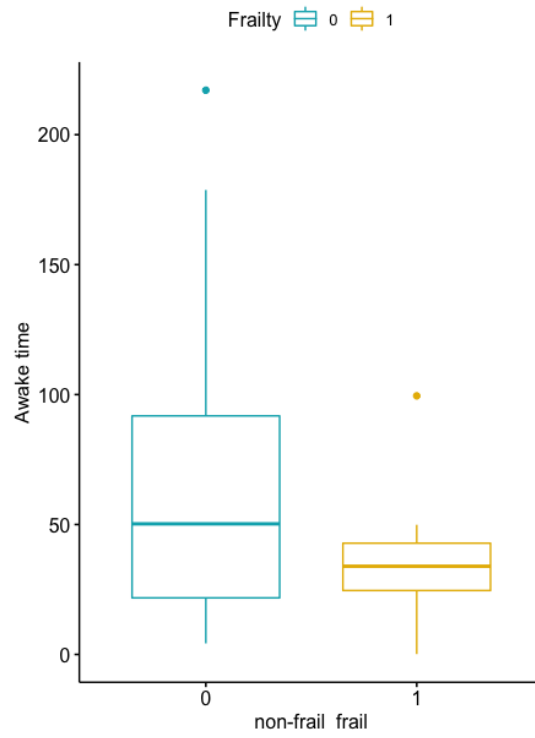
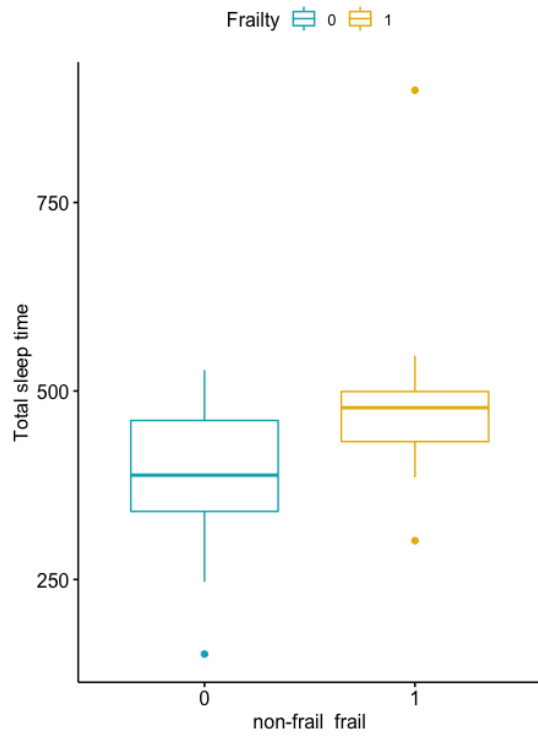
	Statistic value (df)	p-value	Performed statistical analysis
Age, years	1369.00	<0.01*	Mann-Whitney U
Sex	<0.01 (1)	1.00	Chi-square
BMI, kg/m ²	0.73 (20.70)	0.44	t-test
ADL score	180.00	0.43	Mann-Whitney U
CCI score	106.50	0.11	Mann-Whitney U
Marital status	3.76 (3)	0.29	Chi-square
Education	2.45 (2)	0.12	Chi-square
Income	7.34 (2)	0.03*	Chi-square
Income - Prefer not to answer, n=10	5.36 (1)	0.06	Post-hoc
Low income, n=17	1.04 (1)	0.93	Post-hoc
Mid to high income, n=10	0.62 (1)	1.00	Post-hoc
Ethnicity	0.13 (1)	0.71	Chi-square
Homecare Utilization			
Personal support service, hours per week	77.50	0.01*	Mann-Whitney U

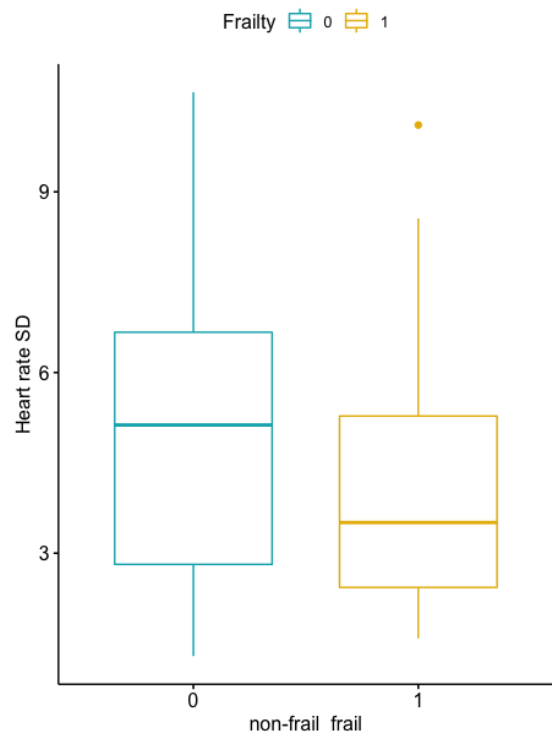
*p<0.05

Appendix C.

Boxplots of the wearable device data comparing frail and non-frail participants







Appendix D

Correlation between the data collected from the wearable devices and the frailty level and its change with exact p-values

	Frailty at T1	p-value	Frailty at T2	p-value	Frailty at T3	p-value
Physical activity data						
Daily step count	-0.76*	0.02	-0.35	0.11	-0.72*	.006
Active time, minutes per day	-0.62	0.12	0.03	0.43	-0.53	.061
Sedentary time, minutes per day	-0.66+	0.06	-0.39	0.36	-0.53	0.13
Sleep data						
In bed, minutes per night	0.10	0.42	0.13	0.75	0.42	0.53
Total sleep time, minutes per night	0.08	0.43	0.13	0.74	0.40	0.53
Awake time, minutes per night	-0.26	0.76	-0.07	0.78	0.07	0.76
Awake count, times per night	-0.31	0.91	0.06	0.23	-0.10	0.74
Sleep quality	0.23	0.46	-0.10	0.50	0.12	0.27
Heart rate data						
Average heart rate	-0.24	0.91	-0.72*	0.046	-0.16	0.94
Heart rate SD	-0.55	0.88	-0.05	0.30	-0.05	0.99
Average nocturnal heart rate	0.06	0.62	-0.21	0.81	-0.19	0.99
Patient characteristics						
Age	0.18	0.61	0.56+	0.06	<0.01	0.99
BMI	0.42	0.481	0.38	0.23	0.47	0.12
ICU length of stay	-0.01	0.409	0.21	0.51	0.00	0.99
Hospital length of stay	0.15	0.183	0.15	0.64	0.05	0.87
Charlson comorbidity index	0.56	0.206	0.12	0.706	0.29	0.36
Glasgow Coma Scale	0.24	0.155	-0.06	0.848	0.15	0.65
Changes in ADL	0.06	0.772	0.34	0.279	0.05	0.89
APACHE II score	0.19	0.636	0.47	0.123	-0.12	0.71

	Frailty change over D1	p-value	Frailty change over D2	p-value	Frailty change over D3	p-value
Physical activity data						
Daily step count	0.55	0.13	-0.46	0.23	0.14	0.57
Active time, minutes per day	0.63	0.56	-0.56	0.32	0.18	0.97
Sedentary time, minutes per day	0.41	0.20	-0.24	0.38	0.25	0.98
Sleep data						
In bed, minutes per night	-0.01	0.14	0.32	0.99	0.45	0.88
Total sleep time, minutes per night	0.01	0.16	0.31	0.97	0.46	0.89
Awake time, minutes per night	0.22	0.64	0.13	0.69	0.50	0.94

Awake count, times per night	0.37	0.79	-0.15	0.75	0.33	0.27
Sleep quality	-0.32	0.35	0.20	0.52	-0.19	0.40
Heart rate data						
Average heart rate	-0.28	0.32	0.37	0.11	0.13	0.47
Heart rate SD	0.54	0.57	-0.01	0.89	0.78*	0.02
Average nocturnal heart rate	-0.22	0.43	-0.04	0.26	-0.37	0.73
Patient characteristics						
Age	0.24	0.48	-0.45	0.16	-0.27	0.55
BMI	-0.11	0.85	0.15	0.27	0.04	0.71
ICU length of stay	0.17	0.56	-0.17	0.61	0.02	0.88
Hospital length of stay	-0.03	0.95	-0.07	0.87	-0.14	0.62
Charlson comorbidity index	-0.44	0.15	0.19	0.48	-0.44+	0.09
Glasgow Coma Scale	-0.27	0.83	0.19	0.24	-0.16	0.57
Changes in ADL	0.20	0.21	-0.23	0.52	-0.02	0.84
APACHE II score	0.17	0.32	-0.50	0.10	-0.47	0.08

* p<0.05

+ p<0.10

Appendix E

Case study

Mr. Greg McDonald, 77-year-old man, was diagnosed with a congestive heart failure a year ago after experiencing chest pain following a big family dinner. His multiple medical conditions include type 2 diabetes, high blood pressure, and high cholesterol.

Before being discharged from the hospital, Mr. MacDonald was counselled on a home diuretic protocol by a care coordinator. Mr. McDonald was given a logbook and asked to measure his weight, blood pressure, heart rate, blood oxygen level, and body temperature twice a day; once in the morning and again at night. He was also asked to answer questions about heart failure symptoms daily. The first few pages of the logbook are Mr. McDonald's personalized treatment plan as filled out and explained by his cardiologist and the care coordinator on site. It instructs on when to increase the dose of diuretic drugs and take additional drugs.

Mr. McDonald was also referred to a pharmacist (on site) for pharmacotherapy assessment and diabetes management. His diabetes is currently being treated with a fast-acting insulin. Mr. McDonald occasionally "takes a little more" insulin when he notes high blood sugar readings. The pharmacist changed to a slow acting insulin and he was explained the dosing concept on the new medications and how this regimen can give him greater flexibility.

The care coordinator signed out an iPad and glucometer and showed how to use the patient portal app to record the measurements. Through the app, he can access a sliding scale to correct for any temporary elevation of blood glucose. He was told to test four times daily and to record his blood glucose results, carbohydrate intake, and insulin doses in the app. Mr. McDonald was told that these data are accessible by the pharmacist who will adjust the insulin based on the recordings. Mr. McDonald was advised to pick up the adjusted doses when the pharmacist contact him and continue with the iPad.

Mr. McDonald was discharged and made his way home with help of his family. With him, he has a stack of information brochure, a logbook, and pulse oximeter for his new heart condition along with an iPad and glucometer for his diabetes.

Appendix F

Data Rating Questionnaire

Data Rating Questionnaire

Please rate the following personal sensing data based on your opinion on their usefulness to the case scenario.

Passively-sensed data: Data that are collected without user input. Minimal effort.					
Data Type	Not at all useful	Slightly useful	Moderately useful	Very useful	Extremely useful
Step count	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Gait information (e.g. stride)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physical activity level (e.g., duration, frequency, intensity)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sleep quantity (e.g. total sleep time, time took to fall asleep)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sleep quality (e.g. sleep efficiency, deep sleep and light sleep, nighttime awakenings)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heart rate (e.g. average heart rate, resting heart rate)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sedentariness level (i.e. duration, frequency)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Body temperature	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Electrodermal activity (measures stress level and emotional arousal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GPS/Location	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Air quality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ambient light	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barometer (i.e. air pressure)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Communication activities (i.e. call, texting)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Social media uses (i.e. Facebook, Twitter)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Typing patterns (i.e. text linguistic, speed, accuracy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Actively-sensed data: Data that are collected with user input. More effort needed.					
Data Type	Not at all useful	Slightly useful	Moderately useful	Very useful	Extremely useful
Weight	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Body fat %	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Blood glucose level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Blood pressure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Peak expiratory flow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Inhaler usage (i.e. puffer for asthma)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pictures (i.e. skin cancer, wound)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Electrocardiography (i.e. smartphone paired ECG device)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mood (i.e. Mood journal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dietary intake (i.e. Food journal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other data types: What other data you may find useful? Tell us what they are.					

Data Type	Not at all useful	Slightly useful	Moderately useful	Very useful	Extremely useful
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>