Continuous Remote Patient Monitoring: Evaluation of the Heart Failure Cascade Soft Launch

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Abstract

Objective We report on our experience of deploying a continuous remote patient monitoring (CRPM) study soft launch with structured cascading and escalation pathways on heart failure (HF) patients post-discharge. The lessons learned from the soft launch are used to modify and fine-tune the workflow process and study protocol.

Methods This soft launch was conducted at NorthShore University HealthSystem's Evanston Hospital from December 2020 to March 2021. Patients were provided with non-invasive wearable biosensors that continuously collect ambulatory physiological data, and a study phone that collects patient-reported outcomes. The physiological data are analyzed by machine learning algorithms, potentially identifying physiological perturbation in HF patients. Alerts from this algorithm may be cascaded with other patient status data to inform home health nurses' (HHNs') management via a structured protocol. HHNs review the monitoring platform daily. If the patient's status meets specific criteria, HHNs perform assessments and escalate patient cases to the HF team for further guidance on early intervention.

Results We enrolled five patients into the soft launch. Four participants adhered to study activities. Two out of five patients were readmitted, one due to HF, one due to infection. Observed miscommunication and protocol gaps were noted for protocol amendment. The study team adopted an organizational development method from change management theory to reconfigure the study protocol.

Conclusion We sought to automate the monitoring aspects of post-discharge care by aligning a new technology that generates streaming data from a wearable device with a complex, multi-provider workflow into a novel protocol using iterative design,

Keywords
- heart failure
- process improvement
- multivariate change index
- home health nurse
- communications

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implementation, and evaluation methods to monitor post-discharge HF patients. CRPM with structured escalation and telemonitoring protocol shows potential to maintain patients in their home environment and reduce HF-related readmissions. Our results suggest that further education to engage and empower frontline workers using advanced technology is essential to scale up the approach.

Background and Significance

Technology advancements such as implantable devices, telecommunication pathways, digital solutions, and home-based monitoring systems provide health care professionals with abundant data and methods for patient management in the post-discharge period.[1,2] In heart failure (HF) there is significant potential to reduce care costs and improve patient outcomes. An estimated 6.2 million adults in the United States (US) are diagnosed with HF,[3] accounting for more than $30 billion of the U.S. health care expenditure annually.[4] Readmissions are a significant burden to patients and the health system, with rates up to 25%[5–7] potentially costing >$25,000 per 30 day readmission.[8,9] Hospitals are incentivized to reduce readmissions through the Hospital Readmissions Reduction Program, which is a Medicare value-based purchasing program that aims to reduce avoidable readmission by improving communication and post-discharge care for patients and caregivers.[10]

Recent efforts to reduce HF-related hospitalization have begun to integrate remote patient monitoring (RPM). Invasive RPM methods like CardioMEMS have been demonstrated to reduce HF-related readmissions in select populations.[11,12] Non-invasive RPM trials commonly use devices to monitor blood pressure, weight, or electrocardiograms with RPM protocols for care management.[13–17] Although the methods and results for non-invasive RPM vary,[13–20] RPM shows promising results in improving quality of life,[18,19] reducing HF readmissions[14,17] and health service utilization.[15] These findings suggest that an active non-invasive HF RPM program involving patients' existing care teams could reduce health service utilization and improve clinical outcomes. However, one of the challenges in adopting advanced technology in health care settings is providers' adoption, which is affected by their perception of the additional workload, prior experiences, and comfort level.[21,22] Little has been published on the implementation experience in other RPM studies.

The Cascade-HF protocol is a continuous RPM (CRPM) study implemented at NorthShore University HealthSystem (NUHS). The soft launch is part of a larger pilot study that focuses on non-invasive CRPM through a structured cascading and escalating alert system. The pilot study plans to enroll a total of 50 eligible HF patients. The study uses wearable biosensors to collect ambulatory physiological data analyzed by machine learning algorithms, potentially identifying risk of decompensation in HF patients.[23] Alerts from this algorithm may be cascaded with electronic patient-reported outcomes (ePROs) to inform management by the home health (HH) team via a structured protocol. The escalation pathway engages NUHS's HH and HF teams. This contrasts with the typical post-discharge care for HF patients which relies on patients to self-track symptoms and weight, and proactively contact health care providers to report abnormalities. Our aim has been to automate aspects of post-discharge monitoring by aligning a new technology that generates streaming data from a wearable device with a complex, multi-provider workflow, into a novel protocol using iterative design, implementation, and evaluation methods with the ultimate goal of reducing readmissions in a high-risk patient population facing a significant burden of post-discharge self-care.

Objectives

The soft launch was designed to deploy and evaluate the study in real-world settings by recruiting five patients (10% of the full pilot study) to fine tune the alerting system, refine the process evaluation metrics, and finalize the structured intervention before the full pilot launch to enroll another 45 patients. This paper describes the soft launch's outcome, participant characteristics, operation metrics, lessons learned, and improvements.

Methods

We describe our approach under three headings: the CRPM solution, the recruitment process, and the intervention. We then discuss the evaluation of the soft launch.

CRPM Solution

The CRPM solution consists of an FDA-cleared wearable solution that collects data from a clinical-grade sensor and applies cloud-based artificial intelligence to the data to alert health care professionals on indication of clinical deterioration (►Fig. 1). Participants enrolled in the program receive wearable biosensors *VitalPatch* (VitalConnect, San Jose, California, United States) that collect near real-time, continuous, ambulatory vitals including heart rate, respiratory rate, electrocardiograms, steps, and sleep, and a dedicated smartphone with a proprietary application from *physIQ* (physIQ, Chicago, Illinois, United States). The application transmits physiological data from the patch to a cloud-based application, which applies clinical rules and machine learning models that alert on a variety of physiological abnormalities such as tachycardia, tachypnea, atrial fibrillation, and on a multivariate change index (MCI).[23] MCI is an algorithm that establishes a

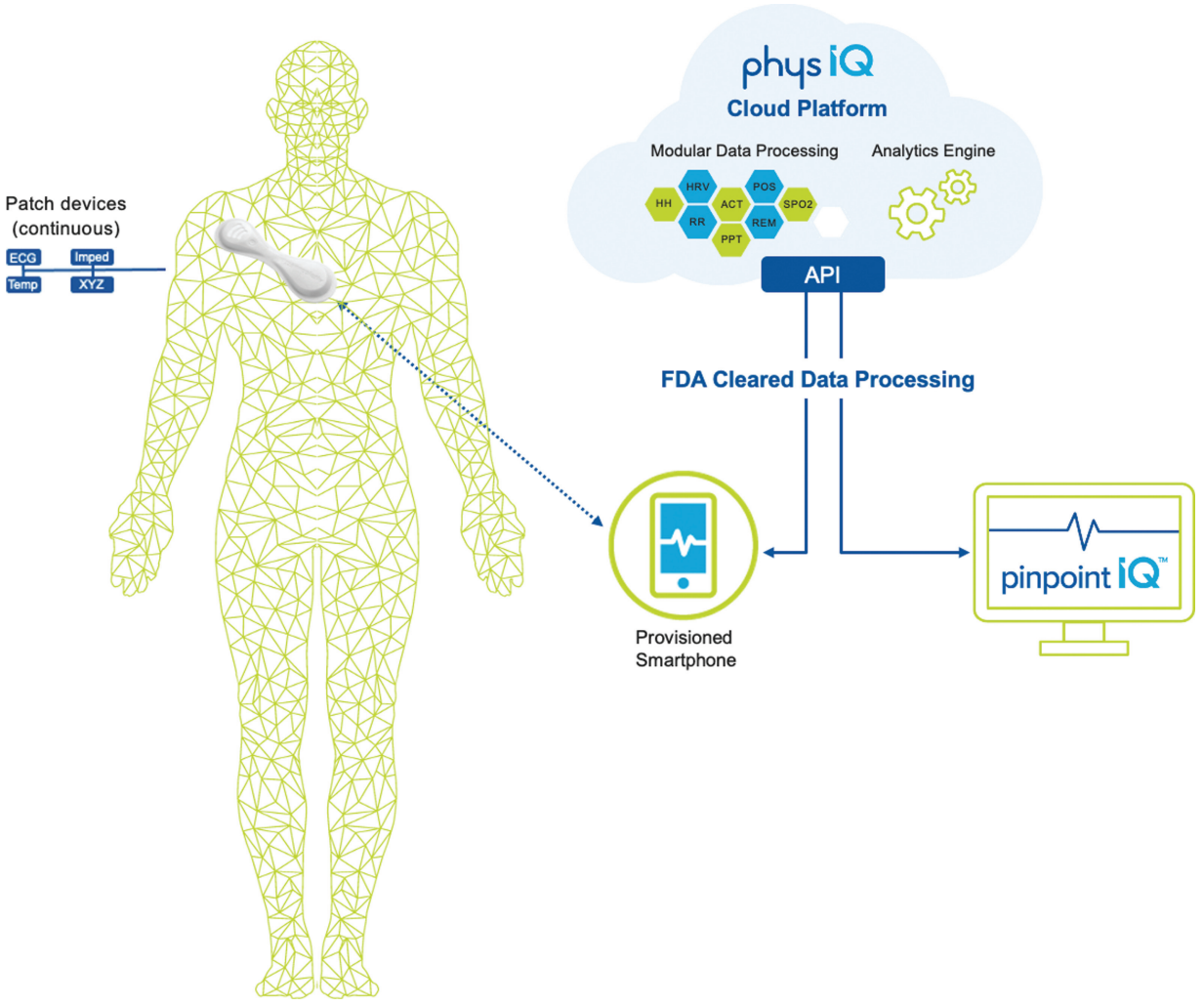

Fig. 1 Continuous remote patient monitoring solution.

personalized physiologic baseline in the first 48 hours by studying each patient's heart rate, respiration rate, sleep, and activities and monitors for subtle changes from that baseline over time. MCI has been shown to identify risk of all cause HF readmission.[23] The smartphone also collects ePROs through a daily two-question survey that asks about patient's daily weight and if they are experiencing any HF exacerbation symptoms. Training on how to use the wearable biosensors and smartphone is provided to patients before discharge. After discharge, patients are reminded to complete daily surveys about their weight and cardiac symptoms.

Individual patient dashboards enable clinicians to view each participant's continuously acquired biosensor data, ePROs, and alerts from the wearable devices on the physIQ monitoring platform, *pinpointIQ*. Web portal access is provided to all team members, including the home health nurses (HHNs), HF registered nurses (RNs), nurse practitioners (NPs), and attending physicians. The cascading system is a sociotechnical combination of technology-mediated communication and human action. If criteria encoded in the alerting algorithms is applied to the physiological data and ePROs are met, then structured, predefined, and automated electronic health record (EHR)-based telephonic management pathways are triggered, leading to communication with the care team. The HHN is the first human-in-the-loop in the cascade. If escalation criteria are met, the HHNs would notify the HF RNs or NPs, who will then notify the HF attendings as needed.

Recruitment

Recruitment was conducted at Evanston Hospital. Hospitalized HF patients who met the study inclusion criteria were assessed using the Clinical Analytics Prediction Engine (CAPE), NUHS's 30-day readmission risk prediction model.[24] The inclusion criteria were top 20% CAPE risk, on the HF service consult list, no CardioMEMS device, speaks English, has New York Heart Association (NYHA) functional class II-IV symptoms, an HF diagnosis. Exclusion criteria include cognition issues such as a documented history of dementia or delirium in the EHR that might prevent patients from complying with study requirements, and allergy to hydrocolloid gels. Research coordinators approached eligible patients identified from the EHR list, introduced the study to patients, including a full demonstration of the wearable devices, and answered all study-related patient questions. Adequate time was given to the patients to discuss the enrollment with

social support or care providers. Research coordinators obtained signed consent forms and conducted education on study requirements, daily symptom surveys, study device usage before discharge. Prior to discharge, the clinical team placed an HH outpatient addendum order with details for diuretic escalation and de-escalation, allowing HHNs to initiate and manage patient diuretic. In addition, HHNs could also reach out to the HF NP or HF attendings for a diuretic order if needed and consult HF team on diuretic management. Enrolled subjects were discharged with the study kit and a rescue intravenous (IV) diuretic dose was prescribed by the HF team. The soft launch recruitment started on December 14, 2020, and the last patient completed the study on March 25, 2021. The study was approved by NUHS's institutional review board (IRB EH20–288).

Intervention

Participants are enrolled in the study for 30 days post-discharge. Fundamental to CRPM workflow are escalating levels of expertise in HF. Alerts are generated and displayed on *pinpointIQ* if patient physiology meets predefined clinical rules. HHNs review the *pinpointIQ* portal watchlist daily in the morning for new clinical alerts generated in the past 24 hours and daily ePRO responses and perform predefined patient assessment and intervention, including diuretic management, diet and medication adherence counseling, in-home evaluation or IV diuretic administration. Diuretic is escalated if a patient meets predefined criteria. HHNs notify the HF team when the diuretic escalation pathway is initiated or collaborate with the HF team to escalate the diuretic. If symptoms are reported, the patient gets a third question the following day to assess if symptoms are getting better, worse, or the same. If symptoms worsen or weight gain increases on an escalated diuretic, the HHN escalates by contacting the HF NPs. If the patient's symptoms and weight are stable, the double diuretic dose remains unchanged. If symptoms resolve or weight gain reverts to dry weight, the HHN deescalates to standard diuretic dosing. HHNs also have the option to order laboratories (►Fig. 2 depicts the HHN workflow). A standardized note in the EHR system automates built-in logic guiding patient assessment, intervention, and communication pathways based on symptoms, weight change, and alert criteria. If the patient meets the alerting criteria, HHNs are required to connect with the patient to conduct a phone assessment of patient status, enter in the fixed inputs in the EHR-based note, including type of alerts, patient-reported symptoms, weight, weight trend, and medication history. The EHR note will automatically highlight the recommended follow-up plans the HHNs should take, including oral diuretic escalation and de-escalation, contact HF RN, contact HF NP, consider administering IV diuretic, assess for home visits, or reinforce medication and diet adherence importance.

On receipt of case communication after diuretic escalation, the HF team may consider HHN-administered IV diuretic, urgent HF clinic appointment, or readmission if other interventions fail. The HF team workflow is left to the clinical care team's discretion, given their prior history with these patients and the difficulty of automating more complex clinical decisions.

Evaluation

Before the official study start date, the research team conducted training meetings to introduce the study devices and trained the HHNs and HF team on navigating *pinpointIQ*, monitoring protocol, and workflow. The research team also conducted an official kick-off meeting to engage the entire clinical team. Personalized operation manuals for the HHNs and the HF team were stored in a shared drive for the ease of access. Throughout the soft launch, the research team maintained communication with HHNs and the HF team through weekly meetings, review information from questionnaires, formal and informal interviews, wearable devices, HHN notes, and EHR outcomes for evaluation purposes. The evaluation allowed for troubleshooting and iteration for the wider feasibility study on the following components:

1. Technical—Usability of provider portal via interviews, appropriateness, and efficiency of patient- and provider-facing platforms, and ease of use of structured clinical notes that guide management and escalation.
2. Operations—Assessment of willingness to enroll (reason for enrollment), reasons for attrition, and adherence to process (adherence to completing daily symptom and weight surveys, number of alerts reviewed by HHNs, numbers of notes filed by HHNs and the HF team). The effective communication of ePROs and physiological signals from the technical platform to the various clinical providers by recording significant events and process lapses.
3. Alert system and clinical burden—Evaluation of decision thresholds, provider and patient burden in relation to clinical outcomes, and understanding the criteria required to escalate care.
4. Clinical process and outcomes—Understanding how clinical parameters are appropriately managed with given structured process map and intervention pathway, and how they are interlinked to technical, operational, and alert issues.

Results

Five patients were enrolled in the Cascade-HF soft launch. ►Table 1 shows participants' characteristics and outcomes. The participants were predominantly female, over 60 years old, and all self-identified as Non-Hispanic Caucasian, (The HF patient population at NUHS is 64.3% Caucasian, 14.5% African American, 7.4% Asian, 13.4% Other.) Four of the participants had chronic HF, and one was newly diagnosed with HF. All participants were NYHA class III and within the top 20% of CAPE 30-day readmission risk.[24] The participants all had more than one comorbidity. The study team also extracted hospitalization numbers and reasons for hospitalization from the EHR system 1 year prior to participants' study enrollment. Four participants had prior hospitalizations within the previous year, and three of them had at least one HF-related hospital admission.

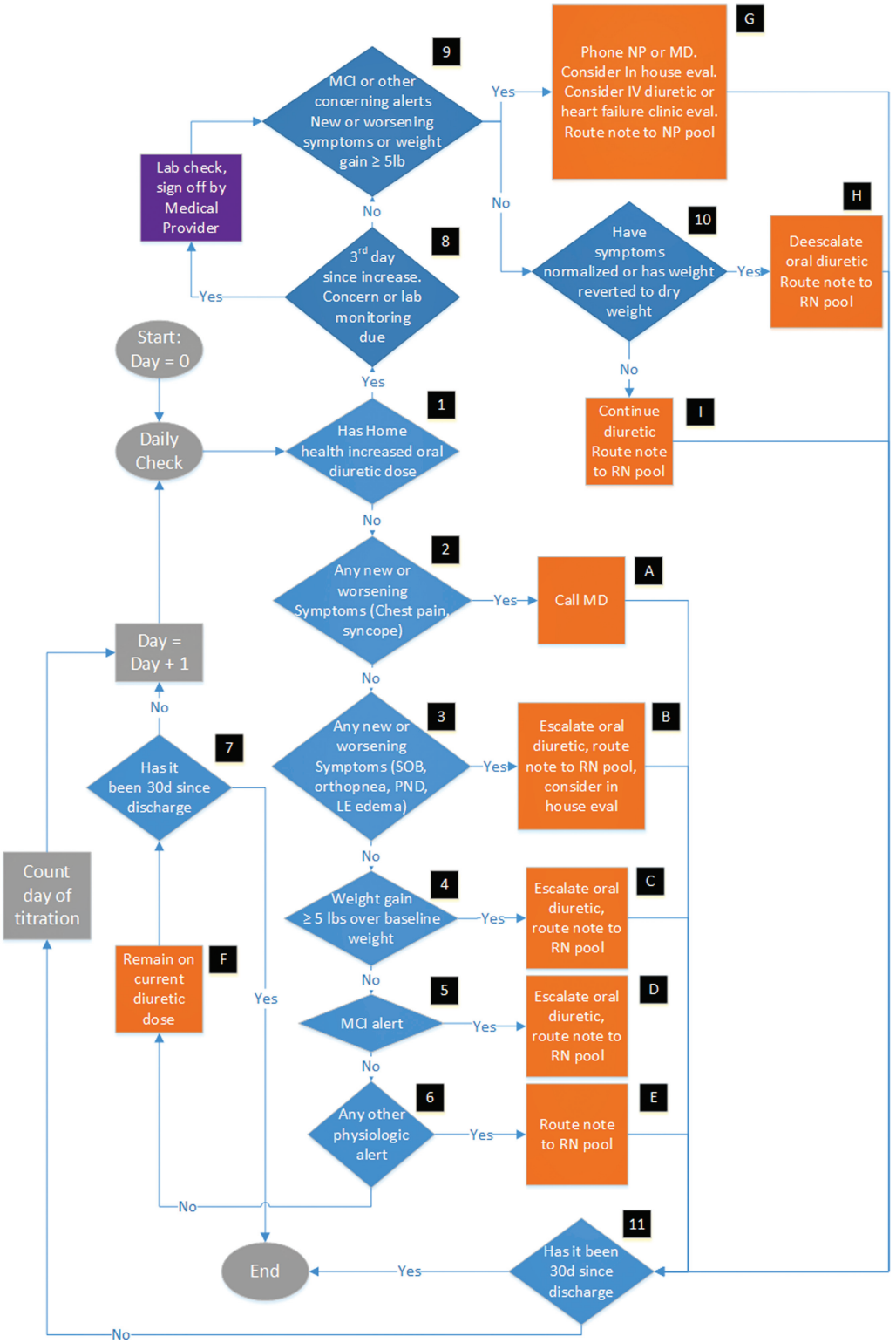

Fig. 2 Soft launch workflow. IV, intravenous; LE, lower extremity; MCI, multivariate charge index; MD, medical doctor; NP, nurse practicer; PND, paroxysmal nocturnal dyspnea; RN, registered nurse; SOB, shortness of breath.

Three participants were enrolled in the study because they were interested in participating in research. Two participants joined mainly due to the additional support and continuous monitoring provided by the study. Four participants are smartphone users, two participants had experience with wearable devices before enrollment, and one participant had experience with telehealth visits. We also recorded caregiver support with study-related activities—

Table 1 Subject demographic and clinical characteristics and outcome

	101	102	103	104	105
Age	70–79	80–89	60–69	60–69	60–69
Sex	Female	Female	Female	Male	Female
Ethnicity	Non-Hispanic	Non-Hispanic	Non-Hispanic	Non-Hispanic	Non-Hispanic
Race	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian
New or chronic HF	Chronic	Chronic	Chronic	New	Chronic
HF type	Diastolic	Systolic and diastolic	Diastolic	Systolic and diastolic	Diastolic
NYHA class	III	III	III	III	III
Most recent ejection fraction	81%	35%	70%	19%	55%
AICD or pacemaker present	No	No	No	No	Pacemaker
BMI on admission	60.47	20.91	19.67	23.01	40.74
Comorbidities					
Atrial fibrillation	Yes	No	Yes	No	Yes
Coronary artery disease	No	Yes	No	Yes	Yes
Chronic obstructive pulmonary disease	No	No	Yes	No	Yes
Diabetes mellitus	Yes	No	No	Yes	No
Chronic kidney disease	Yes	No	No	No	No
Cancer	No	Yes	No	No	No
Anxiety	Yes	No	Yes	No	No
Hypertension	Yes	No	Yes	No	No
Length of stay (days)	8	12	6	10	11
Number of admissions in last year	2	1	1	0	10
Number of HF admissions in last year	1	0	1	0	7
CAPE 30-day readmission score	Top 20%	Top 20%	Top 20%	Top 20%	Top 20%
Reason for enrollment	Interested in research	Interested in additional support	Interested in research	Interested in research	Interested in additional support
Patient prior technical experience					
Smart phone	Yes	No	Yes	Yes	Yes
Wearable solutions	Yes	No	Yes	No	No
Telemonitoring	No	No	Yes	No	No
Caregiver support with study activities	Partial	Full	None	None	None
30-day readmission	No	Yes	Yes	No	No
HF-related readmission	No	Yes	No	No	No

Abbreviations: AICD, automatic implantable cardioverter-defibrillator; BMI, body mass index; CAPE, clinical analytics prediction engine; HF, heart failure; NYHA, New York Heart Association.

subject 101 required partial support. Subject 102's family took over full responsibility. Subjects 103 and 104 were completely independent. Subject 105 had no social support.

Two participants were readmitted within 30 days. Subject 102 for HF exacerbation and 103 for bacteremia and sepsis were unrelated to index hospitalization.

All enrolled participants generated clinical alerts throughout the study (►Table 2). The MCI is an indicator of physiological change from the patient's baseline and is considered a possible sign of decompensation.[23] Subject 101 had atrial fibrillation and bradycardia alerts. Subjects 102, 103, and 104 all had tachypnea alerts and subsequently an MCI alert. None had tachycardia alerts.

Operational alerts include patch memory and impedance alerts, indicating loss of link from the device to the phone, or that the patch is not sticking well to the chest. We collected over 700 hours of data from each of four subjects 101 to 104. Overall, these subjects had good adherence to daily study activities. Subject 105 was non-compliant throughout the study and had fewer data collected.

Table 2 Soft launch operational metrics

	101	102	103	104	105
Total number of clinical alerts	7	34	62	23	2
Number of MCI alerts	0	1/34 (3.0%)	1/62 (1.6%)	1/23 (4.3%)	0
Number of tachypnea alerts	0	33/34 (97%)	61/62 (98.4%)	22/23 (95.7%)	2/2 (100%)
Number of tachycardia alerts	0	0	0	0	0
Number of Afib with RVR alerts	0	0	0	0	0
Number of Afib alerts	6/7 (85.7%)	0	0	0	0
Number of bradycardia alerts	1/7 (14.2%)	0	0	0	0
Total number of operational alerts	2	5	0	0	5
Number of patch memory alerts	1/2 (50%)	0	0	0	1/5 (20%)
Number of impedance alerts	1/2 (50%)	5/5 (100%)	0	0	4/5 (80%)
Amount of data (hours)	707.97	719.28	716.12	752.58	292.47
Adherence to completing daily symptom survey	21/30 (70%)	25/30 (83.3%)	27/30 (90%)	28/30 (93.3%)	3/24 (12.5%)
Adherence to completing daily weights	21/30 (70%)	25/30 (83.3%)	27/30 (90%)	28/30 (93.3%)	3/24 (12.5%)
Average time between clinical events (minutes)	4,943	1051	335	1,868	2,786
Average clinical event duration (minutes)	517	119	158	152	518
Number of alerts reviews by HHN	8/9 (88.9%)	39/39 (100%)	62/62 (100%)	23/23 (100%)	7/7 (100%)
Number of HHN notes filed in EHR	3	0	0	2	0
Number of HHN notes filed in pinpointIQ	2	7	13	5	1
Number of phone calls from HHN during study period	3	7	4	5	1
Number of medication adherence education	3	0	0	2	0
Number of diet adherence education	1	0	0	1	0
Number of home visits related to clinical alerts	3	0	0	0	0
Number of home visits related to operational alerts	0	0	0	0	3
Number of HF RN study-related notes filed in EHR	0	0	0	1	0
Number of HF NP study-related notes filed in EHR	0	0	0	0	0
Number of HF attendings study-related notes filed in EHR	0	0	0	0	0

Abbreviations: Afib with RVR, atrial fibrillation with rapid ventricular response; EHR, electronic health record; HF, heart failure; HHN, home health nurse; MCI, multivariate change index; NP, nurse practitioner.

The average time between clinical events varied widely among the five patients. Subject 103 had the most frequent clinical events which subsequently proved significant. Average clinical event duration, defined as time from clinical alert to HHN closing the event in *pinpointIQ*, also varied significantly. On average, all clinical events were assessed and managed within 2 to 9 hours.

HHNs reviewed all alerts for each subject throughout the soft launch except for missing one clinical alert on subject 101's last day in the study. The standardized HHN note was only filed in the EHR for subjects 101 and 104. However, all subjects had notes filed in *pinpointIQ*. HHNs documented medication and diet adherence education with subjects 101 and 104 in EHR. The HHNs visited subject 101 three times due to clinical alerts to perform clinical assessments, and subject 105 three times due to operational alerts to assist with study activities. The study team also reviewed study-related notes filed by the HF team in the EHR, including case communication to the HHNs related to automated alerts, ePRO responses, and diuretic management, or HF team initiated patient outreach prompted by the study protocol. There was only one study-related note filed in EHR by the HF team.

The study team reviewed patients' daily position on the workflow map and the clinical team's response to the patient

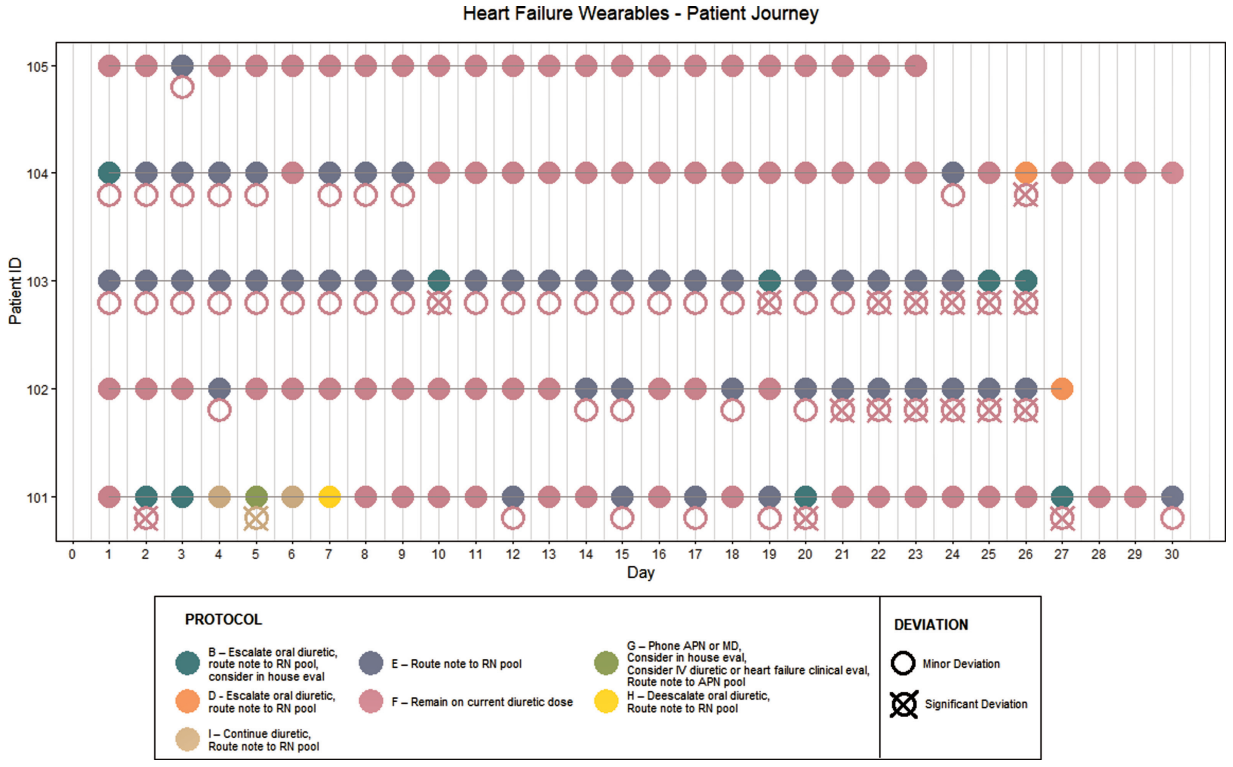

Fig. 3 Patient journey.

status throughout the study. We compared the observed activities with what was expected from the protocol (►Fig. 3). Deviations are marked as significant if the subject had new or worsening symptoms, had >5 lbs of weight gain, or had a noticeable increase in alert frequency that the HHN failed to follow up on, or unsuccessful diuretic escalation, potentially having a significant impact on subjects. Minor deviations are defined as the HHNs failing to route notes to the HF team or failing to call patients that only have minor to no impact on subjects. The expected actions are recorded on the first line in ►Fig. 3. If any deviation was observed, it was recorded on the second line.

Subject 101 had a total of nine protocol deviations, of which four were marked as significant. She continually reported symptoms that would require continued diuretic escalation. After monitoring and daily communication with the patient and family, it was determined that the symptoms reported by 101 were baseline symptoms, and patient was placed back on the standard diuretic dosage.

Subject 102 had a total of 11 protocol deviations, of which six were marked as significant. She first developed tachypnea alerts on day 4 of the study. When HHNs called to assess, the patient's family reported that she was not tachypneic. She remained event-free for 9 days but started to develop tachypnea alerts again. Her tachypnea alerts became more frequent and denser starting on day 21, leading to an MCI alert on the evening of day 26. However, HHNs failed to follow-up with subject 102 on days 21 to day 26 and viewed the tachypnea alerts as false positives. On day 27, the HHN doubled oral diuretic dosage after contacting 102's family and she was readmitted that evening.

Subject 103 had a total of 26 protocol deviations, seven of which were marked as significant. She had daily tachypnea alerts starting on day 1 due to chronic obstructive pulmonary disease (COPD). HHNs were initially checked in with her daily until marking the alerts as chronic baseline tachypnea triggered by COPD. HHNs failed to follow-up and conduct assessments with her when she reported four separate times of new onset of shortness of breath symptoms on days 10, 19, 25, and 26. She started developing increasingly frequent tachypnea alerts on day 22. However, HHNs failed to recognize the change in her vital sign trends and continued managing the frequent tachypnea alerts as baseline symptoms without following up with her. Subject 103 was readmitted on day 26 and developed an MCI alert 2 days after readmission to the hospital.

Subject 104 had a total of 10 protocol deviations, one of which was marked as significant. He had frequent daily tachypnea alerts starting on discharge through day 9. His vital signs stabilized, and he was event-free until later in the study. He developed a tachypnea alert on day 24, during connection with the HHN; he was able to point to exertion at the time of the alert. Subject 104 then developed an MCI alert on day 26. When HHNs called to check in, he reported not taking diuretics for the past few days due to missing his post-discharge HF appointment and running out of prescription. The HHNs coordinated with the HF team to refill his prescription. Due to subject 104's insurance issues, his diuretic was not escalated on day 26.

Subject 105 had a total of one minor protocol deviation. We made multiple attempts to engage her in the study both through research coordinators and HHNs. We communicated with the

Table 3 Lessons Learned from soft launch

Issues identified	Reason for change	Changes for pilot	Evaluation source	Category of change
Patient in the top 20% of CAPE readmission risk model has complicated conditions and poor prognosis.	Barriers and difficulty with recruitment due to patient condition and prognosis preventing patients from wanting to participate in the study.	Patient in the top 50% of CAPE readmission risk model	Study meetings	Process
Insufficient characterization of HF symptoms from custom built survey	Existing HF validated symptom tool with better characterization	Two question symptom survey adapted from the HF management zone tool.	Study meetings Patient interviews	Process
Tailored interventions created only for MCI alert and limited intervention pathways for other non-MCI alerts.	Feedback from HF team and significance of other alerts during soft launch.	Standardized intervention pathways for tachypnea, tachycardia, Afib w/ RVR alerts.	Study meetings Soft launch experience with patients	Process
MCI generated 1 day early for subject 102 and 1 day after readmission for subject 103	MCI alerts are not HF specific	PhysIQ updated the MCI alerting algorithm which will increase MCI sensitivity	Soft launch experience with patients	Process
Diuretic escalation after MCI alert	MCI is a non-specific decompensation alert	MCI alerts result in assessment and laboratory draw	Study meetings Soft launch experience with patients	Process
All patients should discharge with intravenous diuretic rescue dose	Identified barriers related to insurance approval and financial risks.	HF team to prescribe intravenous diuretic rescue dose for select high-risk patients after discharge through pharmacy.	Study meetings Provider interviews Soft launch experience with patients	Process
HHN communicate with HF RN on subject cases	RN not equipped for patient management	HHN communicates with HF NPs and MDs	Study meetings Soft launch experience with patients	Process autonomy
No standardized workflow for HF clinical team	Unclear process for HF RNs and NPs	Standardized workflows and training for HF team	Study meetings Provider interviews	Process autonomy education
HHN contacts individual HF team members	HHN unclear which clinical provider to contact	Created a single centralized pager for the HF team	Study meetings	Process autonomy
Low engagement during weekly all team meeting	Need for HHN and HF team to communicate	Utilize existing HF weekly meeting	Study meetings	Process autonomy
No case review meetings	Need to gain a deeper understanding of data	Recurring case review meetings with all team	Study meetings	Education
Subject 105 unable to comply with research activities	Unclear if the reason that subject 105 could not comply with research activities is due to lack of stable social support.	Added in the ENRICHD survey tool to investigate if social support is associated with patient compliance.	Soft launch experience with patients	Process

Abbreviations: Afib with RVR, atrial fibrillation with rapid ventricular response; CAPE, clinical analytics prediction engine; ENRICHD, enhancing recovery in coronary heart disease; HF, heart failure; HHN, home health nurse; IV, intravenous; MCI, multivariate change index; NP, nurse practitioner; RN, registered nurse.

subject and assessed the reason for non-adherence, re-trained and assisted her with daily symptom reporting and patch changing. The research team also worked with the visiting HHNs who visited subject 105 in person to assist her with study requirements and re-engage her in the study. However, she remained non-compliant with study requirements, including running out of her allocation of patches. She was marked as incomplete on day 26 when she decided to withdraw.

Following evaluation, the research team updated the protocol and workflow for the pilot study according to lessons learned from the soft launch. Changes were made in respect of processes, and care team education and autonomy (►Table 3).

Although all five patients in the soft launch were in the top 20% CAPE readmission risk category, inclusion criteria were extended to 50% in anticipation of recruitment barriers due to the top 20% patient's condition and prognosis. Excluded patients had other care plans, including palliative and hospice care.

Initially, the research team only designed tailored interventions for the MCI alerts, as these were the only alerts that had previously been validated in an HF population to identify patients at risk of HF readmission.[23] In the course of the soft launch, the team identified atrial fibrillation with rapid ventricular rate, tachycardia, and tachypnea alerts as potential signals of a 'patient's deterioration. We mapped out appropriate intervention pathways for these newly added alerts. It is also noted that the MCI alerts are not HF-specific. Upon reviewing the soft launch case series, the team asked HHNs to rely on clinical assessment and laboratory draws when an MCI alert is generated and to consider, rather than automatically escalating oral diuretic going forward. Additionally, the HHNs have a validated HF Management Zone Tool already in use, categorizing HF symptoms by severity,[25,26] which upon review and adaptation, was accepted for HHN daily screening. As a result of learning from the first five patients in the soft launch, physIQ updated the MCI alerting algorithm with improved sensitivity for the larger pilot study.

The team also identified barriers to insurance approval and financial risk to patients discharging with IV diuretics during the soft launch. Consequently, the new workflow provides IV diuretic prescriptions from the hospital pharmacy for those patients whose oral diuretic had been escalated by the HHNs. The patients or caregivers are able to fill the IV diuretic prescription if the HF team believes they are not responding well to the escalation of oral diuretic. This new workflow was co-created with the HF team, HHNs, and the pharmacy team.

During the soft launch, HHNs were required to route notes to HF RNs for communication. However, HHNs reported there was no feedback from the HF team. HF RNs were unfamiliar with the patients and lack the information for effective patient management. The communication pathway was redesigned and moving forward, HHNs will forward study-related notes to HF NPs and physicians for the pilot, standardizing their workflow, so that there is a clear pathway for patient management and team communication. The study team also created a single centralized pager contact for the HF team to ease the communication burden on the HHN team.

After the soft launch, the HF team invited the study team and HHNs to their regular HF internal weekly meeting to communicate about currently enrolled patients. Additionally, the study team set up case review meetings to perform a deep dive into patient cases and learn how best to leverage the continuous remote patient data.

Lastly, subject 105's non-compliance prompted the research team to administer the ENRICHD survey tool to enroll subjects in the pilot study to investigate if patients having stable social and emotional support will help with compliance.[27] This will help the research team identify the patient population that would benefit most from this study.

Implementation and Team Science

The post-discharge period for HF patients is a time of concern, with serious risk of readmission. For post-discharge patients with a recent HF admission, the hospital may seem the safest place to be when symptoms and complex management decisions are hard to manage at home.[28] We devised our protocol in the belief that closer monitoring than nurse-driven spot checks would be both more effective in keeping patients safe at home and an efficient means of remaining alert to their status following discharge. In the course of the soft launch described here, we had to adapt both the protocol implicit in the design of the physIQ algorithm and provider workflows. Communication gaps were identified when indicated actions were not followed through. A committed change management process involved all relevant actors. With the overall collaboration encompassing six independent or quasi-independent teams (HHNs, HF RNs, NPs, attendings, investigators, and physIQ group), both intra- and inter-team communication was subjected to rigorous scrutiny, evaluated, and improved or redesigned. The revised process model served as an essential training tool that improved communication and buy-in through iterative refinement across all teams.

Discussion

Post-discharge patient monitoring by clinical staff is difficult and expensive; to be effective, it requires observations ("spot-checks") to be made at frequent intervals that do not match the patient's actual needs or status at the given moment. The novelty in the method presented here is threefold: it matches the frequency of observations to the patient's status, automated machine learning alerts are generated according to patient physiological data, and it further automates the cascade of patient management and communications that must then occur in order for the process to be as nearly fully automatic as possible, given the diversity of patients and their conditions. On the third point, the EHR-based note requires HHNs to input the ePRO responses and types of alerts, which then automatically highlights suggested follow-up plans, notifying the HHNs if an intervention or escalation is needed. The alerts combined with the EHR algorithm automate and standardize the HF patient post-discharge management, eliminating the need for a skilled HF clinician to confidently perform essential patient management while lessening the HF team workload and burnout. The Cascade-HF is an innovative CRPM platform associated with a cascading alert system based on structured intervention pathways that engage and empower frontline clinicians to more rapidly manage patients at high risk of HF readmission.

Although we had two participants readmitted (one due to HF) in this small cohort, the team took away key lessons from this soft launch that will improve the likelihood of success for the larger pilot study. Specifically, we optimized the CRPM

platform to better identify patients at risk of decompensation, and to build process and train personnel to intervene on patients at risk of decompensation in the ambulatory setting.

Lessons Learned from Monitoring

The correlation between the number of alerts generated and the risk of readmission (subjects 102 and 103) and nonadherence (subject 104) displays the potential of using this CPRM platform to identify patients in the midst or at risk of decompensation. The MCI has previously been shown to predict HF readmission,[23] however, it was unclear what to do with other physiological alerts where similar literature is not present. As a result, the MCI was used to drive diuretic escalation, but other physiological alerts resulted in outreach without clear guidance on interventions. This resulted in two main opportunities for improvement: failure to recognize, and alert fatigue.

Subjects 102 and 103 generated increasing tachypnea alerts prior to readmission, but the MCI only alerted a day before readmission for 102 and after readmission for 103. Tachypnea alert density showed potential in early identification of decompensation in HF patients. It prompted an overhaul of the alerting mechanisms in the process map to take into consideration these alerts as additional key indicators of impending decompensation. HHNs misunderstood these tachypnea alerts to be the patients' baseline, and as a result failed to respond appropriately when there was an increase in the density and concomitant symptoms. Building processes that are more flexible and allow for understanding the nuances in changing alert frequency, associated symptoms, or weight gain are expected to improve the signal-to-noise ratio.

Lessons Learned from Intervention

The system to manage ambulatory patients is not well developed. The CRPM platform revealed opportunities to build out more robust infrastructure to intervene on patients at risk of decompensation identified in the outpatient setting. These opportunities were in communication, engagement, education, and empowerment.

Communication

During implementation, new and existing communication issues surfaced, which resulted in two readmissions. HHNs were routing notes to the HF RNs who are not well placed for patient management and had difficulties reaching HF NPs, who were not forwarding pagers to each other. Consequently, a single centralized pager was created. In the revised plan, the HF clinic manager will update the HF team schedule biweekly to ensure the right person will address study-related communications. A user-friendly standardized HHN note with logic built in to highlight the appropriate communication pathways was also updated. Timely case communication can empower clinical teams to better manage high-risk HF patients and create early intervention opportunities.

Engagement

The CRPM platform showed potential in the early identification of HF decompensation in subjects 101 to 104. However, the data alone is not enough for patient management. Amid disruptive technology implementation, it is critical to respect human values and needs and integrate the users' perceptions into the workflow design to ensure sustainable adoption of CRPM.

The challenges in integrating the CRPM technology into all respective teams' clinical workflows demonstrated the importance of human-centered design. The HF RNs and NPs were not included in the design process but brought on board closer to the official launch, when the process was already finalized. As a result, several issues surfaced, such as initial lack of buy-in, unfamiliarity with research, and confusion on managing alerts, contributing to the challenges in adopting the digital solution. The CRPM process must be driven by the frontline providers who utilize the technology daily.[29] In the revision of the protocol, the research team consulted the HHN and HF teams and co-developed the intervention pathway for the pilot. This created the opportunity to re-emphasize the value and potential impact of CRPM and explored ways to fit the digital solution into the context of the current standard of care provided to patients.

Education and Empowerment

To ensure successful adoption and deployment of advanced technology, health care workers must understand the accuracy and reliability of the advanced technology woven into their workflow.[29,30] Before all changes were finalized, we aligned all team members with the new initiatives for the pilot. Updated and tailored protocol training materials for each clinical team were created and distributed for review and stored in an easily accessible shared portal for easy reference. Stakeholders will offer continuing education and case reviews with all teams to empower providers to interpret the data to assist with clinical management. The research team will continue conducting daily patient journey reviews and root cause analyses with all readmitted patients to ensure all teams fully understand the cause of readmission and identify missed opportunities for patient interventions.

Conclusion

With the advancement in non-invasive technology, there is an increasing opportunity for health care systems to utilize existing solutions to provide patients with affordable and personalized post-discharge care and reduce hospital service utilization. Our soft launch demonstrated that continuous monitoring of vital sign data could potentially create early intervention opportunities before patient deterioration. CRPM protocols should facilitate efficient and targeted communication between providers and increase patient self-efficacy to engage in self-care. To make the CRPM program scalable, it is critical to continue improving the process using a human-centered design approach and offering provider education. Work currently underway will leverage simulation modeling for process analysis and

optimization to establish a standardized automation pathway.

Clinical Relevance Statement

HF is a growing clinical and economic burden. CRPM with a cascading escalating protocol shows potential to manage HF patients at home to decrease hospital service utilization. It is crucial to incorporate human-centered design in the workflow and protocol for continuous usage of the system and integrate frontline users' suggestions.

Protection of Human and Animal Subjects

The study was performed in compliance with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, and was reviewed by NorthShore University Health System's Institutional Review Board.

Multiple Choice Questions

1. What does the Cascade-HF monitoring protocol include?
   a. Invasive telemonitoring with a cascading escalating system.
   b. Non-invasive active telemonitoring with a cascading escalating system.
   c. Home health nurse remote monitoring.
   d. Heart failure providers passive telemonitoring.

   Correct Answer: The correct answer is option b. The Cascade-HF protocol utilized non-invasive biosensors to collect ambulatory physiological data that is analyzed by machine-learning algorithms. The home health team monitors collected data and alerts and escalate patient cases to the HF team for patient management.

2. When implementing new technologies and workflows, which of the following are the preferred approach per Cascade-HF soft launch experience?
   a. Outcome driven.
   b. Technology driven.
   c. Human centered.
   d. Competency based.

   Correct Answer: The correct answer is option c. When implementing disruptive technology in health care systems, it is important to consider frontline users' perspectives and user experience and weave new workflows into the current context of daily work for sustainable usage of new technology.

Conflict of Interest

The study devices, monitoring platform, and tech support are non-financial support by physIQ. K.L. is an employee of physIQ. All other authors do not have any conflict of interest. K.L. reports employment and equity from physIQ, during the conduct of the study; other from physIQ, outside the submitted work. N.S.S. reports non-financial support from physIQ, during the conduct of the study. J.E. reports and I serve on the ACCMedAxiom Board of Trustees. This is the for-profit arm of the ACC. While I have no direct relationships with vendors, the Board approves partnerships with vendors. U.R. is funded by the Daniel F. and Ada L. Rice Foundation. The foundation is not involved in the research design, implementation, or production of the manuscript in any way. Therefore, there is no conflict of interest. W.N.C. is funded by the Daniel F. and Ada L. Rice Foundation. The foundation is not involved in the research study design, implementation, or production of the manuscript in any way. Therefore, there is no conflict of interest.

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References

1 Brahmbhatt DH, Cowie MR. Remote management of heart failure: an overview of telemonitoring technologies. Card Fail Rev 2019;5(02):86–92
2 Bekfani T, Fudim M, Cleland JGF, et al. A current and future outlook on upcoming technologies in remote monitoring of patients with heart failure. Eur J Heart Fail 2021;23(01):175–185
3 Virani SS, Alonso A, Benjamin EJ, et al; American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics-2020 update: a report from the American Heart Association. Circulation 2020;141(09):e139–e596
4 Echouffo-Tcheugui JB, Bishu KG, Fonarow GC, Egede LE. Trends in health care expenditure among US adults with heart failure: the medical expenditure panel survey 2002-2011. Am Heart J 2017;186:63–72
5 Krumholz HM, Merrill AR, Schone EM, et al. Patterns of hospital performance in acute myocardial infarction and heart failure 30-day mortality and readmission. Circ Cardiovasc Qual Outcomes 2009;2(05):407–413
6 Hines AL, Barrett ML, Jiang HJ, Steiner CAConditions with the largest number of adult hospital readmissions by payer, 2011 Statistical Brief #172. Healthcare Cost and Utilization Project (HCUP) Statistical Briefs. Accessed June 4, 2020 at: https://www.hcup-us.ahrq.gov/reports/statbriefs/sb172-Conditions-Readmissions-Payer.jsp
7 Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med 2009;360(14):1418–1428
8 Carey K, Stefos T. The cost of hospital readmissions: evidence from the VA. Health Care Manage Sci 2016;19(03):241–248
9 Lahewala S, Arora S, Tripathi B, et al. Heart failure: Same-hospital vs. different-hospital readmission outcomes. Int J Cardiol 2019;278:186–191
10 Centers for Medicare and Medicaid Services. Hospital Readmissions Reduction Program (HRRP). August 24, 2020. Accessed May 5, 2021: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program
11 Veenis JF, Brugts JJ. Remote monitoring for better management of LVAD patients: the potential benefits of CardioMEMS. Gen Thorac Cardiovasc Surg 2020;68(03):209–218

12 Joshi R, Nair A. The utility of CardioMEMS, a wireless hemodynamic monitoring system in reducing heart failure related hospital readmissions. J Nurse Pract 2021;17(03):267–272
13 Ding H, Jayasena R, Maiorana A, et al. Innovative Telemonitoring Enhanced Care Programme for Chronic Heart Failure (ITEC-CHF) to improve guideline compliance and collaborative care: protocol of a multicentre randomised controlled trial. BMJ Open 2017;7 (10):e017550
14 Ware P, Ross HJ, Cafazzo JA, Boodoo C, Munnery M, Seto E. Outcomes of a heart failure telemonitoring program implemented as the standard of care in an outpatient heart function clinic: pretest-posttest pragmatic study. J Med Internet Res 2020; 22(02):e16538
15 Kraai I, de Vries A, Vermeulen K, et al. The value of telemonitoring and ICT-guided disease management in heart failure: results from the IN TOUCH study. Int J Med Inform 2016;85(01):53–60
16 Ong MK, Romano PS, Edgington S, et al; Better Effectiveness After Transition–Heart Failure (BEAT-HF) Research Group. Effectiveness of remote patient monitoring after discharge of hospitalized patients with heart failure: the better effectiveness after transition—Heart Failure (BEAT-HF) Randomized Clinical Trial. JAMA Intern Med 2016;176(03):310–318
17 Park C, Otobo E, Ullman J, et al. Impact on readmission reduction among heart failure patients using digital health monitoring: feasibility and adoptability study. JMIR Med Inform 2019;7(04):e13353
18 Olivari Z, Giacomelli S, Gubian L, et al. The effectiveness of remote monitoring of elderly patients after hospitalisation for heart failure: the renewing health European project. Int J Cardiol 2018;257:137–142
19 Ammenwerth E, Modre-Osprian R, Fetz B, et al. Herzmobil, an integrated and collaborative telemonitoring-based disease management program for patients with heart failure: a feasibility study paving the way to routine care. JMIR Cardio 2018;2(01):e11
20 Negarandeh R, Zolfaghari M, Bashi N, Kiarsi M. Evaluating the effect of monitoring through telephone (tele-monitoring) on self-care behaviors and readmission of patients with heart failure after discharge. Appl Clin Inform 2019;10(02):261–268
21 Zheng K, Padman R, Johnson MP, Diamond HS. Understanding technology adoption in clinical care: clinician adoption behavior of a point-of-care reminder system. Int J Med Inform 2005;74 (7-8):535–543
22 Jacob C, Sanchez-Vazquez A, Ivory C. Understanding clinicians' adoption of mobile health tools: a qualitative review of the most used frameworks. JMIR Mhealth Uhealth 2020;8(07): e18072
23 Stehlik J, Schmalfuss C, Bozkurt B, et al. Continuous wearable monitoring analytics predict heart failure hospitalization: the LINK-HF multicenter study. Circ Heart Fail 2020;13(03):e006513
24 Shah N, Konchak C, Chertok D, et al. Clinical Analytics Prediction Engine (CAPE): development, electronic health record integration and prospective validation of hospital mortality, 180-day mortality and 30-day readmission risk prediction models. PLoS One 2020;15(08):e0238065
25 Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation 2017;136(06):e137–e161
26 Yancy CW, Jessup M, Bozkurt B, et al; WRITING COMMITTEE MEMBERS American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. Circulation 2013;128(16):e240–e327
27 ENRICHD Investigators. Enhancing Recovery in Coronary Heart Disease (ENRICHD) study intervention: rationale and design. Psychosom Med 2001;63(05):747–755
28 Sevilla-Cazes J, Ahmad FS, Bowles KH, et al. Heart failure home management challenges and reasons for readmission: a qualitative study to understand the patient's perspective. J Gen Intern Med 2018;33(10):1700–1707
29 Reddy S, Allan S, Coghlan S, Cooper P. A governance model for the application of AI in health care. J Am Med Inform Assoc 2020;27 (03):491–497
30 Brodwin E, Ross C. Chapter 3: The emerging science of implementing AI. In: Gil G. Promise and Peril: How Artificial Intelligence is Transforming Health Care. Stat 2020:70–79