Implementation, Scale, and Spread of Telemonitoring for the Management of Heart Failure

by

Patrick Ware

A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy
Institute of Health Policy, Management, and Evaluation
University of Toronto

© Copyright by Patrick Ware 2019
Implementation, Scale, and Spread of Telemonitoring for the Management of Heart Failure

Patrick Ware

Doctor of Philosophy

Institute of Health Policy, Management, and Evaluation
University of Toronto

2019

Abstract

Despite evidence of positive impact, telemonitoring (TM) interventions for the management of heart failure (HF) have seen limited adoption in Canada. Following a literature review that explains evidence inconsistencies on contextual differences between trials, a single case study of the Medly TM program sought to understand the factors that influence the successful implementation, scale, and spread of HF TM.

First, an implementation evaluation found that the Medly program was successfully implemented due to facilitators related to characteristics of the clinic and of the adopting clinicians. Barriers that could limit the program’s sustainability, scale, and spread included complexity of the intervention, costs, and the lack of implementation plan.

Because successful spread is only possible if interventions are used as intended, the second study explored patient adherence to taking daily TM readings. Results showed an overall average adherence rate of 73.6% (SD 25.0) with a significant decline over time; the decline was significantly steeper in patients of younger compared to older age groups ($P=0.04$). Adherence rates were further explained by patients’ perceptions of the program’s benefits, ease of use,
presence of supporting services, and patients’ ability to form a habit around taking daily TM readings.

Finally, because successful implementations generally require the adaptation of interventions to local contexts, a qualitative study identified components of the TM program that could be safely adapted without negatively influencing the program’s ability to yield desired outcomes.

The spread of HF TM has been slowed by intervention and contextual complexities. This thesis describes key insights that have led to the development of an implementation strategy for TM programs to mitigate these barriers in the future. As such, this research has contributed to clarifying a path toward the wider adoption of HF TM such that it is available across Canada for HF management.
Acknowledgments

First, I wish to thank my committee members for offering invaluable academic guidance over the past 4 years. To Dr. Emily Seto, thank you for always treating me like a colleague and for the availability and commitment you offer to all your students – it is enough to make any graduate student jealous. Thank you also for encouraging me to discover my academic interests and for providing the opportunities that enabled me to pursue them. To Dr. Heather Ross, thank you for the thoughtful (and quick!) feedback you provided on all my work. I had the opportunity to speak with several of your patients and was consistently moved by the praise they had for your clinical expertise, your bedside manner, and your commitment to each one of them. These conversations served as a reminder of the incredible patients and clinicians that make up the healthcare system and provided inspiration for getting through the more mundane parts of graduate life. To Dr. Joseph Cafazzo, thank you for your leadership of the Centre for Global eHealth Innovation, a unique organization that embraces graduate students and gives them the opportunity to learn from and to contribute to real-world projects in consumer health informatics. Your commitment to placing focus on the patient perspective has greatly influenced this work. To Dr. Audrey Laporte, I thank you for contributing a fresh perspective to this research – your thoughtful comments have helped ensure that the findings of this research will be applicable to a wide audience.

To the patients and clinicians who participated in this research, thank you for volunteering your time and for your openness in sharing your experiences.

To my colleagues at IHPME and the Centre for Global eHealth Innovation, thank you for your contributions to this work and for being there to distract me when I needed to be pulled out of my research bubble. Your work ethic has been inspiring and your friendship has helped make this a truly enjoyable experience.

I wish express heartfelt thanks to my parents – I recognize and am grateful for all the opportunities that you offered me and the support that helped me get to this point.

Finally, to Charlie – thank you for encouraging this endeavor, for being a willing first editor on all my work, and for all the innumerable ways you have supported me over the years.
# Table of Contents

Chapter 1 Introduction .......................................................................................................................... 1  
1 Introduction ......................................................................................................................................... 1  
1.1 Problem Statement .......................................................................................................................... 1  
1.2 Thesis Outline ................................................................................................................................. 4  

Chapter 2 Evidence and Complexity of Heart Failure Telemonitoring ........................................... 8  
2 Evidence and Complexity of Heart Failure Telemonitoring ............................................................ 8  
2.1 Introduction ..................................................................................................................................... 8  
2.2 The Effect of Telemonitoring on Heart Failure Outcomes: What do we Know? ...................... 9  
2.3 Evidence is Plagued by Heterogeneity ............................................................................................ 11  
2.3.1 Disease Severity .......................................................................................................................... 12  
2.3.2 Characteristics of the Intervention ............................................................................................. 12  
2.3.3 Fidelity of Intervention Use ......................................................................................................... 14  
2.4 A Path Forward: Generating Patient and Context-Centred Evidence ..................................... 16  
2.5 Filling in the Gaps ........................................................................................................................... 19  
2.6 Conclusions ..................................................................................................................................... 20  

Chapter 3 Barriers and Facilitators of Implementation and Clinician Adoption ............................ 21  
3 Barriers and Facilitators of Implementation and Clinician Adoption ............................................. 21  
3.1 Introduction ..................................................................................................................................... 21  
3.1.1 Background ................................................................................................................................. 21  
3.1.2 Study Objectives .......................................................................................................................... 22  
3.2 Methods .......................................................................................................................................... 22  
3.2.1 Study Design ............................................................................................................................... 22  
3.2.2 Intervention .................................................................................................................................. 23  
3.2.3 Implementation Strategy ............................................................................................................. 24  
3.2.4 Implementation Outcomes ........................................................................................................... 24  
3.2.5 Barriers and Facilitators of Implementation ............................................................................... 25  
3.2.6 Data Analysis ............................................................................................................................. 26  
3.3 Results ............................................................................................................................................ 26  
3.3.1 Study Participants ......................................................................................................................... 26  
3.3.2 Implementation Outcomes .......................................................................................................... 27  
3.3.3 Barriers and Facilitators of Implementation ............................................................................... 30  
3.4 Discussion ........................................................................................................................................ 43  
3.4.1 Principal Findings ....................................................................................................................... 43  
3.4.2 Comparison With Prior Work ..................................................................................................... 44  
3.4.3 Limitations .................................................................................................................................. 45
<table>
<thead>
<tr>
<th>Chapter 4 Explaining Patient Adherence</th>
<th>.................................................................</th>
<th>47</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Explaining Patient Adherence</td>
<td>........................................................................</td>
<td>47</td>
</tr>
<tr>
<td>4.1 Introduction</td>
<td>........................................................................</td>
<td>47</td>
</tr>
<tr>
<td>4.1.1 Background</td>
<td>........................................................................</td>
<td>47</td>
</tr>
<tr>
<td>4.1.2 Study Objectives</td>
<td>........................................................................</td>
<td>48</td>
</tr>
<tr>
<td>4.2 Methods</td>
<td>........................................................................</td>
<td>49</td>
</tr>
<tr>
<td>4.2.1 Study Design</td>
<td>........................................................................</td>
<td>49</td>
</tr>
<tr>
<td>4.2.2 The Intervention</td>
<td>........................................................................</td>
<td>50</td>
</tr>
<tr>
<td>4.2.3 Measuring Patient Adherence</td>
<td>........................................................................</td>
<td>53</td>
</tr>
<tr>
<td>4.2.4 Explaining Patient Adherence</td>
<td>........................................................................</td>
<td>54</td>
</tr>
<tr>
<td>4.3 Results</td>
<td>........................................................................</td>
<td>56</td>
</tr>
<tr>
<td>4.3.1 Study Participants</td>
<td>........................................................................</td>
<td>56</td>
</tr>
<tr>
<td>4.3.2 Overall and Longitudinal Adherence Rates</td>
<td>........................................................................</td>
<td>59</td>
</tr>
<tr>
<td>4.3.3 Quantitative Results Explaining Adherence</td>
<td>........................................................................</td>
<td>60</td>
</tr>
<tr>
<td>4.3.4 Qualitative Results Explaining Adherence</td>
<td>........................................................................</td>
<td>63</td>
</tr>
<tr>
<td>4.4 Discussion</td>
<td>........................................................................</td>
<td>71</td>
</tr>
<tr>
<td>4.4.1 Principal Findings</td>
<td>........................................................................</td>
<td>71</td>
</tr>
<tr>
<td>4.4.2 Comparison with Prior Work</td>
<td>........................................................................</td>
<td>73</td>
</tr>
<tr>
<td>4.4.3 Limitations</td>
<td>........................................................................</td>
<td>75</td>
</tr>
<tr>
<td>4.4.4 Recommendations</td>
<td>........................................................................</td>
<td>77</td>
</tr>
<tr>
<td>4.5 Conclusions</td>
<td>........................................................................</td>
<td>77</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 5 Adaptability of a Heart Failure Telemonitoring Program</th>
<th>.................................................................</th>
<th>79</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Adaptability of a Heart Failure Telemonitoring Program</td>
<td>........................................................................</td>
<td>79</td>
</tr>
<tr>
<td>5.1 Introduction</td>
<td>........................................................................</td>
<td>79</td>
</tr>
<tr>
<td>5.1.1 Background</td>
<td>........................................................................</td>
<td>79</td>
</tr>
<tr>
<td>5.1.2 Study Objectives</td>
<td>........................................................................</td>
<td>80</td>
</tr>
<tr>
<td>5.2 Methods</td>
<td>........................................................................</td>
<td>81</td>
</tr>
<tr>
<td>5.2.1 Study Design</td>
<td>........................................................................</td>
<td>81</td>
</tr>
<tr>
<td>5.2.2 The Existing Program</td>
<td>........................................................................</td>
<td>81</td>
</tr>
<tr>
<td>5.2.3 Interview Guide Development</td>
<td>........................................................................</td>
<td>83</td>
</tr>
<tr>
<td>5.2.4 Recruitment</td>
<td>........................................................................</td>
<td>84</td>
</tr>
<tr>
<td>5.2.5 Interview Procedures and Analysis</td>
<td>........................................................................</td>
<td>84</td>
</tr>
<tr>
<td>5.2.6 Adapting the Telemonitoring Program</td>
<td>........................................................................</td>
<td>85</td>
</tr>
<tr>
<td>5.3 Results</td>
<td>........................................................................</td>
<td>85</td>
</tr>
<tr>
<td>5.3.1 Study Participants</td>
<td>........................................................................</td>
<td>85</td>
</tr>
<tr>
<td>5.3.2 Interview Findings</td>
<td>........................................................................</td>
<td>87</td>
</tr>
<tr>
<td>5.3.3 Redesign of the Medly Program for Sustainability and Scalability</td>
<td>........................................................................</td>
<td>93</td>
</tr>
<tr>
<td>5.4 Discussion</td>
<td>........................................................................</td>
<td>95</td>
</tr>
</tbody>
</table>
5.4.1 Principal Findings ........................................................................................................... 95
5.4.2 Comparison With Prior Work ........................................................................................ 97
5.4.3 Limitations ..................................................................................................................... 98
5.5 Conclusions ...................................................................................................................... 99

Chapter 6 Discussion and Application of Key Findings ...................................................... 100
6 Discussion and Application of Key Findings .................................................................... 100
   6.1 The State of the Evidence ............................................................................................. 100
   6.2 Generation of New Evidence ....................................................................................... 101
   6.3 Factors Influencing Implementation Success and Fidelity of Clinician Use ....... 103
   6.4 Factors Influencing Fidelity of Patient Use ................................................................. 103
   6.5 Adaptability of Heart Failure Telemonitoring Interventions ................................. 105
   6.6 The Scalability and Spreadability of Telemonitoring for the Management of Heart Failure ........................................................................................................... 106
   6.7 Operationalizing the Thesis Findings ......................................................................... 109
      6.7.1 Clarifying the Intervention .................................................................................... 109
      6.7.2 Formalizing an Implementation Strategy .............................................................. 110
      6.7.3 Study Limitations ................................................................................................. 120

Chapter 7 Conclusion ........................................................................................................... 121
7 Conclusion ......................................................................................................................... 121

References .......................................................................................................................... 123

Appendices .......................................................................................................................... 135
List of Tables

Table 1. The effect of telemonitoring on all-cause mortality and heart failure-related hospitalization from meta-analyses published between 2012 and 2017 ........................................ 10

Table 2. Study participants and timing of interviews .............................................................................. 26

Table 3. Implementation outcomes indicators ......................................................................................... 27

Table 4. Valence ratings assigned to Consolidated Framework for Implementation Research (CFIR) constructs ............................................................................................................. 30

Table 5. Characteristics of patients included in the quantitative analysis of adherence ............. 56

Table 6. Random effects multivariate regression with cluster-robust standard errors showing the effect of time, sex, NYHA class, and age on average adherence ........................................... 61

Table 7. Patient perceptions of the benefits and effort of using the Medly TM system at 6 and 12 months post-enrollment ................................................................................................................. 63

Table 8. Classification of reasons for patient offboarding ........................................................................ 64

Table 9. Participant characteristics for semi-structured interviews .......................................................... 65

Table 10. Opportunities for program adaptation probed in the user interviews ............................. 83

Table 11. Characteristics of patient interview participants ....................................................................... 86

Table 12. Adaptations to the Medly program to ensure sustainability and scalability .................. 94
List of Figures

Figure 1. Single case study of the Medly program with embedded units of analysis .................. 5

Figure 2. Factors contributing to heterogeneity in clinical trial outcomes ................................. 11

Figure 3. A patient and context-centred approach to determining the impact of telemonitoring on heart failure outcomes ............................................................... 18

Figure 4. Screens of the Medly app ...................................................................................... 51

Figure 5. Average adherence rates compared with adherence rates which include incomplete adherence over time .............................................................. 60

Figure 6. Average adherence rates over time by age group showing higher adherence over time over time for older age groups ..................................................................... 62

Figure 7. Existing roles and information flows in the Medly program .................................. 82

Figure 8. Hard core and soft periphery of the Medly program as informed by user interviews and its role in the intervention’s theory of change ......................................................... 94

Figure 9. Implementation strategy for telemonitoring programs ........................................ 111

Figure 10. Nilsen’s taxonomy of implementation theories, models and frameworks used in implementation science with prominent examples for each category ........................................ 115

Figure 11. Chaudoir multi-level framework predicting implementation outcomes .............. 117

Figure 12. Modified Chaudoir framework to include CFIR domains and constructs from the Clinical Adoption Framework and Unified Theory of Use and Acceptance of Technology 2 .. 118
List of Appendices

Appendix 1. Definition of the Consolidated Framework for Implementation Research Constructs

Appendix 2. Schedule for Assessing CFIR and Proctor Constructs in the Clinician and Program Staff Interviews

Appendix 3. Implementation Evaluation 12-month Clinician Interview Guide

Appendix 4. Interview Questions for Patients

Appendix 5. Patient and Clinician Interview Questions to Inform Adaptations of the Medly Program

Appendix 6. Study Protocol: Implementation and evaluation of a Smartphone-Based Telemonitoring Program for Patients with Heart Failure

Appendix 7. Domains and Questions in the Nonadoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) Framework

Appendix 8. Medly Program Logic Model

Appendix 9. Table of Content for the Generic Standard Operating Procedures of the Medly Program
Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BYOD</td>
<td>Bring your own device</td>
</tr>
<tr>
<td>CAF</td>
<td>Clinical Adoption Framework</td>
</tr>
<tr>
<td>CFIR</td>
<td>Consolidated Framework for implementation Research</td>
</tr>
<tr>
<td>eHI</td>
<td>Centre for Global eHealth Innovation</td>
</tr>
<tr>
<td>EMR</td>
<td>Electronic medical record</td>
</tr>
<tr>
<td>HF</td>
<td>Heart failure</td>
</tr>
<tr>
<td>HF clinic</td>
<td>Ted Rogers Centre of Excellence for Heart Function</td>
</tr>
<tr>
<td>IVR</td>
<td>Interactive voice response</td>
</tr>
<tr>
<td>LVEF</td>
<td>Left ventricular ejection fraction</td>
</tr>
<tr>
<td>NP</td>
<td>Nurse practitioner</td>
</tr>
<tr>
<td>MLHFQ</td>
<td>Minnesota Living with Heart Failure Questionnaire</td>
</tr>
<tr>
<td>MRP</td>
<td>Most responsible physician</td>
</tr>
<tr>
<td>NYHA</td>
<td>New York Heart Association</td>
</tr>
<tr>
<td>PROM</td>
<td>Patient reported outcome measures</td>
</tr>
<tr>
<td>PARIHS</td>
<td>Promoting Action or Research in Health Services</td>
</tr>
<tr>
<td>QIF</td>
<td>Quality Implementation Framework</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>REB</td>
<td>Research Ethics Board</td>
</tr>
<tr>
<td>TAM</td>
<td>Technology Acceptance Model</td>
</tr>
<tr>
<td>THA</td>
<td>Telehealth analyst</td>
</tr>
<tr>
<td>TM</td>
<td>Telemonitoring</td>
</tr>
<tr>
<td>UHN</td>
<td>University Health Network</td>
</tr>
<tr>
<td>UTAUT2</td>
<td>Unified Theory of Acceptance and Use of Technology 2</td>
</tr>
</tbody>
</table>
Chapter 1
Introduction

1 Introduction

1.1 Problem Statement

Heart Failure (HF) directly impacts more than 1,000,000 Canadians [1, 2], many of whom experience chronic symptoms of fatigue and shortness of breath, punctuated by sporadic episodes of decompensation [3]. The unpredictability of these episodes leads to more HF hospitalizations compared to other conditions, representing a significant burden on health systems [4]. For patients with HF, hospitalizations and daily symptoms have a negative impact on quality of life and their ability to work [5].

Guideline directed medical therapy for the effective management of HF typically requires patients to play an active role in their care through a combination of diet, fluid restriction, and taking diuretics and other medications as prescribed [6]. Self-management interventions designed to enable patient engagement in complex care plans can improve outcomes [7] but their implementation can be challenging [8, 9]. Telemonitoring (TM), which involves the transmission of physiological and disease-related data collected in patients’ homes to be viewed and acted upon by clinicians at a remote location, is thought to be a promising vehicle for delivering self-management support [10]. In addition, timely data transmission enables clinicians to catch symptom exacerbations early and allow for remote intervention [11] and, when collected over time, these data provide a more holistic picture of the patient’s condition which can improve the quality of clinical decisions [12]. Several meta-analyses have concluded that TM achieves better health outcomes when compared to the standard of care [13-19]. However, important inconsistencies in the evidence exist, particularly as it relates to its cost-effectiveness [3, 10, 20-22].

An Ernst and Young report on the use of TM in Canada found that only 5000 patients across all disease types were enrolled in a TM program in 2013 [23]. Although no recent numbers have been published, this is far below the 1 million Canadians who live with HF and suggests that TM interventions are not meeting their full potential. Understanding why requires an understanding of the mechanisms of scale and spread. Scale ( synonymous with dissemination), involves an
active and often top down approach to persuading target groups to adopt and implement an innovation (e.g., a government mandating the implementation of an evidence-based innovation within health organizations across its jurisdiction) [24, 25]. Spread (synonymous with diffusion), involves a more passive process reflected in a bottom-up adoption and implementation of new practices into the delivery of care (e.g., health organizations deciding to implement an innovation based on successes observed in a leading or comparable organization) [24, 25]. Although the mechanisms for scale and spread may differ, both processes are highly influenced by contextual factors that can be understood through the field of implementation science. At present, one of the most widely cited implementation frameworks is the Consolidated Framework for Implementation Research (CFIR) which offers an overarching classification of barriers and facilitators to implementation success into 5 domains: (1) intervention characteristics, (2) the outer setting (e.g., policy environment, patient needs, social and professional norms, etc.), (3) the inner setting (organizational characteristics, culture, implementation climate, etc.), (4) characteristics of individuals, and (5) the implementation process [26]. As the name implies, the CFIR was developed to consolidate existing constructs from published implementation theories and frameworks and was heavily influenced by Greenhalgh’s 2004 Conceptual model for the considering the determinants of diffusion, dissemination, and implementation of innovations in health service delivery which, itself, was a comprehensive synthesis of nearly 500 published sources, including Rogers’ seminal work on the diffusion of innovations [24].

An important distinction between the CFIR and its preceding theories is that it refers to health interventions as opposed to innovations. An innovation, according to Rogers and Greenhalgh is defined as “an idea, practice or object that is perceived as new by an individual or another unit of adoption” [27]. Although similar in many respects, an intervention is defined by the World Health Organization as “an activity or set of activities aimed at modifying a process, course of action or sequence of events in order to change one or several of their characteristics such as performance of expected outcome.[28]” By this definition, TM is a health intervention and, even though TM will likely be perceived as novel in most healthcare settings (based on its slow adoption and implementation to date) the more encompassing CFIR term of intervention will be used to throughout this thesis.

Although all the factors included in the CFIR have demonstrated an importance for influencing implementation success, when considering scale and spread of health interventions (as opposed
to one-off implementations), two CFIR constructs within the *intervention characteristics* domain are critical: *evidence strength* and *adaptability*. Evidence strength is important because it influences the decision of health organizations and target end-users to adopt an intervention [26]. Adaptability is both critical and challenging because it requires striking a balance between the need to replicate an intervention in various contexts with the knowledge that a *one-size-fits-all* approach is ineffective for delivering digital health intervention on a wider scale [29].

How is it possible to adapt an intervention while also ensuring that it remains the same? According to the CFIR and other implementation frameworks, the way to address this paradox is to recognize that interventions have a *hard core* and an adaptable *soft periphery* [24, 26]. The hard core is made up of components of the intervention that are essential for delivering expected outcomes and which must be maintained during scale or spread. The adaptable soft periphery includes the components of the intervention that can and that should be modified to enable adoption and successful embedding within different contexts [24, 26, 30]. Although striking a balance between adaptation and intervention fidelity (i.e., sameness across implementation sites) is a fundamental challenge for any implementation, scale, or spread initiative, it is especially true of complex interventions like TM. This is because TM has less to do with the technology (which is easy to replicate) but more to do with human behavior because expected outcomes can only be achieved based on how that technology is used by both clinicians and patients in practice [3]. Thus, patient and clinician adoption and intended use is critical for evaluating and understanding the implementation, scale, and spread of TM interventions.

Therefore, evidence of impact and an understanding of the barriers and facilitators to implementation success (particularly as it relates to clinician and patient adoption and intended use) is necessary to understand the slow adoption and implementation of TM interventions across Canada. When combined with an understanding of the hard core and adaptable soft periphery components of TM interventions, this knowledge will enable the development of successful strategies of scale and/or spread. To that end, the central research question of this thesis is: *What factors influence the successful implementation, scale, and spread of telemonitoring interventions for the management of heart failure?*

This central question will be addressed through 5 specific research questions:

1) What is the state of the evidence for HF TM interventions?
2) What factors influence the successful implementation of HF TM interventions?

3) What factors influence clinician adoption and appropriate use of HF TM interventions?

4) What factors influence patient adoption and appropriate use of HF TM interventions?

5) What are the core components of TM interventions that must be protected to ensure intervention fidelity and which components can be adapted to enable the sustainable embedding across various sites?

1.2 Thesis Outline

This thesis has the objective of understanding the factors that influence the implementation, scale, and spread of TM interventions for the management of HF. Insights gained from this work can be used to inform the development of strategies that will enable the scale and/or spread of TM such that it can address the full burden of HF on both health systems and individuals. The content presented in the thesis chapters is based on the following five publications:


In some cases, the content from these publications has been adapted to ensure a consistency in terminology and to reduce repetition. The following is a summary of the thesis chapters:

**Chapter 2** answers the research question: What is the state of the evidence for HF TM interventions? This chapter presents a literature review summarizing the evidence of the impact of HF TM before adopting an analytical approach aimed at explaining why inconsistencies in the literature exist. Recognizing that strong evidence is required for the scale and spread innovations, this chapter proposes a research agenda that will enable the generation of more definitive answers regarding the impact of TM on HF outcomes. Key elements of that research agenda were addressed in chapters 3-6.

The following three chapters describe research activities related to the evaluation of the *Medly* mobile phone-based TM program which was launched as part of the standard of care at the University Health Network (UHN) and Peter Munk Cardiac Centre’s Ted Rogers Centre of Excellence for Heart Function (HF clinic) in Toronto, Canada. The studies described in chapters 3-5 were conducted as part of a single-case study with two embedded units of analysis [31] as depicted in Figure 1.

![Figure 1. Single case study of the Medly program with embedded units of analysis](image-url)
The case was defined as the implementation of the Medly program in the HF clinic for the duration of 1 year after program launch (defined as the date the first patient was enrolled). The two embedded units of analysis were selected to allow for an in-depth exploration of fidelity of TM use to answer the third and fourth research questions. Therefore, these units of analysis were defined as (1) clinician adoption and use of the Medly system, and (2) patient adoption and use of the Medly system. Although the first embedded unit of analysis (clinician adoption and use) was studied over the same time period (1 year after launch) as the holistic unit of analysis (implementation of the Medly program), the second embedded unit of analysis (patient adoption and use) was studied over an approximately 2-year period in order to achieve an adequate sample size needed for the quantitative methods used. Methods for studying each embedded unit and the case as a whole were guided by prominent theories and conceptual frameworks which are described in the relevant chapters.

**Chapter 3** answers the second and third research questions: What factors influence the successful implementation of HF TM interventions?; and what factors influence the clinician adoption and appropriate use of HF TM interventions? This chapter describes the implementation evaluation of the Medly program which sought to describe implementation success by measuring indicators related to outcomes defined in Proctor et al.’s, Implementation Outcomes Framework [32]. Similar to the CFIR, Proctor et al.’s framework was developed to consolidate inconsistent terminologies and constructs used in the existing literature and to propose a taxonomy of distinct implementation outcomes [32]. It is described as an evaluation framework [33]. Therefore, it was selected to guide the selection of outcomes and indicators that would provide an objective anchor for discussing barriers and facilitators of implementation success. Barriers and facilitators of implementation and clinician adoption and use were explored using methods designed according to the constructs of the CFIR. The chapter concludes with a discussion about applying the CFIR in the evaluation of TM interventions and concrete recommendations for designing TM interventions and implementations strategies to improve chances of implementation success.

**Chapter 4** answers the fourth research question by exploring the factors influence patient adoption and appropriate use of HF TM interventions. This study first quantifies patient adherence to taking daily physiological and symptoms readings in the Medly program and subsequently employs methods based on the Unified Theory of Acceptance and Use of
Technology 2 (UTAUT2) [34] to understand the factors that influence patients’ adherence rates. The UTAUT2 proposes that seven constructs influence consumers’ intention to use a technology, including: (1) performance expectancy, (2) effort expectancy, (3) social influence, (4) facilitating conditions, (5) hedonic motivation, (6) price value, and (7) habit [34]. It should be noted that the UTAUT2 is a synthesis of eight behaviour theories or models of technology use and was updated from its precursor (the UTAUT) to propose constructs that influence technology use by consumers [34]. Although the UTAUT2 is not specific to health-related technologies, many of its underlying theories have a history of being used in health research including: the Theory of Reasoned Action, Theory of Planned Behaviour, Social Cognitive Theory and the Technology Acceptance Model (TAM) [34, 35]. This chapter concludes with technical and service-based recommendations for achieving high degrees of patient adherence in the implementation of TM interventions.

Starting with an acknowledgment of the barriers to implementation and sustainability identified in Chapters 2, **Chapter 5** describes a qualitative study aimed at identifying strategies to adapt the Medly program to ensure its future sustainability. In doing so, the Chapter 5 answers the final research question: What are the core components of TM interventions that must be protected to ensure intervention fidelity and which components can be adapted to enable the sustainable embedding across various sites?

**Chapter 6** reviews key findings from this thesis and discusses how insights gained from each study (chapters 3-5) can be combined with results from the ongoing evaluation of the Medly program’s impact and cost to answer many of the unanswered questions put forth in the proposed research agenda at the end of Chapter 2. In addition to a discussion of overall limitations, key findings are examined in the context of their underlying theoretical frameworks (CFIR and UTAUT2) to enable the transferability of results to other TM interventions and implementation contexts. The chapter concludes with concrete examples of how thesis findings can be applied in practice.

**Chapter 7** is the conclusion for this thesis.
Chapter 2
Evidence and Complexity of Heart Failure Telemonitoring


2 Evidence and Complexity of Heart Failure Telemonitoring

This chapter answers the first research question: What is the state of the evidence for HF TM interventions?

2.1 Introduction

Heart Failure (HF) directly impacts more than 1,000,000 Canadians with approximately 50,000 new cases diagnosed each year [1, 2]. Patients with HF experience chronic symptoms of fatigue and shortness of breath, punctuated by sporadic episodes of decompensation [3]. Due to the unpredictability and severity of these episodes, HF patients experience frequent hospitalizations compared to other conditions [4]. Living with HF has a negative impact on patients’ quality of life, with symptoms often limiting their ability to work [5].

Typical management of HF is done through a combination of diet, fluid restriction, diuretics, and guideline directed medical therapy. An opportunity to improve HF management exists when one considers that half of all HF-related readmissions are preventable and result from inadequate patient education during discharge, non-adherence to medication, poor social supports, and/or failure to have timely follow up with a clinician [36]. Self-management interventions, that is, interventions that help patients adhere to medication, follow clinical recommendations, and actively monitor symptoms [37], have been shown to decrease HF-related hospitalizations and mortality and improve quality of life [7]. Telemonitoring (TM) technologies, due to their capacity for effective information exchange, are seen as a viable mechanism to deliver self-management support. Specifically, TM leverages telecommunication technologies and electronic devices to capture and transmit physiological and disease-related data from patients in the
community to clinicians [10]. In doing so, TM can enhance patient-clinician communication regarding symptoms and health status so that clinicians can intervene early to prevent serious exacerbations [38]. In addition, TM can improve patient understanding of their condition by highlighting the significance of symptoms and lifestyle decisions, which can be important for knowing when and how to engage in self-care practices [39, 40]. TM is a non-invasive intervention and must be distinguished from other forms of remote patient monitoring that transmit data collected from devices implanted in the patient’s body (e.g., cardiac resynchronization therapy devices, internal cardioverter defibrillators (ICD) or implantable hemodynamic monitoring)[14].

Several comprehensive review articles have recently been published on HF TM. While these reviews generally conclude that TM has a positive impact on reducing mortality and hospitalizations [13-19], important inconsistencies in the evidence exist [3, 10, 20]. Our objective is to explore the reasons why primary studies and meta-analyses do not provide definitive answers regarding potential merits of TM. We propose a series of steps and unanswered research questions that need to be addressed before evidence of the impact of TM can be produced to the satisfaction of all stakeholders.

2.2 The Effect of Telemonitoring on Heart Failure Outcomes: What do we Know?

Table 1 presents the results from meta-analyses published in the last five years on the impact of TM on two critical outcomes: all-cause mortality and HF-related hospitalizations. While meta-analyses have found that TM reduces all-cause mortality and HF-related hospitalizations, important differences exist both in terms of significance of the results and the magnitude of the impact. Fewer meta-analyses report on quality of life and other health outcomes. Those that do, were unable to draw clear conclusions because, despite indications that TM can improve quality of life [8, 41] and self-management capacity [42], there are considerable inconsistencies in the results of the original studies [10, 42]. Similarly, researchers have been unable to produce consistent evidence on the cost-effectiveness of TM [22].
Table 1. The effect of telemonitoring on all-cause mortality and heart failure-related hospitalization from meta-analyses published between 2012 and 2017

<table>
<thead>
<tr>
<th>Study</th>
<th>All-cause Mortality</th>
<th>Heart Failure-related Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yun, 2017 [43]</td>
<td>RR, 0.81; 95% CI, 0.70-0.94 (24 studies)</td>
<td>RR, 0.86; 95% CI, 0.74 - 1.00 (12 studies)</td>
</tr>
<tr>
<td>Lin, 2017 [44]</td>
<td>OR, 0.80; 95% CI, 0.71 to 0.91</td>
<td>OR, 0.63; 95% CI, 0.53-0.76</td>
</tr>
<tr>
<td>Kitiou, 2015 [10]</td>
<td>RR, 0.73; 95% CI, 0.62-0.85 (20 studies)</td>
<td>RR, 0.79; 95% CI, 0.69-0.91 (8 studies)</td>
</tr>
<tr>
<td>Flodgren et al., 2015 [41]</td>
<td>RR, 0.89; 95% CI, 0.76 - 1.03 (16 studies)</td>
<td>N/A</td>
</tr>
<tr>
<td>Inglis et al., 2015 [8]</td>
<td>RR, 0.80; 95% CI, 0.68 - 0.94 (17 studies)</td>
<td>RR, 0.71; 95% CI, 0.60-0.83 (8 studies)</td>
</tr>
<tr>
<td>Kotb et al., 2015 [45]</td>
<td>OR, 0.53; 95% CrI, 0.36 - 0.80 (6 studies)</td>
<td>OR, 0.64; 95% CI, 0.39 - 0.95</td>
</tr>
<tr>
<td>Or et al., 2017 [42]</td>
<td>RR, 0.88; 95% CI 0.77 - 1.02 (26 studies)</td>
<td>RR, 0.80; 95% CI, 0.66 - 0.96 (14 studies)</td>
</tr>
<tr>
<td>Conway et al., 2014 [46]</td>
<td>RR, 0.62; 95% CI, 0.50 - 0.77 (3 studies)</td>
<td>RR, 0.75; 95% CI, 0.63 - 0.91 (3 studies)</td>
</tr>
<tr>
<td>Nakamura et al., 2014 [20]</td>
<td>RR, 0.76; 95% CI, 0.62 - 0.93 (13 studies)</td>
<td>N/A</td>
</tr>
<tr>
<td>Pandor et al., 2013 [21]</td>
<td>HR, 0.76; 95% CrI, 0.49 - 1.18 (9 studies)</td>
<td>HR, 0.95; 95% CrI, 0.70-1.34 (3 studies)</td>
</tr>
<tr>
<td>Xiang et al., 2013 [47]</td>
<td>RR, 0.76; 95% CI, 0.66 - 0.88 (27 studies)</td>
<td>RR 0.72; 95% CI, 0.61-0.85 (23 studies)</td>
</tr>
</tbody>
</table>

CI: confidence interval; CrI: credible interval; HR: hazard ratio; OR: Odds ratio; RR: Relative risk
In addition, neutral results from three large RCTs are widely cited in TM discourse as examples of the questionable impact of TM. The first is the 2010 RCT by Chaudhry et al., which tested a TM system in 1653 patients and found no significant difference in readmission or hospitalizations [48]. The second study by Koehler et al. used mobile phones to facilitate the monitoring of patients using external devices for electrocardiogram and blood pressure and found no significant impact on all-cause mortality [49]. More recently, the Better Effectiveness After Transition-Health Failure (BEAT-HF) trial, which included 1437 participants, found no significant difference in readmission or mortality [50]. Possible reasons for the lack of positive outcomes in these large trials, and the general inconsistency of evidence of the impact of TM on HF outcomes are explored in the following section.

2.3 Evidence is Plagued by Heterogeneity

Potential reasons for the lack of a clear answer regarding the impact of TM on HF outcomes include heterogeneity of the TM literature in terms of: patient population (e.g., disease severity), characteristics of the interventions evaluated, and quality of the trial (e.g., degree to which the intervention was used as intended) [20, 21, 41, 47, 51]. We contend that TM cannot, and should not be considered as a single intervention when attempting to draw conclusions of the impact of TM on HF outcomes. Instead, the various components of TM need to be considered when understanding the role of the intervention in changing HF outcomes (Figure 1).

Figure 2. Factors contributing to heterogeneity in clinical trial outcomes
2.3.1 Disease Severity

TM studies have been conducted across all levels of HF severity, New York Heart Association functional classification (NYHA class) 1 to 4, and phenotypes, including those with preserved and reduced left ventricular ejection fraction (LVEF). In addition to considering baseline disease status, the potential impact of TM also depends on stage of disease states such as periods immediately after hospitalization [10]. Although there is evidence that TM yields greater impact in patients recently discharged and with higher symptom severity [10], criteria for the “ideal” TM candidate does not exist.

2.3.2 Characteristics of the Intervention

In their overview of systematic reviews, Kitsiou et al. found that most studies made no attempt to understand how different types of TM interventions yield different outcomes [10]. Characteristics of TM interventions can be classified according to the parameters they measure, the technology, clinician involvement, and the supporting health services.

2.3.2.1 Physiological Parameters

The most common health parameters collected by TM systems are body weight, blood pressure, pulse rate, and self-administered questions (generally for symptoms) [52]. Other parameters monitored can include oxygen saturation and electrocardiogram [52]. TM trials, in addition to studying systems with various combinations of parameters, also differ in the frequency with which patients are expected to take measures. Anker et al. suggest that non-invasive variables be assessed daily [52] which is in line with findings that groups with high measurement frequency experience higher efficacy [20].

2.3.2.2 Telemonitoring System

A range of equipment exists to enable the transfer of patient health data. These can be categorized as those that use specialized TM stations, video consultation technologies, web-
based systems, interactive voice response (IVR) systems, and/or mobile technologies [10]. Distinctions among these technologies are not always present in the TM literature and subgroup analyses have found that each type has a different impact on HF outcomes [10, 46]. The type and quality of the peripheral devices collecting a given parameter should also be considered. For instance, technologies that are Bluetooth-enabled versus those that require manual entry of physiological data could impact usability of a system.

Part of the value proposition put forth by developers of newer TM systems is that algorithms can transform raw patient data into self-management support for patients and decision support for clinicians [53, 54]. Given that these two components have been identified as the mechanism with which TM achieves its desired outcome, there is surprisingly little discussion in the literature about the quality and sensitivity of these algorithms and their ability to improve patient and clinician support [10]. In addition, software can also impact outcomes by determining the format in which data is made available to clinicians. For example, presenting this information alongside other important health information in an electronic medical record (EMR) could improve the quality of decision-making, and thus the impact of the system.

2.3.2.3 Clinician Response to Telemonitoring Data

Interventions also differ with respect to the comprehensiveness of the monitoring. A common dichotomy presented in the literature is to compare interventions that offer monitoring during office hours versus those that provide “24/7 monitoring”. One meta-analysis found that 24/7 TM of patients with stable HF led to better outcomes compared to office hour monitoring [20], while another found that monitoring during office hours is more cost-effective [21]. Confusing this issue further is the question of what actions are taken by clinicians in response to TM data. If part of the mechanism of TM action is clinician intervention, clinician protocols when responding to TM data should also influence outcomes. Currently, professional bodies such as the Canadian Cardiovascular Society do not have recommendations for how clinicians should be acting in response to TM data [6]. Instead, clinician protocols are often left up to the investigators and are rarely described when study results are reported.
2.3.2.4 Supporting Health Services

Difficult to uncouple from the type of clinician response to TM data is the question of who that clinician is and where they fit in the larger provision of a patient’s health services. Some TM models have TM data going to a third-party telehealth clinician who is responsible for managing and acting on this information [14]. It can be argued that this model allows the telehealth clinician to respond to data quickly and act as the bridge between primary care and specialty care. However, equally convincing arguments can be made for TM models which see patient data monitored by clinicians who are actively involved in the patient’s healthcare [14]. The impact of this latter model will differ depending on whether the patient is being monitoring by their primary care physician, cardiologist, HF specialist, or a collaborative care team made up of combinations thereof. One analysis found that the speed of intervention in response to TM data was the most important factor in determining outcomes [20], but which model (third-party clinician or clinician within the immediate care team) can best achieve this is highly dependent on the characteristics of the implementation context.

In interpreting the evidence, one cannot ignore the extent of which characteristics of usual care influence the magnitude of the impact of TM on outcomes. Most meta-analyses pool data from studies where characteristics of usual care differ [3, 10, 20]. Guideline directed therapy includes combinations of pharmaceutical, physical activity/rehabilitation, dietary sodium and fluid restriction, ICD and cardiac resynchronization therapy, as well as the management of co-morbidities [6]. However, without clear data about the degree to which these guidelines are being followed in usual care and without a rich description of the comparator group in clinical trials, the true value add of TM is difficult to determine. For example, the large Telemedical Interventional Monitoring in Heart Failure TIM-HF study by Koehler et al. [49] did not demonstrate an impact, possibly due to the high quality of usual care [3].

2.3.3 Fidelity of Intervention Use

Unlike a medication or a coronary stent, the success of the intervention (and thus, its ability to demonstrate outcomes) is highly dependent on humans in the collection and interpretation of data, not to mention the actions taken in response to this information. For instance, low patient
adherence to the intervention are cited as limitations to the large Telemonitoring to Improve Heart Failure Outcomes (Tele-HF) and BEAT-HF trials [48, 50]. Several systematic reviews have highlighted the various factors that influence the degree to which the intervention is used as intended, and thus its fidelity.

2.3.3.1 Clinician Use

A commonly cited barrier to clinician use of TM is the lack of reimbursement models for clinicians [3], as clinicians are more likely to use a system if they are adequately compensated. Technology related clinician facilitators include a TM system that is usable and reliable, provides accurate patient information, improves clinical decision-making, and is free of technical problems [55-59]. Characteristics of the TM system are also important insofar as the system must be compatible with the context within which it is being implemented. For instance, clinicians are less likely to use a system that causes disruptions to workflow or that is perceived to increase workload [56, 58]. The system must also be compatible with existing infrastructure and technical resources. A common barrier involves a lack of interoperability characterized by an inability of the TM system to fully integrate with existing health information systems such as hospital EMRs [56, 58, 60]. Intrinsic clinician motivation is influenced by personal confidence in using technology and their attitudes toward it [56], as well as a belief in the potential impact of the TM system on patient outcomes [56, 61, 62]. The perceived impact of implementing the system on a clinician’s sense of autonomy is also important; they will not want to use a TM system if they feel that there is a misalignment with their identity as a clinician or if they anticipate a negative impact on the clinician-patient relationship [56, 58, 60, 61, 63].

2.3.3.2 Patient Use

Like clinicians, patients are users of TM and therefore share many influencing factors, especially as it relates to characteristics of the TM system. Facilitators include patients’ perception that TM will give them a clear advantage in terms of managing their health, particularly as it relates to self-care, health outcomes, access to care, and their relationship with clinicians [64]. Other facilitators related to the technology include: the technology being easy to use, free of technical
problems, and it must provide an adequate sense that one’s health information will be secure [61, 64]. Factors such as the perceived advantage of using the system and its ease of use can be influenced by patient characteristics including demographics, comfort with technology, and disease severity.

Long-term adherence has only been superficially studied thus far when it comes to HF TM. Adherence is thought to be related to the same factors associated with patient adoption but is also dependent on other factors such as remembering to engage with the system [64]. A review article concluded that adherence tended to be highest at the start of a study but tends to drop off over time [65].

2.3.3.3 Implementation Strategy

Even the best TM system will not deliver its expected outcomes unless it is properly implemented. Successful implementation of TM interventions in clinical trials is highly dependent on the patient and clinician use factors previously discussed. However, it also requires an effective implementation strategy. This includes establishing a detailed operational plan, engaging with stakeholders, and developing context-specific training plans [26]. Finally, continuous reflection and evaluation of progress is necessary to ensure fidelity to the implementation plan and intervention use [26].

2.4 A Path Forward: Generating Patient and Context-Centred Evidence

The evidence for TM is likely strong enough to convince early adopters who are confident in its potential. However, more robust and consistent evidence is required to convince skeptics and decision makers who must decide if, and how to fund wide-scale implementation of these interventions. Outlined in Figure 2 is a series of questions based on knowledge gaps identified in the reviewed literature. These questions are categorized in four steps that provide a logical plan for how the necessary evidence should be produced. The first step it to characterize the patient population and to establish their HF-management needs; this can be based on disease severity
and other personal characteristics. Second, based on the patients’ needs, the ideal TM system and service should be defined. This includes reflecting on whether TM is appropriate in the first place. Depending on the situation and setting (e.g., primary care vs. specialty care) some systems may be better than others. Therefore, the system and service designs should be developed in parallel. Third, define an implementation strategy to ensure fidelity of the intervention. This will improve the likelihood of study results being attributable to the TM intervention. Fourth, study designs alternative to traditional RCTs must be considered to accommodate the evolving nature of the hardware and software that make up TM systems. Included in the fourth step is the selection of patient reported outcome measures (PROMs) to measure the impact of TM from the patient’s perspective. Choosing commonly used PROMs (e.g., Minnesota Living with Heart Failure Questionnaire [MLHFQ] [66] or the Kansas City Cardiomyopathy Questionnaire [67]) will enable comparisons of studies and allow data to be pooled in future meta-analyses. Only when these questions are addressed will researchers be able to design, implement, and study TM interventions in such a way that will offer robust and consistent evidence regarding the impact of HT on HF outcome.
Figure 3. A patient and context-centred approach to determining the impact of telemonitoring on heart failure outcomes

In addressing these questions, there is an opportunity to increase patient centricity within the generation of evidence (Figure 2). For example, we should be asking what is the ideal form of TM for a specific patient population; not, what is the ideal patient for a form of TM. While this is unlikely to change much at the individual study level, researchers should ground their research questions according to the type of answers users of that evidence value. By placing patients as
the first step, it also highlights the fact that we will likely never have a single answer to the question about the impact of TM on HF outcomes. Rather, in acknowledging the heterogeneity of TM interventions, the output of following the four steps will result in a body of evidence based on various combinations of patient populations, TM services, and implementation contexts.

2.5 Filling in the Gaps

The questions identified in Figure 2 cannot be answered by a single research study, rather, it requires collective action among TM researchers. Below are some examples of how individual researchers can play a role.

- As was done in some of the meta-analyses reviewed [10, 20, 46], subgroup analyses can be performed to understand which patients, and in which circumstances, benefit from different types of TM interventions. However, this approach comes with important methodological limitations [10] and may be best suited for the generation of hypotheses that can inform future research.

- Factorial trials can be employed to identify which component(s) of an TM service is/are most effective. Factorial trials can maintain statistical power while minimizing sample size by systematically adding and removing individual elements of a multi-component intervention over the course of the trial [68].

- Authors of original research can provide more contextual information about their studies. Understanding the limits imposed by journals for word counts, this additional information can be added as a supplementary file. In addition to being useful for audiences in understanding the implications of the reported results, this information can help authors of meta-analyses know when it is appropriate to pool results from primary studies. Perhaps more importantly, rich contextual information provides fuel for realist syntheses. Unlike systematic reviews and meta-analyses that seek to summarize evidence of an intervention’s impact, a realist synthesis is a type of literature review that seeks to
understand the mechanism for how an intervention leads to outcomes [69], making them well suited to answer many of the questions outlined in Figure 2.

Many of the questions in Figure 2 are well suited to be answered through case studies [70, 71]. These are highly adaptive study designs that can make use of both qualitative and quantitative methods to answer multiple research questions in a single study [31]. An opportunity exists to leverage the efforts of early adopters who are implementing TM interventions as part of usual care by conducting case study evaluations of those interventions.

2.6 Conclusions

TM has been shown to reduce mortality and HF hospitalizations and improve clinical outcomes in HF patients. Despite this evidence, significant heterogeneity exists in the design of TM interventions, the implementation context, and outcomes of individual studies, leading to ambiguity about the true impact of TM on HF outcomes. TM is not one, but rather a collection of complex interventions for which success or failure is linked to a range of contextual factors. These factors cannot be ignored if researchers are to design studies that will offer more definitive answers about the impact of TM on HF outcomes.
Chapter 3
Barriers and Facilitators of Implementation and Clinician Adoption


3 Barriers and Facilitators of Implementation and Clinician Adoption

This chapter answers the second and third research questions: What factors influence the successful implementation of HF TM interventions?; and What factors influence the clinician adoption and appropriate use of HF TM interventions?

3.1 Introduction

3.1.1 Background

Systematic reviews present extensive lists of various barriers and facilitators to TM implementation [56, 72, 73]. External barriers include the lack of a clear business model in single-payer health systems [74] and the lack of acceptable reimbursement methods for clinician users [75]. Furthermore, clinician adoption is influenced by the quality and usability of the technology, compatibility of the intervention with existing work processes, and intrinsic clinician motivation to adopt TM as part of their practice [56, 72, 73]. In fact, a recent review found that the challenge presented by new and often ill-defined clinician roles within changing workflows was a key factor in leading to the failure of eHealth interventions [76]. One multisite qualitative study similarly highlights the importance of contextual factors for clinician adoption, including the degree of support clinicians receive in their new roles and alignment with organization objectives [77]. However, most TM implementation studies have been conducted retrospectively, which does not allow for a robust analysis of how these barriers and facilitators exert their
influence over the entire implementation period. In addition, few studies report on quantitative outcomes to justify judgments of the implementation success or failure.

3.1.2 Study Objectives

A mobile phone-based TM program called Medly was implemented as part of the standard of care at a specialty heart function clinic in Toronto, Canada. This program features a system that has previously demonstrated improvements in clinical outcomes, patient self-care, and quality of life [78]. The objective of this study was to evaluate the implementation of the Medly program by answering two research questions: (1) To what extent was the Medly program successfully implemented? and (2) What were the barriers and facilitators to implementing the Medly program?

3.2 Methods

3.2.1 Study Design

This study used a longitudinal single case study design. The case was defined as the TM intervention and the implementation site as described below for one year following the enrollment of the first patient (August 23, 2016). The units of analysis for this evaluation were the HF clinic and program staff with data for determining the implementation success being collected through a document review. In addition, barriers and facilitators were assessed using semi-structured interviews with program staff guided by the CFIR [26]. Notably, the patient perspective, including reasons for use, adherence, and withdrawal will feature in an upcoming chapter. In this study, data collection was conducted within the context of a larger quality improvement program evaluation [79], which has been approved by the UHN Research Ethics Board (REB) (16-5789).
3.2.2 Intervention

The *Medly* program consists of two components: (1) the technology (hardware and software) and (2) the human-dependent interactions and services.

3.2.2.1 Medly Technology

The patient-facing technology includes the *Medly* mobile phone app, which works by allowing patients with heart failure to record the following four parameters: (1) weight; (2) blood pressure; (3) heart rate; and (4) symptoms. Based on these data inputs by patients at home, the *Medly* app, which contains a rule-based algorithm customized according to patient-specific target ranges, displays self-care messages and generates alerts that are automatically relayed to a clinician when signs of clinically significant health status deterioration occur. Patients were instructed to record the four parameters daily, and they would receive an automated phone call if they had not done so before 10 am; this was intended to assist with compliance. For the launch of the program, each patient was provided with all the required equipment, which includes a mobile phone with a data plan, a Bluetooth-enabled weight scale, and a Bluetooth-enabled blood pressure monitor.

The clinician-facing technology seeks to support the management of the patient alerts; this is primarily conducted through a Web-based interface (i.e., the dashboard) containing a list of patient alerts, graphs showing patient-level trends of the three clinical parameters monitored, and heart failure-specific lab results. In addition, clinicians have the option of receiving alerts through automated emails, which contain the latest weight, blood pressure, and symptoms. Furthermore, the email contains the patients’ current medication list, heart failure-related laboratory results, and contact information.

3.2.2.2 Medly Services

Enrollment into the program was based on clinical judgment. After discussing the program with patients, a clinician (i.e., a cardiologist, a nurse practitioner (NP), or a resident) fills out a form to indicate the desired target ranges needed to customize the algorithm. Then, a telehealth analyst
(THA) provides patients with the Medly technology and training on how to use it. When alerts are triggered, they are viewable by patients’ treating cardiologist and NPs. The clinicians might act independently or communicate among themselves by email or in person to determine the best course of action. If required, a clinician will follow up with patients either by phone or email, documenting all actions and decisions in the hospital EMR. Furthermore, patients and clinicians are instructed to contact the THA to receive the technical support, if required.

3.2.2.3 Implementation Site

The HF clinic, part of UHN, is a high-volume specialty care clinic for patients with HF in Toronto. The intervention was developed by UHN’s Centre for Global eHealth Innovation (eHI) in close collaboration with clinicians from the HF clinic. The THA is employed by the UHN Telehealth Department with 25% of their time dedicated to supporting the Medly program. The HF clinic, UHN telehealth services, and eHI are physically located in the same building.

3.2.3 Implementation Strategy

Preparations for the program launch included the development of training materials for patients (user manual and training checklist). In addition, clinician users were provided with a user guide and a training session lasting approximately 1 hour. Moreover, members of the eHI team followed a service design methodology, consisting of mapping clinic workflows and producing a service blueprint for the Medly program, which sought to minimize the disruption to existing HF clinic processes.

3.2.4 Implementation Outcomes

We selected 4 of 8 implementation outcomes from Proctor et al’s Implementation Outcomes Framework as measures of the implementation success for this study [32]. In addition, data on the outcomes, defined below, were collected after 4 and 12 months of the launch through a document review process and semi-structured interviews.
• **Adoption:** The number of clinicians deciding to monitor patients using the *Medly* system.

• **Penetration:** The level of integration of the *Medly* program within the existing services of the HF clinic.

• **Feasibility:** The extent to which the *Medly* program can be successfully used by patients.

• **Fidelity:** The extent to which the *Medly* program is being used as initially intended.

Other Proctor outcomes of *acceptability* (perception that the *Medly* program is agreeable, palatable, or satisfactory) and *appropriateness* (perceived fit or compatibility of the *Medly* program within the HF clinic) [32] are analogous to the CFIR constructs of *Knowledge and beliefs about the intervention* and *compatibility*, respectively, [26] thus are not repeated here. The outcomes of *implementation cost* will be addressed in a future publication as described in Chapter 6. Finally, the 1-year study time frame was too short to objectively measure the Proctor outcome of *sustainability*, although Chapter 5 will explore this concept in significant detail.

### 3.2.5 Barriers and Facilitators of Implementation

Semi-structured interviews were developed based on the constructs of the CFIR, which provides a pragmatic organization of theory-informed constructs known to impact the implementation success across the following 5 domains: (1) intervention characteristics, (2) outer setting (e.g., patient needs and resources, external policy and incentives, etc), (3) inner setting (networks and communication, implementation climate, readiness for implementation, etc), (4) characteristics of individuals, and (5) process [26]. A full list of CFIR constructs and their definitions is provided in Appendix 1. Further interview probes were developed to explain the quantitative implementation outcome indicators (Appendix 2). Moreover, interviews were conducted prior to the program launch, and again after 4 and 12 months (Appendix 3), each session lasting 30-60 minutes. Of note, all adopting clinicians and eHI Medly program staff were invited for participation. In addition, clinicians who had not adopted the system by 12 months were also invited to participate. All interviews were recorded and transcribed for later qualitative analysis.
3.2.6 Data Analysis

The interview transcripts were analyzed by two independent investigators (PW and KG) using the Framework Method [80]; this involved a largely deductive thematic analysis using a codebook based on the CFIR constructs [26]. PW and KG independently coded the transcripts and then met to discuss contradictory codes and passages. The management of source documents and coding was done with the help of NVivo version 11 (QSR International, Doncaster, Victoria, Australia). To determine the degree to which the barriers and facilitators impacted the implementation, valence ratings were attributed by PW and KG to each construct according to the criteria outlined by Damschroder et al [81]. Qualitative findings and valence ratings were validated during a meeting with key members of the clinician and eHI program staff (n=6).

3.3 Results

3.3.1 Study Participants

In this study, 8 clinicians participated. One cardiologist, who was the only clinician who had not adopted the technology before the end of the study period, did not respond to requests to be interviewed prior to completion of the manuscript. Table 2 shows the interview schedule and the role of each participant.

Table 2. Study participants and timing of interviews

<table>
<thead>
<tr>
<th>Study identifier</th>
<th>Role in the Program</th>
<th>Role descriptor</th>
<th>Interview time points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician 1</td>
<td>Cardiologist and clinical lead of the Ted Rogers Centre of Excellence for Heart Function</td>
<td>Early adopter</td>
<td>X</td>
</tr>
<tr>
<td>Clinician 2</td>
<td>Nurse practitioner</td>
<td>Early adopter</td>
<td>X</td>
</tr>
<tr>
<td>Clinician 3</td>
<td>Nurse practitioner</td>
<td>Early adopter</td>
<td>X</td>
</tr>
<tr>
<td>Clinician 4</td>
<td>Cardiologist</td>
<td>Late adopter (9 months)</td>
<td>X</td>
</tr>
<tr>
<td>Clinician 5</td>
<td>Cardiologist</td>
<td>Late adopter (11 months)</td>
<td>X</td>
</tr>
<tr>
<td>Clinician 6</td>
<td>Cardiologist</td>
<td>Late adopter (11 months)</td>
<td>X</td>
</tr>
<tr>
<td>Clinician 7</td>
<td>Cardiologist</td>
<td>Late adopter (11 months)</td>
<td>X</td>
</tr>
<tr>
<td>Clinician 8</td>
<td>Cardiologist</td>
<td>Late adopter (11 months)</td>
<td>X</td>
</tr>
<tr>
<td>eHealth 1</td>
<td>Project manager</td>
<td>Left on maternity leave after 4 months</td>
<td>X</td>
</tr>
<tr>
<td>eHealth 2</td>
<td>Project manager</td>
<td>Replaced original project manager</td>
<td>X</td>
</tr>
<tr>
<td>eHealth 3</td>
<td>Program operations lead</td>
<td>New position was created after 3 months</td>
<td>X</td>
</tr>
<tr>
<td>eHealth 4</td>
<td>Telehealth analyst</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

### 3.3.2 Implementation Outcomes

Table 3 presents the results of implementation outcomes, which are discussed below.

**Table 3. Implementation outcomes indicators**

<table>
<thead>
<tr>
<th>Implementation outcome</th>
<th>Indicator</th>
<th>4 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adoption</td>
<td>Number of clinicians having decided to use Medly to monitor patients</td>
<td>n=3</td>
<td>n=8</td>
</tr>
<tr>
<td>Penetration</td>
<td>Percentage from the ratio of clinicians using <em>Medly</em> over the total number of potential clinician users in the Ted Rogers Centre of Excellence for Heart Function</td>
<td>38%</td>
<td>89%</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Cumulative number of patients enrolled in the <em>Medly</em> program</td>
<td>42</td>
<td>98</td>
</tr>
<tr>
<td></td>
<td>Cumulative number of patients removed from the <em>Medly</em> program for clinical reasons (e.g., received a heart transplant)</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Cumulative number of patients having chosen to leave the <em>Medly</em> program</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Number of deaths (all unrelated to the program)</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Fidelity</td>
<td>Cumulative number of calls or emails made to the telehealth analyst for technical assistance</td>
<td>56</td>
<td>195</td>
</tr>
<tr>
<td></td>
<td>Cumulative number of requests for changes to the <em>Medly</em> technology</td>
<td>15</td>
<td>72</td>
</tr>
</tbody>
</table>

*a*Implementation outcomes are defined in the framework by Proctor et al [32].

### 3.3.2.1 Adoption and Penetration

The program was launched with 3 clinician users (1 cardiologist and 2 NPs). By the 12-month time point, 5 additional cardiologists were monitoring patients using *Medly*, representing an increase in the penetration of the *Medly* program in the HF clinic from 38% to 89%, a diffusion pattern that is explained in the interviews.

All participants described how the *Medly* program was initially only open to the 3 clinicians who were most actively involved in its development. By the 11th month of the program, the clinical lead of the HF clinic decided to open its availability as a resource to other cardiologists. Many of the later adopting clinicians had always expected to be involved and were simply waiting to be invited.
I had no involvement a year ago, I was aware of it, and very supportive of it... [The request] probably came through [Clinician 1] finally saying “we’re at a mature point, Medly is really working, we have good capacity, let’s let the others in...I was just waiting to see when it would happen. [Clinician 7]

Although all cardiologists who adopted Medly after the initial launch had a similar perspective, some were concerned about the time it would add to their workday. They ultimately decided to participate because they felt a responsibility to share in the workload being taken on by their colleagues. Another important factor swaying their decision was a concern that they could be excluded from their patients’ circle of care.

I’d like to be more involved but I also like to know that I have the time... I think [the reason I decided to participate is] just a sense of fairness. I think it’s just not fair for one person to take over the ownership of it. Again, that speaks to the sustainability. It’s not sustainable for one physician or one nurse or one healthcare professional to be remote monitoring all the data and all the patients all the time...In this case, it’s a cardiologist that I know and trust very well...But again, you don’t want to be left outside the circle of care for a patient that is your patient and your responsibility. [Clinician 5]

3.3.2.2 Feasibility

By 12 months, 98 patients were enrolled in the Medly program; this was a lower number than initially anticipated and is partially explained by a low initial penetration within the clinic. In addition, throughout the implementation, clinicians began to realize that patients benefited differently depending on their disease severity, ability to use the technology, ability to adhere to taking measures, and receptivity to self-care messages, which led to clinicians becoming more selective of which patients were enrolled.

I also think and I respect that they’re doing their due diligence and they’re trying to figure out not just to try to get everybody on Medly, it’s about actually finding the right patients. The clinicians need to make sure they’re only targeting patients that would benefit and not someone that they’ll just take off after a week... So of course, it’s a little difficult on their side. They have to do a lot, you have to think a lot more about it. But I feel like they’re being more mindful about it. [eHealth 4]

Feasibility is also demonstrated by the relatively low number of patients who chose to stop using the system (n=5). Additionally, 5 patients passed away during the evaluation period. These deaths were determined to be unrelated to the Medly program and were explained by clinicians as being reflective of the severe disease state of the patient population.
3.3.2.3 Fidelity

Overall, the intervention is generally being used as intended with clinicians reviewing all alerts generated by Medly, following up with patients when necessary, and documenting all actions in EMR. The Medly program was launched with the idea that both the system and the service would continue to improve and evolve over time. Throughout the implementation, the THA received 159 calls from patients and 36 calls from clinicians related to problems with the system (e.g., receiving adherence calls when they had taken their readings, usability issues, and general connectivity problems between the phone and the peripheral Bluetooth equipment), all representing examples of when the system was not working as intended. However, these, as well as the 72 documented feature requests by patients and clinicians, are evidence of a properly functioning quality improvement mechanism.

3.3.3 Barriers and Facilitators of Implementation

Table 4 describes the barriers and facilitators of the implementation along with a valence rating signifying the degree to which it had an impact on the implementation of the Medly program. Unless otherwise discussed, valences were relatively consistent throughout the entire 12-month implementation period.

Table 4. Valence ratings assigned to Consolidated Framework for Implementation Research (CFIR) constructs

<table>
<thead>
<tr>
<th>CFIR domains and constructs^a</th>
<th>Operational Definition^a</th>
<th>Rating assigned to construct^b</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. INTERVENTION CHARACTERISTICS</td>
<td>Evidence strength and quality</td>
<td>Perception of the quality and validity of the evidence supporting the use of telemonitoring for heart failure.</td>
</tr>
<tr>
<td>Variable</td>
<td>Description</td>
<td>Score</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Relative advantage</td>
<td>Perception of the advantage of implementing the <em>Medly</em> program versus an alternative solution.</td>
<td>+2</td>
</tr>
<tr>
<td>Adaptability</td>
<td>The degree to which the <em>Medly</em> program can be adapted to meet the needs of the HF clinic.</td>
<td>+2</td>
</tr>
<tr>
<td>Complexity (reverse rated)</td>
<td>Perceived complexity of the <em>Medly</em> program as reflected by the degree of disruptiveness to existing workflows and number of steps involved in using the intervention as intended.</td>
<td>−1</td>
</tr>
<tr>
<td>Design quality and packaging</td>
<td>Perceived quality of the <em>Medly</em> program (technology and service components) and how well these components are bundled and work together.</td>
<td>0</td>
</tr>
<tr>
<td>Cost</td>
<td>Financial and opportunity costs of implementing the <em>Medly</em> program.</td>
<td>−1</td>
</tr>
</tbody>
</table>

II. OUTER SETTING

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient needs and resources</td>
<td>The degree to which heart failure patients’ needs are known and prioritized by the HF clinic (i.e., patient-centeredness).</td>
<td>+2</td>
</tr>
<tr>
<td>External policy and incentives</td>
<td>Policies and incentives that support or hinder the implementation of telemonitoring programs.</td>
<td>0</td>
</tr>
</tbody>
</table>

III. INNER SETTING

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Networks and communications</td>
<td>The quality of the communication networks that support the implementation and daily operations of the <em>Medly</em> program.</td>
<td>−1</td>
</tr>
<tr>
<td>Culture</td>
<td>Norms and values of the HF clinic and UHN&lt;sup&gt;d&lt;/sup&gt;.</td>
<td>+2</td>
</tr>
<tr>
<td>Implementation Climate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tension for change</td>
<td>The degree to which stakeholders perceive a need for change in the clinical management of patients in the HF clinic.</td>
<td>+2</td>
</tr>
<tr>
<td>Compatibility</td>
<td>The degree of fit between the Medly program and the HF clinic’s values, norms, needs, and existing workflows and systems.</td>
<td>+1</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------</td>
<td>----</td>
</tr>
<tr>
<td>Relative priority</td>
<td>Stakeholders’ perception of the importance of implementing the Medly program.</td>
<td>+2</td>
</tr>
<tr>
<td>Learning climate</td>
<td>The degree to which the HF clinic and UHN have a climate that provides time and space for reflective thinking and that allows team members to feel essential, valued, and safe to try new methods.</td>
<td>+2</td>
</tr>
</tbody>
</table>

**Readiness for Implementation**

| Leadership engagement              | Commitment, involvement, and accountability of the HF clinic lead.                                                                                           | +2 |
| Available resources                | The level of resources dedicated for the implementation and ongoing operations of the Medly program.                                                      | +2 |
| Access to knowledge and information| Ease of access to digestible information and knowledge about the Medly program and how to incorporate it within existing HF clinic workflows.                 | 0  |

**IV. CHARACTERISTICS OF INDIVIDUALS**

| Knowledge and beliefs about the intervention | Clinicians’ attitudes toward and value placed on the Medly program.                                                                                           | +2 |
| Self-efficacy                               | Clinicians’ and telehealth analyst’s belief in their own capabilities to execute their role within the Medly program and achieve implementation goals.               | +2 |

**V. PROCESS**

| Planning | The degree to which a plan for implementing the Medly program was developed in advance and the quality of that plan. | –1 |
| Engaging |                                                                                                                      |    |
The constructs and operational definitions are adapted from the Consolidated Framework for Implementation Research [26].

Definitions of valence ratings are adapted from Damschroder et al’s study [81]: –2, the construct had a strong negative influence on the implementation effort; –1, the construct had a minor negative influence on the implementation effort; 0, the construct had a neutral influence on the implementation effort. Alternatively, different aspects of the construct had a positive influence, while others had negative influence: +1, the construct had a minor positive influence on the implementation effort; +2, the construct is a strong positive influence on the implementation effort.

HF clinic: Ted Rogers Centre of Excellence for Heart Function.

UHN: University Health Network.

3.3.3.1 Intervention Characteristics Domain

3.3.3.1.1 Evidence Strength and Quality

Clinician participants acknowledged ambiguity in the literature of the impact of TM for HF. However, this did not impact the implementation for reasons identified in the construct knowledge and beliefs about the intervention.
3.3.3.1.2 Relative Advantage

The Medly program was perceived as having a relative advantage over alternative TM options. Unlike many TM systems, Medly measures multiple clinical parameters, offers algorithm-based self-care instructions with structured telephone support when necessary.

*It’s another version of what other people have tried. It has more elements than just daily weight because I think we know that daily weights are inadequate for measuring the state of somebody’s heart failure. It can [also] be used with other things, structured telephone follow up as needed. I think the interactions with the nursing staff are an important value add related to Medly.* [Clinician 5]

3.3.3.1.3 Adaptability

Many statements revealed the adaptability of both the technology and service components of the Medly program, giving this a strong positive valence. Examples include flexibility in how clinicians perform program-related tasks (e.g., documentation), workflow adaptations to make more efficient use of the THA’s time, and changes to the Medly algorithm.

*Pulling us out [of the clinic] was a good change. That’s more to the workflow... When it comes to the actual product, there have been changes, well a lot of feature requests to change the algorithm or to change some copy of the alert and things like that... There are multiple examples of how algorithm changes have already been made and that has helped.* [eHealth 4]

3.3.3.1.4 Complexity

Several statements revealed the complex nature of the Medly program, giving this construct a negative valence in the early stages of the implementation. Examples of complexity include (1) need for extensive documentation, (2) relying on engagement from patients, (3) challenges in identifying program candidates, (4) communicating patient information between Medly clinicians, and (5) setting algorithm parameters.

1) *The biggest time for me is having to create all these communication notes in [the EMR] to document my conversations with people.* [Clinician 3]
2) The patient also has an almost 50/50 responsibility. They don’t have to be there when I call, but if I leave a message and if I leave a call back number... I expect that someone is going to call me back. [Clinician 3]

3) There is no literature out there to clearly say who’s the right person...I mean people that I’ve learned are more challenging are people with cognitive impairment and people who, for a variety of reasons, aren’t engaged enough to respond when we contact them. [Clinician 3]

4) If [another clinician], for example, has had to deal with several alert-related issues for a particular patient, how is that information then communicated over to me...if there’s some issue I have to follow up on? [Clinician 2]

5) [Another challenge] is this idea of trying to guess what your range of variation is going to be for each patient. I think there are probably more accurate mathematical models to try to come up with that rather than me sort of flipping a coin and deciding, ‘Okay, it’s going to be 3 pounds + or –, or 2.5 pounds. [Clinician 6]

As these challenges were identified and solutions to mitigate their impact implemented, the complexity of the program was no longer viewed as negatively impacting the program’s continued growth.

3.3.3.1.5 Design Quality and Packaging

General satisfaction with the Medly program and its design were a pervasive theme throughout the interviews. However, some design-related factors were perceived as barriers to continued growth of the program and sustainability even if they did not significantly impact clinician adoption. For example, clinicians expressed a desire for a more seamless integration with existing technologies and workflows by (1) integrating the dashboard with the hospital EMR to facilitate documentation, (2) making the dashboard available on mobile devices, (3) providing more patient details in the dashboard, and (4) allowing for multiple patient-clinician communication modalities (e.g., short message service text messaging).

I really wish it worked on my iPhone or my iPad, particularly in the odd time where [Clinician 1] has been away and I’ve had to do it on the weekend, you know, or [when] I needed to check something when I was trapped in New York and I couldn’t work remotely because I can’t get it on my phone. [Clinician 3]

I find dashboard right now is very intuitive. I think the part that I find really challenging is that I have to usually have [the EMR] open with Dashboard and so it would be nice to
have some patient information in the Dashboard so that you’re not having to go back all the time between those two platforms. The other thing I would say, they’re minor things but you know, contact information for patients. Not simply just one phone number but also an email at the top or the ability to text a patient or do something like that that’s good for you to kind of manage clinical alerts. [Clinician 2]

3.3.3.1.6 Cost

Most of the costs associated with implementing the Medly program were related to the equipment, which were perceived as high and unsustainable. However, plans are being made to reduce costs by having patients use their own devices. The other major cost involved the THA’s time, which was higher than initially anticipated.

Currently the system is CAD$2,200 a pop for the phone, the data plan, the weight scale and the cuff so obviously, we don’t yet have a mechanism to pay for that and thankfully through [philanthropy] we’ll be able to cover the costs of the program. [Clinician 1]

I think with time, we can drive the cost of [equipment] down. As we move to “bring your own device”, the phone costs [will] matter less... Where I think we’ve gone over budget [is that] we had anticipated that [telehealth] support would cost 25% of a person’s time and I think it’s coming closer to 50-75% of their time... and that overflows into the rest of the teams. [eHealth 2]

This construct received a ranking of –1 because although the equipment cost was not a large initial barrier due to philanthropic funding, it was a barrier to the sustainability that would need to be addressed. Furthermore, although the additional THA time requirements did not significantly impact the Medly implementation, it did have important opportunity costs related to that individual’s ability to work on other projects. A formal economic evaluation of the impact of the Medly program from the perspectives of patients, HF clinic, and public payer will be subsequently conducted.
3.3.3.2 Outer Setting Domain

3.3.3.2.1 Patient Needs and Resources

This construct represents the idea that the implementation site comprehends and seeks to address patients’ needs. Numerous examples of the HF clinic’s patient-centred approach to care made this a strong facilitator.

*It's a very supportive environment for patients and families, and that is something that I repeatedly hear in clinic, especially patients who have been in the clinic for a long period of time, how thankful and how grateful they are for the care that they receive. You hear this a lot, people just...they don’t want to go somewhere else.* [Clinician 2]

3.3.3.2.2 External Policy and Incentives

This construct had a neutral impact because although the program was perceived as compatible with government policies seeking to encourage more comprehensive chronic disease care outside of the hospital, factors like regulation, funding, and clinician reimbursement were flagged as crucial barriers to the program’s sustainability.

*Any tool that we can develop that will actually improve patient-centred care...and potentially impact communication between different members of the team, which is the ultimate goal of Medly...are all in line with where the ministry of health is taking us.* [Clinician 1]

3.3.3.3 Inner Setting Domain

3.3.3.3.1 Networks and Communication

Three networks of communication were identified as having an influence on the implementation success. First, communication within the HF clinic was described as generally good and had a positive influence. Second, communication between clinicians and the THA involved in the day-to-day operations of the Medly program was also perceived as positive for the implementation. Finally, communication among high-level stakeholders was described as an early barrier to the implementation, particularly as it is related to decision making about the program and having clear channels to operationalize those decisions. This barrier was identified and remarkable improvements were made by the 4-month time point.
In the past, I think it was every possible channel... There were emails [that] didn't always go to the same people... Everyone knows what happens in the meetings, but it's what happened outside of those meetings where I think things were a lot more confusing. In addition to that, there was a lot of back-channel communication happening, and by that I don't mean between us, but I think between the stakeholders themselves... and then the rest of us eventually figure it out. So it was all over the place. And right now, I think it's consolidated a lot better. [eHealth 2]

3.3.3.3.2 Culture
The HF clinic’s culture of teamwork was perceived as having facilitated both the implementation and the daily operations of the Medly program.

This hospital is like working in a 5-star hospital... we are a multidisciplinary team, so there are many people taking care of our patients, it’s not just us. It’s fantastic, it’s excellent. We are very patient-centred. In general, the environment or the mood in the clinic is positive and constructive. [Clinician 8]

3.3.3.3 Implementation Climate
3.3.3.3.1 Tension for Change
Clinician participants were proud of the quality of care they offered to patients. However, a perceived gap existed between the current and ideal state of providing holistic patient care. Coupled with a busy clinic with limited staff and space resources, this created a tension for change.

[Clinic capacity] is an ongoing concern for me and I think we're at a bit of a crux where we couldn’t handle somebody not coming to work and we can't handle any more volume. [Clinician 1]

3.3.3.3.2 Compatibility
The Medly program was perceived as compatible with the values of the organization and complimentary to existing services offered in the HF clinic.
Offering patients something different and unique that is more based on technology that they can use at home, I think totally fits with UHN’s goals and vision with advancing patient care...I don’t see anything else that we’re doing that overlaps with what Medly’s doing. I mean, one of the things that we want to try and do a lot more of is education in the clinic environment for patients and I think, if anything, Medly just completely supports those messages that we give to patients about why salt restrictions are important and those kinds of things. So I don’t see it as a duplication, I think it just kind of nicely fits together in terms of more comprehensive care for patients. [Clinician 2]

Early apprehension about increased clinician workloads speaks of the incompatibility of the TM program with existing clinic workflows. However, by the end of the first year, evidence exists that a new normal has been created such that this initial incompatibility did not significantly impact the overall implementation success.

I organize my time differently now...I've changed the way I do things because I can’t be in clinic doing clinic and trying to run back and forth because that’s challenging. So, I try to carve out like at least the first half an hour or hour of my day to deal with Medly and then I go [to clinic]. [Clinician 3]

3.3.3.3.3 Relative Priority

The implementation of the Medly program was perceived as having a high priority by all participants.

My understanding is that Medly is a fairly high priority...A lot of the other [initiatives] are still important and they’re going on simultaneously, but I would say (Medly)’s up there. [Clinician 3]

3.3.3.3.4 Learning Climate

Participants describe a work environment that values ongoing quality improvement. They feel the climate offers a safe space for learning and trying new things, making this construct a strong positive influence on implementation success.

I work with a great staff, very closely with a few heart failure physicians who have been fantastic in advancing my knowledge and teaching me along the last one year. [Clinician 2]
3.3.3.3.4 Readiness for Implementation

3.3.3.3.4.1 Available Resources

Important to the success of this implementation was the availability of financial and human resources. No new clinicians were employed; rather, existing NPs were expected to perform Medly-related tasks within their salaried hours. Although this was possible, the added NP workload should not be underestimated.

[I am] not complaining about [responding to alerts] because that is part of why I'm hired. It's just that there needs to be, in order for Medly to work, you have to have a clinician who is devoting time to do all of that, to answer alerts, to document, and to see patients that are unwell in clinic. [Clinician 3]

The THA was an additional resource that was hired to support this program. Flexibility with respect to this resource, both in terms of quantity of time and time during the day, was an important facilitator that might not be realistic in other sites.

It makes it a lot easier when they call me down to the clinic or they have a patient come to the clinic and I am available and I can just run down and be there in five minutes. My worry would be if it was a different site and they need that kind of instant support. It may be difficult getting someone there. [eHealth 4]

Funding for the equipment came from philanthropic donations, thereby mitigating the potential barrier of nonavailability of funds common in many real-world implementations.

The cost, although improved, is still an issue, because right now Medly is being funded [by philanthropy] and obviously, we're not here to fund it for the province. [Clinician 1]

Finally, insufficient physical space is a challenge for the HF clinic and was likely an indirect barrier as clinic rooms are required for patient onboarding.

What hasn’t been solved is the fact that there aren’t enough resources in terms of rooms, in terms of workflow around patients getting seen and into the rooms, we’re limited by the physical space. [Clinician 7]

3.3.3.3.4.2 Access to Knowledge and Information

The availability of the THA to provide on-call and personalized information about how to use the intervention was an important facilitator. However, although clinicians perceive the training
they received to be sufficient, some felt that more comprehensive training around understanding the algorithm was required. In addition, the novelty of this program meant that no clear medical-legal guidelines existed on exactly what information needed to be documented. Therefore, this is a challenge that clinician users needed to navigate on their own.

That was a little bit confusing maybe [for us], what should be documented in terms of alerts and what should not. So that's kind of just been teased out as we've been going through it for the last four months. [Clinician 2]

3.3.3.4 Characteristics of Individuals Domain

3.3.3.4.1 Knowledge and Beliefs About the Intervention

Clinician knowledge and positive beliefs about the Medly program likely helped overcome the potentially negative influence of the equivocal scientific evidence.

I don't know if I'm just being an optimist. I actually think [the Medly program] is going to show reduced hospital length of stay and admissions. And so I think that if the system has proven to do this, I think it’s going to be useful across the board because heart failure is everywhere. [Clinician 4]

3.3.3.4.2 Self-Efficacy

A strong sense existed that despite initial apprehensions about the increased workload, the clinician and eHI teams were confident that they would be successful in implementing the program.

I don’t think that there’s any doubt that we will be implementing it I think as intended. While I may be apprehensive, it doesn’t mean that I don’t think that we still actually need to try and actually see. [Clinician 3]
3.3.3.5 Process Domain

3.3.3.5.1 Planning

Despite user training being planned and the initial service design work leading up to the program launch, an overarching implementation plan was never explicitly developed at the outset; this was perceived as having a negative impact during the initial months of the implementation. However, after realizing this deficiency, ongoing plans were formalized by the team; this was perceived as having a positive influence on the current and future program.

Since the four-month, we regrouped as an operations team... I think we have a much better strategy for what we’re trying to do and we actually now have people dedicated to that... I think there’s a much more coherent strategy and a much more coherent plan. [eHealth 2]

3.3.3.5.2 Engaging Champions and Opinions Leaders

The presence of a clinician champion or opinion leader was an important facilitator for both the development and implementation of the Medly program. Importantly, the fact that this champion or opinion leader set a positive example appears to have had more of an impact on the implementation success than this individual’s role as a formal leader.

I think certainly that from the clinic side, that [Clinician 1] is the champion of this. She’s pushed very hard for its development and rollout and by far I think she’s certainly enrolled the largest number of patients onto the system. [Clinician 3]

3.3.3.5.3 Executing

Although no formalized implementation plan existed, overall, there is a perception that the eHI team has been effective in doing what was necessary to support the implementation. However, the team’s inability to deliver rapid technology adaptations was perceived as a barrier by all participants.

I think there have been some deviations, but overall, I think the team is doing a relatively good job with meeting the expectations. I think some of the deviations are reasons outside of our control or some of them are just because of delays in development. I know a lot of the things we want to do with the program around streamlining it involve adapting the
technology and we haven’t been able to fully do that. But on the process side, we’ve been responding pretty well. [eHealth 2]

3.3.3.5.4 Reflecting and Evaluating

Embedded within the Medly program was a mechanism to facilitate the ongoing quality improvement. All participants spoke positively of the benefits of being able to quickly identify and evaluate problems and implement solutions when possible.

We meet every two weeks to discuss the recruitment in the program, how things are going, any issues or problems that people have faced. And then we discuss those issues, identify solutions and come up with a plan for how we want to address them. We also talk about achievements that have happened, so recruitment milestones, things like that. [eHealth 2]

3.4 Discussion

3.4.1 Principal Findings

This longitudinal implementation evaluation found that the Medly program had been successfully implemented, as demonstrated by the steady growth in patient enrollment and by the fact that after 1 year, there was a high degree of clinician adoption and intervention fidelity. Costs were relatively high because of the decision to initially supply patients with all the TM equipment. That said, these costs were not estimated to have significantly impacted the implementation and are expected to dramatically decrease, as the program shifts to bring your own device (BYOD) model. This study also identified 24 CFIR constructs that explain these measures of implementation success. Fifteen constructs were facilitators predominately clustered in the domains of inner setting and characteristics of individuals. Four CFIR constructs were minor barriers in the earlier phases of implementation—complexity, cost, networks and communication, and planning. Five additional constructs had a mixed valence and therefore were determined to have a neutral impact on the implementation.
3.4.2 Comparison with Prior Work

The implementation barriers and facilitators identified in this study are very much in line with results from other TM implementation studies. Systematic reviews have concluded the importance of characteristics of the technology, people involved, extraorganizational environment, and implementation setting [56, 72, 73]. In addition, the literature suggests that having undefined roles in the context of new workflows is a common barrier to eHealth implementations [76]. This study provides concrete examples of these barriers as they relate to the CFIR constructs of complexity and compatibility. For example, in the absence of clear guidelines for documentation, identifying ideal patient candidates and setting parameter thresholds needed for the algorithm, clinicians are forced to develop experiential knowledge to be able to perform these tasks. The development of this tacit knowledge can often only happen over time and might be challenging in a fast-paced clinic environment. The learning climate in this study was perceived as being an important facilitator, which likely helped overcome this challenge. However, clear guidelines for clinician staff roles will likely be required to ensure implementation success where learning climates might not be as favorable.

In addition to providing a framework that allows for the easier transferability of study results, using CFIR-guided methods allowed this research to make two additional contributions to the field of implementation science. To the best of our knowledge, this is the first study to demonstrate the feasibility of using the CFIR for evaluating complex telehealth interventions [82]. However, the CFIR lacks granularity for identifying factors that might be unique to health information systems. Researchers wanting an in-depth understanding of the impact of the technology (as opposed to the full intervention) should consider informing their methods using an additional framework that will help open the black box of design quality and packaging. For example, the Clinical Adoption Framework (CAF) could be useful for designing probes around the quality of the system, quality of the information within the system, and quality of the services supporting the system [83]. Another limitation of the CFIR is that we consider most software updates to be an inherent quality of software-based health interventions. As such, we do not think that a technology’s capacity to iterate is adequately captured in the CFIR construct of adaptability, which relates more to the components of an intervention that can be adapted or tailored.
Unlike studies that present a list of barriers and facilitators, the CFIR guides the classification of these factors into broader domains. For example, the strongest influencing factors on the Medly program were in the CFIR domains of *inner setting, characteristics of individuals,* and *process.* This is not to say that the characteristics of the intervention were not important, but it makes the point that the implementation context cannot be ignored.

### 3.4.3 Limitations

This study was conducted at a single implementation site. Therefore, we acknowledge that the characteristics of the HF clinic might differ compared with other settings in terms of the availability of resources, structure of care delivery, and characteristics of the individuals involved. In addition, we acknowledge the absence of the patients’ perspective in this study. That said, a mixed method study of factors that influence patient adoption, use, and adherence to the Medly program will feature in an upcoming chapter. Finally, one cardiologist did not agree to participate in an interview; therefore, barriers to adoption for this individual are unknown.

### 3.4.4 Recommendations

We offer the following recommendations based on key study findings to facilitate the transferability of results to other implementation settings:

1) **Evaluate contextual barriers:** This study highlights the importance of contextual factors. Early identification of potential barriers as part of a readiness assessment would allow for the development of mitigating strategies. Using a framework such as the CFIR could facilitate this task; our results provide an example of how the CFIR constructs can be operationalized for telehealth interventions.

2) **Define all components of the intervention:** Complexity is an important barrier for the successful implementation of eHealth interventions [76]. However, this negative influence can be mitigated by an explicit definition of each intervention component. In this study, contextual facilitators helped overcome the lack of protocolized clinician
roles; however, better definition of nontechnology intervention components and roles could facilitate clinician adoption in future implementations.

3) **Plan and document the implementation strategy**: The lack of a clearly defined implementation plan was identified as an early barrier in this study, which was moderated by contextual facilitators and other *process* factors, including the presence of a strong clinical champion and a robust mechanism for ongoing reflecting and evaluation. The Quality Implementation Framework (QIF) [84] offers a prescriptive approach that can help formulate an implementation strategy that incorporates an assessment of many of the constructs outlined in the CFIR [26].

### 3.5 Conclusions

This study presents results from the real-world implementation evaluation of a mobile phone-based TM program for patients with heart failure. The overall success of the implementation, as determined by the four implementation outcomes, was explained by the presence of several facilitators and relatively few barriers. Although the results are consistent with other TM implementation studies, this study also demonstrates how barriers and facilitators are dynamic and can influence the implementation success differently over time. Finally, we highlight a previously undescribed challenge—TM interventions often rely on clinicians’ ability to build experiential knowledge to use the system as intended. The results from this research can inform the development of TM interventions and their implementation strategies. Hence, evidence-based implementation is important to ensure the success of real-world TM deployments as well as for ensuring that TM studies can yield unambiguous evidence of effectiveness, which will be required for the wider diffusion of TM.
47

Chapter 4
Explaining Patient Adherence

Publication: Ware P, Dorai M, Ross HJ, Cafazzo JA, Laporte A, Boodoo C, Seto E. Patient Adherence to a Mobile Phone-Based Heart Failure Telemonitoring Program: Longitudinal Mixed Methods Study. JMIR Mhealth Uhealth (forthcoming). doi:10.2196/13259

4 Explaining Patient Adherence

This chapter answers the fourth research question: What factors influence patient adoption and appropriate use of HF TM interventions?

4.1 Introduction

4.1.1 Background

Heart Failure TM interventions are designed to transform traditional HF management from one of episodic care (during periods of symptom exacerbation or scheduled follow-up visits) to one of continuous management, extending into patients’ daily lives. TM systems enable patients to take home readings (e.g., weight, blood pressure, pulse rate, oxygen saturation, symptoms [52]) which then get transmitted to clinicians at a remote location [10]. The main outputs of this data transfer are threefold. First, the act of taking regular measurements instills in patients a sense of active participation in their care while providing information required to engage in self-care [40, 64]. Second, timely data transmission enables clinicians to catch symptom exacerbations early and allow for remote intervention [11]. Finally, even in the periods of patient stability, longitudinal data collected by TM systems provides a more holistic picture of patients’ condition which can improve the quality of clinical decisions [12]. According to several meta-analyses, these mechanisms work together to improve quality of life and reduce mortality and healthcare utilization compared to the standard of care without TM [10, 20, 43, 44, 47]. However, large and well-designed RCTs have reported null or mixed results which cannot be ignored [48, 49, 85, 86]. We have previously made the case that inconsistencies in the evidence can be explained, in
part, by varying fidelity with which interventions are implemented in trials, including the degree to which patients adhere to taking prescribed home readings [87].

Despite the importance of ensuring consistent patient adherence over the course of a TM intervention, there is a dearth in the literature on this topic [42, 65] and existing knowledge is difficult to generalize. First, although systematic reviews describe general trends of adherence as starting high in the early months and dropping off over time, there is significant heterogeneity with overall rates between 40-90% being reported across studies [64, 65]. Second, much of the remote monitoring literature on adherence relates to IVR-based interventions with much fewer studies related to newer forms of TM that leverage devices already familiar to patients (e.g., mobile phones) [64]. Third, adherence is defined and measured inconsistently across studies with many simply reporting engagement with the technology (e.g., taking a single measure) which does not always encompass the full set of patient behaviours needed to optimize the intervention’s mechanisms of action [88, 89]. Finally, the phenomenon of patient adherence is typically measured in the context of RCTs, limiting the understanding of patient adherence within real-world TM contexts which may be less likely to limit patient use of an intervention to a pre-defined study period.

4.1.2 Study Objectives

In August 2016, a HF TM program was deployed as part of the standard of care in a specialty heart function clinic in Toronto, Canada. A previously published case study of this program’s implementation described and explained clinician adoption as well as the degree of integration within the clinic [90]. This study aimed to describe the patient perspective within the case study. The objectives were to (1) quantify the degree to which patients adhered to taking prescribed home readings and (2) explain longitudinal adherence rates based on duration of program enrollment, patient characteristics, and patient perceptions of the TM program.
4.2 Methods

4.2.1 Study Design

The study used a mixed methods explanatory sequential design whereby overall and monthly patient adherence rates were first analyzed over a 1 year period. These adherence rates subsequently informed the sampling strategy for semi-structured interviews with the objective of explaining overall adherence rates. Additional explanatory data were collected including questionnaires and reasons for leaving the program, all of which were triangulated with the interview findings to explain adherence rates.

Methods used to explain adherence were guided by the Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) which outlines how 7 constructs influence consumers’ intention to use a technology [34]. These constructs, whose definitions have been adapted to facilitate their operationalization within this study, include: (1) **performance expectancy** (the degree to which using the TM system is perceived to provide benefits for patients and is analogous to relative advantage in the diffusion of innovation literature and perceived usefulness in the Technology Acceptance Model), (2) **effort expectancy** (the degree of ease associated with patients using the TM system), (3) **facilitating conditions** (patients’ perception that there are resources available to support their use of the TM system), (4) **social influence** (the extent to which others important to the patients (e.g., family and friend) support the use of the TM system), (5) **hedonic motivation** (the fun or pleasure derived from using the TM system), (6) **price value** (patients’ cognitive trade-off between the benefit of using the TM system and the monetary and time costs to them), and (7) **habit** (the extent to which patients take their required readings automatically because of learning). The UTAUT2 also proposes that the influence of these 7 constructs on behavioural intention to use technology is modified by age, gender, and experience with using the technology [34].

Key methods for this study have been published in a protocol for a larger quality improvement program evaluation [22] which has been approved by the University Health Network Research Ethics Board (16-5789). This approval included the analysis of all data collected as part of the standard of care (i.e., TM usage data). Informed consent was obtained by patients who completed questionnaires and interviews.
4.2.2 The Intervention

4.2.2.1 Telemonitoring Technology

The central component of the Medly TM program is the Medly smartphone app that patients use to take weight, blood pressure and heart rate readings as well as record their symptoms using a questionnaire composed of between 5 and 11 ‘yes/no’ questions. Patients are instructed to take these 4 readings daily within 30 minutes of each other before 12pm. If this is done, the recorded data gets processed by a clinically validated algorithm embedded in the app, which has been contextualized according to each patient’s target thresholds for each of the 4 readings. If the algorithm identifies that key readings are within the acceptable range, the ‘normal’ readings are presented without any further instruction. However, if the algorithm identifies that key readings are out of range or that there is a worrying trend in weight gain, the app generates and displays self-care feedback messages or ‘alerts’ which are highlighted in a different color depending on the determined urgency (Figure 3). Types of self-care feedback messages include: informing patients when they are outside their normal range, instructing them to take their prescribed diuretic medication, and suggesting when to contact their care providers or go to the emergency department. Similarly, clinicians also receive alerts when readings are out of range which they can receive via email or view within the clinician facing Medly dashboard.
Other features of the Medly app include the ability to view graphical trends of each reading’s values and, to assist with adherence, an automated phone call to their primary phone line (personal mobile phone or home landline) to remind patients if they have not yet taken morning readings by 10am. This feature can be disabled at the patient’s request. The development of Medly features aimed at promoting patient self-care was guided by the Connelly Framework for Self-Care in Chronic Illness [91] (a derivation of the Health Belief Model [92]) using an iterative user-centered design process which included a formal needs assessment [93] and multiple rounds of usability testing.

4.2.2.2 Program Enrollment and Onboarding

Because the Medly program is offered as part of the standard of care, enrollment is decided jointly between patients and their treating cardiologist during a follow up appointment or after an
inpatient hospital stay. After the treating cardiologist explains the Medly program and the patient agrees to participate, they are immediately escorted to a private room where they receive training on how to use the technology. Part of this training includes highlighting the importance of taking daily readings.

4.2.2.3 Ongoing Monitoring

Throughout their participation in the Medly program, patients are expected to complete the 4 daily morning readings and to follow the self-care feedback displayed in the app. If clinical alerts are triggered, a designated clinician at the heart function clinic reviews these alerts as soon as possible. Most clinical alerts result in a call being made to the patient to obtain more information or to provide relevant clinical guidance.

4.2.2.4 Offboarding

Offboarding refers to the process of ending a patient’s participation in the Medly program. Unlike many TM interventions, the Medly program does not have a predefined end date. Thus, as with most medical interventions, patients remain enrolled for as long as there is a perceived clinical benefit. Patients or clinicians can, at any time, initiate a conversation about the appropriateness of the Medly program as part of a patient’s treatment plan. Once the joint decision to offboard a patient is made, patients return any equipment they borrowed (mobile phone or peripheral devices) which get recycled and used for future participants.

4.2.2.5 Adaptations to the Program Since its Launch

When the program first launched in August 2016, patients were provided with a Medly Kit which included a smartphone with a data plan with the Medly app already downloaded along with a Bluetooth-enabled weight scale and blood pressure cuff. This enabled data from the peripheral devices to be transmitted directly and automatically to the Medly app. Training and ongoing technical support was provided by an analyst from the hospital’s telehealth department and the
The triage of clinical alerts was done by nurse practitioners on staff at the clinic. Since program launch, two key changes have been implemented to enable the sustainability and scalability of program. First, in January 2018, it became possible for patients with iPhones to download the Medly app on their own smartphones and to use their personal weight scales and blood pressure cuffs (the app is now also available for Android users, however, this option was not available at the time of data analysis). Patients without Bluetooth-enabled peripheral devices manually entered measures directly into the app. Second, as of May 2018, a Medly coordinator role was created whereby a registered nurse took over the role of triaging clinical alerts in addition to providing frontline technical support. Details and rational for these changes have been published elsewhere [94].

4.2.3 Measuring Patient Adherence

Because patients are instructed to take weight, blood pressure, heart rate, and symptoms readings every morning (these 4 readings are required for the Medly algorithm to generate self-care instructions for patients and alerts for clinicians), adherence was defined as the proportion of days patients took all 4 morning readings over the total number of days they were enrolled up to 1 year. Due to ongoing enrollment, not all patients had completed 1 year at the time of analysis. Thus, varying durations were accounted for in the proportion denominator. Similarly, monthly adherence rates were calculated as the number of completed morning readings over each 30-day period following the date of their enrollment up to 1 year. Proportions were multiplied by 100 to get monthly adherence rates expressed as a percentage of prescribed completed readings. To further understand patient engagement, we also calculated incomplete adherence rates which was defined as the percentage of days patients took at least 1 reading but not all 4 (such that, although data is transmitted, no clinical alerts or patient feedback is generated). Usage data required to determine adherence rate was collected between August 2016 and October 2018 and extracted from the Medly program server.
4.2.4 Explaining Patient Adherence

4.2.4.1 Quantitative Data and Analyses

4.2.4.1.1 Explanatory Variables

Patient demographic variables were collected to characterize the patient population using a questionnaire administered immediately after program enrollment to patients who provided informed consent (n=174). Simple linear regression for full and incomplete adherence over time was performed. In addition, because adherence was collected using repeated measures over a 12-month period, a panel multivariate regression approach was used to determine the impact of time on adherence when controlling for key variables. Preliminary diagnostics included the Hausman and Lagrange multiplier to choose between pooled ordinary least squares, fixed effects, or random effects models and the Breusch-Pagan test to detect the presence of heteroscedasticity [95]. Ultimately, random effects models with cluster-robust standard errors (to adjust for the presence of heteroscedasticity [96]) proved best suited for the dataset. Selected explanatory variables for the multivariate regression included age categorized by decade and sex (both moderating variables in the UTAUT2 [34]), and New York Heart Association functional classification (NYHA class), a subjective measure of HF symptom severity, based on the hypothesis that that sicker patients may benefit more. Data for baseline NYHA class (sometimes documented as a range), age, and sex were extracted from patients’ chart in the hospital electronic medical record.

4.2.4.1.2 Patient Questionnaires

As part of a larger questionnaire used in an impact evaluation, consenting patients responded to questions about their satisfaction with the Medly program at 6 and 12 months, offering an opportunity to triangulate these quantitative findings with results from patient interviews (described below). Items in the satisfaction questionnaire could be classified according to the key UTAUT2 constructs of performance expectancy (3 items) and effort expectancy (4 items); no questionnaire items could be classified within the remaining UTAUT2 constructs and thus were not quantitatively assessed.
Descriptive statistics for questionnaire responses, adherence rates, and the linear regressions were performed using SPSS version 24 (IBM Corporation, USA). Multivariate regression analyses were conducted in RStudio v.1.0.153 (RStudio Inc) using the “plm” package [97]. For all statistical tests, a P value of <0.05 was used to indicate statistical significance. Temporal trends were graphically represented using Microsoft Excel (Microsoft Corporation, Redmond, WA).

4.2.4.2 Qualitative Data and Analyses

4.2.4.2.1 Reasons for Offboarding

Reasons leading to patients being offboarded were recorded in the Medly coordinator’s records as part of the standard offboarding procedures. These reasons were qualitatively analyzed and classified into themes before being transformed into a count for each category.

4.2.4.2.2 Patient Interviews

Semi-structured interview guides, which were developed to understand the patients’ experience in the Medly program, included probes based on the constructs in the UTAUT2 (Appendix 4). Participants were identified using a purposeful sampling approach to ensure a variety of opinions and to reach information saturation [98]. Variables considered in this sampling approach were age, sex, overall adherence rates, and time since enrollment. The latter involved selecting patients who had been enrolled for different durations, including: baseline (to understand initial perceptions without actual experience), approximately 1 month (the intervention was still fresh but patients had been using it long enough to experience benefits and barriers to use), and approximately 6 and 12 months (to align with questionnaire administration and assess patients’ perceptions after longer term use). Interviews were recorded and took place in a private room during a scheduled clinic visit or over the telephone.

Interview transcripts were analyzed by two independent investigators (PW, MD) using the Framework Method [80]. This approach involved a first round of largely deductive thematic analysis using an initial coding framework based on the UTAUT2 constructs. PW and MD met
to discuss results of the first round and to agree upon subthemes within those constructs. Next, a second round of independent coding was done using the updated coding framework, which was followed by a meeting to discuss contradictory codes and passages. The management of source documents and coding was accomplished with the help of NVivo version 11 (QSR International, Doncaster, Victoria, Australia).

4.3 Results

4.3.1 Study Participants

Participants of the Medly program were predominantly male (184/232, 79.3%) and had an average age of 57.6 years (SD 16.0). Other demographics presented in Table 5 are representative of the patient characteristics typically followed in this urban heart function clinic. With respect to HF severity, approximately half experienced relatively mild daily HF symptoms with 48.5% (109/225) having an NYHA class of 2 or less at the time of program enrollment and the average LVEF of patients was 32.1 (SD 13.2). Most patients included in this analysis (201/231, 87%) used the Full Kit version of the Medly system, 8.2% (19/231) used their personal smartphone but were given peripheral devices by the clinic, and the remaining 4.8% (11/231) used their personal smartphone and either purchased or used their own weight scales and blood pressure cuffs. The option for patients to use their own equipment started approximately 1.5 years after the launch of the program [94].

Table 5. Characteristics of patients included in the quantitative analysis of adherence

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, mean (SD)</td>
<td>57.6 (16.0)</td>
</tr>
<tr>
<td>Age in years (categorical), n (%)</td>
<td></td>
</tr>
<tr>
<td>70 or more</td>
<td>60 (25.9)</td>
</tr>
<tr>
<td>60-69</td>
<td>56 (24.1)</td>
</tr>
<tr>
<td>50-59</td>
<td>50 (21.6)</td>
</tr>
<tr>
<td>40-49</td>
<td>34 (14.7)</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Statistics</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>39 or less</td>
<td>32 (13.8)</td>
</tr>
<tr>
<td><strong>Sex, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>184 (79.3)</td>
</tr>
<tr>
<td>Female</td>
<td>48 (20.7)</td>
</tr>
<tr>
<td><strong>Ethnicity, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>115 (66.0)</td>
</tr>
<tr>
<td>Black</td>
<td>14 (8.0)</td>
</tr>
<tr>
<td>Asian</td>
<td>21 (12.1)</td>
</tr>
<tr>
<td>Other</td>
<td>24 (13.8)</td>
</tr>
<tr>
<td><strong>Rurality, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>100 (58.1)</td>
</tr>
<tr>
<td>Suburban</td>
<td>49 (28.5)</td>
</tr>
<tr>
<td>Rural</td>
<td>23 (13.4)</td>
</tr>
<tr>
<td><strong>Place of birth, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>85 (48.9)</td>
</tr>
<tr>
<td>Elsewhere</td>
<td>89 (51.1)</td>
</tr>
<tr>
<td><strong>Highest education achieved, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>13 (7.5)</td>
</tr>
<tr>
<td>High school</td>
<td>34 (19.5)</td>
</tr>
<tr>
<td>College/University</td>
<td>127 (73.0)</td>
</tr>
<tr>
<td><strong>Income, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;$15,000</td>
<td>26 (15.1)</td>
</tr>
<tr>
<td>$15,000-$49,999</td>
<td>57 (33.1)</td>
</tr>
<tr>
<td>&gt;$50,000</td>
<td>58 (33.7)</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Statistics</td>
</tr>
<tr>
<td>---------------------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Preferred not to answer</td>
<td>31 (18.0)</td>
</tr>
</tbody>
</table>

**Work, n (%)**

- Working full time                                        | 35 (20.2)        |
- Working part time                                         | 17 (9.8)         |
- Retired                                                  | 87 (50.3)        |
- Unemployed / homemaker                                   | 14 (8.1)         |
- Other                                                    | 20 (11.6)        |

**Supplementary health insurance, n (%)**

- Yes                                                      | 104 (60.8)       |
- No                                                       | 67 (39.2)        |

**NYHA<sup>a</sup> class, n (%)**

- 2 or less                                               | 109 (48.5)       |
- 2-3                                                     | 48 (21.3)        |
- 3 or more                                               | 68 (30.3)        |

**Left ventricular ejection fraction, mean (SD)**

- 32.1 (13.2)                                              |

**Have a smartphone, n (%)**

- Yes                                                     | 119 (70.4)       |
- No                                                      | 50 (29.6)        |

**Comfort with Smartphone, n (%)**

- Not comfortable                                          | 5 (4.0)          |
- Somewhat comfortable                                     | 24 (19.2)        |
- Comfortable                                              | 47 (37.6)        |
- Very comfortable                                         | 49 (39.2)        |

**Equipment used by patients, n (%)**
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Medly kit</td>
<td>201 (87.0)</td>
</tr>
<tr>
<td>Patients used personal phone and were provided with peripherals</td>
<td>19 (8.2)</td>
</tr>
<tr>
<td>Patients used all personal equipment</td>
<td>11 (4.8)</td>
</tr>
</tbody>
</table>

*NYHA class: New York Heart Association functional classification.

### 4.3.2 Overall and Longitudinal Adherence Rates

The average overall adherence rate for the 231 patients included in the analysis was 73.6% (SD 25.0), indicating that the average patient completed their prescribed morning readings 5 days per week over the course of their enrollment in the program. When considering days where patients took at least one but fewer than all 4 morning readings (i.e., including incomplete adherence), the average rate was 80.0% (SD 21.7). Longitudinal examination of monthly adherence rates shows a relatively high average adherence in the first month of 81.2% (SD 23.0) with a gradual decline to 63.1% (SD 37.0) after 12 months of enrollment (see Figure 4). Outputs of the simple linear regression indicates that time is a significant predictor of adherence ($\beta=-1.42$, $P<.001$) with each month since enrollment accounting for a 1.4% decrease in adherence.
Figure 5. Average adherence rates compared with adherence rates which include incomplete adherence over time.

### 4.3.3 Quantitative Results Explaining Adherence

#### 4.3.3.1 Multivariate Regression

Random effects multivariate regression with cluster-robust standard errors was performed as described in the Methods section. The results, presented in Table 6, confirm a significant effect of time on adherence with each passing month starting after the second month of program enrollment. Patient age was a significant predictor of adherence \((P=0.04)\); the positive coefficient indicates that adherence rates were higher with each increasing age category such that older patients maintained higher adherence over time. Figure 5 shows adherence rates over time with respect to the age groups included in the regression model. Disease severity (NYHA class) and sex were not significant predictors of adherence.
Table 6. Random effects multivariate regression with cluster-robust standard errors showing the effect of time, sex, NYHA class, and age on average adherence

<table>
<thead>
<tr>
<th>Variables</th>
<th>Coefficient (β)</th>
<th>SE</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>87.57</td>
<td>4.03</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Month 1</td>
<td>Ref</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Month 2</td>
<td>-1.27</td>
<td>1.98</td>
<td>.52</td>
</tr>
<tr>
<td>Month 3</td>
<td>-5.63</td>
<td>2.36</td>
<td>.02</td>
</tr>
<tr>
<td>Month 4</td>
<td>-8.21</td>
<td>2.80</td>
<td>.004</td>
</tr>
<tr>
<td>Month 5</td>
<td>-9.84</td>
<td>2.85</td>
<td>.001</td>
</tr>
<tr>
<td>Month 6</td>
<td>-12.65</td>
<td>3.05</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Month 7</td>
<td>-15.87</td>
<td>3.33</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Month 8</td>
<td>-12.45</td>
<td>3.32</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Month 9</td>
<td>-13.71</td>
<td>3.63</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Month 10</td>
<td>-15.11</td>
<td>4.20</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Month 11</td>
<td>-19.55</td>
<td>4.84</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Month 12</td>
<td>-20.98</td>
<td>5.13</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Sex</td>
<td>-2.33</td>
<td>5.61</td>
<td>.68</td>
</tr>
<tr>
<td>NYHA</td>
<td>-0.34</td>
<td>2.60</td>
<td>.90</td>
</tr>
<tr>
<td>Age</td>
<td>3.49</td>
<td>1.68</td>
<td>.04</td>
</tr>
</tbody>
</table>

SE: Standard error of the coefficient
Figure 6. Average adherence rates over time by age group showing higher adherence over time over time for older age groups.

4.3.3.2 Patient Questionnaires

Results from the patient questionnaires show that a clear majority of patients perceived value in using the Medly system after 6 months with 90.6% (87/96) agreeing or strongly agreeing with the statement that the TM system is important for managing their HF and 87.4% (83/95) agreeing with the statement that it would be useful for them to continue using the system (Table 7). The percentage of patients who agree with these same statements increased to 95.8% (46/48) and 93.9% (46/49) after 12 months, respectively. Responses related to effort expectancy at 6 months similarly show a high level of agreement with 92.7% (89/96) of patient agreeing with the statements that the TM system was easy to use and to learn how to use. Perceptions of ease of use remained consistent with 89.4% (42/47) and 91.8% (45/49) agreeing with these same statements at 12 months, respectively.
Table 7. Patient perceptions of the benefits and effort of using the Medly TM system at 6 and 12 months post-enrollment

<table>
<thead>
<tr>
<th>Item in questionnaire</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Performance Expectancy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The monitoring system is important for managing my heart failure</td>
<td>87 (90.6)</td>
<td>46 (95.8)</td>
</tr>
<tr>
<td>I think using the monitoring system improved my health</td>
<td>65 (70.7)</td>
<td>36 (75.0)</td>
</tr>
<tr>
<td>It would be useful for me to keep using the monitoring system</td>
<td>83 (87.4)</td>
<td>46 (93.9)</td>
</tr>
<tr>
<td><strong>Effort Expectancy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learning to operate the monitoring system was easy for me</td>
<td>89 (92.7)</td>
<td>45 (91.8)</td>
</tr>
<tr>
<td>I found the monitoring system to be easy to use</td>
<td>85 (92.4)</td>
<td>42 (89.4)</td>
</tr>
<tr>
<td>Taking my blood pressure at home was easy</td>
<td>93 (96.9)</td>
<td>47 (95.9)</td>
</tr>
<tr>
<td>Taking my weight was easy</td>
<td>93 (96.9)</td>
<td>47 (95.9)</td>
</tr>
</tbody>
</table>

4.3.4 Qualitative Results Explaining Adherence

4.3.4.1 Reasons for Offboarding

Of the 61 patients who left the Medly program during the study period, 52% (32/61) were offboarded because a change in their HF condition made it such that the Medly program would no longer be a beneficial part of their care plan. Three patients were offboarded because they were not adhering to taking measures or with following clinician instructions (Table 8). A further 28% (17/61) of patients chose to leave the program due to a lack of interest or a feeling that the benefits of enrollment were not worth the effort, that daily monitoring was causing stress, and for
other unknown reasons. Finally, 20% (12/61) of the offboardings were due to patient death. These deaths were attributed to the severity and the natural progression of HF.

Table 8. Classification of reasons for patient offboarding

<table>
<thead>
<tr>
<th>Reason of offboard</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinician-initiated offboardings</strong></td>
<td></td>
</tr>
<tr>
<td>Received heart transplant or surgical repair of the heart</td>
<td>14 (23)</td>
</tr>
<tr>
<td>Switched to more invasive form of remote monitoring (e.g., CardioMEMS)</td>
<td>5 (8)</td>
</tr>
<tr>
<td>Patient recovered ventricular function</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Significant change in health status (e.g., shift to palliative care)</td>
<td>6 (9)</td>
</tr>
<tr>
<td>Patient was not compliant with taking readings or with following clinician instructions</td>
<td>3 (4)</td>
</tr>
<tr>
<td><strong>Patient-initiated offboardings</strong></td>
<td></td>
</tr>
<tr>
<td>Not interested in participating or a belief that the benefits are not worth the effort</td>
<td>5 (8)</td>
</tr>
<tr>
<td>Stress caused by taking daily readings</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Life circumstances (e.g., shift work, sick relatives)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Poor eyesight</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Other (e.g., unknown, moved provinces, etc.)</td>
<td>5 (8)</td>
</tr>
<tr>
<td><strong>Mortality</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>12 (20)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>61 (100)</td>
</tr>
</tbody>
</table>

4.3.4.2 Interview Findings

4.3.4.2.1 Interview Participant Characteristics

The interviewed participants (n=24) largely matched the distribution of age and sex of the larger patient sample as shown in Table 9. Patients interviewed had overall adherence rates ranging between 22.2% and 98.6% and were interviewed at various times since program enrollment. This
included 17% of patients (4/24) being interviewed the day they were onboarded and 2 patients who agreed to participate after deciding they wanted to leave the program.

Table 9. Participant characteristics for semi-structured interviews

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Sex</th>
<th>Age at enrollment (years)</th>
<th>Time of interview since enrollment (month)</th>
<th>Average adherence rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HFpro009</td>
<td>M</td>
<td>76</td>
<td>12</td>
<td>92.2</td>
</tr>
<tr>
<td>HFpro011</td>
<td>M</td>
<td>72</td>
<td>12</td>
<td>80.0</td>
</tr>
<tr>
<td>HFpro018</td>
<td>M</td>
<td>60</td>
<td>6a</td>
<td>90.0</td>
</tr>
<tr>
<td>HFpro019</td>
<td>M</td>
<td>46</td>
<td>3</td>
<td>30.3</td>
</tr>
<tr>
<td>HFpro027</td>
<td>M</td>
<td>59</td>
<td>6</td>
<td>82.28</td>
</tr>
<tr>
<td>HFpro028</td>
<td>M</td>
<td>67</td>
<td>6</td>
<td>93.1</td>
</tr>
<tr>
<td>HFpro037</td>
<td>F</td>
<td>62</td>
<td>0</td>
<td>90.3</td>
</tr>
<tr>
<td>HFpro038</td>
<td>M</td>
<td>63</td>
<td>6</td>
<td>97.5</td>
</tr>
<tr>
<td>HFpro048</td>
<td>M</td>
<td>44</td>
<td>1a</td>
<td>96.7</td>
</tr>
<tr>
<td>HFpro052</td>
<td>M</td>
<td>83</td>
<td>6</td>
<td>70.3</td>
</tr>
<tr>
<td>HFpro059</td>
<td>M</td>
<td>76</td>
<td>6</td>
<td>54.2</td>
</tr>
<tr>
<td>HFpro060</td>
<td>F</td>
<td>81</td>
<td>6</td>
<td>96.3</td>
</tr>
<tr>
<td>HFpro061</td>
<td>M</td>
<td>62</td>
<td>6</td>
<td>45</td>
</tr>
<tr>
<td>HFpro064</td>
<td>M</td>
<td>45</td>
<td>6</td>
<td>67.9</td>
</tr>
<tr>
<td>HFpro089</td>
<td>M</td>
<td>57</td>
<td>9</td>
<td>72.2</td>
</tr>
<tr>
<td>HFpro091</td>
<td>F</td>
<td>61</td>
<td>12</td>
<td>94.4</td>
</tr>
<tr>
<td>HFpro107</td>
<td>M</td>
<td>54</td>
<td>6</td>
<td>62.8</td>
</tr>
<tr>
<td>HFpro109</td>
<td>M</td>
<td>41</td>
<td>1</td>
<td>68.3</td>
</tr>
<tr>
<td>HFpro129</td>
<td>M</td>
<td>22</td>
<td>1</td>
<td>22.2</td>
</tr>
</tbody>
</table>
4.3.4.2.2 Interview Themes

Interview themes were classified according to UTAUT2 constructs of performance expectancy, effort expectancy, facilitating conditions, social influence, and habit; no statements related to hedonic motivation or price value were identified by the coders. No overarching patterns emerged in the themes based on patients’ age, sex, or time since enrollment. Therefore, the themes and representative quotes discussed in the following sections predominantly help distinguish between high and low adherers.

4.3.4.2.2.1 Performance Expectancy

This theme refers to the perceived benefits, both expected and experienced, of being part of the Medly program. Subthemes included: (1) self-management support, (2) peace of mind, (3) relationship with care team, and (4) lack of context.

Self-Management Support

The most commonly mentioned benefit of the Medly program is that it supports patients in their ability to self-manage their HF. Participants discuss how, through taking their daily readings, the system keeps them accountable and provides guidance in their self-care tasks:

*I rarely ever took my weight which was a big issue getting admitted into the hospital because I retain so much water. So yeah, it's been helpful for monitoring things that I normally wouldn't...It keeps me on track and lets me know if I need to take medication*
that I normally don't have to take it...I had the expectation that it would be helpful for me because it keeps me on a routine and it's lived up to those expectations. [HFpro154]

Underpinning this self-management support is the immediateness of the patient self-care feedback which allows patients to plan for their day around the results of readings they have just taken:

I can start my day off with knowing that I've got to be extra careful...I'm going to plan my day from what Medley is telling me. That's how it helps me every morning, I know what to do and what not to do for the rest of the day. [HFpro089]

Peace of Mind

The automated self-care feedback works alongside clinician monitoring to provide many patients with peace of mind. For some, this peace of mind brings a heightened sense of confidence when they are trying to decide if their symptoms are bad enough to warrant a trip to the hospital.

I'm very diligent...I basically rely on it. I just love the peace of mind that it represents. When you're as sick as I was, it's good to have a big brother or big sister out there. [HFpro107]

It gives me comfort (knowing that) somebody's watching over me, I don't have to go to the hospital all the time. [HFpro052]

Relationship with Care Team

Patients who had been in the program for longer periods said that it improved their relationship with clinical members of their care team:

At first it didn't bother me (that I didn’t have a lot of interaction) but now actually you gain trust, you know, a relationship with the person on the other end...When (the Medley nurse) calls sometimes, we're talking for 20 minutes and she's really getting a full history of things because you just can't get a full history on a minute conversation. [HFpro089]

However, for some, this closer relationship helps explain lower adherence in patients who did not like the idea of clinicians being able to see transgressions of daily life:

There is a feeling, and it sort of upsets me or disturbs me (that) they know (everything I do). If I want to go out on a binge and watch a soccer game or a hockey game and eat lots ...they're going to know because my weights going to go up and so there's a fear of, “Oh God, I'm going to be told off”. Will it stop me (from) doing that? No, what will stop me doing it is the fact that it's bad for my health... I forget to take my weight (laughs) (because) there's a feeling that they're looking. [HFpro061]
**Lack of Context**

Patients with lower overall adherence rates expressed the opinion that the readings, particularly the symptoms, don’t accurately capture the full context of their health status. Consequently, some felt that the self-care feedback messages did not always reflect how they were feeling and they eventually learned that they should not immediately act on these alerts:

*(The feedback messages) are a little bit too alarming... because sometimes they say ‘have somebody take you immediately to emergency’, and usually it turns out it's okay, so I got used to that.* [HFpro009]

**4.3.4.2.2.2  Effort Expectancy**

Patient uptake and adherence can also be explained by the perceived efforts involved in using the system. Subthemes included: (1) usability and (2) technical difficulties.

**Usability**

The qualitative findings mirror those from the questionnaire insofar as most patients found the Medly system easy to learn and use. Furthermore, some patients were frequent travelers and described how the portability of the system allowed them to continue taking their readings wherever they were:

*I'm of the age where I’m not as computer literate with cellphones... But it was fine, it’s easy. If I can learn it, it’s pretty easy to learn.* [HFpro027]

*It's been all over Canada with me... we just throw it in the car. I even took my weight at Tim Horton's first thing in the morning and that was in Edmonton. We just left the hotel and it was in the car and...before we left (on) the road I said I didn’t take my weight. And my wife went out and got it, hooked it up to the Wi-Fi at the Tim Hortons and bam, (I) took it right there.* [HFpro089]

A minority of patients described some difficulty using the peripheral devices and the cognitive effort in trying to decide how to accurately answer the ‘yes/no’ symptoms questions:

*The equipment is highly sensitive. For me I have dizziness constantly because of my medications and my low blood pressure and my heart condition. So, if I sway or move on the scale, the scale has different readings... The scale is very narrow... and I'm a very wide guy and I need to have my feet spread apart in order to be stable on the scale...*
same with my arm, if I move my arm a little bit or anything, (it) will make the blood pressure monitor go into error mode and it's frustrating. [HFpro064]

With the (symptoms) questionnaire sometimes I'm sort of on the edge because it says “Are they worse?” Well no, they're not any worse but sometimes I am like a little bit short of breath. [HFpro091]

Technical Issues

The quality of the system was perceived as high across all patients and time points. However, several patients, from various adherence levels, recounted experiencing technical issues, particularly related to Bluetooth connectivity between the peripheral devices and the mobile phone.

There are times when I’m not impressed, because I weigh myself but it doesn't record. And, then I get this call saying that I didn't do it and it throws me off. But, generally, it's okay. I've had, I think about three times where it's misfired sort to speak...I think, “what did I do wrong?” [HFpro060]

4.3.4.2.2.3 Facilitating Conditions

Facilitating conditions are the resources and supports available to facilitate the use of Medly. Subthemes included: (1) technical support, (2) automated adherence calls; and (3) informal caregivers.

Technical Support

The technical issues described did not seem to have severely impacted adherence rates because of the easy access to technical support services. In addition, the presence of comprehensive onboarding process helped with initial uptake:

I can't see (a reason to not use Medly). I mean, as far as running into technical difficulties, you've given me all the numbers, there's people I can contact so I don't foresee there being that big of a problem that I wouldn't be able to work through it. [HFpro027]

(The training was) a piece of cake...it was private, we were in a closed room, the information was face to face, the equipment was right there, it had hands-on... it was great. [HFpro018]
Automated Adherence Calls

The automated call that is sent to patients if they have not taken their readings before 10am, although sometimes described as annoying, was a facilitating condition expressed by many:

(Taking my readings) is what I do first thing in the morning before I get the phone call with the annoying ringing (laughs)... I do (appreciate the call but)...I'm also a single dad of two kids so any opportunity that I possibly can to rest and sleep I take it... A text would be better than a phone call. [HFpro064]

Informal caregivers

Although the technology is designed to support the HF patient experience, some patients receive support from family members who help with all aspects of HF management, including reminding them to take their Medly readings:

I have a built-in monitor at home (laugh)...which is very, very beneficial because if (my wife) wasn't there at all, you know, I'd probably be worse than I am, as far as habits are concerned. So, having that extra person, she polices me pretty good. [HFpro028]

4.3.4.2.2.4 Social Influence

Social influence is the degree to which individuals in patients’ lives were supportive of the use of TM. Patient responses revealed that their family and friends overwhelmingly support their participation in the Medly program:

Everybody knows (I use Medly). I write about it all the time...everybody is very envious that I'm on this type of program and envious that I have doctors that care about me this much. [HFpro064]

Some patients had family members who raised privacy concerns, but this does not seem to have impacted willingness to participate:

Well, (my friends and family) think it's great. There's a few that think it's kind of Big Brother (saying) “wow, they know a lot of information on you”. But their fear of Big Brother is kind of secondary to my doctor need(ing) to know what’s going on. [HFpro019]

Finally, the fact that the Medly program was endorsed by a trusted clinician also appears to have been a motivating factor for patients:
(My cardiologist) is always very supportive saying, "(Medly)'s really doing a good job for you keeping you out of emergency". [HFpro009]

4.3.4.2.2.5 Habit

Evidence of the formation of a habit was more prominent in patients with higher adherence rates with many describing how taking measures eventually became part of their delay routine. Once a habit was established, events or conditions breaking that routine explained why some readings where missed:

It's part of a habit now. I don't forget it. ... (It's) automatic. [HFpro038]

(When I forget) I think I can smell my wife making the coffee... The sense of smell is very strong ... and it just beats the other senses out of my head (that) say "go weigh yourself first". The smell of fresh coffee coming down the hallway, honestly that's the only time I would miss it. [HFpro089]

Although the formation of a habit helps, it is not essential to ensure high adherence. One patient described the hassle of taking daily readings yet still maintained a high level of adherence (90.0%) throughout their enrollment. In this example, factors like guilt and recognizing the importance of a behavior may be been enough to motivate a behavior of daily readings even if this behavior did not become automatic:

I don't like doing it every day, it's a bit of drag, because sometimes I want to sleep in and I feel kind of guilty because I haven't got it done...I'm just sort of getting old and lazy and don't want to do anything but that's part of my regimen, I never miss. [HFpro018]

4.4 Discussion

4.4.1 Principal Findings

This paper presents the findings of a mixed methods study seeking to describe and explain patient adherence rates to taking daily prescribed home readings over a 1 year period in the context of a mobile phone-based HF TM program offered as part of the standard of care. Results found an average overall adherence rate of 73.6% and an average 1.4% drop in adherence with each passing month. The random effects model, which enabled repeated measures of monthly
adherence (effect of time) to be included in the same regression as other demographic variables found a significant effect of age on monthly adherence rates. Specifically, adherence rates were highest (and more consistent over time) for the older age group (70+) and was progressively lower for each younger decade.

Additional methods employed could not fully explain the temporal decline in adherence but they did provide evidence that patients’ perceptions of the program and other contextual factors contribute to explaining higher and lower adherence rates. Factors explaining patients’ motivation to adhere include: (1) perceived benefits of the program (self-management support, peace of mind, and improvement in clinical care), (2) ease of use, (3) a positive opinion of the program from family and friends, (4) supporting services (training and technical support), and (5) the ability to form a habit. Themes explaining low and imperfect adherence included: (1) technical issues, (2) life circumstances that interfered with a formed habit and (3) a perception that the benefits of the program were suboptimal due to the system’s inability to adequately capture and communicate the full context of patients’ health state. These explanatory findings fit within the constructs of the UTAUT2 of performance expectancy, effort expectancy, facilitation conditions, social influence, and habit.

There were no findings related to the UTAUT 2 constructs of hedonic motivation and price value, however this is likely due to the context in which this study was conducted. First, although patients expressed numerous benefits, it remains that the use of TM systems occurs in the context of disease management and therefore is unlikely to be described as fun or enjoyable. Second, Canada has a public payer health system which means that patients did not have to pay out-of-pocket to use the technology. In addition, those who used their own smartphones and peripheral devices either already had that equipment or were assessed for their ability to pay or cover the costs through supplementation health insurance. Thus, patients were not put in a position of having to weigh the supplemental personal costs and benefits of being part of the Medly program.

Finally, although the principle aim of this study was to explain adherence using a definition based on the prescribed patient behavior needed to optimize program benefits, the finding that the incomplete adherence rate was 6.4% higher than full adherence should not be discounted. A certain percentage of these incomplete morning readings are likely due to the Bluetooth
connectivity issues expressed by patients which would have prevented the taking of a weight or blood pressure reading until the issue could be fixed. Other possible explanations may include patients not recognizing or remembering the importance of taking the full set of readings. Alternatively, patients may make the decision to take measures that are most relevant based on how they are feeling (due to a high sense of self-efficacy for self-management) and may not necessarily lead to poorer outcomes. These hypotheses cannot be confirmed by the explanatory data generated in this study and should be empirically tested in future studies. The impact of adherence rates and health outcomes will be explored in subgroup analysis of the upcoming impact evaluation of the Medly program [79].

4.4.2 Comparison with Prior Work

4.4.2.1 Measuring Adherence

The findings from this study are in line with the literature review by Maeder et al. which found that adherence rates in home-based telehealth projects ranged from 40% to 90% and tended to be higher in earlier months before dropping off over time [65]. A recent and similar study looked at adherence to taking vital signs in TM interventions addressing various conditions and found an average adherence rate of 64.1% to scheduled daily readings. However, this study also found a trend toward increasing adherence after a steep initial drop off which are difficult to interpret alongside our results. The authors did not fully explain this initial drop but hypothesized that patients may be encouraged to adhere only after longitudinal values could be generated and they have had enough time to experience the value of the intervention [99]. In another study, adherence to completing IVR calls was 90% in HF patients [100] but calls were only scheduled once per week, again, limiting comparison to a regimen that asks patients to take readings daily.

4.4.2.2 Explaining Adherence

The finding that older patients maintained a high level of adherence is seen in another remote monitoring study [100] but without explanation. The UTAUT2 proposes that the moderating impact of age is such that the effect of effort expectancy and facilitating conditions is strongest in
older people [34]. In addition, it has been found that after a habit has been formed through repeated use, it becomes more difficult for changes in one’s external environment to override that behavior in older compared to younger people [34]. In other words, the ease of use of the Medly system and the availability of supporting services likely led to higher use in older patients which would have led to the formation of a habit. A habit which, once formed, would be more difficult to disrupt compared to younger patients. Although this may explain some of the difference between age groups, it is also possible that younger patients experience more potential distractors (work, dependent children, etc.) than older patients. Further research is required to understand the effect of age when it comes to adherence to TM interventions.

Factors explaining higher and lower adherence in this study were similar to the barriers and facilitators to TM, mHealth, and telehealth use described in the literature. With respect to performance expectancy, the literature cites similar perceived benefits including the degree to which the intervention improves health management (including both self- and clinician-directed management), peace of mind, and enhanced relationship between patients and clinicians [3, 40, 64, 76, 89, 101-105].

Often cited factors related to effort expectancy include user friendliness of the equipment, technical barriers, health literacy or language barriers, and limited answer options [40, 64, 89, 101-106]. The latter was seen in this study with patients who struggled with the ‘yes/no’ format of symptoms.

In terms of facilitating conditions, studies support the availability of technical support services and features to help with remembering as important factors in technology use [64, 89, 103, 104].

Similar factors related to social influence are discussed in a systematic review by O’Connor which cites lack of clinical endorsement as a barrier to patient uptake [105]. A survey study found that the construct of social influence contributed to explaining patients’ intention to use eHealth beyond what could already be explained by performance and effort expectancy [101]. In this study, we found overwhelming support for the use of Medly by family, friends, and the patient’s treating cardiologist. Thus, although social influence was likely not a strong enough factor in isolation, it likely contributed to higher adherence in the initial stages of enrollment.
Barriers such as failure of daily readings to become automatic and integrated into patients’ everyday tasks are cited in the literature [40, 105] and were categorized in the construct of habit in our study. If an automatic habit is not created, the added energy of taking daily readings likely contributes to user fatigue over time.

This discussion is intended to highlight the prevalence of UTAUT2 themes in the literature. However, it is important to recognize that each TM intervention is different and may yield different experiences for patients. For example, a study by Fairbrother et al. concluded that, although patients experienced peace of mind, the TM intervention did not increase the sense of ownership over their condition [107]. This contrasts with many of the patients in our study who described Medly as facilitating self-management. This is likely explained by the automated self-care feedback messages not part of the TM system in the Fairbrother study. This is an example of how different patient experiences can explain some of the heterogeneity of results across adherence studies. This study focused on patient perceptions because it is individuals’ experiences that are most likely to influence the degree to which they adhere to a TM intervention. The evaluation of the program’s outcomes, including quantitative measures for quality of life and self-care, is outside of the scope of this study and will be discussed in an upcoming publication. [79]

4.4.3 Limitations

Several limitations related to this study’s pragmatic design should be considered when interpreting the results. First, unlike TM interventions in RCTs, the Medly program was adapted over the 2-year period in which data collection occurred. As described elsewhere [94], these changes were made such that the essence of the intervention was maintained but it remains that some patients may have had different experiences.

Second, because enrollment in the intervention was not contingent on patients being part of a study, we were conscious of not overburdening patients with interviews at multiple time points. This decision meant that we did not collect qualitative data of individuals as they progressed through the program.
Third, reasons for offboarding was limited to the administrative data collected by clinicians and not all patients in the program had consented to being approached for an interview.

Fourth, the lack of strict inclusion criteria means that, by experimental standards, selection bias likely occurred; enrolled patients who were more likely to be engaged and who would not face language barriers. Further limiting the generalizability of findings is the overrepresentation of male patients in the Medly program. This is consistent with studies which find an under-representation of women enrolled in heart function clinics and clinical research despite a similar prevalence of HF among both sexes [108, 109]. Although exploring the reasons for why fewer women have access to heart failure management interventions is outside the scope of this study, there is clearly a need for research into sex or gender-based differences, including as it relates to uptake, use, and adherence to TM interventions. For instance, it is possible that the reason sex was not correlated with adherence rates is because of relatively small number of female participants in this study.

Fifth, the sample size of available data got progressively smaller with each passing month and although this was accounted for in the regression analyses, it is likely that patients with strong negative opinions of the program left the program before the 12-month point (and thus did not complete the questionnaires).

Sixth, a previously published protocol [79] included a description of the quantitative methods for measuring patient adherence and explaining these adherence rates using interviews guided by the UTAUT2. However, other data were collected as part of this pragmatic evaluation (ie, patient satisfaction questionnaire and reasons for offboarding) and were reported because they offered an opportunity to further explain patient adherence through triangulation with patient interviews. However, because the satisfaction questionnaire was not initially developed to explain adherence, it only contained items related to 2 of the 7 UTAUT2 constructs. Researchers conducting questionnaire-based work related to the UTAUT2 should consider using tools which include the validated items for that framework [34].

Finally, we did not have data allowing us to account for periods when patients were unable to take readings for legitimate reasons (e.g., traveling, admitted in the hospital, system down time, etc.), which would ideally be accounted for when measuring adherence. This limitation likely underestimates true adherence rates in the Medly program.
4.4.4 Recommendations

Based on the findings from this study, we agree with recommendations from other studies that patients should receive comprehensive training and may benefit from refresher sessions aimed at reminding them of the proper use of the TM system, the benefits of the TM intervention, and the process for obtaining technical support when needed [12, 65]. We also advocate for the involvement of supportive family members in those discussions and as part of the onboarding process. In addition, because many HF patients receive support from informal caregivers, further research into how best to incorporate that role within the design of TM systems would be beneficial. Reminders (such as adherence calls) were found to be important in this study. Therefore, developers of TM systems should offer a range of options (e.g., phone call, text, app notification) that users can choose from based on their preferences such that these reminders do not become so disruptive that they opt to disable the feature. Finally, study results offer important insights for how user-centred design of TM systems is conducted. Although there is value for scenario-based usability testing in laboratory environments, new TM systems should also be piloted in the real world before full deployment with users of all age groups. This is needed to allow TM designers to understand how patients use (or don’t use) the system in the context of their existing habits and personal lives. In addition, although self-care messages can be simulated in a single usability testing session, it is preferable to give patients the opportunity to use a TM system over a period of time to evaluate the accuracy and appropriateness of self-care messages in response to fluctuations in their health state.

4.5 Conclusions

This study presents the results of a mixed methods study aimed at explaining longitudinal adherence rates of patients enrolled in a mobile phone-based HF TM program. The study found that, on average, patients took weight, blood pressure, heart rate, and symptoms readings 73.6% percent of the days they were enrolled in the program. Results also show a consistent decline in adherence over the 12 months which is further influenced by patients’ age such that patients of older age groups maintained higher and more consistent adherence rates throughout the study period whereas the declining rate of adherence became progressively more pronounced for younger age groups. Levels of adherence were further explained through interview findings.
which indicated that the perceived benefits of the program, ease of use, social support and technical support, and ability to form a habit around taking daily readings. These findings can inform the design of TM interventions that maximize patient adherence. When implemented in the context of effectiveness trials, interventions with high fidelity of use will enable a more accurate evaluation of impact and when implemented as part of the standard of care, they will ensure the optimization of resources and satisfaction from patient and clinician users.
Adaptability of a Heart Failure Telemonitoring Program

This chapter answers the fifth and final research question: What are the core components of TM interventions that must be protected to ensure intervention fidelity and which components can be adapted to enable the sustainable embedding across various sites?

5.1 Introduction

5.1.1 Background

Although differences in the way TM interventions are delivered can lead to contradictory evidence, understanding these differences and how they might influence outcomes could hold one of the keys to scalability. This is because theories of diffusion of innovation have suggested that to be sustained and scaled, interventions must be able to adapt if they are to be embedded within local conditions [84, 110]. This notion of adaptability is a prominent theme in studies of delivering digital health interventions at scale, which reinforce the view that a one-size-fits-all approach does not work [29]. The challenge is determining how to undertake necessary adaptations without compromising intervention fidelity [111].

A useful analogy used by theorists to discuss the notion of adaptability is the idea that health interventions have a hard core and a soft periphery [24, 26, 30]. The hard core represents the essence of an intervention, in other words, the central mechanism(s) for producing desired health outcomes in the intervention’s theory of change [111]. When considering TM, the hard core can be conceptualized as an intervention that leverages technology to enable the collection and
transmission of patient biometric data to be viewed and acted upon by a clinician at a distant location [10].

In contrast, the adaptable soft periphery represents the different ways this intervention can be delivered in practice. Adaptability of this soft periphery to local contexts allows interventions to spread without negatively impacting the intervention’s ability to yield desirable outcomes [30], thus maintaining intervention fidelity. As it relates to TM, elements of the soft periphery may include differences in the hardware used, intensity of clinician monitoring, duration of a TM intervention, and format of training or technical support services. However, many of these intervention components are essential for a TM program to function. Therefore, delineating the line between the hard core and soft periphery of complex interventions such as TM is particularly difficult. Despite this challenge, implementation and scaling require a clear definition of an intervention’s core components to ensure that fidelity is maintained when adaptations are undertaken to ensure implementation, scale, or spread success [84, 111].

5.1.2 Study Objectives

In fall 2016, a HF TM program was made available to patients of a heart function clinic at an urban hospital in Toronto, Canada. A previous study concluded the initial implementation to be a success based on the degree of integration within the clinic, number of patients enrolled, and fidelity of program delivery as part of the standard of care [90]. However, this study also identified important barriers related to the cost of the equipment and supporting human resources, which could hinder the sustainability and scalability of this program [90]. The objectives of this paper were to (1) understand which components of the TM program could be modified to reduce costs and adapted to other local contexts while maintaining program fidelity and (2) describe the changes made to the TM program to enable its sustainability within the initial implementation site and scalability to other health organizations.
5.2 Methods

5.2.1 Study Design

This qualitative study was designed to elicit insights from end users to better understand the hard core and soft periphery of an existing TM program. These insights would inform adaptations required to reduce to costs of delivering the intervention. Semi-structured interviews were conducted within the context of a larger quality improvement program evaluation [79], which was approved by the UHN REB (16-5789).

5.2.2 The Existing Program

5.2.2.1 Integration Within the Standard of Care

The Medly program was implemented as part of the standard of care at the UHN HF clinic in Toronto, which serves patients with complex and advanced HF. Other services currently embedded within the clinic include in-depth teaching from clinic staff about the chronic nature of HF, necessary lifestyle changes, and how to manage complex medication schedules. Typically, relatively stable patients are seen for regular follow-up visits every 6 months, with more acute patients seen more frequently as required. It is also not uncommon for patients to consult with clinic staff over the phone or by email in between visits. The Medly program is intended to enhance these existing health services, not replace them.

5.2.2.2 The Medly Telemonitoring System and Services

Central to the Medly program is an algorithm-based smartphone app, which patients use to record daily weight, blood pressure, heart rate, and symptoms as soon as they wake up. If there are signs of deterioration in a patient’s health, the Medly algorithm triggers a self-care message displayed to the patient in the Medly app. In addition, an alert is sent to both a NP (via a secure Web-based clinical Dashboard) and the most responsible physician (MRP) via automated emails (Figure 6). The MRP is the physician who has overall responsibility for directing the medical care of a patient; in the context of the Medly program, this refers to the staff cardiologist responsible for the longitudinal care of patients in the Heart Function clinic. Typically, the NPs
are responsible for acting on the alerts during weekdays, with the MRP taking over responsibility for more critical alerts and for responding to all alerts during off hours (evenings and weekends). An earlier version of this intervention was evaluated in a randomized controlled trial of 100 patients that demonstrated improved patient self-care and quality of life compared with a control group [78].

Figure 7. Existing roles and information flows in the Medly program

The decision to enroll patients is based on clinicians’ judgment in collaboration with patients. To decide whether someone would be a good candidate, clinicians consider disease severity (usually NYHA class 2 or 3), need for self-care support, and a perception that they can adhere to taking daily measurements and be engaged enough to follow self-care instructions provided by the TM
system or the care team. Similarly, the decision to end participation in the Medly program is determined jointly between the patient and clinicians. Unlike many other TM interventions, there is currently no specified end date; patients remain in the program for as long as they are perceived to be benefiting.

The program was launched by providing patients with a Medly kit, which includes a smartphone installed with the Medly app, a Bluetooth-enabled weight scale, and a blood pressure cuff, which allows for automatic data transfer from these devices to the Medly app. A THA role was created within UHN’s telehealth department to provide technical support by telephone, email, or in person to both patients and clinician user groups. In addition, the THA role included the management of inventory and onsite face-to-face training for each new user.

5.2.3 Interview Guide Development

Separate interview guides were developed for patients and clinicians to inform possible strategies for lowering costs and improving program efficiency by gaining a better understanding of the program’s soft periphery (Appendix 5). Specifically, participants were asked to comment on the topics presented in Table 10. In their responses, participants were encouraged to consider HF TM in general, and not just the Medly program. The Medly software (with embedded rules-based algorithm) was developed around the program’s theory of change [53]. As such, it is considered part of the program’s hard core; thus, no probes related to this component were included.

Table 10. Opportunities for program adaptation probed in the user interviews

<table>
<thead>
<tr>
<th>Program component</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral devices</td>
<td>To understand if providing all patients with standardized Bluetooth-enabled peripheral devices free of charge is an essential component of a telemonitoring program. A bring your own device (BYOD) model, whereby patients use existing equipment (smartphone, blood pressure cuff, and weight scale), would drastically reduce costs of delivering the program.</td>
</tr>
<tr>
<td>Technical support services</td>
<td>One-on-one technical support is resource intensive. Exploring alternative modalities of offering this service could lower direct and opportunity costs by decreasing the time taken to perform these tasks.</td>
</tr>
<tr>
<td>Program component</td>
<td>Rationale</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Clinician role</td>
<td>Knowing the minimal clinician qualifications for monitoring alerts could save costs because of differences in salary, reimbursement models, and scopes of practice across professions.</td>
</tr>
<tr>
<td>Duration of patient enrollment and intensity of monitoring (business hours vs 24/7(^a))</td>
<td>The literature does not provide consistent answers regarding the optimal duration of enrollment nor the intensity of monitoring in a TM service [8]. Understanding the degree to which these program components can be adapted while maintaining fidelity can produce cost savings through the optimization of resources and inform scaling strategies for TM programs.</td>
</tr>
</tbody>
</table>

\(^a\)24/7: 24 hours per day, 7 days per week.

5.2.4 Recruitment

Patients (n=23) were identified through purposeful sampling based on age, gender, and time since enrollment in the Medly program to ensure a variety of perspectives. This included patients who were interviewed immediately after enrollment and, thus, had no prior experience being monitored in the program. Interviews with patients were conducted until theme saturation was reached (no new themes or perspectives were found in the data) [98]. This was achieved by setting an a priori target of 20 patient interviews. Three additional interviews were conducted, which yielded no new findings, thus confirming theme saturation. All clinicians actively monitoring patients using the Medly system at the time of the interviews (n=4) were invited to participate. In addition, 4 clinicians within the UHN HF clinic who had not yet begun using the system were also interviewed to obtain the views of nonusers. Written informed consent was obtained from all participants.

5.2.5 Interview Procedures and Analysis

Patients had the option of being interviewed in a private room at the UHN HF clinic during one of their regularly scheduled visits or over the phone. Clinicians were interviewed in their private offices. Interviews lasted 15 to 60 min and were recorded and transcribed verbatim. Transcripts
were analyzed using conventional content analysis [112]; PW and KG each independently coded the transcripts and then met to discuss the results and discrepancies with themes. Once a finalized coding scheme was agreed upon, it was used to code the transcripts before a final analysis of themes. NVivo version 11 (QSR International, Doncaster, Victoria, Australia) was used to organize the data analysis.

5.2.6 Adapting the Telemonitoring Program

On the basis of the qualitative findings, PW and KG interpreted the degree to which each of the Medly program components explored in the interviews could be adapted without impacting program fidelity. Ideas for redesign were discussed during biweekly operations meetings and prioritized for implementation according to their (1) potential to impact sustainability and scalability through cost reductions and optimization of clinic resources, (2) feasibility of implementing the change, and (3) perceived risks of negatively influencing program fidelity (and ultimately effectiveness).

5.3 Results

5.3.1 Study Participants

The demographic characteristics for the patients interviewed were representative of the patients enrolled in the Medly program. The average age was 60 years (SD 15) and 74% were male (17/23); see additional demographic characteristics and clinical variables (NYHA and LVEF) in Table 11. At the time of the interviews, 13% (3/23) of patients had been enrolled for 12 months; 48% (11/23) had been enrolled for 6 months; and 9% (2/23) had been enrolled for 1 month. In addition, 22% (5/23) were interviewed immediately after receiving training on their first day and, thus, had no prior experience being monitored in the Medly program. Of the 8 clinicians who participated, 2 NPs and 2 cardiologists had 9 to 12 months of experience monitoring patients with the Medly system. The remaining 4 cardiologists had no first-hand experience monitoring patients in the Medly program.
Table 11. Characteristics of patient interview participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, mean (SD)</td>
<td>60 (15)</td>
</tr>
<tr>
<td><strong>Sex, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>17 (74)</td>
</tr>
<tr>
<td>Female</td>
<td>6 (26)</td>
</tr>
<tr>
<td><strong>Ethnicity, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>14 (67)</td>
</tr>
<tr>
<td>Other</td>
<td>7 (33)</td>
</tr>
<tr>
<td><strong>Place of birth, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>12 (57)</td>
</tr>
<tr>
<td>Other</td>
<td>9 (43)</td>
</tr>
<tr>
<td><strong>Highest education achieved, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>1 (5)</td>
</tr>
<tr>
<td>High school</td>
<td>6 (29)</td>
</tr>
<tr>
<td>College or university</td>
<td>14 (67)</td>
</tr>
<tr>
<td><strong>Rurality, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>8 (38)</td>
</tr>
<tr>
<td>Suburban</td>
<td>9 (43)</td>
</tr>
<tr>
<td>Rural</td>
<td>4 (19)</td>
</tr>
<tr>
<td><strong>Income in Can $, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;$15,000</td>
<td>3 (14)</td>
</tr>
<tr>
<td>$15,000-$49,999</td>
<td>8 (38)</td>
</tr>
<tr>
<td>&gt;$50,000</td>
<td>6 (29)</td>
</tr>
<tr>
<td>Preferred not to answer</td>
<td>4 (19)</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Statistics</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td><strong>Supplementary health insurance, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>14 (70)</td>
</tr>
<tr>
<td>No</td>
<td>6 (30)</td>
</tr>
<tr>
<td><strong>NYHA(^a) class, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>12 (52)</td>
</tr>
<tr>
<td>3</td>
<td>11 (48)</td>
</tr>
<tr>
<td><strong>LVEF(^b), mean (SD)</strong></td>
<td>33 (13)</td>
</tr>
</tbody>
</table>

\(^a\)NYHA class: New York Heart Association classification.

\(^b\)LVEF: left ventricular ejection fraction

### 5.3.2 Interview Findings

The following is a discussion of participants’ perceptions of opportunities for adapting existing program components aimed at reducing costs and optimizing clinic resources. Themes included were as follows: (1) Bring Your Own Device, (2) technical support, (3) clinician role, (4) duration of patient enrollment, and (5) intensity of monitoring.

#### 5.3.2.1 Bring Your Own Device

When the Medly program was launched, the intent was to shift to a BYOD model; however, at the time of the interviews, only minimal plans had been made to operationalize this change. The interviews highlight that clinicians were generally supportive of patients using their own equipment as it was necessary to ensure the sustainability of the program:

*I think [a BYOD model] is excellent. In fact, I’ve had patients ask me about it...I think, for sure that would be helpful and certainly, more cost effective because we obviously can’t give kits to everybody.* [Clinician 3]
Some concerns were raised about the questionable quality of patients’ current equipment and the
fact that, in the absence of Bluetooth data transfer, patients may accidentally manually enter
values incorrectly. The possibility of patients purposefully entering inaccurate information was
raised by 4 clinicians, but it was ultimately believed that mutual trust between parties is a
prerequisite for any TM program to be effective:

*I guess the only thing you’d have to really make sure of is that they typed things in
properly. People make typos, but I guess there would have to be something factored in
for a double-check...I don’t believe that people are going to be lying about their numbers.
If I thought people were going to lie right, left, and centre, then no, that would be
ridiculous and I wouldn’t want to participate in that. But I’d like to believe that if you’re
going to commit enough to take the time to take those readings and enter them every day,
then I think you’re doing it correctly.* [Clinician 3]

Although clinicians believed a BYOD model is required for the financial sustainability of the
program, they believe some kits need to be available to ensure equitable access to the program.
The general opinion was that Medly kits should be available for distribution on a case-by-case
basis and could be informed by the patients’ socioeconomic status, degree of cognitive
impairment, and level of dexterity:

*I think there’s still a role for a hybrid kind of model where some people are provided with
the full Medly kit and some people are provided with the less expensive intervention.
You pick your battles and you’d be extremely cautious as to giving a BYOD to someone
who has dexterity problems for instance.* [Clinician 6]

Most patients who received a full Medly kit as part of the program said that they would prefer
downloading the Medly app to their personal smartphone. Common reasons include the
inconvenience of being responsible for multiple phones, unfamiliarity with the smartphone
provided, and feeling that their health data could be more transportable if it were on their
personal device:

*I just wish I had more control over it through my [personal] phone because then...I could
pull out all those reports from Medly myself and give it to a doctor, a walk-in,
anywhere...I was given a phone that I was not familiar with...so it took me awhile to learn
it and to get familiarized with it.* [HFpro064]

One patient who did not own a smartphone said they would prefer if the Medly app was available
on a tablet:
A minority of patients interviewed said they preferred having the separate Medly phone because they like to keep all the equipment together. Although a separate phone was their preference, all patients said they would use their own device if that was the only option. Many patients understood the economic implications and felt it was reasonable:

\[
I \text{ think that it makes it so much easier to have [the phone, weight scale, and blood pressure cuff] all together...I know it might be more cost-effective but it is so much easier on your mental being that you go in, you do what you have to do...[But] you do what you have to do.} \quad \text{[HFpro052]}
\]

A clear majority of patients preferred the convenience of Bluetooth data transfer but also said they would manually enter biometric data if their existing peripheral devices were not Bluetooth-enabled:

\[
The \text{ bonus of this whole system is the Bluetooth...Typing in numbers, you [would] get tired of it...For me if I’m looking at my own health, it wouldn’t bother me a bit but I’m different from someone else.} \quad \text{[HFpro089]}
\]

\[
I \text{ like the fact that [the data transfer] is done for you. If I had no other choice, then you have no other choice.} \quad \text{[HFpro154]}
\]

Approximately half of the patient participants said they would purchase Bluetooth devices out-of-pocket, but some participants perceived this option as being unfair, echoing clinician concerns of accessibility:

\[
I \text{ might [purchase the equipment]...but I’m not sure it’s really fair to ask people to do that because you’d automatically filter out a lot people who either couldn’t claim it on insurance or weren’t going to do that...[the] system would all go wrong; it would just be upper middle-class people.} \quad \text{[HFpro061]}
\]

5.3.2.2 Technical Support

Clinicians, not having had direct experience with training and giving technical assistance to patients, did not have strong feelings regarding the format of technical support. However, 1 clinician stated there is an opportunity to minimize resources required for onboarding a patient:
It would be nice as much as possible to automate aspects of the onboarding...because I think actually paying somebody to be there to onboard people will be difficult to scale. [Clinician 1]

Another clinician said that although the format of training needs to be appropriate, it is also important that the patient can start with the program immediately after the decision is made as opposed to scheduling training on a future date:

When you go in as a clinician and you have a conversation with the patient about a plan of care and the role of [TM], what it can offer and why it’s important. You [need] an immediate...“Okay here’s your system, you’ve been immediately trained, you’ve been setup,” versus them going home, 2-3 weeks going by [with the patient thinking] “Oh maybe it’s not that important.” [Clinician 2]

All patients described a positive experience with the face-to-face onboarding, but when asked if it was essential, many reflected that it might not be because the system was intuitive to use. Even those who were not tech savvy said they could figure it out at home by themselves or with the help of a family member, especially if they could follow along with a video:

I think the face-to-face was good because I watched [the THA] as she was putting the stuff in and I’m a visual learner...If I see it, it makes perfect sense...I tell people all the time, if you’re stuck on something there’s a video on YouTube of everything...I mean, it was nice having the face-to-face but that’s not always an option. [HFpro159]

Although most patients had positive things to say about calling the technical support services, others hesitated before seeking help for fear of being a burden and confusion about who to call:

Well [I didn’t contact technical support because] I just don’t want to bother anybody. [HFpro064_6m]

It wasn’t Bluetoothed properly [and] I didn’t really know who to call. I probably had [the] number, but that was kind of a little bit bothersome. [HFpro106_6m]

5.3.2.3 Clinician Role

Clinicians believed that the scope of practice of a registered nurse (RN) or NPs is well suited for triaging and addressing many TM alerts. All clinicians agreed that an MRP with HF experience needs to be involved, particularly to deal with the more serious alerts:
I think that the first line of defense is totally appropriate to be nursing with some training in HF because [Medly] is rules-based system and therefore critical alerts should escalate to the physician. The non-critical alerts I absolutely believe that the first line of defense could be a nurse, nurse practitioner, physician assistant, all would be appropriate. [Clinician 1]

It’s ultimately a great role for nurse practitioners to champion because you need to have that person that can assess and make a clinical decision about changing a med[ication] or bringing someone in urgently to be seen in the clinic. [Clinician 2]

Regardless of the type of professional involved, most respondents believed that TM programs would be most effective if the clinician receiving and responding to alerts was part of the patient’s care team as opposed to the alerts being sent to a third-party telehealth clinician:

I think one of the issues with Medly...is you still need to have the most responsible person for the Medly involved in the actual patient's clinical care in some way. [Clinician 2]

Patients generally agreed with this sentiment, expressing that they prefer the person receiving TM alerts to have the ability to act immediately. One patient made this point by contrasting the Medly program with their previous experience with another TM program:

I accepted [to be enrolled because they] said [my health information] would go straight to [UHN]...I think [with my previous TM system] they sent it to [various people] and eventually [my doctor] would see it. But he might be 4th or 5th down the line. [HFpro159]

5.3.2.4 Duration of Patient Enrollment

Clinicians felt that patients could eventually be removed from a TM program if they were no longer actively benefitting (i.e., had learned how to self-care or their condition had stabilized). However, a generalizable duration of enrollment could not be established:

Some [patients] just might like the comfort of knowing that [they] ’re tied into a clinical team that’s still there if you need help. But I think you have to look at it from your larger team because you can’t just have endless people enrolled in the program, you probably will have to have a maximum at some [point]...I think if someone’s been really stable for 6 months, they haven’t had a lot of alerts, they are very confident as to what their target weight is, what they need to do in terms of lifestyle modifications and symptoms to watch for, then they’ve learned what they needed to learn in that 6 months and they don’t require [the program]. [Clinician 2]
I think there may be an optimal time to improve self-care...there may be a curve and the curve plateaus and there may not be any further incremental benefit to self-care other than knowing that there is this rules-based system keeping an eye on them right. So it may be that you optimize self-care within 3 months...but patients [might] want to stay on it. And again, if you can really demonstrate value I don’t have a problem with that.

[Clinician 1]

Many patients spoke of HF as being a lifelong condition and that they would like to stay in the program for as long as possible or until something came up that made the program unnecessary, such as undergoing a heart transplant:

I think for me [HF is] a lifestyle thing now. I think I’d be a fool not to use [Medly], I guess that sums it up. I was so sick and dead that I take my recovery very seriously...I think I’d be a fool not to take advantage of it. [HFpro107]

I’ve got a lifelong condition so I don’t really see an end time, unless I end up going for a heart transplant, which I’m not going to hopefully have to do anytime soon. So yeah, I think [my participation] will be ongoing. [HFpro019]

5.3.2.5 Intensity of Monitoring

Clinicians recognized that asking clinicians to be available at all times to receive and respond to TM alerts is not scalable. However, they also strongly felt that TM interventions are most effective if there is someone monitoring alerts 7 days per week:

It’s not really fair for a single person to be on-call 24/7. You have to take that into consideration in terms of physician burnout and all those things. There should be a mechanism to deal with that, whether it goes to the physician on-call or something like that. But I do think that in order for this to be effective, a 24/7 tool would be more appropriate than a business hours tool because it’s not like people get sick only during business hours. [Clinician 6]

Although participating clinicians said they would strive to have alerts monitored 7 days per week, their responses also highlighted that the requirements for intensity of monitoring are dependent on the TM system itself. For example, many clinicians highlighted that the rules-based algorithm in the Medly system provides patients with clinically validated messages, allowing for a form of 24/7 feedback even if a clinician is not always available.

I may be camping somewhere where I am not accessible. But I think the whole thing of the Medly system is it doesn’t rely on me [seeing] the alerts, the patients are instructed to
do things [by the algorithm]. We have set up a plan and they have to act accordingly. They don’t have to wait for me to respond to [follow the instructions]. [Clinician 8]

Patients both with and without experience in the Medly program felt that someone should be available to respond to alerts 7 days per week but that this may also be contingent on the disease severity of the patients enrolled in the program:

If somebody weren’t that sick and they just had a bit of a heart issue, I don’t know if they would like this big brother, big sisterly thing where the [clinician] call first thing in the morning on Sunday...I love that part. I think that’s the essence of the system...I mean [my doctor] is a world-renowned cardiologist and she calls me on Sunday morning at 7, because my reading is a little high. I can’t believe it, it’s the ultimate professionalism. If she didn’t, I wouldn’t be heartbroken, but I just think that she uses the system as it should be used. [HFpro107]

5.3.3 Redesign of the Medly Program for Sustainability and Scalability

Qualitative results related to opportunities to modify components of the Medly program were interpreted and classified according to the degree to which they could be adapted while maintaining program fidelity. As shown in Figure 7, the format of technical support and the peripheral equipment used were considered highly adaptable and, thus, clearly part of the Medly program’s soft periphery. The participation of a clinician (role and intensity of monitoring) and the monitoring of patients over time are central components of any TM program theory of change, indicating some overlap with the intervention’s hard core. However, the interviews suggest some degree of adaptability depending on contextual factors, which explains why intensity of monitoring, clinician role, and duration of enrollment were classified as moderately adaptable and part of a fuzzy boundary between the hard core and soft periphery. These findings informed the decisions to adapt the Medly program as described in Table 12.
Figure 8. Hard core and soft periphery of the Medly program as informed by user interviews and its role in the intervention’s theory of change

Table 12. Adaptations to the Medly program to ensure sustainability and scalability

<table>
<thead>
<tr>
<th>Opportunities for adaptation</th>
<th>Decisions related to the Medly program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral devices</td>
<td>Move forward with the implementation of a hybrid Bring Your Own Device model, whereby most patients use their own mobile and peripheral devices with some Medly kits still being distributed to patients in need (e.g., lack of ability to pay, low cognitive ability, and dexterity problems). This involved changes to the operational procedures, including (1) generation of a list of recommended clinically valid weight scales and blood pressure cuffs for patient purchase, (2) clinician prescription of peripherals so that costs can be reimbursed by private medical insurance or tax deductions, and (3) expanding technical troubleshooting procedures to cover the most common devices on the market.</td>
</tr>
</tbody>
</table>

Software development needed to implement this decision included (1) the development of a manual entry version of the Medly app with features to protect against inaccurate data entry and (2) adapting the Medly app for tablets. The one-time costs of this developmental work are being incurred by the organization developing the Medly system. Thus, it is not considered part of the program’s implementation costs.
## Opportunities for adaptation

<table>
<thead>
<tr>
<th>Decisions related to the <em>Medly</em> program</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technical support</strong></td>
</tr>
<tr>
<td>A website was built containing patient training content and an extensive frequently asked questions section. It is expected that this website will allow patients to be more self-sufficient and greatly reduce the number of calls made for technical support. In addition, development is underway to build a self-training feature directly into the <em>Medly</em> app. This will also increase the feasibility of providing same-day onboarding by minimizing scheduling challenges that exist with face-to-face training. The shift toward lower-touch technical support made it possible for most of the frontline technical support tasks (patient training, managing inventory, and basic troubleshooting) to be taken up by clinic staff. It is believed that this model more closely resembles what will be feasible in most health care settings, and it is expected to improve the patient experience by having a single point of contact.</td>
</tr>
<tr>
<td><strong>Clinician role</strong></td>
</tr>
<tr>
<td>An RN(^a) was hired to take over the primary clinical management of alerts from the existing nurse practitioners as well as the technical support role from the existing telehealth analyst. This RN was responsible for triaging alerts and escalating clinical issues to (^b)MRPs when necessary.</td>
</tr>
<tr>
<td><strong>Duration of patient enrollment</strong></td>
</tr>
<tr>
<td>No change. A universally applicable duration of enrollment could not be determined as it depends on patient characteristics.</td>
</tr>
<tr>
<td><strong>Intensity of monitoring</strong></td>
</tr>
<tr>
<td>No change. The 7 days/week monitoring will be maintained at the HF clinic with cardiologists volunteering their time to cover weekend alerts and transferring alerts to a colleague if they will be unavailable for extended periods. Modifications are being made to the <em>Medly</em> dashboard to facilitate the transfer of alerts from one MRP to another.</td>
</tr>
</tbody>
</table>

\(^a\)RN: registered nurse.

\(^b\)MRP: most responsible physician.

## 5.4 Discussion

### 5.4.1 Principal Findings

This qualitative study is the first to describe adaptations to an existing HF TM program aimed at enabling its sustainability and scalability. The redesign was informed by interviews with clinicians and patients to identify which program components could be adapted while
maintaining program fidelity. User perceptions helped identify that the type of peripheral devices used and the format of technical support were highly adaptable, making them ideal targets for cost reduction measures. This led to the decision to move forward with a hybrid BYOD model and lower-touch technical support services, which would substantially reduce the cost burden to the clinic for delivering the program. In addition, findings related to the clinician role confirmed that frontline alert management should be done by someone within the patient’s immediate circle of care rather than being outsourced to an offsite telehealth clinician. This informed a more cost-effective model in using an RN to replace the existing NPs as the frontline manager of TM alerts and to absorb the technical support functions previously performed by the THA. The notion of an RN playing both the central clinical and operational roles within a TM services is supported in the literature [12, 113]. In this case, hiring of an RN made sense as a resource optimization measure because of the existing program structure, which involves escalating alerts to an MRP. In sites where a physician is not as readily available, a professional with an ability to make medication changes (e.g., NP) might be more appropriate to lead a TM service.

Because no generalizable dose with respect to duration of enrollment and intensity of monitoring could be established, no changes were made at the existing program site. However, the moderately adaptable nature of these components may reveal opportunities for scale and spread as they might be tailored to allow for program integration within sites with different patient populations, resources, and objectives. For example, although rapid feedback from a clinician is often described as the most important component of a TM service [104], a clinical site serving patients with a lower disease severity may not require 7 days per week monitoring. In addition, a site with resource constraints may wish to prioritize improving patient self-care, in which case, a 3- to 6-month duration might represent an optimized duration of enrollment. Alternatively, sites with available resources and different organizational values may wish to prioritize the patient’s experience in addition to improving self-care and decide to monitor patients indefinitely. Finally, although the clinicians in this study felt comfortable receiving alerts during off hours, the medicolegal implications of continuous monitoring must be considered on a site-by-site basis. For example, it is possible that 7 days per week monitoring is deemed important for a specific patient population but that receiving alerts during off hours represents a medicolegal concern that cannot be addressed through the hiring of additional staff or on-call personnel. Such a situation
may leave a site no choice but to offer a weekday-only TM program, with the understanding that the impacts of the program may be suboptimal.

5.4.2 Comparison with Prior Work

Several studies have explored the barriers to and facilitators of implementing telehealth systems [56, 73] but few have described the process of adapting an existing intervention to ensure its sustainability and scalability. One multiple case study by Taylor et al describes a participatory approach to implementing solutions for expanding a telehealth program [114], but the description of these activities remained high level without concrete examples, leading to limited transferability of results.

Many authors cite the ubiquity of smartphones as an opportunity for delivering TM services at a lower cost [115, 116]. However, most studies of mobile phone–based TM have provided patients with this mobile equipment [117], and little is known about clinicians’ and patients’ perceptions of a BYOD model. From a usability perspective, there is a clear preference among patients, both in the literature [104, 118, 119] and in this study, for using Bluetooth-enabled peripheral devices. However, what appears most important is that patients can access TM services using devices they are most familiar with (i.e., personal smartphones and tablets) [120-122] and that the perceived advantages of a TM program are greater than any usability inconveniences caused by manually entering physiological and symptom data. To our knowledge, ours is the first study to confirm that BYOD is perceived by both clinician and patient users as a viable option for delivering TM services with a caveat that considerations are required to ensure universal accessibility.

The finding that clinicians believe patients could exit a TM program after they have stabilized or gained self-care skills is supported by other studies [107]. We found a similar perspective among clinicians in this study, but we also found that many patients grow accustomed to being remotely monitored and would like to continue over a longer term. Until now, considerations about the duration of telemonitoring interventions have primarily been driven by costs. However, this perspective ignores the natural history of HF, whereby although patients may stabilize for a period, they will rarely improve [123]. Therefore, as opportunities are leveraged to deliver TM
interventions at lower costs (including clinicians’ time through the development of more sophisticated decision-support capabilities), it is conceivable that the costs of delivering certain TM programs will become sufficiently low so that it removes the need to ration their use. Thus, future work should seek to answer whether it is better (from the patient, clinician, and health system perspectives) to (1) remove patients from a low-cost TM program when they have stabilized only to reinstate them in the program when their condition has worsened or (2) leave them enrolled in the program indefinitely.

5.4.3 Limitations

First, although participants were asked to consider their responses with respect to TM in general, it is likely that their responses were influenced by their experiences with the Medly program. In stating this limitation, we emphasize that our intent was to describe adaptations to a specific TM program rather than to provide a detailed blueprint for implementing all HF TM interventions in any given clinical context. We argue that the context-dependent nature of implementing complex interventions makes the creation of such a blueprint impossible. Rather, we have sought to provide foundational considerations for developers of TM interventions and for implementation scientists who wish to sustain and scale existing TM interventions to other clinical sites and health care organizations. Second, the pragmatic nature of this study meant that patients can be enrolled in the Medly program without consenting to participate in the evaluation activities, making them ineligible to participate in the interviews. Our inability to purposely sample these patients may have led to selection bias. Third, the interview guides were developed to probe the opinions of users on specific program components. We recognize that our approach for compartmentalizing and defining the various components of this complex intervention was subjective and context specific; this should be considered when determining the transferability of results to alternative settings. Finally, although the resulting user-guided adaptations are expected to maintain the fidelity of the intervention, the true impact of these changes was not empirically tested in this study. This important question will be evaluated as part of a subsequent evaluation on the overall impacts of the Medly program as well as patient adoption and adherence to the intervention.
5.5 Conclusions

Theories of diffusion of innovation suggest that one of the keys to the scale and spread of health interventions lies in adapting elements of its delivery to better fit the implementation context. However, this is only true if fidelity of the intervention can be maintained and its potential effectiveness is not compromised. This concept has informed the implementation of cost reduction measures of an existing HF TM program to ensure its sustainability. Our findings suggest that the peripheral devices used in TM interventions and the format of technical support are highly adaptable, making them ideal targets for cost reduction measures. Duration of enrollment and intensity of monitoring are inextricable components of a TM intervention, but the dose of these components required to yield expected outcomes is highly context dependent. Our efforts provide a user-centred example of how necessary actions can be taken to improve the sustainability and scalability of TM interventions.
Chapter 6
Discussion and Application of Key Findings

6 Discussion and Application of Key Findings

The objective of this thesis was to understand the factors that influence the implementation, scale, and spread of TM interventions for the management of HF. This was accomplished through a review of contemporarily published meta-analyses and of the TM implementation literature to explain heterogeneity in the evidence of HF TM outcomes. Further, a case study of the implementation of the Medly TM program enabled the in-depth study of factors that influenced the implementation and spread of a TM intervention within that organization. The following is a discussion of key research findings and of how they can be applied to future TM research and implementation initiatives.

6.1 Clarifying the State of the Evidence

Evidence is critical for the implementation, scale and spread of interventions because, according to most implementation frameworks (including the CFIR), the strength of the evidence and its perceived quality, is an important influencing factor on stakeholders’ willingness to adopt that intervention [26, 110].

According to Rycroft-Malone et al. there are four types of evidence: (1) research evidence, (2) knowledge from clinical experience, (3) knowledge from patients, and (4) knowledge from local context [124]. Research evidence, that is, the product of scientific inquiry, is what generally comes to mind when the term ‘evidence’ is invoked and is often inaccurately perceived as holding absolute truth. Nevertheless, research evidence is a powerful tool for guiding decision-making related to health practices. Knowledge from clinical experience, described as “practical know-how,” is tacit and is accrued by clinicians through their own practice and the observed experiences of colleagues. Knowledge from patients, refers to patients’ perceptions of the care they received and must be considered in a holistic definition of evidence. For example, an intervention might demonstrate an ability to reduce healthcare utilization but achieving this
outcome may come at the expense of a poor patient experience and begs the question of whether such an ‘evidence’-based practice should spread. Finally, knowledge from local context, refers to information obtained locally (including administrative data) and analyzed for quality improvement and planning purposes [124]. Importantly, although there is much focus on generating research evidence of effectiveness, understanding the role of evidence in influencing implementation, scale and spread requires stakeholders to embrace a more holistic definition that seeks coherence among these four sources of knowledge.

Practically, quantitative research evidence of effectiveness is generally prioritized by decision makers and clinicians alike (including the clinicians interviewed in the study described in Chapter 3). As such, the article presented in Chapter 2 was a review that summarizes the state of the research evidence as it relates to the impact of HF TM on key outcomes common to most studies. This review found 11 meta-analyses published between 2012 and 2017 with most reporting significant reductions in mortality and HF-related hospitalizations in patient groups enrolled in a TM intervention compared to those who received the standard of care. Although positive evidence exists for cost-effectiveness and other outcomes such as quality of life and self-management capacity, there was considerable heterogeneity in the results of those review studies. This heterogeneity extends to the main outcomes of mortality of HF hospitalizations as demonstrated by the 4 of 11 meta-analyses which showed no significant impact on one or both outcomes in addition to the large and often cited RCTs which report no impact. Chapter 2 argued that this inconsistency in research evidence exists due to key differences between studies with respect to patient populations (including disease severity), characteristics of the interventions, and the fidelity with which the intervention were used in the context of the trials.

6.2 Generation of New Evidence

To further the evidence base for HF TM, a protocol was published to generate evidence of effectiveness, clinician and patient experiences, and local context. This protocol was not included as a chapter because the collection and analysis of data on the Medly program’s impact and costs were outside the scope of thesis. The protocol, which is available in its full form in Appendix 6, describes the single case study of the Medly program with four objectives aimed at evaluating the: (1) impact; (2) cost impact; (3) barriers and facilitators to implementation and
clinician adoption; and (4) patient adherence. Evaluation of the impact employs a pre-post study design with primary outcomes related to health service utilization (number of hospitalizations, visits to the emergency department, visits to family doctor, and HF-related outpatient visits). Additional impact measures include LVEF, laboratory tests (brain natriuretic peptide, creatinine, sodium, potassium, hemoglobin, uric acid), mortality, and predicted survival (estimated using the Seattle Heart Failure Model [125]). Finally, data for patient reported outcomes related to general and HF-specific quality of life (measured using the EQ-5D-5L [126] and MLHFQ [127] respectively) and self-care capacity (measured using the Self-Care of HF Index [128]) are also being collected. The primary analysis involves evaluating the within-patient differences of these outcome metrics between baseline and 6 months.

The cost impact of implementing the Medly program is being evaluated from the perspectives of the public payer, the hospital, and the patient over a 6-month time horizon. Cost from the public payer perspective will be based on healthcare utilization, including: hospitalizations, ED visits, HF clinic visits, family physician visits, and use of home care services. Cost from the hospital perspective includes the cost of the human resources as it relates to clinician time spent reviewing and responding to alerts as well as equipment costs and the human resources involved in the training and onboarding of patients. Finally, costs from the patient perspective will be determined based on time spent accessing care (based on employment status and annual income), travel costs, and out of pocket costs.

The remaining two objectives outlined in the protocol (evaluation of the implementation and patient use) were the focus of this thesis. Together, knowledge acquired from clinician experience, patient experiences, and local data collected as part of the implementation evaluation in this thesis will be combined with findings from the impact and cost evaluations to provide a holistic picture of the evidence of the Medly program and interventions like it. In addition, these findings will contribute to answering many of the questions proposed at the end of Chapter 2, including: what are the characteristics of HF TM interventions (technology, parameters measures, dosage, etc.) that will meet the clinical needs and patient preferences of various patient populations?
6.3 Factors Influencing Implementation Success and Fidelity of Clinician Use

With respect to the second specific research question (implementation success), Chapter 3 concluded that the Medly program was successfully implemented based on the degree of penetration (extent of adoption by clinical staff in the HF clinic), the level of patient adoption, and the fact that it was generally operating as intended. Clinician adoption and fidelity of clinician use were demonstrated through the triangulation of data from interviews with program staff and administrative sources. Together, these data indicated that clinicians were reviewing all the alerts generating by Medly, following up with patients when necessary, and documenting the appropriate actions in the EMR.

The implementation study uncovered several facilitators that explained the implementation success and appropriate use by program staff, most of which fell within the CFIR domains of characteristics of the individuals and inner setting. Thus, the conclusion was that much of the program’s implementation success and fidelity of clinician use was highly dependent on contextual factors. These contextual facilitators likely mitigated the barriers related the CFIR domains of intervention characteristics (high complexity and unsustainable costs) and process (lack of implementation planning). Future HF TM implementations should address these barriers to ensure that success can be achieved when contextual facilitators are not present to the same degree that they were in the Medly case study. A subsequent section (6.7.2) will outline a theory-based approach for identifying potential barriers to implementation prior to intervention deployment and for designing an implementation plan to help mitigate them.

6.4 Factors Influencing Fidelity of Patient Use

The study described in Chapter 4 used a mixed method approached to understanding the factors that explain patients’ adherence to taking daily TM readings. Consistent with other studies, this study found a significant decrease in overall average adherence over time. One key finding was that the adherence levels of older patients remained consistently high throughout their entire first year in the Medly program whereas patients in younger age groups showed a steeper decline in
adherence. This supports other studies that contradict the stereotype that older people are less tech savvy and thus less willing to adopt and use health technologies [129, 130].

The interview findings did not conclusively explain why adherence decreased over time. However, through the use of the UTAUT2 as an analytical framework, results indicated that patients’ adherence is influenced by: (1) performance expectancy (improvements in HF management and peace of mind), (2) effort expectancy (ease of use and technical issues), (3) social influence (support from family, friends, and trusted clinicians), (4) facilitating conditions (availability of technical support and automated adherence calls), and (5) habit (degree to which taking readings became automatic). With these results, this study demonstrated the applicability of the UTAUT2 for studying patients’ use of TM interventions. One advantage of using this framework is that it incorporates the most important constructs (perceived usefulness and perceived ease-of-use) from another widely used framework, the TAM) [131], in addition other constructs not found in the TAM such as of social influence and facilitating conditions. Probing users’ experiences with questions related to these constructs uncovered insights into how to better implement TM interventions (e.g., the inclusion of features that enable the formation of a habit and easy access to supporting services).

Although this study did not identify findings related to the UTAUT2 constructs of hedonic motivation and price value for reasons discussed in Chapter 4, these constructs should not automatically be discounted when aiming to achieve optimal patient use of TM. For instance, gamification has long been explored, with varying success, as a tool to promote patient use of digital health interventions [132] and may present an opportunity to influence higher and more consistent adherence. Finally, Chapter 2 identified the challenges in finding a sustainable business model for the implementation of TM interventions in single payer jurisdictions. However, setting aside ethics and Canadian values, decisions to pass costs onto patients warrant further pause because there is a theoretical basis for predicting that this can impact patient’s intention to be part of a TM intervention.

Finally, although this study confirmed the moderating effect of age and time (a proxy for experience) on patient use, other patient characteristics may influence their use of consumer health technologies beyond those proposed in the UTAUT2. For example, as it relates to the topic of this thesis, education and mental health status have been shown to influence self-care
behaviours in HF populations [133]. In addition, this research highlighted the importance of informal caregivers in supporting patient adherence. However, in their current form, the definitions of the UTAUT2 constructs of facilitating conditions and social influence do not adequately account for the dynamic and complex nature in which social structures and informal caregivers may influence the management of chronic diseases. This possible gap in constructs related to patient characteristics and the questionable relevance of the constructs of price value and hedonic motivation in the healthcare context points to the need for further research in theories proposing to explain patient use of health technologies.

6.5 Adaptability of Heart Failure Telemonitoring Interventions

As discussed in Chapter 1 and Chapter 5, adaptability is one of the keys to scale and spread because it enables implementers to tailor an intervention to fit within local workflows and resource structures. Thus, replicating an intervention at multiple sites in a process of scale and/or spread requires a defined intervention which includes an understanding of which components need to be maintained to ensure intervention fidelity and which components can be modified in a process of planned adaptation [111]. The study in Chapter 5 concluded that the format of technical support and the equipment used (smartphone, blood pressure cuff and weight scales) were part of the Medly program’s highly adaptable soft periphery, meaning that they could be adapted without negative consequences to the program’s ability to yield desirable impacts. Also adaptable, albeit to a lesser degree, was the dosage of the intervention (intensity of monitoring and the duration of program enrollment). Based on the user opinions reported in Chapter 5 and the literature review in Chapter 2, there is not enough evidence to define a dosage within the program’s unadaptable hard core. Therefore, Chapter 5 concluded that the intensity of monitoring and duration of enrollment is likely to be dependent on the severity of the patient population and the context in which the intervention is being implemented, particularly with respect to other services already existing as part of the standard of care.

Results from this chapter make an important contribution to the implementation literature as it relates to the adaptability construct in the CFIR. The CFIR, and implementation theories that come before it, discuss interventions as having core components (sometimes referred to as the hard core [30]) and an adaptable soft periphery (called “fuzzy boundary” in Greenhalgh’s model
However, this thesis highlights how the degree of adaptability of intervention components exists on a spectrum and the notion that they can be classified as either within the core or the adaptable periphery is perhaps a false dichotomy for many complex interventions. Although this idea of varying degrees of adaptability may seem obvious to seasoned implementation scientists, the existing terminology may lead to frustration among non-academics who are attempting to follow evidence-based implementation guidelines and struggling with the often difficult or impossible task of uncoupling intervention components so that they can be defined adaptable or not. Therefore, although the term *fuzzy boundary*, when used by Greenhalgh, was synonymous with the CFIR term *adaptable periphery*, Chapter 5 re-introduces this term because it speaks to the lack of clearly delineating boundary that exists in trying to define the adaptability of the components of complex interventions.

### 6.6 The Scalability and Spreadability of Telemonitoring for the Management of Heart Failure

In 2017, Greenhalgh et al. published the Nonadoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework which was the product of an extensive hermeneutic systematic review of 28 technology implementation frameworks. The NASSS outlines an exhaustive list of factors that influence the likelihood of implementation, scale-up and spread success - many of which overlap with the factors described in the CFIR [110]. The framework includes a series of questions classified into 7 domains which aim to guide the classification of implementation initiatives as *simple*, *complicated*, or *complex*. Intuitively, the framework suggests that initiatives characterized by simplicity are relatively easy to implement with the likelihood of success decreasing as the level of complexity increases. The following is a brief analysis of the 7 NASSS domains as it relates to HF TM. Through this analysis, findings from this research and the literature are summarized with the intent of characterizing the degree of complexity, and thus the scale and spread potential of HF TM. The NASSS questions that structure this analysis are listed in Appendix 7.

1. **The condition or illness - Complicated to complex.** Heart failure is a condition with multiple and complex pathophysiologies and often presents with co-morbidities. Thus, its clinical management generally requires an individualized and multi-pronged approach.
2. **The technology – Complicated.** Most HF TM systems are composed of “off-the-shelf” equipment (peripheral devices) and proprietary software that is often not interoperable with existing health information systems. The TM system in the Medly case study was described as easy to use by patients and intuitive by clinicians but the clinician’s role as an extension of that technology requires detailed instructions, training, and ongoing support. In addition, as the review in Chapter 2 highlights, there is no clear consensus about which parameters need to be monitored. Finally, most TM interventions ask patients to input symptoms which requires a subjective assessment of one’s health which can be difficult for many patients (as reported in Chapter 4).

3. **The value proposition - complicated to complex.** There is complexity from the supplier side (i.e., technology vendor) where the business case for HF TM in Canada (a single-payer health system), is limited. The demand side is complicated because, as was described in Chapter 2, there is evidence of positive impact. However, heterogeneity in the evidence-base, particularly as it relates to cost-effectiveness, leaves the question of clinical value open for debate.

4. **The adopter system – complicated to complex.** Existing clinical staff must learn new skills to use TM systems or new staff must be appointment. For some clinicians, this requires a change in their scope of practice which may be interpreted as a threat to professional identity [134]. Following enrollment, patients have the relatively routine task of taking consistent readings. However, complexity is introduced when patients are expected to make self-care judgements and act on information from the TM system. This was true in the case of Medly where some patients reported feeling that the self-care messages did not always reflect how they were feeling. In such cases, patients had to make judgement calls about not taking an extra dose of their diuretic medication or going to the emergency department if they felt like they were inappropriately prompted to do so.

5. **The organization – complicated to complex.** This domain refers to the implementation site’s capacity to innovate and its readiness to change. Although the site described in this research could be classified as *simple* in this regard (the strongest facilitators were related to the *inner setting* domain of the CFIR), most TM implementations in the Canadian
context will have limited slack resources. Therefore, if organizations do not have a
culture of learning and quality improvement, they will be more averse to taking risks,
thus creating complicatedness in this domain. The same is true for organizational
readiness. Although the Medly case study identified a good fit of the TM program within
HF clinic workflows, clinical buy-in, and widespread clinician support, these facilitating
conditions are unlikely to all be present in average organizations. Decisions based on
funding are prone to complicate adoption and implementation of TM as it is unlikely that
most organizations will be able to implement a TM intervention using solely existing
human and equipment resources. Finally, future TM implementations require the
formation of new team routines which will necessitate implementation activities that
require energy and resources to engage stakeholders, ensure the proper uptake of new
practice, and monitor impact.

6. **The wider system - Complex.** As Chapter 3 highlights, TM interventions in Canada align
well with political and sociocultural trends toward providing patient-centred care and
shifting care from hospital to home. However, the lack of supportive policies brings
complexity to this domain. This interacts highly with the *value-proposition* domain
whereby, in many jurisdictions, there are no established mechanisms to appropriately
compensate clinical staff for their role in monitoring patients (e.g., lack of billing codes
for physicians or alternative incentives)[135].

7. **Embedding and adaptation over time – complicated.** As Chapter 5 highlights, there is
some latitude for adapting TM interventions. However, each organization will differ in
their capacity to support the adaptations required to enable long term embedding of the
new TM practice.

The preceding analysis demonstrates the relatively high degree of complexity when it comes to
implementing HF TM across Canadian health organizations. Based on the 2018 synthesizing
work of Shaw et al [25], interventions characterized by higher complexity, such as HF TM, are
more amenable to mechanisms of bottom-up spread as opposed to top-down scale-up [25].
Although governments have an important role to play in creating a supportive policy
environment (particularly with respect to reimbursements and protections for clinicians) and
contributing operational funding, a jurisdiction-wide initiative of concurrent HF TM
implementations is unlikely to succeed on its own. Instead, stakeholders intent on seeing the wider adoption and implementation of HF TM are more likely to achieve their objective through strategies of spread which include grassroots actions aimed at influencing local decisions through the development of relationships and collaborative networks. In addition, implementation teams should be prepared with a collaborative approach for adapting the intervention to enable its embedding within local contexts. Finally, as with all innovation spread (in contrast to innovation scale-up), champions of HT TM will have to exercise persistence because change through innovation spread occurs more slowly at first before building momentum over time [25].

6.7 Operationalizing the Research Findings

The prospective nature of this research enabled the findings to inform the development of tools and processes that would improve the chances of sustainability of the Medly program in its current setting and its spread to others. These are described in the following sections as they can serve as a model to support the spread of other HF TM interventions.

6.7.1 Clarifying the Intervention

Although HF TM interventions have an inherent degree of complexity due to their multi-component nature, much of the complexity identified in this research resulted from the intervention being initially ill-defined, particularly is it related to clinician and support staff roles.

To address this gap, a generic logic model was developed to depict the Medly program, including its theory of change and intended outcomes (see Appendix 8). This logic model is intended to act as a point of reference when undertaking planned adaptations in other sites. Accompanying this logic model are standard operating procedures (SOPs) for the Medly program (Appendix 9). This document outlines, in significant detail, the roles and responsibilities of the various actors required to operationalize the Medly program, including how actors interact with program artifacts. Beyond the Medly TM technology itself, program artifacts include: the onboarding form (completed by the MRP to set patient-specific thresholds and other system parameters),
statement of responsibility (given to patients to outline their roles and responsibilities in the program), patient-facing website, and user manuals. Documentation of intervention components, particularly of clinical and support staff roles is recommended for the implementation of any TM intervention because it will facilitate clinician adoption and act as a point of reference for evaluating intervention fidelity.

6.7.2 Formalizing an Implementation Strategy

Chapter 3 identified a lack of a formalized implementation plan. In response, a phased implementation strategy was developed based on the research findings discussed in chapters 3-5 and relevant concepts from implementation frameworks which could be applied to future implementations of the Medly program or other TM interventions. The strategy is also infused with principles of Service Design, a relatively new approach in health care that uses design principles to conceptualize a service (e.g., a TM intervention) by putting people (users, support staff, and decision makers) and their needs as the central point of focus when designing processes to optimize value for each group [136]. The 3 phases of the implementation strategy are: (1) engagement and needs assessment; (2) service and implementation plan adaptation; and (3) execution of the implementation plan. These phases are depicted in Figure 8 and described below.
6.7.2.1 Phase 1 – Engagement & Needs Assessment

Regardless of whether a TM program is expanding through mechanism of scale or spread, the first step is to engage with representatives from the future implementation site and obtain official buy-in. This will always include discussions with local decision makers but efforts should also be made to identify and obtain buy-in from a clinical champion. Including a clinician who will use the technology and who is an opinion leader within the organization throughout the entire implementation process will enhance chances of success.

The needs assessment activities come after an organization’s decision to adopt and is achieved using methods informed by the CFIR to identify the barriers and facilitators to implementation. This can be done through informal (e.g., conversation) or formal (e.g., baseline interviews as was conducted in Chapter 3) qualitative means. Alternatively, for large or multisite implementations, validated survey tools can be used to streamline the needs assessment. One example of such a tool is the Organizational Readiness to Change Assessment tool [137] which is based on the Promoting Action or Research in Health Services (PARIHS) framework [138] which covers
many of constructs in the CFIR [26]. If implementers suspect resistance on the part of future program staff, the needs assessment can be supplemented by the Theoretical Domains Framework (TDF) [139] to probe deeper in the CFIR’s characteristics of the individuals domain. The TDF is an integrative framework of 14 domains and 84 theoretical constructs that was developed to identify influences of clinician behavior related to the implementation of evidence-based recommendations but has been extensively used in implementation research [139]. Thus, the TDF would be a complementary framework to guide a needs assessment aimed at identifying potential barriers to clinician adoption.

In line with service design methodology, information from the needs assessment should be supplemented by a site visit aimed at understanding the existing clinical and administrative workflows within the target organization. This first phase will have 3 key deliverables. First, a formal written agreement between the implementation site and the vendor or implementing team’s organization, confirming a commitment to move forward with implementation of the program and detailing any terms and conditions defined up to that point. Second, a site ‘snapshot’ (approximately 1 page) outlining site objectives, metrics of success, key barriers to be mitigated, and key facilitators to be leveraged. As multiple players might be involved in the upcoming implementation phases (service adaptation and execution of the implementation plan), this site snapshot will serve as a reference document so that all members of the implementation team are on the same page. Finally, a current-state workflow map will be created to accompany the site snapshot.

6.7.2.2 Phase 2 – Service and Implementation Plan Adaptation

The service adaptation phase includes adapting the program to the new site as well as developing an implementation plan that will guide the remaining implementation/change management activities. Inputs for the service design of the program include the deliverables from Phase 1 (site snapshot and current-state workflow map) as well as the TM program SOPs and program artifacts (described in section 6.7.1). Activities in this phase will be case and resource-dependent but will generally involve service design methodologies related to iterative ideation, prototyping, and input from site stakeholders [140]. Importantly, because service design approaches are best suited for designing novel services, the typical design approaches outlined in service design
“how-to” guides will be supplemented by principles of planned adaptation (adaptations while adhering to a program’s theory of change [111]). This will ensure that adaptations to a TM intervention to fit a site’s resources, workflows, and needs will maintain intervention fidelity.

In addition to designing the TM program to best fit the implementation site, service design methodologies can also be used to develop a customized implementation plan based on the needs addressed in Phase 1. An implementation plan (also called an implementation blueprint in the implementation science literature) explicitly states the goals and strategies that will be used to achieve implementation success and should document: 1) the stated purpose of the implementation; 2) a description of the scope of change (including which of the organization’s units or departments are being targeted); 3) the implementation or change management strategies (e.g., training, system integration, building in-house capacity, etc.) that will be used; 4) timeline and milestones for completing those activities; 5) enumeration of process measures that will be used to evaluate implementation progress; and 6) plans to develop infrastructure for monitoring and continuous quality improvement [141]. Although many implementation and change management strategies will be similar for each site, they should be tailored based on the implementation and behavioral barriers identified in Phase 1. A tool (https://cfirguide.org/choosing-strategies/) created by the developers of the CFIR and the Expert Recommendations for Implementing Change (an inventory of 73 discrete theory-based implementation strategies) can facilitate the mapping of barriers to appropriate mitigating strategies [141].

Outputs from Phased 2 will include: 1) site-customized SOPs and program artifacts, 2) a future state workflow map, and 3) a formal implementation plan.

6.7.2.3 Phase 3 – Execution of the Implementation Plan

Activities in this phase will differ depending on the customized implementation plan. Typically, this will always include staff training activities but implementation teams should also be prepared to provide: technical assistance (beyond day-to-day technical support provided as part of the program), collection and analysis of process evaluation and quality improvement data, feedback of findings, and refinement of the services (technology and processes). The output of
this last phase is a fully integrated and sustained HF TM program whereby the site has the capacity and knowledge needed to perform monitoring and quality improvement after the official implementation period is over.

6.7.3 Theoretical Contributions

6.7.3.1 Situating this Work Within Implementation Science

In 2015, Per Nilsen proposed a taxonomy to classify the proliferating number of implementation theories, models and frameworks [33]. The result of this work, depicted in Figure 9, is a taxonomy of five categories of theories, models, and frameworks, organized under three research aims. The first aim of guiding the translation of research knowledge into practice is achieved through the use of process models which typically outline a series of steps or phases for undertaking an implementation as seen in the often-cited Knowledge-to-Action Framework [142] and the QIF [84]. The second aim is met by theoretical approaches that seek to explain or understand the factors that influence implementation success or failure; three categories fall under this aim. Determinants frameworks generally accomplish this through a structured classification of domains and constructs of barriers and facilitators to implementation. Popular determinants frameworks include the CFIR [26], TDF [139], PARIHS [138] (all previously discussed in this thesis). Classic theories, such as Roger’s Theory of Diffusion of Innovation [27] and social networks theories, have origins outside of implementation science but have applications for explaining certain aspects of implementation through causal mechanisms. These are similar to implementation theories which are developed specifically by implementation researchers. For example, Normalization Process Theory [143] is a commonly employed theory because it describes the mechanisms by which innovations are embedded and normalized within clinical practice. The final category in the taxonomy is evaluation frameworks which are used to achieve the third and final aim of evaluating implementation success. This thesis used the outcomes framework from Proctor et al., [32] although other commonly used evaluation frameworks include the RE-AIM [144] and PRECEDE-PROCEED frameworks [145].
Nilsen’s taxonomy is described to situate the theoretical approaches and outputs of this research within the field of implementation science. First, it is important to recognize the breadth of existing theories, models, and frameworks. Therefore, while this thesis highlights the advantages of using the CFIR and Proctor frameworks, it should be recognized that these were selected to align with the specific research aims outlined in Chapter 1 and, as such, their blanket use for all implementation research is not recommended. Others wanting to research the implementation of health interventions, including TM, should explore the range of models, theories, and frameworks at their disposal and select the ones that best align with their research aims. The taxonomy is also described to contextualize the contribution of the Implementation Strategy described in Section 6.7.2. The intent in presenting this strategy was not to propose a new generalizable theory to be classified somewhere in this taxonomy. Rather, it is a strategy aimed at operationalizing important theoretical concepts to guide the implementation of TM interventions. For example, the proposed phases mirror those of prominent process models like

Figure 10. Nilsen’s taxonomy of implementation theories, models and frameworks used in implementation science with prominent examples for each category
the QIF but the activities described in each phase are heavily influenced by frameworks in other categories of Nilsen’s taxonomy. For instance, the needs assessment phase is guided by the CFIR and TDF (both determinant frameworks) and the development of the implementation plan includes the selection of implementation outcomes from Proctor et al. (evaluation framework). Further distinguishing the proposed TM implementation strategy from theory is the inclusion of service design methodology to guide the adaptation of soft periphery components. Prominent theoretical frameworks such as the CFIR and QIF highlight the importance of these adaptations but, due to their general nature, do not provide practical guidance how to do it.

6.7.3.2 Advancing Theory on the Implementation of Telemonitoring

Although most theoretical approaches can be firmly classified into one of the five Nilsen categories, some researchers have sought to combine frameworks from different categories. One notable example is the framework by Chaudoir et al. which was developed as part of a systematic review of measures used to evaluate the implementation of health innovations [146]. The resulting framework (depicted in Figure 10) includes causal factors (typically included in determinants frameworks) as the precursor to implementation outcomes from the Proctor framework. Although Chaudoir’s work provides a logical framework for which to consider different components of implementation evaluations, a key limitation is that it was developed specifically to guide the identification and classification of existing evaluation tools and thus, the framework does not include definitions nor theory-based explanations for each of its constructs. As such, it is not as practical for guiding research methods and analyses compared to its original underlying determinant and evaluation frameworks. Another limitation is the lack of domain that captures the implementation process. However, with these limitations comes an important strength that separates the Chaudoir framework from the CFIR, and that is the inclusion of a patient domain.
Figure 11. Chaudoir multi-level framework predicting implementation outcomes

One of the Chaudoir framework’s main strength is its ability to visually capture the complexity of studying the various components of health innovation implementation. Therefore, I have borrowed the logical structure of this framework, and proposed updates (see Figure 11) to address the limitations described and to frame the discussion of possible further theoretical work. Three modifications to the original Chaudoir framework are proposed. First, the terminology used to depict the causal factors has been replaced with the terminology of the corresponding domains used in the CFIR. The implication here is that the CFIR has a comprehensive list of the relevant constructs, each of which have accompanying definitions along with an extensive evidence-based rationale. Second, the CFIR domain of process is included in the image. Third, because the Chaudoir framework correctly identifies the importance of including factors that influence both patients and provider adoption and use of an intervention (this is especially true of TM interventions), an insert is included in Figure 11 to present hypotheses of how clinician and patient use might influence one another. These possible links are discussed using the key constructs from the CAF (proposed in Chapter 3 as a means to further understand clinician use of TM) and the UTAUT2 (used in Chapter 4 to understand patient use of TM).

The CAF [83] has a conceptual foundation in the DeLone and McLean Information System Success Model [147] and, although the CAF includes many contextual constructs at the meso and macro levels hypothesized to influence clinician adoption and use, these are nearly identical to the constructs in the inner, outer, and characteristics of the individual domains of the CFIR and therefore are not discussed here. Factors influencing clinician use of health technologies at
the micro level (most relevant for understanding the individual use of TM and the potential interplay with patient use) involves 3 characteristics of the clinical information system, these include: 1) quality of the system, 2) quality of the information within the system, and 3) quality of the supporting services [83]. How these three CAF constructs influence clinician use is depicted in the insert in Figure 11. The right side of the insert depicts the constructs of the UTAUT2 previously defined in Chapter 4.

Figure 12. Modified Chaudoir framework to include CFIR domains and constructs from the Clinical Adoption Framework and Unified Theory of Use and Acceptance of Technology 2
The insert in Figure 11 depicts three hypothesized interactions (denoted by dashed arrows) between clinician and patient use which are informed by the results of this thesis.

The first hypothesis is that user satisfaction of a clinician can influence patient use via the UTAUT2 construct social influence. In Chapter 3, results showed that the clinicians in the case study all had strong positive opinions of the Medly system and in Chapter 4 it was found that patients were influenced to use Medly by trusted clinicians who recommended it to them. Therefore, it is logical to assume (though not yet empirically proven) that a clinician’s satisfaction with a TM system can lead them to recommending its use to patients, thus increasing patient behavioural intention to use.

The second hypothesized link is between clinician use and patient’s perception of performance expectancy. Chapter 4 identified that one of the strongest influencers on patient adherence was the perceived benefits of using the TM system, particularly the peace of mind that comes from knowing that trusted clinicians would be alerted and call them at the first sign of trouble. Although the high fidelity of clinician use in the case study did not enable testing of this hypothesis, it is logical to assume that if clinicians do not perform their role as intended (e.g., do not review and respond alerts in a timely manner) patients will perceive less benefit of using the TM system which could impact their own use of it.

The final hypothesis is that patients’ use (particularly their degree of adherence) will influence the CAF construct of information quality. Information quality refers to the availability of information that facilitates the clinician’s ability to perform their role, which, in the case of TM, is to offer disease management support [83]. The availability of that information is dependent on the consistency with which patients use a TM system to record disease-specific measures. Therefore, if patient data is missing, this can inhibit perceived utility of the TM system in terms of clinical decision support and thus lessen clinician satisfaction and ultimately use of the system. Chapter 4 discussed how some patients were removed for having low adherence and Chapter 3 discussed how clinicians learned to consider levels of engagement in the selection of good candidates for the program. This implies that nonadherence does play a role in the TM intervention functioning as intended and ultimately the satisfaction of clinicians.
6.7.4 Overall Research Limitations

Study-specific limitations have been discussed in their respective chapters. However, important overarching limitations of this research project exist that are worth highlighting. First, this research employed a single case study design. Therefore, generalization of individual study findings is not possible. Consequently, research findings were presented and discussed in such a way as to achieve transferability of results which was accomplished through a detailed description of the context, participants, and methods used. This, in addition to the fact that the objective of the research was to identify implementation factors that are malleable to other contexts, means that various audiences will be able to gain insights applicable to their respective circumstances.

Second, the nature of this case study meant that the exploration of factors that influence implementation, scale and spread could be directly studied at the micro (individual) and meso (organizations) levels. However, although some of the interview participants could speak to the macro (social and political) level factors, the sample sizes were too small to explore these factors in significant depth. These external factors related to government funding priorities, complexities of different clinician reimbursement models, public-private innovation policies, medical device statutory regulations, and procurement practices cannot be overlooked when trying to understand an organization’s initial decision to adopt a TM intervention.

Finally, the very nature of the central research question implies the likely presence of pro-innovation bias throughout this work. Although inconsistencies in the evidence suggest there is value in pursuing research questions about whether the use of HF TM intervention should be expanded, ambiguity in evidence will always exist and thus the questions posed in this thesis are valid given the abundance of studies showing the positive impact of HF TM.
Chapter 7
Conclusion

7 Conclusion

Heart failure directly impacts more than 1,000,000 Canadians [1, 2] representing a significant burden for patients and the Canadian healthcare system. Although TM is an intervention with a demonstrated ability to ease that burden by facilitating self-care for patients and decision support for clinicians, its spread as part of the standard of care across Canada has been lagging.

This research was designed to explain this slow adoption and implementation and to identify factors that, once understood, could inform the development of strategies of scale and spread. To that end, the central research question of this thesis was: What factors influence the successful implementation, scale, and spread of telemonitoring interventions for the management of heart failure? Addressing this central question was accomplished by characterizing the state of the evidence and exploring factors that influence implementation, and clinician and patient adoption of HF TM interventions. Finally, this research also sought to identify the core components of TM interventions that must be protected to ensure intervention fidelity and which components can be adapted to enable the sustainable embedding across multiple healthcare organizations.

This research found that both inconclusive evidence and barriers to clinician and patient use contribute to the slow adoption and implementation of HF TM intervention across Canada. Specifically, a literature review highlighted that inconsistent evidence exists due to important differences between studies related to characteristics of patient populations, TM interventions, and fidelity with which those interventions are implemented and used. This led to the enumeration of several questions that remain to be answered before more definitive evidence can be produced which will be able to (1) convince reluctant adopters of the value of HF TM, and (2) guide the design of interventions for stakeholders already willing to implement HF TM in their organizations.

In addition, factors for developing an optimized implementation strategy that will maximize intervention fidelity have been identified. Specifically, the implementation evaluation found that even when positive perceptions of a TM system exist, HF TM interventions are complex and generally carry extra costs related to human resources, equipment, and implementation activities.
As Chapter 5 highlights, opportunities exist to reduce these costs but the barrier of funding will always be present in a fiscally conservative single-payer health system where costs are unlikely to ever be passed onto patients. Importantly, this study found that strong facilitators related to the characteristics of a health organization and clinicians can be substantial enough to overcome these barriers of complexity and cost. However, because these facilitators are unlikely to exist in all health organizations, plans will need to be made to identify contextual barriers and mitigate them if HF TM interventions are to be adopted in diverse settings.

Although patient experiences are difficult to generalize, this research identified several relevant factors for the design of TM interventions that can augment patient fidelity of use. Importantly, benefits towards patients must exist for the duration of TM program enrollment and TM systems must be easy to use, with technical support easily accessible. In addition, long-term adherence to taking required TM readings is enhanced if patients can form a habit. Therefore, further design considerations aimed and fostering habit formation is required and should account for variability among patients’ daily lives. Finally, older patients maintained high levels of adherence throughout their enrollment which contrasted with patients in younger age groups who became progressively less adherent over time. This suggests that, although the health and usability needs of older patients must continue to be considered in the design of TM systems, the blanket assumption that older patients cannot use consumer health technologies is not a valid reason (on its own) for resisting the implementation of such interventions. These findings, along with work done to identify the core components of TM programs needed to ensure fidelity, enabled the development of an implementation strategy to guide the implementation of HF TM interventions.

Interpreting these findings alongside the notion that complex implementation initiatives are more likely to achieve success through mechanisms of spread suggests that stakeholders’ intent of seeing the wide adoption and implementation of HF TM should focus energies on forging relationships with candidate implementation sites and utilizing implementation strategies which place focus on adapting interventions to best fit local conditions. As such, this research has contributed to clarifying a path toward the wider adoption and implementation of HF TM such that it will be available to all Canadians with HF who can benefit.
References


114. Taylor J, Coates E, Wessels B, Mountain G, Hawley MS: **Implementing solutions to improve and expand telehealth adoption: participatory action research in four community healthcare settings.** *BMC Health Serv Res* 2015, **15**:529.

115. Boulos MNK, Wheeler S, Tavares C, Jones R: **How smartphones are changing the face of mobile and participatory healthcare: an overview, with example from eCAALYX.** *Biomed* 2011, **10**(1):24.


117. Athilingam P, Jenkins B: **Mobile Phone Apps to Support Heart Failure Self-Care Management: Integrative Review.** *JMIR Cardio* 2018, **2**(1):e10057.


119. Kim BYB, Lee J: **Smart Devices for Older Adults Managing Chronic Disease: A Scoping Review.** *JMIR mHealth and uHealth* 2017, **5**(5):e69.


Appendices
Appendix 1.  
Definition of the Consolidated Framework for Implementation Research Constructs


<table>
<thead>
<tr>
<th>Construct</th>
<th>Short Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I. INTERVENTION CHARACTERISTICS</strong></td>
<td></td>
</tr>
<tr>
<td>A Intervention Source</td>
<td>Perception of key stakeholders about whether the intervention is externally or internally developed.</td>
</tr>
<tr>
<td>B Evidence Strength &amp; Quality</td>
<td>Stakeholders’ perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.</td>
</tr>
<tr>
<td>C Relative Advantage</td>
<td>Stakeholders’ perception of the advantage of implementing the intervention versus an alternative solution.</td>
</tr>
<tr>
<td>D Adaptability</td>
<td>The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.</td>
</tr>
<tr>
<td>E Trialability</td>
<td>The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.</td>
</tr>
<tr>
<td>F Complexity</td>
<td>Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.</td>
</tr>
<tr>
<td>G Design Quality &amp; Packaging</td>
<td>Perceived excellence in how the intervention is bundled, presented, and assembled.</td>
</tr>
<tr>
<td>H Cost</td>
<td>Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.</td>
</tr>
</tbody>
</table>

| **II. OUTER SETTING**                   |                                                                                   |
| A Patient Needs & Resources             | The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization. |
| B Cosmopolitanism                       | The degree to which an organization is networked with other external organizations. |
| C Peer Pressure                         | Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge. |
| D External Policy & Incentives          | A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting. |

<p>| <strong>III. INNER SETTING</strong>                  |                                                                                   |
| A Structural Characteristics            | The social architecture, age, maturity, and size of an organization. |</p>
<table>
<thead>
<tr>
<th>Construct</th>
<th>Short Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>B Networks &amp; Communications</strong></td>
<td>The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.</td>
</tr>
<tr>
<td><strong>C Culture</strong></td>
<td>Norms, values, and basic assumptions of a given organization.</td>
</tr>
<tr>
<td><strong>D Implementation Climate</strong></td>
<td>The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.</td>
</tr>
<tr>
<td><strong>1 Tension for Change</strong></td>
<td>The degree to which stakeholders perceive the current situation as intolerable or needing change.</td>
</tr>
<tr>
<td><strong>2 Compatibility</strong></td>
<td>The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals’ own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.</td>
</tr>
<tr>
<td><strong>3 Relative Priority</strong></td>
<td>Individuals’ shared perception of the importance of the implementation within the organization.</td>
</tr>
<tr>
<td><strong>4 Organizational Incentives &amp; Rewards</strong></td>
<td>Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.</td>
</tr>
<tr>
<td><strong>5 Goals and Feedback</strong></td>
<td>The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.</td>
</tr>
<tr>
<td><strong>6 Learning Climate</strong></td>
<td>A climate in which: a) leaders express their own fallibility and need for team members’ assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.</td>
</tr>
<tr>
<td><strong>E Readiness for Implementation</strong></td>
<td>Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.</td>
</tr>
<tr>
<td><strong>1 Leadership Engagement</strong></td>
<td>Commitment, involvement, and accountability of leaders and managers with the implementation.</td>
</tr>
<tr>
<td><strong>2 Available Resources</strong></td>
<td>The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.</td>
</tr>
<tr>
<td><strong>3 Access to Knowledge &amp; Information</strong></td>
<td>Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.</td>
</tr>
</tbody>
</table>

**IV. CHARACTERISTICS OF INDIVIDUALS**

<table>
<thead>
<tr>
<th>Construct</th>
<th>Short Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A Knowledge &amp; Beliefs about the Intervention</strong></td>
<td>Individuals’ attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.</td>
</tr>
<tr>
<td><strong>B Self-efficacy</strong></td>
<td>Individual belief in their own capabilities to execute courses of action to achieve implementation goals.</td>
</tr>
<tr>
<td><strong>C Individual Stage of Change</strong></td>
<td>Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.</td>
</tr>
<tr>
<td><strong>D Individual Identification with Organization</strong></td>
<td>A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.</td>
</tr>
<tr>
<td><strong>E Other Personal Attributes</strong></td>
<td>A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.</td>
</tr>
<tr>
<td>Construct</td>
<td>Short Description</td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>V. PROCESS</strong></td>
<td></td>
</tr>
<tr>
<td>A Planning</td>
<td>The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.</td>
</tr>
<tr>
<td>B Engaging</td>
<td>Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.</td>
</tr>
<tr>
<td>1 Opinion Leaders</td>
<td>Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.</td>
</tr>
<tr>
<td>2 Formally Appointed</td>
<td>Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.</td>
</tr>
<tr>
<td>Internal Implementation</td>
<td></td>
</tr>
<tr>
<td>3 Champions</td>
<td>“Individuals who dedicate themselves to supporting, marketing, and ‘driving through’ and [implementation]” [101] (p. 182), overcoming indifference or resistance that the intervention may provoke in an organization.</td>
</tr>
<tr>
<td>4 External Change Agents</td>
<td>Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.</td>
</tr>
<tr>
<td>C Executing</td>
<td>Carrying out or accomplishing the implementation according to plan.</td>
</tr>
<tr>
<td>D Reflecting &amp; Evaluating</td>
<td>Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.</td>
</tr>
</tbody>
</table>
Appendix 2.
Implementation Evaluation 12-month Clinician Interview Guide

Note: Sub-points are intended as prompts for the interviewer and the questions in the interview guide were slightly modified when interviews were conducted with later adopting clinicians and other program staff.

- Please tell me about your experience with the Medly program.
  - How do you think the program is going? Why?
  - Do you believe it is meeting the expectations of those who conceived of and developed the program?
  - What have been the barriers and facilitators to its implementation?

- How well do you think the Medly program meets the needs of the patients being followed in the Heart Function Clinic?
  - What is the impact, positive or negative, of the Medly program on…
    - Ability to self-care
    - Number of hospitalizations
  - What feedback have you gotten from patients regarding their experiences with the Medly program?

- How well does the Medly program fit within existing work processes and practices in the Heart Function Clinic?
  - What kinds of changes (e.g., changes in workflow, or changes in clinician roles) have been needed to accommodate the Medly program?
  - Does the work you do in the context of the Medly program align with what is expected from you from your colleagues, superiors, or professional associations.
    - Do you feel supported in this work?

- Please describe the process that leads to a patient being enrolled in the Medly program?
  - What are the characteristics of the ideal candidate for Medly?
  - What barriers do patients face in participating in the Medly program?

- We have talked about the impact of Medly on patients. Now, from your perspective as a clinician, please tell me about the advantages and/or disadvantages of participating in Medly Program.
  - What impact has the Medly program had on…
    - Your productivity and workflows
    - Quality of care and decision-making
  - Has Medly the system or program changed the nature of the relationship with the patients being followed?
  - How does the Medly program compare to other interventions or services offered by the Heart Function clinic?
  - Without discussing a dollar amounts, please explain how you are remunerated for your work at the Heart Function clinic and whether that changed because of the Medly program?
Do you perceive any non-financial incentives for clinicians to participate in the program?

- Do you believe the Medly program in its current form is sustainable? Why?

- What factors external to the Heart Function Clinic influenced the implementation of the Medly program?
  - What kind of local, provincial, or national performance measures, policies, regulations, or guidelines influenced the implementation the Medly program?

- What costs were incurred to implement the Medly program?
  - Where is the funding of this program coming from?

- In general, please describe your level of satisfaction with the Medly system. By this I’m referring to the devices given to patients, the Medly Dashboard, as well as the services provided for the system.

- What is your perception of the quality of the Medly system?
  - Is it easy to use?
  - Is it reliable?

- I have no more questions. Is there anything else that you would like to add?
Appendix 3. Schedule and Definitions for Assessing CFIR and Proctor Constructs in the Clinician and Program Staff Interviews

<table>
<thead>
<tr>
<th>Construct</th>
<th>Definition*</th>
<th>BL</th>
<th>4m</th>
<th>12m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proctor et al.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptability</td>
<td>Perception that program is agreeable, palatable, or satisfactory</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Perceived fit relevance, or compatibility of the innovation or evidence based practice.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Fidelity</td>
<td>The degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers.</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Satisfaction</td>
<td>General satisfaction with the program and the implementation process</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>CFIR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>Source of intervention, evidence strength, relative advantage, adaptability, trialability, complexity, cost</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outer setting</td>
<td>Patient needs, external policy and incentives</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Inner setting</td>
<td>Networks &amp; communication, culture, tension for change, compatibility, relative priority, incentives, goals/feedback, leadership, resources</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Characteristics of individuals</td>
<td>Knowledge, beliefs, personal attributes</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process</td>
<td>Planning, engagement, execution, and evaluation of implementation plan</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>


Appendix 4.
Interview Questions for Patients

Note: Sub-points are intended as prompts for the interviewer.

**Interview questions for patient interviewed immediately after enrollment**

- What are your current habits when it comes to managing your heart failure and your heart failure symptoms?
  - How often do you take your weight and blood pressure, is this part of a routine?
  - What are your habits around taking your heart failure medications?

- Please describe your experience and your level of satisfaction with the Heart Function clinic.
  - Do you feel that you are receiving the care that you need?
  - How would you describe your relationship with your doctors and nurses at the Heart Function clinic?

- Have you had any previous experience using a telemonitoring system?
  - If yes - What was that experience like?
  - If no - What is your understanding of the purpose of a telemonitoring program?

- What were your initial thoughts when you first heard about the Medly program?

- Based on what you have seen and what we have told you, what are your expectations of the Medly program?
  - Do you expect it to be useful?
    - Will it help you manage your heart failure?
    - Will it help your doctors and nurses take better care of you?
  - What features do you think will be most useful?

- Based on what you have seen and what we have told you, do you think the Medly system will be easy to use?

- How did you feel about the training you just received?
  - Do you feel confident that you will be able to use the Medly system when you get home?
  - Is there something you feel is missing from the training or could be changed?

- How do you think you will react if you run into technical problems? What actions will you take?

- Is there anything that could happen, whether it is related to the technology or not, that would make you want to stop using Medly?

- I have no more questions. Is there anything else that you would like to add?
Interview questions for patient interviewed after experience in the Medly program

- Please tell me about your experience with Medly program so far.

- What are your current habits when it comes to managing your heart failure and your heart failure symptoms?
  - How often do you take your weight and blood pressure?
    - Is this part of a routine?
  - Please explain how you use the Medly system within your daily activities.
    - What times of day?
    - Do you often forget?
  - In what ways has the Medly program changed the way you manage your heart failure?
  - Have you ever received a telephone message reminding you to take your measures?
    - Did you appreciate that reminder or did you find it annoying?
  - Do you ever choose to not take your measure? Why?

- To what degree is the Medly program meeting your expectations?
  - What features do you find most useful? – why?
  - Are there any features that you do not use or dislike? – why?
  - Did you find that the alerts or messages you receive make sense based on your weight, blood pressure, and symptoms entered?
  - Has the system ever told you everything was ok when you felt that you weren’t?
    - If yes - What do you do when this happened?

- Have you had any previous experience using a telemonitoring system?
  - What was that experience like?
  - How does your experience with Medly compare?

- Was it easy to learn to use the Medly system?
  - What could have made it easier?
  - What is your opinion of the training you received?
  - Is there any equipment or are there any features of the Medly system that you find difficult to use?

- Have you had any problems with the equipment?
  - Please describe the issue.
  - What did you do to resolve it?

- How would you describe your relationship with your doctors and nurses at the Heart Function clinic?
  - Do you think Medly has changed your relationship with them? In what way?

- What do your family and friends think about you being part of the Medly program?
  - Are they encouraging?
  - Do they see the value it in?
If the patient is still part of the Medly program

- Do you intend to keep using the Medly system?
  - Have you wanted to decrease your use of it since starting? Why?
  - What motivates you to persist using it?

If the patient is being offboarded

- What was the reason for you stopping to use Medly?
  - Was it your decision or your doctor’s decision?
  - Did you use it for as long as you would have liked?

- I have no more questions. Is there anything else that you would like to add?
Appendix 5.
Patient and Clinician Interview Questions to Inform Adaptations of the Medly Program

<table>
<thead>
<tr>
<th>Topic</th>
<th>Patient questions</th>
<th>Clinician questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening question</td>
<td>• What are the characteristics of an ideal telemonitoring program?</td>
<td>• What are the characteristics of an ideal telemonitoring program?</td>
</tr>
</tbody>
</table>
| Peripheral devices        | • How would you feel about patients using their own personal smartphones instead of a phone being provided by the telemonitoring program?  
  o Do you like that the Medly app is on a separate phone or would you prefer it was on your own phone? Why?  
  o Would this change the way you use the system or incorporate it into your daily activities?  
• How would you feel about using your own weight scale and blood pressure cuff and then manually entering the numbers into the phone using your fingers?  
  o Would you pay extra to buy a Bluetooth-enabled weight scale or BP cuff? How much? |
| Clinician role            | • Please describe your experience being monitored and communicating by the nurses at the Heart Function clinic  
• Would you prefer if you were being monitored by another one of your doctors? For example, your family doctor or another specialist? |
| Duration of enrollment    | • How long do you think people with your condition should be enrolled in this kind of telemonitoring program? |
|                           |                                                                                     | • In your opinion, what type of health professional should be responsible for the day-to-day management of telemonitoring alerts?  
  o Does this require a change in the scope of practice?  
• What kind of healthcare organization is best suited for a heart failure telemonitoring program?  
• What is your opinion regarding the optimal duration for which a patient should be enrolled in a heart failure telemonitoring program?  
• From your experience, what are some of the reasons patients should be leave a heart failure telemonitoring program? |
<table>
<thead>
<tr>
<th>Topic</th>
<th>Patient questions</th>
<th>Clinician questions</th>
</tr>
</thead>
</table>
| Intensity of monitoring | • For a telemonitoring program to work, do you think there should be someone available to respond to alerts 24 hours a day, 7 days a week. Or, do you think a program like Medly could still work if doctors or nurses only respond during normal work hours? | • In your opinion, how responsive should clinicians be for a telemonitoring program to be effective?  
  ○ How frequently should clinicians be reviewing alerts throughout the day?  
  ○ How soon does a clinician need to respond?  
  ○ For the system to work, does it required 24/7 monitoring? |
Appendix 6.
Study Protocol: Implementation and Evaluation of a Smartphone-Based Telemonitoring Program for Patients with Heart Failure


Implementation and Evaluation of a Smartphone-Based Telemonitoring Program for Patients With Heart Failure: A Mixed-Methods Study Protocol

Abstract

Background: Meta-analyses of telemonitoring (TM) for patients with heart failure (HF) conclude that it can lower the utilization of health services and improve health outcomes compared with the standard of care. A smartphone-based TM program is being implemented as part of the standard of care at a specialty care clinic for patients with HF in Toronto, Canada.

Objective: The objectives of this study are to (1) evaluate the impact of the TM program on health service utilization, patient health outcomes, and their ability to self-care; (2) identify the contextual barriers and facilitators of implementation at the physician, clinic, and institutional level; (3) describe patient usage patterns to determine adherence and other behaviors in the TM program; and (4) evaluate the costs associated with implementation of the TM program from the perspective of the health care system (i.e., public payer), hospital, and patient.

Methods: The evaluation will use a mixed-methods approach. The quantitative component will include a pragmatic pre- and posttest study design for the impact and cost analyses, which will make use of clinical data and questionnaires administered to at least 108 patients at baseline and 6 months. Furthermore, outcome data will be collected at 1, 12, and 24 months to explore the longitudinal impact of the program. In addition, quantitative data related to implementation outcomes and patient usage patterns of the TM system will be reported. The qualitative component involves an embedded single case study design to identify the contextual factors that influenced the implementation. The implementation evaluation will be completed using semi-structured interviews with clinicians, and other program staff at baseline, 4 months, and 12 months after the program start date. Interviews conducted with patients will be triangulated with usage data to explain usage patterns and adherence to the system.

Results: The TM program was launched in August 2016 and patient enrollment is ongoing.

Conclusions: The methods described provide an example for conducting comprehensive evaluations of TM programs. The combination of impact, implementation, and cost evaluations will determine the quality improvement of the existing program and will yield insights into the
sustainability of smartphone-based TM programs for patients with HF within a specialty care setting.

**Introduction**

**Background**

Currently, one of the greatest challenges for health care systems worldwide is the growing fiscal and social burden of preventing and managing chronic diseases [1]. Heart failure (HF) is one of the most expensive chronic diseases, partly because 50% of patients with HF get readmitted within 1 year [2]. Evidence suggests approximately half of all readmissions are preventable and result from inadequate discharge teaching, nonadherence to medication, or failure to have early follow-up with a clinician [3].

There is mounting evidence that embedding self-care within existing health care services provides an effective model to meet these needs for a number of chronic diseases, including HF [4-7]. Although more traditional self-care interventions such as health coaching or patient education can be effective [8,9], their implementation often proves challenging [10,11]. Health information technology is one avenue that can support the delivery of self-care interventions. For example, telemonitoring (TM) is thought to be crucial to offer patients the right care at the right time [12] by allowing patients to collect clinical data at home, which is then transmitted via technology to be viewed and acted upon by a clinician at a distant location [13].

In HF, meta-analyses conclude that TM lowers the utilization of health services, improves HF health outcomes, and improves health-related quality of life (QoL) [14-20]. However, results vary widely between individual trials [21], and 2 of the largest studies, the Tele-HF [22] and BEAT-HF trials [23], reported null results. One problem is that results come from trials of varying quality, and there is often little discussion about the intervention itself or the degree to which the patients have adhered to it over the course of the study [24]. Furthermore, studies looking at the implementation of TM have identified technical, cost, organizational, and behavioral barriers, which may explain why these technologies are not yielding consistent positive outcomes [12,25]. In addition, this may explain why, despite some evidence of cost-effectiveness [26], there is still inconclusive evidence regarding the impact of TM in terms of its cost to patients with HF [26].

Although the ubiquity of mobile phones is believed to have the potential to make TM interventions more accessible and cost-effective [27,28], additional knowledge gaps exist in the emerging use of smartphones for TM of chronic diseases. Randomized controlled trials (RCTs) employing mobile phone–based TM interventions have been conducted and have shown similar positive results to those reported for more traditional TM [29,30]. However, this type of TM is novel, and therefore, there have been no comprehensive implementation studies on smartphone-based TM interventions completed to date.

**Implementation of a Smartphone-Based Telemonitoring Program**

**The Intervention**

An algorithm-based smartphone-based TM program for patients with HF, called the Medly Program, is being implemented as part of the standard of care at the University Health Network’s Ted Rogers Center of Excellence for Heart Function in Toronto, Canada (hereafter referred to as
the HF clinic). The objective of the Medly program is similar to other HF TM programs, which are used to improve patient self-management and decrease health care utilization [31]. Patients enrolled in the Medly program will receive a Medly kit that includes a smartphone (Samsung Galaxy Grand Prime) with a limited data plan and the Medly app already downloaded. In addition, patients receive a Bluetooth-enabled weight scale and blood pressure cuff. Patients are instructed to take daily weight and blood pressure readings using these devices and record their symptoms using the Medly app first thing in the morning. Automated self-care instructions are immediately displayed in the Medly app after these 3 parameters are processed by an algorithm that was developed in close consultation with HF clinicians. In addition, patients have access to graphs displaying historical trends for these parameters. To assist in compliance, patients receive an automated call on their primary phone line if they have not taken their readings before 10 AM. The Medly program is initially providing patients with all the equipment to mitigate the potential operational and software development challenges of offering the service on different devices during the critical early stages of implementation. However, a transition to a bring your own device model is planned, which would enable patients with smartphones to use their own devices by downloading the Medly app.

If there are signs of deteriorating health of a patient, the Medly algorithm generates an alert to a HF clinician who is part of the patient’s care team. The alerts are made available to clinicians in 2 formats. The first is through an automated email containing the latest weight, blood pressure, and symptoms along with the patient’s target ranges. In addition, the email contains the patients’ latest medication list and HF-related laboratory results, and contact information. Second, clinicians can choose to view the alerts by accessing a secure Web portal that presents a list of all the alerts triggered. Here, clinicians can review details of the latest alert and graphs showing historical weight, blood pressure, symptoms, and HF-specific laboratory results, which are visually contextualized according to the patient’s target ranges. The clinician will follow-up with the patient depending on the clinical need, documenting all actions and decisions taken in response to the alert in the hospital EMR.

The Medly program is intended to be delivered as part of the standard of care; as such, the goal is for it to be seamlessly integrated within the existing workflows of the HF clinic. Before deployment, a service blueprint was created through ethnographic methods including observation and informal interviews with clinicians and support staff in the HF clinic. This helped identify areas where the processes of the Medly program could be incorporated. In addition, an RCT of 100 patients with an embedded qualitative component was previously conducted in the HF clinic with an earlier version of the Medly system. This study concluded that patients receiving the intervention experienced improvements in QoL and self-care maintenance compared with a control group [30]. Lessons learned from this RCT helped justify the decision to implement the Medly program as part of the standard of care and informed the program’s implementation strategy. The current program offers an opportunity to evaluate the implementation and effectiveness of Medly under real-world conditions.

**User Training and Support**

Training as to how to use the Medly app and associated devices is provided to patients at the time of enrollment into the Medly program by a telehealth analyst. Clinicians monitoring patients through the Medly system participated in a formal training session approximately 1 month before program deployment. Both patients and clinicians are provided with a user manual to supplement
the in-person training along with contact information of the telehealth analyst who offers technical support during normal business hours.

**Evaluation Objectives and Research Questions**

**Objective 1**
The first objective is to evaluate the impact of the *Medly* program on health service utilization, patient health outcomes, and their ability to self-care. Alerts sent to patients and clinicians will help identify periods of symptom exacerbation and volume overload. The impact of this is expected to permit earlier intervention for worsening conditions, thus avoiding trips to the emergency department (ED) and hospitalizations. For patients who are enrolled into the *Medly* program, on hospital discharge, the program is expected to reduce 30-day readmission rates. In addition, participation in the *Medly* program is expected to improve patients’ ability to self-care, leading to improved clinical outcomes and QoL.

**Objective 2**
The second objective is to evaluate the degree to which the *Medly* program was implemented as intended and to identify the contextual barriers and facilitators of implementation. This objective will answer the following questions:
- To what extent did the HF clinic implement the *Medly* program as intended?
- What contextual factors influence the implementation of the *Medly* program?
- What adaptations were needed to implement and sustain the program within existing clinical workflows?

**Objective 3**
The third objective is to describe patient usage patterns to determine adherence and other behaviors in the *Medly* program. This objective will answer the following questions:
- To what degree do patients adhere to the *Medly* program and how do adherence patterns change over time?
- What factors influence patient adherence?

**Objective 4**
The fourth objective is to evaluate the costs associated with the implementation of the TM program from the perspective of the health care system (i.e., public payer), the hospital, and patients.

**Methods**

**Overview of the Study Design and Evaluation Framework**
Data for the 4 objectives will be collected using mixed-methods. This approach will include a multiple pre-and posttest design for the evaluation of patient-level impacts, patient adherence, and cost. Quantitative data will include data collected as part of the standard of care (including health care utilization data and laboratory results obtained using a chart review) and usage data from the TM system. Additional patient-level data will be collected using questionnaires at baseline, 1 month, 6 months, 12 months, and 24 months. The qualitative component will take the form of an embedded single case study [32]. The 2 embedded subunits of analysis include clinicians and patients, as it relates to their adoption and use of the *Medly* system. The case is defined as the *Medly* program at the HF clinic for the duration of 1 year starting from the program’s launch date (August 23, 2016). Qualitative methods, including semistructured
interviews and document reviews, will be used to gain insights regarding patient self-care practices (objective 1), the barriers and facilitators to program implementation (objective 2), and explanations for patient adherence and usage of the system (objective 3).

**Study Participants**
Representatives from all stakeholder groups involved in the implementation of the Medly Program will be recruited for participation.

**Patients**
Patients can be enrolled into the Medly program provided they (1) are 18 years or older, (2) have been diagnosed with HF and are followed by a cardiologist at the HF clinic, (3) can speak and read English (or have an informal caregiver who does) to adequately understand the text prompts in the Medly app, and (4) are able to comply with using Medly (e.g., able to stand on the weight scale, able to answer symptom questions). As the Medly program is being implemented as part of the standard of care, there is no explicit exclusion criteria for participating in the program and its evaluation. The duration of program participation will be decided by patients and their treating cardiologist on an individual basis.

Upon enrollment into the Medly program, patients will be presented with the option of answering questionnaires and participating in interviews related to the program evaluation. Patients will be asked to sign a written consent form before participating in the evaluation.

**Program Staff**
All members of the Medly program staff will be asked to participate in semistructured interviews. These include clinicians providing care for patients with HF in the HF clinic (n=7), telehealth analyst (n=1), project manager (n=1), and members of the implementation team (n=2). These individuals will be asked to sign a consent form before their first interview.

**Data Collection and Analysis**

**Objective 1—Measuring the Impact of the Medly Program**

**Impact Indicators**
The primary outcome for evaluating the impact of the Medly program is the number of hospitalizations because of HF in the 6 months before versus the 6 months after enrollment. Secondary impact outcomes comparing 6-month to baseline values are described below.

**Health Service Utilization**
The number of hospitalizations (all-cause), 30-day readmission rate, days in hospital (HF and all-cause), number of ED visits (HF and all-cause), visits to family doctor (HF and all-cause), number of HF-related outpatient visits, and changes to medication will be recorded.

**Left Ventricular Fraction and Laboratory Tests**
The following HF-specific clinical parameters will be collected: left ventricular ejection fraction (LVEF), brain natriuretic peptide (BNP), creatinine, sodium, potassium, hemoglobin, and uric acid levels.

**Mortality and Prediction of Survival**
Patient mortality will be tracked. In addition, the Seattle Heart Failure Model (SHFM) will be calculated at program entry. Projected SHFM survival versus actual survival will be compared
The calculation of this score requires data on age, gender, New York Heart Association (NYHA) classification, weight, LVEF, systolic blood pressure, list of medications (including diuretics), laboratory results (hemoglobin, lymphocytes, uric acid, total cholesterol, and sodium), and QRS interval.

Dyspnea
Patients will be asked to describe their level of breathlessness using a visual analogue scale for dyspnea on a scale ranging from 0 (no shortness of breath) to 10 (shortness of breath is the worst it can be).

Quality of Life
The EQ-5D-5L is a measure of generic health status and will be administered to all patients as a measure of QoL [34,35]. This 5-item instrument has undergone validity and reliability testing for several conditions including HF. Due to the generic nature of this measure, it is recommended that it be administered along with supplementary measurements to capture more disease-specific aspects related to QoL. Hence, the Minnesota Living with Heart Failure Questionnaire (MLHFQ) will also be administered. The questionnaire contains 21 items scored on a 5-point Likert scale, the responses of which are summed to produce a total score and subscores for the domains of physical and emotional QoL. The MLHFQ is widely used in studies involving HF-related QoL and has been shown to have a high level of reliability and validity [36].

Self-Care
The self-care of HF index asks respondents to respond to 22 items on a 4-point Likert scale to assess their ability to self-care across 3 subscales (maintenance, management, and confidence). The tool has undergone validity and reliability testing involving patients with HF [37].

Demographic Variables
Demographic information will also be collected using a questionnaire, which includes the following: age, sex, income, native language, living arrangements (living alone, with a partner, or other), whether or not they have a caregiver (formal or informal), and type of living areas (e.g., urban, suburban, or rural). In addition, patient comorbidities will be tracked. Finally, questions will be asked to assess the patient’s experience and comfort level with technology and smartphones, including frequency of use.

Data Acquisition
Data collection will occur at baseline, 1 month, 6 months, 12 months, and 24 months, or until the patient exits the program. Data collected in addition to the primary evaluation period (baseline to 6 months) will provide an opportunity for post-hoc analyses aimed at quality improvement, including recommended duration of use. For example, the 1-month time point was included to determine if the bulk of changes to self-care and QoL occur immediately after enrollment. Similarly, longitudinal data will help determine whether patient-level impacts are sustained or change when using the system long term.

Health service utilization, laboratory results, mortality, prediction of survival, and select demographic information will be obtained from the hospital EMR. In addition, health service utilization information will be verified by patient participants through self-reports via a questionnaire.
Baseline and follow-up questionnaires containing the validated survey tools listed in Table 1 will be distributed to patients during regularly scheduled visits. Upon study enrollment, patients will be asked whether they prefer to be mailed the questionnaire or completing it using an online survey tool (SurveyMonkey [38]) in the event that they do not have a clinic visit scheduled for the data collection time point. In these situations, the questionnaires will be sent to the patient according to the preferred format and they will be given 2 weeks to respond, after which a member of the evaluation team will call the patient to remind them to complete the questionnaire.

Table 1. Timing of outcome assessments for the impact evaluation.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Measure</th>
<th>BL&lt;sup&gt;a&lt;/sup&gt;</th>
<th>1M&lt;sup&gt;b&lt;/sup&gt;</th>
<th>6M</th>
<th>12M</th>
<th>24M</th>
<th>Exit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health service utilization</td>
<td>30-day readmission</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of hospitalizations</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of days in hospital</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of ED&lt;sup&gt;d&lt;/sup&gt; visits</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of HF&lt;sup&gt;e&lt;/sup&gt;-related outpatient visits</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of visits to family doctors</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Clinical outcomes</td>
<td>LVEF&lt;sup&gt;f&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood work: BNP&lt;sup&gt;g&lt;/sup&gt;, creatinine, sodium, potassium, hemoglobin, and uric acid</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>VAS&lt;sup&gt;h&lt;/sup&gt; for dyspnea</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SHFM&lt;sup&gt;i&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-care</td>
<td>SCHFI&lt;sup&gt;j&lt;/sup&gt; [37]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Quality of life</td>
<td>EQ-5D-5L [34,35]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MLHFQ&lt;sup&gt;k&lt;/sup&gt; [36]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>BL: baseline.  
<sup>b</sup>X: data is collected at this time point.  
<sup>c</sup>M: months.  
<sup>d</sup>ED: emergency department.  
<sup>e</sup>HF: heart failure.  
<sup>f</sup>LVEF: left ventricular ejection fraction.  
<sup>g</sup>BNP: brain natriuretic peptide.
Planned Analyses
The primary analyses will be paired Student $t$ tests and Wilcoxon signed rank tests comparing baseline and 6-month values for all patient-level outcomes. For patients enrolled in the Medly program, on hospital discharge, the 30-day readmission rate will be compared with the readmission rate before the launch of the Medly program, as determined using hospital administrative data. Secondary analyses aimed at determining the longitudinal impact of the Medly program (i.e., using outcome data from the additional time points), and the correlation of independent variables (e.g., patient characteristics and adherence rates) with outcomes will be analyzed using general linear mixed model procedures. In addition, descriptive statistics will be produced for all variables collected, which may inform necessary subgroup analyses. All statistical analyses will be performed using the statistical software application SPSS (IBM Corporation, USA) [39].

Power Consideration
We will aim to recruit at least 108 patients into the Medly program at the HF clinic before analyses of patient-level outcomes are undertaken. This number is based on being able to detect a small effect size ($\text{Cohen } d=0.3$) in the number of hospitalizations because of HF within the first 6 months of enrollment with 80% power and an alpha of .05 (two-sided) [40]. This number considers that approximately 20% of patients will be “lost to follow-up,” which includes patient mortality and those who withdraw from the program before the 6-month time point. We anticipate recruiting this number in the first 18 months of the program.

Objective 2—Implementation Evaluation
The mixed-methods implementation evaluation will be guided by the framework by Proctor et al, which describes outcomes that can serve as indicators of implementation success [41], and the Consolidated Framework for Implementation Research (CFIR). The CFIR describes factors influencing implementation success according to 5 domains: (1) intervention characteristics, (2) outer setting, (3) inner setting, (4) characteristics of individuals, and (5) process [42].

Implementation Outcome Indicators
Implementation outcomes are defined by Proctor et al as “the effects of deliberate and purposive actions to implement new treatments, practice, and services” [41]. A total of 5 implementation outcomes were selected as quantitative indicators and are presented in Table 2. These data will be obtained from the hospital’s EMR, the Medly system’s audit trails, and technical support logs.
<table>
<thead>
<tr>
<th>Implementation outcome</th>
<th>Definitions&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adoption</td>
<td>The intention, initial decision, or action to try or employ an innovation or evidence-based practice. Adoption may also be referred to as “uptake”</td>
<td>Number of clinicians having decided to use Medly to monitor patients</td>
</tr>
<tr>
<td>Implementation cost</td>
<td>The cost impact of the implementation effort</td>
<td>See objective 4 for cost outcomes associated with implementation of the Medly program</td>
</tr>
<tr>
<td>Feasibility</td>
<td>The extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting</td>
<td>Number of patients enrolled</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rate of patient enrollment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Number of patient-initiated dropouts from the program</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Number of physician-initiated dropouts from the program—or no uptake</td>
</tr>
<tr>
<td>Fidelity</td>
<td>The degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers</td>
<td>Number and nature of calls or emails made to the telehealth analyst</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of the number of alerts acknowledged over the total number of alerts</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of the number of phone calls to patients over the total number of alerts triggered</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion of the number of false or inappropriate alerts over the total alerts triggered</td>
</tr>
<tr>
<td>Penetration</td>
<td>The integration of a practice within a service setting and its subsystems</td>
<td>Percentage of clinicians using Medly over the total number of potential clinician users in the HF clinic</td>
</tr>
</tbody>
</table>

<sup>a</sup>Definitions are based on the definitions provided by Proctor et al [41].

Semistructured Interviews With Program Staff
Separate semistructured interview guides based on the constructs in the CFIR will be formulated for each category of program staff previously outlined. Interviews will be conducted at baseline,
4 months, and 12 months to align with the different phases of Stetler et al’s typology of formative evaluations [43]. The interviews are expected to last approximately 30 min and will be conducted at a location convenient to the participants. All interviews will be audiotaped for later transcription and analysis.

Planned Analyses
Descriptive statistics will be produced for the indicators of the implementation outcome to provide an objective measure of implementation success.

Furthermore, 2 independent researchers will analyze interview transcripts and documents using the Framework Method of qualitative analysis [44]. An initial round of coding will use a deductive approach by looking for themes that match the constructs in the CFIR. A second round of coding will be inductive using an open coding approach, which will involve researchers looking for unexpected themes that are not represented in the guiding CFIR framework. Throughout the analysis, both reviewers will discuss the themes and codes from their independent analyses to come up with a single analytical framework. This finalized framework will be applied in a final coding of all transcriptions using NVivo (QSR International, Doncaster, Victoria, Australia) [45].

Quantitative and qualitative data will be triangulated such that the interview data will help explain success or failure of the implementation.

Objective 3—Describing Patient Adherence and Usage Patterns
A concurrent parallel mixed-methods approach [46] will be used consisting of a quantitative measurement of patient adherence and semistructured interviews with patients at 4 time points.

Patient Adherence
Adherence will be assessed by analyzing patient usage rates of the Medly system—specifically, the proportion of days for which the patient took a complete reading (weight, blood pressure, and symptoms) over the previous 30 days. Usage data will be obtained and exported on a regular basis through Google Analytics [47].

Semistructured Interviews
A sample of patients enrolled in the Medly program will participate in semistructured interviews aimed at understanding reasons for adherence or nonadherence and their general experiences with the Medly program. Interview guides will be formulated based on the constructs of the Unified Theory of Acceptance and Use of Technology 2 [48]. For example, we will explore how patients’ expectations, ease of use of the intervention, facilitating conditions (e.g., quality of technical support services), and the direct or indirect influence of clinicians and loved ones could explain levels of uptake, adherence, and use. Unlike adherence, which will be calculated for all patients enrolled in the Medly program, interviews will be conducted until information saturation is reached using maximum variation sampling [49] based on age, sex, experience with technology, health status, time since enrollment, and level of adherence. As recommended by Francis et al for theory-based interview studies, an a priori target of 10 patients is being set as the initial analysis sample [50]; however, interviews will continue until no new themes emerge [50]. For patients who withdraw from the Medly program before the end of the evaluation period, reasons for this withdrawal will be documented as part of standardized off-boarding procedures.
and a sample will be asked to participate in an interview. The interviews are expected to last 20 to 30 min and will be conducted in a quiet and private space within the clinic (e.g., consultation room) during a regular clinic visit or over the telephone. All interviews will be audiotaped and transcribed for later analysis.

Planned Analyses
Monthly adherence rates will be examined using descriptive statistics to identify any patterns in the increase or decrease of patient adherence to Medly over time. In addition, general linear mixed model procedures will be performed to determine if any baseline patient characteristics (e.g., age, sex, and HF severity) or time since program enrollment predicts patient adherence to the Medly system. Semistructured interviews will be analyzed using the Framework Method [44], as previously described.

Objective 4—Cost Impact of Implementing the Medly Program
The costs associated with implementing the Medly program will be determined from the perspectives of the public payer, hospital, and patient. In reporting these results, costs will be interpreted in relation to the patient-level impacts determined in objective 1.

Data Acquisition
Costs will be calculated using a 6-month time frame. Specifically, we will compare costs before the implementation of the Medly program (assessed at baseline) versus the costs after enrollment of patients into the program (measured at 6 months). This time frame was chosen because it represents the time horizon over which most of the health effects and costs of using the Medly Program are expected. Most of the cost variables will be self-reported by patients and triangulated using administrative data whenever possible (e.g., EMR data). Therefore, questions related to the cost will be added to the patient outcome questionnaires (objective 1) and will be administered at baseline and 6 months.

Public Payer Perspective
Costs to the public payer will be determined by looking at health care utilization of patients enrolled in the Medly program before versus after their enrollment. These will include hospitalizations, ED visits, HF clinic visits, family physician visits, and use of home care services. In addition, costs for inpatient medications will be considered.

Hospital Perspective
Costs from the hospital perspective will be valued based on time spent by human resources involved in the Medly program. This time will be converted to costs based on those individuals’ respective salaries. This will include time the clinicians spent reviewing and responding to Medly alerts as well as time the clinicians spend in training sessions, learning to use the system, and seeking technical support. In addition, costs for the hospital perspective will include equipment costs (Medly kit, smartphone data plan, and server) and the salary for employing a telehealth analyst responsible for recruiting, training, onboarding, managing inventory support, and providing training.

Patient Perspective
Costs for patients will primarily be determined by the time they spend accessing care for HF. This will involve determining their employment status and annual income as well as time they
spend traveling to and from appointments, time spent at appointments, and how much work time was missed because of their HF condition (vacation or unpaid). In addition, this will include the time patients spent learning to use the Medly system, time spent using the system, and time getting technical support. Additional costs considered include travel, parking, and all other out-of-pocket costs related to accessing care or using the intervention. Moreover, time of informal caregivers (e.g., friend or family member who helps the patient to manage their HF) will be valued as part of the patient perspective. Costs for informal caregivers will be based on the average hourly rate of personal support workers.

**Results**
The Medly program was launched in August 2016. As of April 4, 2018, 166 patients have been enrolled. The primary impact analysis is expected to be conducted by January 2019.

**Discussion**
This study aims to evaluate the implementation and impact of a smartphone-based TM program being implemented as part of the standard of care in a specialty care setting in a large Canadian city.

**Limitations**
Unlike TM systems evaluated in the context of academic research, the lack of strict patient inclusion and inclusion criteria for the Medly program has the potential to lead to heterogeneity among evaluation participants, which will make it difficult to generalize the results to other health care settings. Another important limitation is that the nature of this evaluation and the availability of data do not allow for a distinct comparator group. Without discounting these limitations, we believe that one of the strengths of this evaluation is its pragmatic nature and that these threats to internal and external validity will be mitigated through a detailed description of the context and participants when results are reported. The interpretation of the Medly program evaluation results will include comparisons with previous TM RCTs conducted within the HF clinic [30] and other comparable settings, as well as other RCTs evaluating interventions designed to promote self-care through education and health coaching conducted within the HF clinic [51]. This is possible because of the selection of outcome metrics common in other TM studies.

**Conclusions**
Unlike other TM studies that focus primarily on quantitative outcomes, this evaluation will also examine the context and mechanisms that lead to them. Therefore, this pragmatic mixed-methods study will allow for an interpretation of results using realist evaluation principles [52]. The information gathered during this evaluation will inform if, and how, a smartphone-based TM system improves the self-care capacities, clinical management, and health outcomes of patients with HF. This evaluation will lead to quality improvement of the current program and provide evidence that will inform the implementation and sustainability of other TM programs.

**References**


24. Mattera JA. Patients' Adoption and Adherence to a Heart Failure Telemonitoring Intervention. Boston: Boston University; 2011.


Appendix 7.
Domains and Questions in the Nonadoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) Framework


<table>
<thead>
<tr>
<th>Domain/question</th>
<th>Simple</th>
<th>Complicated</th>
<th>Complex</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domain 1: The condition or illness</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1A. What is the nature of the condition or illness?</td>
<td>Well-characterized, well-understood, predictable</td>
<td>Not fully characterized, understood, or predictable</td>
<td>Poorly characterized, poorly understood, unpredictable, or high risk</td>
</tr>
<tr>
<td>1B. What are the relevant sociocultural factors and comorbidities?</td>
<td>Unlikely to affect care significantly</td>
<td>Must be factored into care plan and service model</td>
<td>Pose significant challenges to care planning and service provision</td>
</tr>
<tr>
<td><strong>Domain 2: The technology</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2A. What are the key features of the technology?</td>
<td>Off-the-shelf or already installed, freestanding, dependable</td>
<td>Not yet developed or fully interoperable; not 100% dependable</td>
<td>Requires close embedding in complex technical systems; significant dependability issues</td>
</tr>
<tr>
<td>2B. What kind of knowledge does the technology bring into play?</td>
<td>Directly and transparently measures [changes in] the condition</td>
<td>Partially and indirectly measures [changes in] the condition</td>
<td>Link between data generated and [changes in] the condition is currently unpredictable or contested</td>
</tr>
<tr>
<td>2C. What knowledge and/or support is required to use the technology?</td>
<td>None or a simple set of instructions</td>
<td>Detailed instruction and training needed, perhaps with ongoing helpdesk support</td>
<td>Effective use of technology requires advanced training and/or support to adjust to new identity or organizational role</td>
</tr>
<tr>
<td>2D. What is the technology supply model?</td>
<td>Generic, “plug and play,” or COTS® solutions</td>
<td>COTS solutions requiring significant customization</td>
<td>Solutions requiring significant organizational</td>
</tr>
<tr>
<td>Domain/question</td>
<td>Simple</td>
<td>Complicated</td>
<td>Complex</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>requiring minimal customization; easily substitutable if supplier</td>
<td>or bespoke solutions; substitution difficult if supplier</td>
<td>reconfiguration or medium- to large scale-bespoke solutions; highly</td>
</tr>
<tr>
<td></td>
<td>withdraws</td>
<td>withdraws</td>
<td>vulnerable to supplier withdrawal</td>
</tr>
<tr>
<td></td>
<td><strong>Domain 3: The value proposition</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3A. What is the developer’s business case for the technology (supply-side value)?</td>
<td>Clear business case with strong chance of return on investment</td>
<td>Business case underdeveloped; potential risk to investors</td>
<td>Business case implausible; significant risk to investors</td>
</tr>
<tr>
<td></td>
<td><strong>Domain 4: The adopter system</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4A. What changes in staff roles, practices, and identities are implied?</td>
<td>None</td>
<td>Existing staff must learn new skills and/or new staff be appointed</td>
<td>Threat to professional identity, values, or scope of practice; risk of job loss</td>
</tr>
<tr>
<td></td>
<td><strong>Domain 5: The organization</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5A. What is the organization’s capacity to innovate?</td>
<td>Well-led organization with slack resources and good managerial relations; risk taking encouraged</td>
<td>Limited slack resources; suboptimal leadership and managerial relations; risk taking not encouraged</td>
<td>Severe resource pressures (e.g., frozen posts); weak leadership and managerial relations; risk taking may be punished</td>
</tr>
<tr>
<td>5B. How ready is the organization for this technology-supported change?</td>
<td>High tension for change, good innovation-system fit, widespread support</td>
<td>Little tension for change; moderate innovation-system fit; some powerful opponents</td>
<td>No tension for change; poor innovation-system fit; many opponents, some with wrecking power</td>
</tr>
<tr>
<td>5C. How easy will the adoption and funding decision be?</td>
<td>Single organization with sufficient resources; anticipated cost savings;</td>
<td>Multiple organizations with partnership relationship; cost-benefit balance favorable or</td>
<td>Multiple organizations with no formal links and/or conflicting agendas; funding depends</td>
</tr>
<tr>
<td>Domain/question</td>
<td>Simple</td>
<td>Complicated</td>
<td>Complex</td>
</tr>
<tr>
<td>----------------</td>
<td>--------</td>
<td>-------------</td>
<td>---------</td>
</tr>
<tr>
<td>5D. What changes will be needed in team interactions and routines?</td>
<td>No new team routines or care pathways needed</td>
<td>New team routines or care pathways that align readily with established ones</td>
<td>New team routines or care pathways that conflict with established ones</td>
</tr>
<tr>
<td>5E. What work is involved in implementation and who will do it?</td>
<td>Established shared vision; few simple tasks, uncontested and easily monitored</td>
<td>Some work needed to build shared vision, engage staff, enact new practices, and monitor impact</td>
<td>Significant work needed to build shared vision, engage staff, enact new practices, and monitor impact</td>
</tr>
</tbody>
</table>

**Domain 6: The wider context**

| 6A. What is the political, economic, regulatory, professional (e.g., medicolegal), and sociocultural context for program rollout? | Financial and regulatory requirements already in place nationally; professional bodies and civil society supportive | Financial and regulatory requirements being negotiated nationally; professional and lay stakeholders not yet committed | Financial and regulatory requirements raise tricky legal or other challenges; professional bodies and lay stakeholders unsupportive or opposed |

**Domain 7: Embedding and adaptation over time**

| 7A. How much scope is there for adapting and coevolving the technology and the service over time? | Strong scope for adapting and embedding the technology as local need or context changes | Potential for adapting and coevolving the technology and service is limited or uncertain | Significant barriers to further adaptation and/or coevolution of the technology or service |
| 7B. How resilient is the organization to handling critical events and adapting to unforeseen eventualities? | Sense making, collective reflection, and adaptive action are ongoing and encouraged | Sense making, collective reflection, and adaptive action are difficult and viewed as low priority | Sense making, collective reflection, and adaptive action are discouraged in a rigid, inflexible implementation model |

*COTS: customizable, off-the-shelf.*
Appendix 8.
Medly Program Logic Model
Appendix 9.
Table of Content for the Generic Standard Operating Procedures of the Medly Program

Table of Contents

1. Introduction .................................................................................................................. 2
   1.1 Purpose of the Standard Operating Procedures .................................................... 2
   1.2 Overview of Program Roles ................................................................................... 2

2. Onboarding .................................................................................................................. 3
   2.1 Determine Program Appropriateness .................................................................... 3
   2.2 Review Patient and Clinician Responsibilities ...................................................... 3
   2.3 Onboarding Form .................................................................................................. 3
   2.5 Training Patients .................................................................................................. 3
   2.6 Enroll in BE study (if applicable) .......................................................................... 4
   2.7 Patient Accounts in Dashboard .......................................................................... 5

3. Day-to-Day Clinical Support ...................................................................................... 6
   3.1 Clinical Triage (ongoing) ..................................................................................... 6
   3.2 Addressing Alerts ................................................................................................. 6
   3.4 Mitigating Non-Compliance ................................................................................ 7

4. Day-to-Day Technical Support .................................................................................... 8
   4.1 Basic Troubleshooting .......................................................................................... 8
   4.2 Monitoring of the Medly System ........................................................................ 8
   4.4 Maintain and Manage Inventory ......................................................................... 8
   4.4 Tier 2 Technical Support ...................................................................................... 8
   4.5 Tier 3 Technical Support ...................................................................................... 8

5. Day-to-Day Program Management ............................................................................ 9
   5.1 Monitor Ongoing Program Operations .................................................................. 9
   5.2 Quality Improvement ......................................................................................... 9
   5.3 Ongoing Benefits Evaluation ............................................................................. 9
   5.4 Push Application Updates ................................................................................. 9

6. Offboarding Patients .................................................................................................. 10
   6.1 Exit Time ............................................................................................................. 10
   6.2 Collection of Equipment ..................................................................................... 10
   6.3 Recycling Kits and Devices ................................................................................ 10
   6.4 Archiving Dashboard Account and Labs ............................................................ 10

Appendix 1: Inventory of Supporting Artifacts ............................................................... 11