The Case for an Effective and Innovative Approach to the Ongoing Management of the Advanced HF Population within the Value-Based Medicare Population

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Introduction

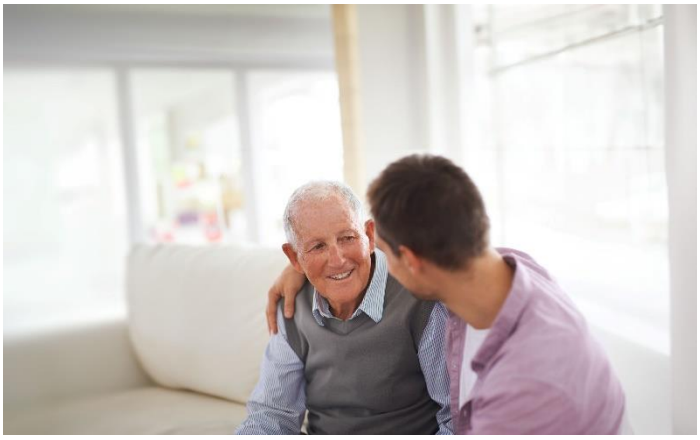
More than 10% of Medicare fee-for-service (FFS) beneficiaries have a diagnosis of heart failure[1]. According to the Center for Medicare and Medicaid Services (CMS), the heart failure ("HF") population represents a significant percentage (over 34%[1]) of the overall Medicare medical spend and is the number one cause of unplanned hospital admissions[2]. As the population of America continues to age, the incidence of heart failure and other chronic diseases will continue to grow at a rapid pace, resulting in a continued growth in Medicare spending in excess of the inflation rate.

A critical component to driving performance in a value-based arrangement is effectively addressing and proactively care managing chronically ill populations. The HF patient population is one of the greatest opportunities to improve care for chronically ill patients. A recent actuarial claims data analysis commissioned by ADI has shown that a relatively small subset of these HF patients (25%) account for a

[1] Fitch K, Pelizzari PM, Pyenson B. Inpatient Utilization and Costs for Medicare Fee-for-Service Beneficiaries with Heart Failure. Am Health Drug Benefits. 2016 Apr;9(2):96-104. PMID: 27182428; PMCID: PMC4856234.

[2] Ansah, John P., Chui, Chi-Tsun, Projecting the chronic disease burden among adult population in the United States using a multi-state population model, Frontiers in Public Health, 2022 doi: 10.3389/fpubh.2022.1082183 PMCID: PMC9881650 PMID 36711415

majority of the acute events and costs of the HF population[3]. It is estimated that the per person per year (PPPY) cost for this population is ~ $100K compared to $30K for the overall HF population and $15K for the entire Medicare population[2]. It is estimated that most patients with worsening HF are treated reactively in the acute setting of care leading to increased cost and reduced outcomes.



To date, efforts for managing these patients have been focused on the acute episode of care following admission to the hospital, with the objective of reducing readmissions as opposed to developing strategies to prevent the episode. Overall, the efforts of combining care management with generic remote patient monitoring (RPM) focused on late-stage HF symptomology have demonstrated[4] limited effectiveness in reducing admissions and cost, due to an overwhelming wave of false positives and the inability to determine which patients actually need intervention without overburdening the clinical team.

In contrast, the philosophy of *preventing* acute episodes has been successful in the treatment of diabetics. Effective programs to manage diabetes have been developed and implemented throughout the country to prevent acute episodes, reducing hospitalizations, and overall costs. We can use these diabetes programs as models for how to manage heart failure more effectively.

Managing Diabetes: A Model for Managing Chronic Disease

In 1997, an innovative approach was developed in Asheville, North Carolina to manage complex diabetic patients for the city of Asheville and Mission Hospital employees. This model, referred to as “The Asheville Project,” has been successfully replicated and implemented in over 100 communities across the country[5]. According to the American Pharmacists Association Foundation, the key attributes of this program [resulted in/are] improved health (more than 50% of diabetic patients improved their A1C and lipid scores), reduced complications (fewer hospitalizations), and reduced total cost of care for diabetic patients (from over $3000 to $1872 per patient per year).

[3] Analysis of Medicare Heart Failure Spending and Changes Over Time. Institute for Accountable Care. October 28, 2021.

[4] Voigt J, Sasha John M, Taylor A, Krucoff M, Reynolds MR, Michael Gibson C. A reevaluation of the costs of heart failure and its implications for allocation of health resources in the United States. Clin Cardiol. 2014 May;37(5):312-21. doi: 10.1002/clc.22260. PMID: 24945038; PMCID: PMC6649426.

[5] Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc (Wash). 2003 Mar-Apr;43(2):173-84. doi: 10.1331/108658003321480713. PMID: 12688435.

Key elements of this program to manage complex diabetics included:

- Risk stratifying the population based on severity attributes,
- Ongoing monitoring of a key risk factor (Hemoglobin A1C),
- Active engagement as needed by a qualified care professional (usually a pharmacist),
- A standardized patient education program,
- The use of protocols (guideline directed therapy developed by the ADA) to ensure consistency of treatment, and
- Eventually, the integration of new value-based payment models to align economic incentives.

Because his model has led to a documented reduction in acute episodes, complications, and hospitalizations of complex diabetic patients, and can serve as a roadmap when looking to address similar challenges in managing heart failure patients[4].

Managing Heart Failure in a Value-Based Environment

The effective management of the heart failure patient is more intricate and difficult than even the complex diabetic population. Heart failure patients usually have multiple co-morbidities such as Chronic Obstructive Pulmonary Disease (COPD) and Chronic Kidney Disease (CKD) and are even more predisposed to acute events than complex diabetics. However, the potential savings in preventing acute episodes in this population offer organizations much greater cost savings opportunities than the management of the individual complex diabetic. Therefore, value-based payment should align the providers economic incentive with the clinical practice to improve quality and lower total cost of care.

> *Value based payment links provider payments to improved performance by health providers. This form of payment holds health care providers accountable for both the cost and quality of care they provide. It attempts to reduce inappropriate care and to identify and reward the best-performing providers.*
>
> (www.healthcare.gov>glossary)

In comparison to diabetes management, value-based providers and health plans have had more difficulty developing programs to address the costs of unplanned admissions that result from worsening HF due to the complexity of managing a HF patient. Heart failure impacts the three major systems in the body; the heart, lungs, and kidneys, and often involves other comorbidities such as CKD, COPD, and conditions such as Atrial Fibrillation (AFIB). This challenge is illustrated by national Medicare claims data, which demonstrates that of the 1.5 million patients that come to the hospital for worsening HF each year, over 66% are admitted for worsening heart failure and 50% of these patients are readmitted within 180 days[6]. Also, over 4.4 million HF patients are admitted for other conditions related to HF[2].

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[6] Retrum JH, Boggs J, Hersh A, Wright L, Main DS, Magid DJ, Allen LA. Patient-identified factors related to heart failure readmissions. Circ Cardiovasc Qual Outcomes. 2013 Mar 1;6(2):171-7. doi: 10.1161/CIRCOUTCOMES.112.967356. Epub 2013 Feb 5. PMID: 23386663; PMCID: PMC4082819.

For patients with HF, late-stage symptomology monitoring results in an overload of information (weight, blood pressure, and SPO2), which is generally concurrent with the acute episode and therefore not decisive in preventing the worsening event on a timely basis. Pre-symptomatic hemodynamic changes that correlate to late-stage symptomology occur in HF patients and often go unnoticed or under the radar of existing remote patient monitoring (RPM) modalities and represent an opportunity to support earlier intervention.

While there are existing implantable solutions such as invasive Pulmonary Artery (PA) pressure measurement and Cardiac Resynchronization Therapy (CRT) devices with algorithms that have been proven to provide predictive insights, it is difficult to apply these solutions into a broader population due to the risk and cost of these invasive technologies9,10. In lieu of this, many value-based organizations have been reliant on building costly, hard to scale, large care management organizations (CMOs). These CMOs, even when supplemented with RPM, are not able to provide timely, sensitive, and specific insights predictive of a worsening HF acute event.

Because of these challenges and the incentives contained in the Medicare Hospital Readmission Reduction Program (HRRP), many programs have focused solely on reducing 30-day readmissions with varied impact. In fact, a majority of such programs have been discontinued due to the significant resources required to operate them. The task of tackling the primary problem still remains: preventing the acute HF admission, which normally occurs from the home to the hospital.

Ongoing Management of the Advanced Heart Failure Population

Daily physiological measurement through the use of invasive devices has demonstrated the efficacy of monitoring early hemodynamic changes in HF patients, allowing for intervention prior to an acute episode [7,8]. A novel, non-invasive approach to the ongoing management of the HF population has been developed by Analog Devices Inc. (ADI). This approach combines the acuity of high-quality predictive measurements that are trended and combined with ongoing data assessment, identification, and triage of patients with increased risk of a future HF-related acute event. Ultimately, the Sensinel™ CPM System by ADI is designed to fit into the provider's existing clinical and IT-based pathways without requiring any significant additional investments into care management or IT infrastructure.

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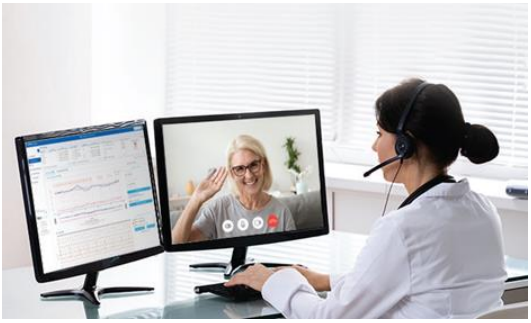
[7] Abraham, William T, et al. "Wireless Pulmonary Artery Haemodynamic Monitoring in Chronic Heart Failure: A Randomised Controlled Trial." *The Lancet, vol. 377, no. 9766, 19 Feb. 2011, pp. 658–666, www.sciencedirect.com/science/article/pii/S0140673611601013?casa_token=gBqpIXWBHMgAAAAA:CbgU-DkPODaGcjcieIW60cpB-i_Wt0Aota4-, https://doi.org/10.1016/S0140-6736(11)60101-3.*

[8] Boehmer, John P., et al. "A Multisensor Algorithm Predicts Heart Failure Events in Patients with Implanted Devices." *JACC: Heart Failure, vol. 5, no. 3, Mar. 2017, pp. 216–225, https://doi.org/10.1016/j.jchf.2016.12.011*

Identifying and Recruiting the Right Patients



This innovative and proactive approach to managing advanced heart failure patients can be used to monitor general care adult patients including heart failure patients in class 2 with multiple comorbidities, class 3, and some class 4 s, based upon the New York Heart Association (NYHA) Functional Classifications. This patient cohort comprises about 25% of patients in the heart failure population and represent an average PPPY cost of ~ $100,000[2], averages 3 admissions per year and 67% of total heart failure population spend. A significant percentage of these costs are associated with worsening HF, hospitalizations, emergency room visits, and skilled nursing home admissions. For instance, the elimination of just one heart failure specific hospitalization or readmission could reduce the total cost of care for each Medicare patient by $12,000 to $18,000[2], in addition to the costs associated with readmissions, skilled nursing, and home care. This innovative model could also reduce patient and family anxiety levels by providing data to facilitate the care team in understanding whether the patient remains in a stable state, thus reducing the fear of an acute episode.

Timely Insight without Overloading the Provider Team through a Turnkey End-to-End Solution

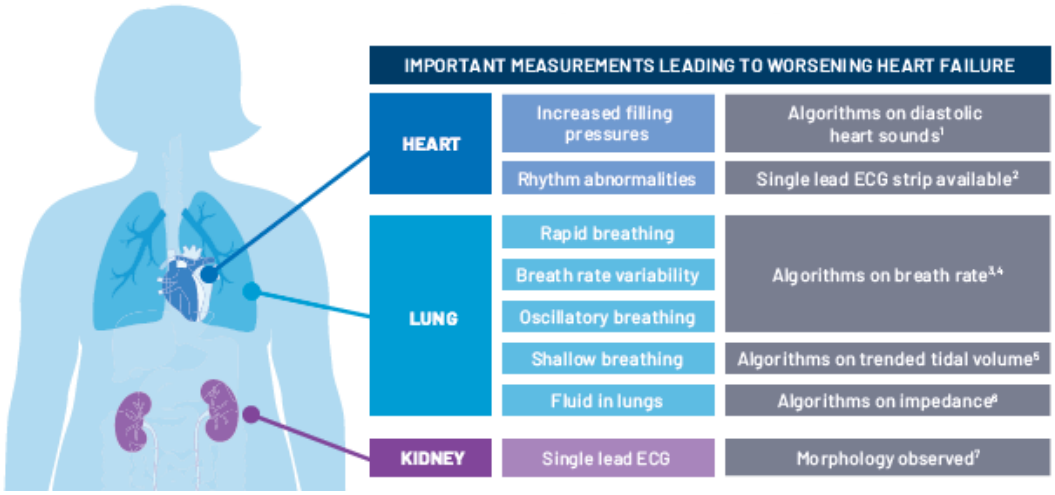
A key challenge is how to help the patient remain in a steady state and avoid the acute episode. Monitoring must be conducted in the home setting that does not require a significant increase in staff and cost, and should not overburden physicians and other caregivers. The approach must be scalable to provide proactive care to thousands of heart failure patients in a population. This will not only require a change in focus of care, but also a change in clinical mindset. Clinicians must prioritize managing this chronic condition proactively and design care that maintains the heart failure patient in a steady state in the home, rather than solely focusing on treating an acute episode in the hospital.

The ongoing, non-invasive approach to managing heart failure includes many components that are similar to the successful approach to managing the complex diabetic developed nearly 30 years ago. This solution for heart failure management is not just the application of a non-invasive wearable, but can be tailored to the provider's needs using a comprehensive, end-to-end approach. Moreover, the wearable itself has been designed for easy and convenient application in order to address the concern about patient adherence.

The system contains the following attributes:

- A proactive approach to managing and maintaining heart failure patients in a steady state and preventing acute episodes.
- An innovative technology which includes sensors, computer chips and intelligent algorithms, which provide data to care teams and could enable a shift in the focus of care from solely treating acute episodes to avoiding acute episodes.
- An integrated, non-invasive, multi-parameter sensor platform. This platform measures multiple specific and sensitive physiological parameters that are analyzed and trended on a daily basis.
- Intelligent algorithms, which provides the opportunity to assist care teams in proactively identifying patients at increased risk of worsening HF and a potential acute episode.
- An optional data review and triage service, in conjunction with notifications within the Sensinel system, to assist clinical care teams in prioritizing patients, reducing the likelihood of an acute episode, and minimizing the clinical care team's effort associated with false positives.
- A shift in the focus of monitoring to a lower cost home setting versus the hospital or skilled nursing facility.
- Designed to align with new value-based payment models (including MA plans, REACH programs, PACE programs, and advanced risk bearing ACOs), with the potential to prevent higher costs.

Summary



Traditional approaches to heart failure have not met expectations.

There are two traditional approaches to heart failure management.

- The first approach focuses on managing patients during their acute episode.
- The second approach focuses on preventing the acute episode using either:
  - Traditional measures such as weight, blood pressure, and pulse oximetry or

- Implanting a sensor in the pulmonary artery
- Both alternatives are less than optimal and may not provide the scalability and return on investment (ROI) necessary for providers and payers to invest their time and resources in these efforts. The weight, blood pressure, and pulse oximetry approach does not permit the caregivers adequate warning to change the treatment plan to prevent acute episodes and hospitalization[9].

The invasive approach of implanting a sensor in the patients' pulmonary artery is expensive and places the patient at a higher risk for complications than a non-invasive approach. Many patients do not want to have an invasive procedure. In order to address unmet needs in the market for managing heart failure patients, ADI developed a non-invasive remote patient monitoring model that is scalable and is designed to provide the opportunity to not only improve care and outcomes, but also for a reasonable return on investment (ROI).

ADI's novel approach to managing heart failure is much like the solution for proactively managing the diabetes population that has been effectively implemented throughout the nation.

Combining technology and an end-to-end solution with value-based payment models has the potential to create the necessary ROI to permit the scalable implementation of this new and innovative solution, and thus to improve the lives of millions of heart failure patients.

[9] Ong MK, Romano PS, Edgington S, Aronow HU, Auerbach AD, Black JT, de Marco T, Escarce JJ, Evangelista LS, Hanna B, Ganiats TG, Greenberg BH, Greenfield S, Kaplan SH, Kimchi A, Liu H, Lombardo D, Mangione CM, Sadeghi B, Sadeghi B, Sarrafzadeh M, Tong K, Fonarow GC, for the 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(3):310–318. doi: 10.1001/jamainternmed.2015.7712