Original Paper

Evaluating the Implementation of a Smartphone-Based Telemonitoring Program: A Longitudinal Study Guided by the Consolidated Framework for Implementation Research

Abstract

**Background:** Telemonitoring (TM) has shown promise for alleviating the burden of heart failure on individuals and health systems. However, real-world implementation of sustained programs is rare.

**Objective:** The objective of this study is to evaluate the implementation of a smartphone-based TM program which has been implemented as part of standard care in a specialty heart function clinic.

**Methods:** A longitudinal single case study was employed. Implementation success was evaluated using 4 implementation outcomes: adoption, penetration, feasibility, and fidelity. Semi-structured interviews based on the Consolidated Framework for Implementation Research (CFIR) were conducted at 0, 4, and 12 months with 12 program staff to identify the barriers and facilitators of implementation.

**Results:** One year after implementation, 98 patients and 8 clinicians were enrolled in the Program. Despite minor technical issues, the intervention was used as intended. Qualitative data were obtained from clinicians (N=8) and implementation staff (N=4) for 24 CFIR constructs. Thirteen constructs were strong facilitators clustered in the CFIR domains of: **inner setting** (networks and communication, culture, tension for change, relative priority, learning climate, available resources), **characteristics of individuals** (knowledge and beliefs about the intervention and self-efficacy) and **process** (engaging, reflecting and evaluating). Other notable facilitators were identified from the **characteristics of the intervention** domain (relative advantage and adaptability) and the **outer setting** (patient needs and resources). Four constructs were perceived as minor barriers: complexity of the intervention, cost, and inadequate communication among high level stakeholders, and the absence of a formal implementation plan. The remaining CFIR constructs had a neutral impact on the overall implementation.

**Conclusions:** This is the first comprehensive evaluation of the implementation of a smartphone-based TM program. By identifying what works and does not in a real-world clinical context using a framework-guided approach, these results may inform the design of technologies, services, and implementation strategies of similar TM interventions.

**Keywords:** health failure; telemedicine; diffusion of innovation

**Introduction**

Heart failure TM systems are developed with the objective of reducing mortality and hospitalizations, and improving patient quality of life (QoL) [1]. However, despite patient acceptance [2-4], the diffusion of these services is lagging [5]. Meta-analyses tend to support claims of the positive impacts on heart failure outcomes [1, 6-9] but important inconsistencies in the evidence still exist [10]. Inconsistencies are believed to result from the heterogeneity of the intervention and patient populations used in primary studies and lack of consistency with which
Interventions are used (ie, fidelity) in clinical trials [10]. Much remains to be learned on how to best implement TM interventions such that true effectiveness can be measured and their benefits fully realized.

Systematic reviews present extensive lists of various barriers and facilitators to the implementation of TM [11-13]. External barriers include the lack of a clear business model in single payer health systems [14] and a lack of acceptable reimbursement methods for clinician users [15]. Further, 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 [11-13]. 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 whole of the implementation period. In addition, few studies report on quantitative outcomes to justify judgments of implementation success or failure.

A smartphone-based TM program Medly was implemented as part of the standard of care at a specialty heart function (HF) clinic in Toronto, Canada. This program features a system that has previously demonstrated improvements in clinical outcomes, patient self-care, and QoL [16]. 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? (2) What were the barriers and facilitators to implementing the Medly Program?

**Methods**

**Study Design**

This study employed a longitudinal single case study design. The case was defined as the 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 are the HF clinic and program staff. The patient perspective, including reasons for use, adherence, and withdrawal will feature in an upcoming publication.

**Intervention**

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

**Medly Technology**

The patient-facing technology includes the Medly smartphone app which works by allowing heart failure patients to record 3 parameters: 1) weight, 2) blood pressure, and 3) symptoms. Based on these data inputs by the patient 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 which are automatically relayed to a clinician when there are signs of clinically significant health status deterioration. Patients are instructed to take the three parameters daily and will receive an automated phone call if they have not done so before 10am. 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 smartphone with a data plan, a Bluetooth-enabled weight scale, and a Bluetooth-enabled blood pressure monitor.
The clinician-facing technology seeks to support management of the patient alerts. This is primarily through a web-based interface (ie, the Dashboard) containing a list of patient alerts, graphs showing patient-level trends of the 3 clinical parameters monitored, and heart failure-specific lab results. Clinicians also have the option of receiving alerts through automated emails, which contain the latest weight, blood pressure, and symptoms. The email also contains the patients’ current medication list, heart failure-related laboratory results, and contact information.

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

**Implementation Site**
The Ted Rogers Centre of Excellence for Heart Function (HF clinic), part of the University Health Network (UHN), is a high-volume specialty care clinic for patients with heart failure in Toronto. The intervention was developed by UHN’s Centre for Global eHealth Innovation (eHI) in close collaboration with the 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 all physically located in the same building.

**Implementation Strategy**
Preparations for the program launch included development of training materials for patients (user manual and training checklist). Clinician users were also provided a user guide and a training session lasting approximately one hour. In addition, 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 disruption to existing HF clinic processes.

**Implementation Outcomes**
Four implementation outcomes from Proctor et al’s Implementation Outcomes framework were selected as measures of implementation success [17]. Data on the outcomes, defined below, were collected at 4 and 12 months post-launch through a document review process and semi-structured interviews.

- **Adoption**: The number of clinicians making the decision to monitor patients using the *Medly* system.
- **Penetration**: The level of integration of the *Medly* Program within the existing services of 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.
Barriers and Facilitators to Implementation

Semi-structured interviews were developed based on the constructs of the Consolidated Framework for Implementation Research (CFIR) which provides a pragmatic organization of theory-informed constructs known to impact implementation success across five 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[18]. Further interview probes were developed to explain the quantitative implementation outcome indicators. Interviews were conducted prior to program launch, and again after 4 months and 12 months, each session lasting between 30-60 min. All adopting clinicians and eHI Medly program staff were invited to participate. 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.

Data Analysis

Interview transcripts were analyzed by two independent investigators (PW, KG) using the Framework Method [19]. This involved a largely deductive thematic analysis using a codebook based on the constructs of the CFIR [18]. 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, valences ratings were attributed by PW and KG to each construct according to the criteria outlined by Damschroder et al [20]. Qualitative findings and valence ratings were validated during a meeting with key members of the clinician and eHI program staff (n=6).

Results

Study Participants

Eight clinicians participated in the interviews. 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. Table 1 shows the interview schedule and role for each participant.

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Role in Program</th>
<th>Role Descriptor</th>
<th>Baseline</th>
<th>4 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician1</td>
<td>Cardiologist and clinical lead of the HF clinic</td>
<td>Early adopter</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Clinician2</td>
<td>Nurse Practitioner</td>
<td>Early adopter</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Clinician3</td>
<td>Nurse Practitioner</td>
<td>Early adopter</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Clinician4</td>
<td>Cardiologist</td>
<td>Late adopter (9 months)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinician5</td>
<td>Cardiologist</td>
<td>Late adopter (11 months)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinician6</td>
<td>Cardiologist</td>
<td>Late adopter (11 months)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinician7</td>
<td>Cardiologist</td>
<td>Late adopter (11 months)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinician8</td>
<td>Cardiologist</td>
<td>Late adopter (11 months)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>eHealth1</td>
<td>Project manager</td>
<td>Left on maternity leave after 4 months</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>eHealth2</td>
<td>Project manager</td>
<td>Replaced original project manager</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>eHealth3</td>
<td>Program operations lead</td>
<td>New position was created after 3 months</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>eHealth4</td>
<td>Telehealth Analyst</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

>aX: interview conducted at this time point

Implementation Outcomes
Results for implementation outcomes are presented in Table 2 and discussed below.

Table 2: 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># of clinicians having decided to use <em>Medly</em> to monitor patients</td>
<td>N=3</td>
<td>N=8</td>
</tr>
<tr>
<td>Penetration</td>
<td>Percentage of clinicians using <em>Medly</em> over the total # of potential clinician users in the HF clinic</td>
<td>38%</td>
<td>89%</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Cumulative # of patients enrolled in the <em>Medly</em> Program</td>
<td>42</td>
<td>98</td>
</tr>
<tr>
<td></td>
<td>Cumulative # 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 # of patients having chosen to leave the <em>Medly</em> Program</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td># of deaths (all unrelated to the program)</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Fidelity</td>
<td>Cumulative # of calls or emails made to the THA for technical assistance</td>
<td>56</td>
<td>195</td>
</tr>
<tr>
<td></td>
<td>Cumulative # of requests for changes to the <em>Medly</em> technology</td>
<td>15</td>
<td>72</td>
</tr>
</tbody>
</table>

THA: Telehealth analyst

*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*. This represents an increase in penetration of the *Medly* Program within the HF clinic from 38% to 89%, a diffusion pattern that is explained in the interviews.
All participants spoke of the Medly Program initially being open to the 3 clinicians who were most actively involved its development. By the 11\textsuperscript{th} month of the program, the decision was made by the clinical lead of the HF clinic 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 (Clinician1) 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. [Clinician7]

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 patient’s 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. [Clinician5]

**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. This led to clinicians become 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. [eHealth4]

Feasibility is also demonstrated by the relatively low number of patients who chose to stop using the system (n=5). An additional five 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.
**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 the 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 (eg, 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.

**Barriers and Facilitators of Implementation**
The barriers and facilitators of implementation are described below and summarized in Table 3 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 3: Valence ratings assigned to CFIR constructs
<table>
<thead>
<tr>
<th>I. Intervention Characteristics</th>
<th>Operational Definition(^a)</th>
<th>Rating assigned to construct(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence Strength &amp; Quality</td>
<td>Perception of the quality and validity of the evidence supporting the use of telemonitoring for HF.</td>
<td>0</td>
</tr>
<tr>
<td>Relative Advantage</td>
<td>Perception of the advantage of implementing the Medly Program versus an alternative solution.</td>
<td>+2</td>
</tr>
<tr>
<td>Adaptability</td>
<td>Degree to which the Medly 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 Medly 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 &amp; Packaging</td>
<td>Perceived quality of the Medly 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 Medly Program.</td>
<td>-1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>II. Outer setting</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Needs &amp; Resources</td>
<td>Degree to which heart failure patients’ needs are known and prioritized by the HF clinic (ie, patient centeredness).</td>
<td>+2</td>
</tr>
<tr>
<td>External Policy &amp; Incentives</td>
<td>Policies and incentives that support or hinder the implementation of telemonitoring programs.</td>
<td>+1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>III. Inner Setting</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Networks &amp; Communications</td>
<td>The quality of the communication networks that support the implementation and daily operations of the Medly Program.</td>
<td>-1</td>
</tr>
<tr>
<td>Culture</td>
<td>Norms and values of the HF clinic and UHN.</td>
<td>+2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Implementation Climate</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Tension for Change</td>
<td>To 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>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>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, safe to try new methods.</td>
<td>+2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Readiness for Implementation</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership Engagement</td>
<td>Commitment, involvement, and accountability of the HF clinic lead.</td>
<td>+2</td>
</tr>
<tr>
<td>Available Resources</td>
<td>The level of resources dedicated for implementation and on-going operations of the Medly Program.</td>
<td>+2</td>
</tr>
<tr>
<td>Access to Knowledge &amp; Information</td>
<td>Ease of access to digestible information and knowledge about the Medly Program and how to incorporate it within existing HF clinic workflows.</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IV. Characteristics of</th>
<th></th>
<th></th>
</tr>
</thead>
</table>
Operational Definition are based on the definitions of the CFIR constructs[18].

-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. Or, different aspects of the construct had 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.

Intervention Characteristics Domain
Evidence Strength and Quality
Clinician participants acknowledged ambiguity in 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.

Relative Advantage
The Medly Program was perceived as having a relative advantage over other 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. [Clinician5]

Adaptability
Many statements spoke to 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 (eg, documentation), workflow adaptations to make more efficient use of THA time, and changes to the Medly algorithm.

So 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. [eHealth4]

Complexity
Several statements spoke to 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 identifying program candidates, (4) communicating patient information between Medly clinicians, and (5) setting algorithm parameters.
The biggest time for me is having to create all these communication notes in (the EMR) to document my conversations with people. [Clinician3]

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. [Clinician3]

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. [Clinician3]

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? [Clinician2]

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. [Clinician6]

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

**Design Quality and Packaging**

General satisfaction with the Medly Program and its design was a pervasive theme throughout the interviews. However, some design-related factors were perceived as barriers to the 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 Dashboard with the hospital EMR to facilitate documentation, (2) making Dashboard available on mobile devices, (3) providing more patient details in Dashboard, and (4) allowing for multiple patient-clinician communication modalities (eg, text messaging).

I really wish, really wish it worked on my iPhone or my iPad, particularly in the odd time where (Clinician1) 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. [Clinician3]

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’s good for you to kind of manage clinical alerts. [Clinician2]

Cost
Most of the costs associated with implementing the Medly Program 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 THA 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. [Clinician1]

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. [eHealth2]

This construct received a ranking of -1 because, although equipment cost was not a large initial barrier due to philanthropic funding, it was a barrier to sustainability that would need to be addressed. In addition, the higher than anticipated THA time was a barrier which did not significantly impact the Medly implementation but 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 the patient, HF Clinic, and public payer will be published subsequently.

Outer Setting Domain
Patient Needs and Resources.
This construct represents the idea that the implementation site comprehends and seeks to address patient needs. There were numerous examples of the HF clinic’s patient-centred approach to care making 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. [Clinician2]

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 being a crucial barrier 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. [Clinician1]

Inner Setting Domain
Networks and Communication
Three networks of communication were identified as having an influence on 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 a positive for the implementation. Finally, communication among higher level stakeholders was described as an early barrier to implementation, particularly as it related to making decisions about the program and having clear channels to operationalize those decisions. This barrier was identified and significant 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. [eHealth2]

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]

Implementation Climate
Tension for change
Clinician participants were proud of the quality of care they offer patients. However, there was a perceived gap between the current and ideal state. 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. [Clinician1]
Compatibility
*Medly* was perceived as compatible with the values of the organization and complimentary to existing services offered in 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.* [Clinician2]

Early apprehension about increased clinician workloads speak to the incompatibility of the TM program with existing clinic workflows. However, by the end of the first year, there is evidence that a new normal has been created such that this initial incompatibility did not significantly impact 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).* [Clinician3]

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.* [Clinician3]

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 of 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.* [Clinician2]

Readiness for Implementation
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. [Clinician3]

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 may 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. [eHealth4]

Funding for the equipment came from philanthropic donations, thereby mitigating the potential barrier of non-availability 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. [Clinician1]

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. [Clinician7]

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 there were no clear medical-legal guidelines 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. [Clinician2]

Characteristics of Individuals Domain
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 the 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. [Clinician4]

Self-Efficacy
There was a strong sense that despite initial apprehensions about 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. [Clinician3]

Process Domain
Planning
Despite user training being planned and the initial service design work leading up to 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 op(eration)s 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. [eHealth2]

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

I think certainly that from the clinic side, that (Clinician1) 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. [Clinician3]

Executing
Although there was no formalized implementation plan, 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. [eHealth2]

Reflecting and Evaluating
Embedded within the Medly Program was a mechanism to facilitate 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. [eHealth2]

Discussion
Principal Results
This longitudinal implementation evaluation found that the Medly HF program had been successfully implemented as demonstrated by the steady growth in patient enrollment and clinician adoption, and by the fidelity with which the intervention was being used in clinical practice. Costs were relatively high due to 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 decrease dramatically as the program shifts to a BYOD model. This study also identified 24 CFIR constructs that explain these measures of implementation success. Sixteen constructs were facilitators clustered in the domains of the inner setting and characteristics of individuals. Four CFIR constructs were minor barriers in the earlier phases of the implementation: complexity, networks and communication, and planning. Four additional constructs had a mixed valence and therefore were determined to have a neutral impact on the implementation.

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 conclude the importance of characteristics of the: technology, people involved, extra-organizational environment, and implementation setting [11-13]. However, our results bring to light additional barriers related to the CFIR constructs of complexity and compatibility not previously covered in the clinician TM adoption literature. 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 may 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 may not be as favourable.

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
implementation science. This is the first study to demonstrate the feasibility of using the CFIR for evaluating complex telehealth interventions [21]. That said, we note that the CFIR lacks granularity for identifying factors that may 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 could be useful for designing probes around quality of the system, quality of the information within the system, and quality of the services supporting the system [22]. 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 the inner setting, characteristics of individuals, and process. This is not to say that characteristics of the intervention were not important, but it makes the point that the implementation context cannot be ignored.

Limitations
This was a study conducted at a single implementation site. We acknowledge that the characteristics of the HF clinic may differ compared to other settings in terms of the availability of resources, structure of care delivery and characteristics of the individuals involved. Therefore, we recommend interpreting results within the context of the CFIR to help determine their applicability to other sites. We also acknowledge the absence of the patient perspective in this study. That said, a mixed method study of the factors that influence patient adoption, use, and adherence to the Medly Program will feature in a future publication. Finally, one cardiologist declined to participate in an interview and while their perspective is missing, it should be noted that they adopted the Medly program as part of their practice three months after the end of the study.

Conclusions
This study presents results from the real-world implementation evaluation of a smartphone-based TM program for patients with heart failure. The overall success of the implementation, as determined by 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 implementation success differently over time. Finally, we highlight a previously undescribed challenge, which is that TM interventions 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 programs and their implementation strategies. 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.
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PW led the overall design, data collection, data analysis, and write-up of this study. HR, AL, JC, and ES contributed to the design. KG contributed to the analysis and interpretation of the qualitative data. All authors reviewed and edited the manuscript. All authors read and approved the final version of the manuscript.

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Conflicts of Interest
HR, JC, and ES hold intellectual property in the Medly system and may profit from future commercialization of the technology.

Abbreviations
BYOD: bring your own device
CFIR: Consolidated Framework for Implementation Research
eHI: Centre for Global eHealth Innovation
EMR: electronic medical record
HF: heart function
NP: nurse practitioner
QoL: quality of life
TM: telemonitoring
UHN: University Health Network

References


