Continuous Remote Patient Monitoring: Evaluation of the Cascade Heart Failure Study Phases 1 and 2

Wei Ning Chi, MBBS, MPH[1], Courtney Reamer, MD[1], Robert Gordon, MD, PharmD[1], Nitasha Sarswat, MD[1,2], Charu Gupta, MD[1], Emily White VanGompel, MD, MPH[1,2], Safwan Gaznabi, MD[1,2], Izabella Szum, RN[1], Melissa Morton-Jost, MBA[1], Urmila Ravichandran, MS[1], Tovah Klein[1], Karen Larimer, PhD[3], David Victorson, PhD[4], John Erwin, MD[1,2], Lakshmi Halasyamani MD[1,2], Anthony Solomonides, PhD[1], Rema Padman, PhD[5], Nirav S Shah, MD, MPH[1,2]

[1]NorthShore University HealthSystem, Evanston, IL, USA; [2] University of Chicago Pritzker School of Medicine, Chicago, IL, USA; [3] physIQ, Inc., Chicago, IL, USA; [4] Northwestern University, Evanston, IL, USA; [5] Carnegie Mellon University, Pittsburgh, PA, USA.

Background

- Heart failure (HF) is a public health issue with high readmission rate and increased economic burden.[1]
- Post-discharge remote monitoring shows improvement in HF readmission rates.[2]
- Continuous remote patient monitoring (cRPM) using machine learning techniques applied to physiologic data provides early indication of worsening HF and allows early intervention.[3]
- NorthShore University HealthSystem deployed a continuous remote patient monitoring (cRPM) platform with structured cascading and escalation pathways for at-home monitoring of post-discharge HF patients for 30 days.

Objective

The primary goal is to determine feasibility of the cRPM program.

Research Design

- CASADE HF is an ongoing 3-phase, prospective, non-randomized study.
- HF patients at or above NYHA II were enrolled at index hospitalization and managed for 30-days post-discharge using a cRPM solution.
- Continuous physiologic data was streamed from chest- worn, non-invasive biosensors and analyzed by machine learning algorithms.
- Notifications of physiological perturbation were generated, and patient-reported outcome responses (weight and exacerbation symptoms) were displayed on a web-based portal and reviewed daily.
- Personalized alerts included rule-based alerts and an alert that recognizes when the person's physiology is changing compared to their baseline physiology (multi-variate change index [MCI]).
- Notifications were displayed and reviewed daily by a home health nurse who escalated to HF team for further evaluation and early intervention (Figure 1).
- Study outcome is 30-day readmission.
- We compared the observed activities of HHN and HF teams with what was expected from the protocol and recorded workflow deviations.
- We configured the technology with five initial HF patients in phase 1, paused to conduct evaluation and change management and updated protocol.[4] We then enrolled additional 15 HF patients for calibration and testing of the revised protocol and workflows in phase 2.

Figure 1: Heart Failure Monitoring Workflow

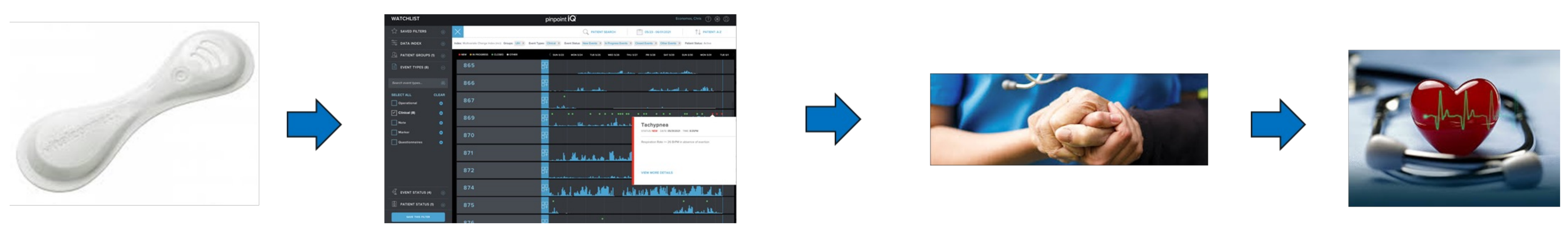

Figure 2. CASCADE HF Research Progress

Phase 1
Dec 20-Mar 21

- 5 patients enrolled
- Pragmatic learning experience

Pause

- Program evaluation
- Protocol update
- Provider education
- Change management

Phase 2
April 21-Oct 21

- 15 patients enrolled
- Testing and calibration of new protocol and workflow

Table 1: Subject Outcomes and Operational Metrics

	Phase 1 soft launch					Phase 2 calibration period						Phase 2 testing period								
Number of \ Subject ID	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20
MCI alerts	0	1	1	1	0	0	4	0	0	4	2	6	0	0	1	1	0	0	0	0
Tachypnea alerts	0	33	61	22	2	0	5	0	0	68	0	0	0	0	0	0	0	0	0	0
Other alerts	7	0	0	0	0	39	0	0	37	0	0	0	0	0	0	0	0	0	0	0
HHN EHR notes	3	0	0	2	0	25	22	5	20	28	21	8	0	9	4	20	6	0	7	3
HHN phone calls	3	7	4	5	1	20	14	5	19	26	17	8	1	8	4	14	4	0	6	2
Diuretic escalations	1	1	0	0	0	1	2	0	0	2	1	1	0	1	0	3	1	0	1	1
HF clinician notes	0	0	0	0	0	3	4	1	6	6	5	3	0	0	0	5	2	0	0	0
30-day readmission?	N	Y	Y	N	W	N	N	N	N	N	N	Y	S	N	N	Y	Y	W	N	N

Abbreviations: MCI, multivariate change index; HHN, home health nurse; EHR, electronic health record; APN, advanced nurse practitioner; N, no; Y, yes; W, withdrew; S, screen fail

Table 2. Study Workflow Deviations

	Phase 1 soft launch	Phase 2 calibration and testing period
Number of minor deviations	31	2
Number of significant deviations	18	11

Significant deviation = If the subject had new or worsening symptoms, high-risk alerts, or had >5 lbs of weight gain that the clinical care team failed to follow up on, significantly impacting the patients; Minor deviations = HHNs not routing notes to the HF team or failing to call patients with minor or no impact on the subjects

Results

- Of the 20 patients enrolled, 5 readmitted (2 HF-related and 3 non HF-related), 2 patients withdrew due to non-adherence to study procedures.
- All patients were at or above NYHA function class II; all were in the top 50% of the health system's 30-day readmission risk score.[5]
- Tachypnea alerts demonstrated the potential to predict patient decompensation.
- Increased provider engagement in phase 2 with new protocol.
- Providers identified additional oral diuretic escalation opportunities in phase 2 with new protocol.
- Significant reductions in minor deviations, only minor reduction in significant deviations.

Conclusions

- cRPM with a structured escalation protocol shows the potential to monitor patients in their home environment, prevent decompensation, and reduce HF-related readmissions.
- Minor deviations were decreased due to frequent provider workflow training and increased engagement with the study.
- Difficulty with reducing significant deviations due to constrained resources and lack of communication over weekend escalations.
- Phase 2 results reinforce the learning from phase 1 that a human-centered socio-technical approach, coupled with negotiated engagement and empowerment of frontline workers, is essential to scale up the study.

Future Plans

This study will further evaluate the preliminary efficacy and feasibility of a cRPM program for HF patients in phase 3.

References

1. Echouffo-Tcheugui JB, Bishu KG, Fonarow GC, Egede LE. Trends in health care expenditure among US adults with heartfailure: The Medical Expenditure Panel Survey 2002-2011. Am Heart J. 2017 Apr; 186:63-72.
2. Koehler F, Koehler K, Deckwart O, et al. Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial. Lancet. 2018 Sep; 392(10152):1047-1057. doi:10.1016/S0140-6736(18)31880-4
3. 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 Mar; 13(3):e006513.
4. Chi WN, Reamer C, Gordon R, et al. Continuous Remote Patient Monitoring: Evaluation of the Heart Failure Cascade Soft Launch. Appl Clin Inform. 2021;12(5):1161-1173. doi:10.1055/s-0041-1740480
5. Shah N, Konchak C, Cherok 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 Aug; 15(8):e0238065.