Continuous Wearable Monitoring Analytics to Improve Outcomes in Heart Failure: Vanguard Phase Results and Study Design of the Randomized Phase of LINK-HF2 multicenter study

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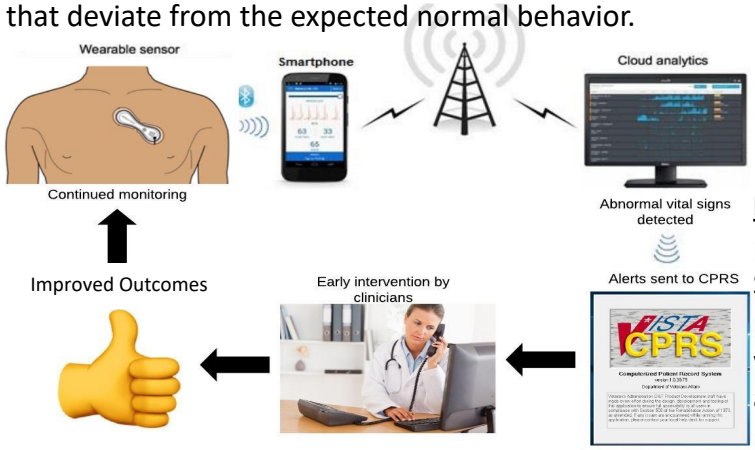
Background: LINK-HF study has shown that multivariate physiological telemetry from a wearable sensor combined with machine learning can provide accurate early detection of impending heart failure (HF) hospitalization. Whether early intervention based on predictive data generated through artificial intelligence (AI) analytical methods could improve outcomes in HF is not known.

Methods: The LINK-HF2 study consists of two phases. The completed, non-randomized vanguard phase enrolled 27 patients with HF at 2 VA sites, and the ongoing main randomized phase will enroll 240 patients at 5 VA sites. The predictive AI system used in this study is a cloud-based analytic platform that generates a multivariate change index (MCI) to identify changes in observed physiological patterns that deviate from the expected normal behavior.



Results: In the vanguard phase, comprehensive implementation program was developed and examined integration of non-invasive remote monitoring and subsequent algorithmic response to the clinical workflow. Clinicians responded to notifications within 24 hours in 95% of instances and clinical action was taken in 25% of instances.

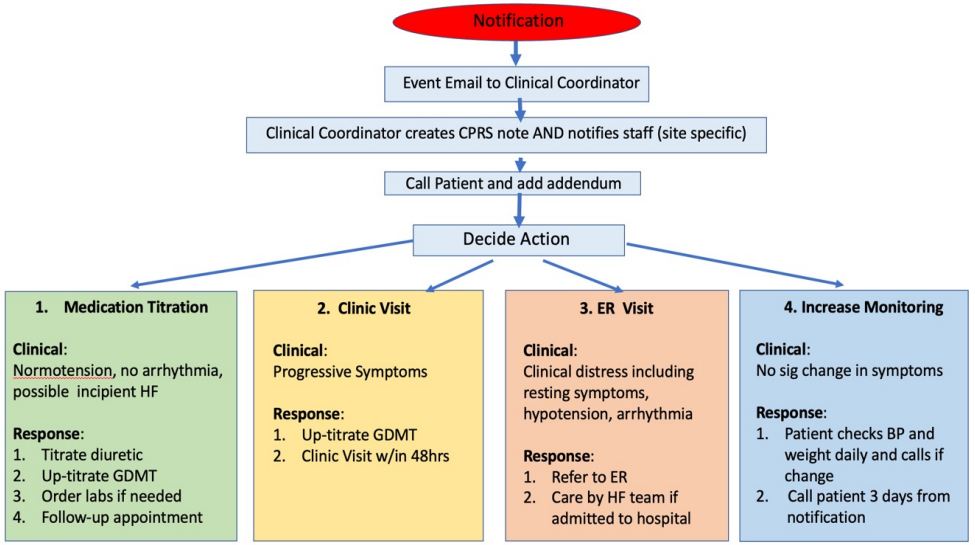
Challenges

- Over-Alerting
- Time needed for data review
- Staffing
- Deference to other providers

Protocol Adjustments

- Refinement of the algorithmic response to predictive alerts
  Expansion of clinician education
  Improved education of study subjects on the meaning of predictive notifications
  Aggregating repeated MCI alerts within 72 hours into a single event

Randomized phase: Initiated in 01/2022. 50 out of the projected 240 subjects with HF have been enrolled. Subjects will be fitted with the non-invasive monitor and randomized to either an active arm, in which notifications will be communicated to clinical providers and followed by an algorithmic response, or to a control arm where notifications will not be communicated to the clinical team.



Outcomes

- HF hospitalization
- All-cause hospitalization
- Hospitalization length
- Health-related quality of life (KCCQ12, VAS)
- Cost of medical care

Conclusions: LINK-HF2 study will provide clinical utility data for and approach where algorithmic response will be taken to AI predictive analytics derived from multivariate physiological telemetry from a wearable sensor