A CASE STUDY:

Defining An Effective Workflow For Integrating The ZOLL® Heart Failure Management System Into Clinical Practice

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Overview

The ZOLL® Heart Failure Management System* (HFMS) is a novel, non-invasive, patch-based device that uses radiofrequency technology to provide early detection of changes in pulmonary fluid levels, an increase in which is an early indicator of heart failure decompensation. These changes, as measured by the Thoracic Fluid Index (TFI), are monitored by ZOLL's Independent Diagnostic Testing Facility (IDTF). The ZOLL IDTF notifies clinicians when TFI trends are out of range, which in turn allows clinicians to assess an appropriate course of action for the patient.

HFMS is recommended for use with patients who require remote pulmonary fluid management following an acute heart failure decompensation event that resulted in a hospitalization or clinic visit.

Data from the BMAD trial were made public at ACC 2023 in the form of a Late Breaking Clinical Trial presentation. The data demonstrate that use of ZOLL HFMS resulted in a 38% relative risk reduction in 90-day heart failure readmission (7% absolute risk reduction, NNT=14.3).[1]

Our program at Piedmont Heart was selected as a limited market release (LMR) site. This case study details our experience with defining a clinical workflow to successfully integrate HFMS into our practice.

Historical Context

Heart failure rehospitalization for congestion is an unfortunately common occurrence in the United States with approximately 1 in 3 heart failure patients readmitting within 90 days.[2] The patient management strategy following an acute decompensated event, and prior to optimized guideline directed medical therapy, has remained largely unchanged for decades.[3]

Legacy remote patient management tools, such as weight scales and telemonitoring, have shown significant limitations in the prevention of heart failure readmissions.[3,4] Medical professionals have relied upon these legacy remote patient management tools in the absence of more efficacious options.

The patient management strategy at Piedmont Heart for these ambulatory heart failure patients has historically involved monthly in-office follow-up visits and clinic visits as needed based on patient symptoms.

Early Questions

One of our early objectives was defining an effective process for identifying, prescribing, and following appropriate patients. There were several questions we needed to answer:

- When in the patient care continuum is it optimal to engage with HFMS?
- Who will prescribe?
- What method will we use to prescribe, e.g. EMR, ZOLL Patient Management (ZPM) Network platform?
- Who manages the alert notifications that are communicated to us by the IDTF?
- How will we triage patient data in the reports provided by the IDTF?
- How do we manage TFI out-of-range notifications?
- What interventions will be made based on the TFI out-of-range notifications?

These questions have subsequently been used to inform ZOLL's approach to workflow mapping when partnering with new accounts during the HFMS enrollment process.

HFMS Workflow at Piedmont

Patient Identification

Patients in need of ongoing pulmonary fluid management can often be described as:
- Currently hospitalized heart failure patient
- Post-hospitalization heart failure patient
- Post-ER treated heart failure patient
- Heart failure patient is seen/treated in the heart failure clinic
- Heart failure patients requiring escalating doses of outpatient diuretic

It's important to note that neither ejection fraction nor NYHA class are determining factors in identifying patients that would benefit from ZOLL HFMS, but rather the need for pulmonary fluid management.

In the inpatient setting, I and three APP's at the Fayetteville, GA, facility identify appropriate patients and prescribe HFMS based on who is covering rounds, with a typical prescription length of 90 days. Patients that have been admitted for CHF exacerbation and have ongoing fluid management needs are typically prescribed the HFMS device after patient education occurs at pre-discharge. Prescription is always a shared decision with the patient.

Ordering Process & Set-Up

Hospital Case Managers typically place the order when patients are identified in the inpatient setting. Clinic RN's are typically placing the order when patients are identified in the out-patient setting. HFMS is ordered through the ZOLL Patient Management portal. The device is subsequently shipped from ZOLL directly to the patient's home. ZOLL contacts the patient and walks them through the device application and set-up.

HFMS Management

It should be noted that the optimal HFMS patient management workflow will likely vary by institution based on what works best for any given practice. At Piedmont, patients that were prescribed an HFMS monitor are managed by the RN team in the outpatient clinic. All alert notifications received from the IDTF go directly to the RNs for initial review and are then triaged to the appropriate following Provider (APP or Dr. Darlington).

The RN team triages patients by asking a standard series of questions:
- Have you experienced any changes in your diet?
- Are you taking your medications as prescribed?
- Have you added any new medications?
- Have you missed any doses of your medication in the past week?
- Have you experienced any swelling of the lower extremities?
- Have you experienced any sudden weight change?

Answers are sent to the appropriate Provider for clinical intervention. Common interventions include:
- Adjust diuretics
- Classify which types of heart failure medicines may be up-titrated or added, e.g.:
  - Entresto
  - SGLT2 inhibitor class (Farxiga and Jardiance)
  - Beta Blockers
  - Spironolactone
- Follow up with patient by phone within two days
- If TFI continues to be elevated escalate to a face-to-face encounter if needed (generally within 3-5 days).

Workflow Diagrams @ Piedmont Heart Institute – Fayetteville, GA

Inpatient Identification	Prescription	Enrollment
Day 2 or 3 of HFH Hospitalization period allows for: • Education • Rapport building • Identification of appropriate candidates	Executed by: • Dr. Darlington • Rounding APP • Focused on 90-day prescriptions	• Case Management • Minimizes provider burden • Via ZOLL Patient Management Network portal

Outpatient Identification	Prescription	Enrollment
• Clinic based assessment of patients at regularly scheduled OV or symptom driven OV	Executed by: • Dr. Darlington • APP's • Focused on 90-day prescription	• Clinic RN's • Clinic staff • Via ZOLL Patient Management Network portal

Alerts & Patient Triage	Intervention Plan	Patient Engagement
• RN's receive notifications for initial review • Patients contacted, questioned, & triaged to providers	Determined by: • Dr. Darlington • APP's Common interventions: • Diuretics • HF meds • Subsequent follow-up plan	• Patients contacted with intervention plan by Dr. Darlington, APP's, or RN's

Best Practices

- Thorough establishment of the HFMS workflow prior to initiating prescriptions is paramount.
- There may not be one particular path for every patient. Interpreting the alert data sent by ZOLL IDTF will determine more realistic options for each patient.
- Having support for HFMS implementation with both a "Clinical" and "Executive" Champion has a positive downstream effect on clinical engagement & staff management.
- Patients are educated pre-discharge by the prescribing provider utilizing the HFMS patient brochure. Patients receive additional education from ZOLL's IDTF once they receive the device at home post-discharge.
- The most recent HFMS Weekly Report (via ZPM) is reviewed for complete patient assessment at the time of the office visit. These Weekly Reports include TFI details, Biometric Data, and Arrhythmia Events based on alert criteria, all of which are factors used in determining the next steps in patient care.

Experience to Date

A carefully planned workflow for ZOLL HFMS integration into our practice has been critical to our successful use of this product with patients. TFI notifications sent by the IDTF have allowed for impactful interventions with patients, typically via remote medication and lifestyle adjustments. Having a "Clinical" champion and an "Executive" champion has made the implementation process run more smoothly, with a positive downstream effect on clinical and staff engagement. A committed and engaged staff has helped improve patient adherence to their respective care plans.

A few positive conclusions that came about after integrating ZOLL HFMS into our practice include a larger than expected volume of identified patients that stand to benefit, improved patient adherence to care plans, and a frequently perceived improvement in patient quality of life.

An example of the effective HFMS management component of the workflow in practice:

A 65 y/o male had two heart failure hospitalizations in a six-month period despite adherence to GDMT. EF 35-40%. He had previous trips to Heart Failure Recovery Center for intravenous diuretics as well. Following the most recent heart failure hospitalization he was treated and discharged on appropriate medical therapy and was also prescribed a ZOLL HFMS.

Approximately two weeks post-discharge our office was contacted by the ZOLL IDTF to notify us of an elevated TFI reading on three sequential days. The patient was contacted via phone. Following the standard RN administered triage questions (see above) the provider adjusted Torsemide to twice daily dosing and moved the next office visit up in order to expedite a face-to-face evaluation.

HFMS total wear time was 90 days. The patient has not been hospitalized since discharge six months prior. There has been an improvement in subsequent office visit compliance, as well as overall medication adherence.

Summary

ZOLL HFMS provides a critical new tool for managing ambulatory heart failure patients with pulmonary fluid monitoring needs. Establishing a workflow that effectively integrates HFMS into clinical practice requires planning on the front end and internal resource alignment. We anticipate HFMS usage increasing at Piedmont as the heart failure population in the United States continues to grow.

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* FDA registered name: μcor™ Heart Failure and Arrythmia Management System

[1] Boehmer J, et al. Impact of Heart Failure Management Using Thoracic Fluid Monitoring From a Novel Wearable Sensor: Results of the Benefits of Microcor (μCor™) in Ambulatory Decompensated Heart Failure (BMAD) Trial. Presented as Late Breaking Clinical Trial at the 2023 American College of Cardiology Annual Scientific Session, March 6, 2023.

[2] Khan MS, Sreenivasan J, Lateef N, et al. Trends in 30- and 90-Day Readmission Rates for Heart Failure. Circ Heart Fail. 2021;14(4):e008335.

[3] Fudim, M., et al. Role of Volume Redistribution in the Congestion of Heart Failure. JAHA. Aug 2017;6

[4] Ong MK., et al. 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