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The design of the Dashboard Activated Services and Telehealth for Heart Failure (DASH-HF) study: A pragmatic quality improvement randomized implementation trial for patients with heart failure with reduced ejection fraction

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ABSTRACT

Background: Gaps in the receipt and dosing of guideline-directed medical therapy (GDMT) persist for patients with heart failure with reduced ejection fraction (HFrEF) [1]. In 2020, the Veterans Affairs (VA) developed a heart failure (HF) specific population dashboard to monitor care quality and performance on standard HFrEF performance measures [2]. *Methods:* The Dashboard Activated Services and Telehealth for HF (DASH-HF) study is a pragmatic randomized

quality improvement study designed to evaluate the utility of proactive population management clinics using the VA's HF dashboard to optimize GDMT for patients with HFrEF. Panel management telemedicine clinics incorporated multidisciplinary clinicians to perform chart review and impromptu telephone encounters to evaluate current HFrEF management and opportunities to optimize GDMT. The study will evaluate the efficacy of proactive panel management to usual care at 6 months as quantified by the GDMT optimization potential score. Secondary outcomes include hospitalizations, mortality, and clinician time per intervention. The study completed enrollment and randomization of 300 participants. The intervention was performed from September to December 2021.

Conclusion: DASH-HF will contribute to the literature by evaluating use of the existing VA dashboard to identify HF patients with the lowest adherence to GDMT and proactively target this group for the intervention. **Registration:**https://clinicaltrials.gov/. Unique identifier: NCT05001165.

1. Introduction

An estimated 6 million people live with heart failure (HF) in the U.S. [3] HF is a leading diagnosis for hospitalization with a high risk of readmission [4,5]. Despite robust clinical trial data and strong

recommendations by professional societies, there is a well-documented gap in delivering guideline-directed medical therapy (GDMT) for patients with reduced ejection fraction (HFrEF) [1,6–8]. GDMT includes Class I indicated medications from the following classes: beta blockers (BB), angiotensin-converting enzyme inhibitors (ACE), angiotensin II

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receptor blockers (ARB), angiotensin receptor neprilysin inhibitors (ARNI), mineralocorticoid receptor antagonists (MRA), sodium glucose cotransporter-2 inhibitors (SGLT2i) [6,7,9].

Patients with HFrEF are optimally managed by team-based, multidisciplinary cardiovascular HF clinics [10]. Prior quality improvement initiatives to systemically optimize GDMT for HF include structured HF disease management and medication titration pathways [11–13], computer-based reminder systems [14–16], digital health-based optimization [17,18], and remote electronic health record-based optimization programs [19]. Typically, patients are referred to cardiology or HF clinics from primary care or emergency department clinicians, or referred post-hospitalization. We have been able to decrease HF admissions and improve HF medication adherence with a multidisciplinary HF clinic focused on the immediate period after a HF admission [20]. However, patients may be lost to follow-up, not referred even with a prior HF hospitalization, and clinicians may miss opportunities to optimize use and dosing of GDMT for HFrEF.

In 2020, the United States Department of Veterans Affairs (VA) developed a HF dashboard using natural language processing derived left ventricular ejection fraction (LVEF) measurement and electronic health record (EHR) data of laboratory and pharmacy information to structure standardized GDMT performance measures to monitor and improve outpatient HF management [2]. The Dashboard Activated Services and Telehealth for HF (DASH-HF) study will evaluate the utility of the existing VA HF dashboard and telemedicine panel management clinics to proactively implement evidence-based care for patients with HFrEF. DASH-HF is registered on http://clinicaltrials.gov (identifier NCT05001165).

2. Trial design and methods

DASH-HF is a pragmatic, open-label, randomized controlled trial of a quality improvement (QI) intervention to evaluate the effectiveness of a prospective panel management intervention to optimize medical treatment for Veterans with HFrEF compared with the receipt of usual VA health care services over a 6-month period (Fig. 1). Pragmatic trials are useful in evaluating the real-world effectiveness and implementation of health services interventions at minimal research costs. DASH-HF was designed as a pragmatic trial to include a heterogenous group of participants in various home settings, including nursing homes, and be implemented by clinicians across disciplines (eg, physicians, nurse practitioners, and pharmacists) [21,22]. The study incorporates the existing VA HF dashboard to target actionable patients with gaps in performance measures for GDMT. The outcomes of the study were pragmatically ascertained from routinely collected data and quality measures from the VA dashboard. The dashboard data includes demographics, hospitalization risk scores, number of VA hospitalizations in the past 12 months, vital signs, key laboratory values, active GDMT prescriptions, and upcoming appointments.

The trial is registered on http://clinicaltrials.gov and its unique identifier is NCT05001165. The study was reviewed by the VA IRB board and given the minimal risk of the study design was granted exemption from IRB supervision or patient consent.

2.1. Patient population

Patients with HFrEF receiving care at the VA Greater Los Angeles and included in the VA dashboard were considered for inclusion on September 17, 2021. Inclusion criteria included the following: (1) patient receives care at VA Greater Los Angeles; (2) eighteen years of age or older; (3) primary diagnosis of HFrEF (last documented LVEF \leq 35%); (4) estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min; (5) last documented potassium less than 5; (6) last documented systolic blood pressure over 90 mmHg; (5) Optimization potential score (OPS) of less than or equal to 5 out of 10; and (6) no upcoming general cardiology or HF appointments in the upcoming 2 weeks. Exclusion criteria included if the dashboard indicated that the patient was currently hospitalized at the Greater Los Angeles VA.

The OPS was created by the investigators, using an approach similar to other validated scoring systems used to characterize baseline GDMT



Fig. 1. The CONSORT recruitment and enrollment flow diagram for the DASH-HF study.

use and dosing of clinical trial participants [23–25], to quantify the extent of GDMT optimization (Table 1). It was calculated based on the presence of each class of GDMT and total daily dose of each medication as listed on the patient's active medications in the VA dashboard. The OPS ranged from 0 to 10. Scores of 0 indicated the highest potential for further optimization and a score of 10 indicated that the patient is on all recommended medications at target doses. As an example, a patient on target doses of beta-blocker and ARNI but not an MRA or SGLT2i would receive a total of 6 optimization points. ARNI are recommended for patients with HFrEF on optimal doses of ACE/ARB. Since a clinician in the VA is recommended to optimize ACE/ARB and BB for outpatients prior to switching to an ARNI, two additional points are granted for this additional titration step giving the presence of an ARNI a total of 4 points to reflect the complexity of titration.

2.2. Recruitment

We utilized the VA's dashboard to generate a list of actionable patients with HFrEF and LVEF \leq 35%. An LVEF of \leq 35% was chosen as this was the threshold utilized in the landmark RALES trial for mineralocorticoid initiation, one of the GDMT classes included in the OPS [26]. Study participant numbers were assigned to the list of patients sorted based on the OPS and patients with a score of less than or equal to 5 were included in the study.

2.3. Randomization

We randomized in permuted blocks of 6 individual patients to usual VA care or a novel proactive panel management strategy. Treatment assignment was based on 1:1 randomization using fixed blocks (size = 6) to assure an equivalent number of patients randomized to the intervention and usual care. The supervising statistician generated concealed randomization assignments by participant identification numbers. The randomization assignments were merged with baseline study dataset and exported as password protected Excel and PDF documents.

2.4. Blinding

The randomization sequence was concealed from the clinicians until after randomization had already been completed. Post-randomization, study staff were not blinded to allocation. The intervention did not allow for blinding of participants in the intervention arm. Patients in the usual care arm were unaware that they were part of the control group for the study.

2.5. Intervention

Study investigators divided the intervention arm into lists of 10 to 15 patients per clinic. Intervention patients were assigned to panel management telehealth clinics (half-day clinic lasting 3.5 h). Each panel management clinic was staffed by a cardiovascular clinician or a healthcare clinician (medical trainees, advanced practice nurse

Table 1

Optimization potential score (OPS).

| | Points | | | |
|--------------|--------|----------|---------------|--|
| | None | Low Dose | Targeted Dose | |
| ACE/ARB/ARNI | 0 | 1 | 2 | |
| Beta Blocker | 0 | 1 | 2 | |
| MRA | 0 | 1 | 2 | |
| ARNI | 0 | 1 | 2 | |
| SGLT2i | 0 | - | 2 | |

ACE Angiotensin-converting enzyme inhibitors, ARB angiotensin receptor blocker, ARNI, Angiotensin Receptor-Neprilysin Inhibitor, MRA mineralocorticoid receptor antagonist, SGLT2i sodium-glucose cotransporter-2 inhibitors. practitioner, or clinical pharmacist) with supervision by a licensed and board-certified cardiologist.

Clinicians staffing the intervention clinics reviewed dashboard data and EHR and decided whether to proceed to evaluate and recommend treatment over the phone to patients directly. If the clinicians did not have sufficient time to review all patients on their clinic list, the remaining participants were redistributed to future intervention clinics. Patients that did not answer phone calls received chart review notes for primary care and cardiology clinicians and were not reassigned to future panel management clinics. Patients who were difficult to reach (e.g., missing contact details, non-operating phone number) also received templated letters regarding following up with the primary care or cardiology clinic regarding their HF management. Intervention clinics were held until each patient assigned the intervention had a chart review or attempted telephone contact.

Clinicians were trained on how to use the dashboard information and chart review to identify opportunities for optimization and provided guidance on the sequence of GDMT optimization based on latest guidelines (Supplement S1 GDMT Optimization Guide). If a patient did not qualify for further optimization (i.e., chart documentation of prior intolerance or patient preference), clinicians documented a short note in the EHR that informed the patient's existing providers that based on chart review, no opportunity currently existed but they may consider further GDMT titration in the future. If a patient appeared to have an opportunity for further titration, the clinician contacted the patient impromptu to see if they were available to discuss their HF care. Patients that received the intervention were informed this is a pilot quality improvement effort with informal consent before proceeding to the clinical interventions. Intervention patients had the opportunity to refuse to participate after being contacted by phone in the intervention. If the patient agreed, a formal telehealth cardiology visit took place over phone. If the patient was interested but did not have time for a visit, a brief telephone note was placed and a request for a future cardiology clinic visit was requested. There were no investigational medical treatments used for this study. All recommended prescription therapies are FDA approved with Class I indication for use in heart failure with reduced ejection fraction. All recommendations and care provided for proactive telehealth intervention and control arms are based on AHA/ ACC/HFSA guidelines. For the study to remain pragmatic and valid for all patients with heart failure in our health system, formal informed consent is not warranted nor feasible for either intervention or usual care patients.

If a formal telehealth visit occurred, clinicians were asked to inquire about key details around medication titration (Supplement S2 Interview Guide). Based on the interview, the patient was given recommendations and all questions were answered. The data from the dashboard, chart review, and patient interviews was documented on an Excel document (Supplement S3 Clinician Documentation Form). Any medication addition or titration with indicated laboratory and diagnostic tests, returnto-clinic orders, and referrals to HF or general cardiology clinic were ordered per usual care. Lastly, clinicians asked each participant for feedback on the proactive phone call. Primary care and regular cardiology clinicians were notified of any changes in medication management in the EHR.

2.6. Control group

The control arm consisted of the usual delivery of health services with routine scheduled appointments for primary care or cardiology.

2.7. Study outcomes

The duration of the study will be 6 months from the last patient to receive the intervention, marking the completion of the intervention.

2.8. Primary outcome

The primary outcome of the study is the OPS 6 months after the end of the intervention, defined by active prescriptions and prescribed doses for each class of GDMT.

2.9. Secondary outcome

The secondary outcomes include the following at 6 months after the end of the intervention:

1. Active prescriptions for individual classes of GDMT

- a. ACE/ARB/ARNI
- b. Beta Blocker
- c. MRA
- d. ARNI
- e. SGTL2i
- 2. Hospitalizations
 - a. Total number of all-cause hospitalizations
 - b. Total number of primary HF hospitalizations
 - c. Proportion of patients with any hospitalization
 - d. Proportion of patients with any HF hospitalization
- 3. Number and proportion of patients with deaths
- 4. Clinician time spent per patient from opening chart to end of patientspecific intervention and documentation.
- 5. Health service efficiency
 - a. Number of patients reviewed or contacted per half-day clinic
 - Number of medication adjustments (stop, start, titration) per halfday clinic
 - c. Number of laboratory tests ordered per half-day clinic
 - d. Number of imaging/diagnostic procedures ordered per half-day clinic
 - e. Number of referrals for consults/device therapy per half-day clinic
 - f. Number of return-to-clinic orders
- 6. Qualitative evaluation of patient surveys who received the intervention.

2.10. Sample size and statistical analysis

The study was powered to detect superiority of the intervention compared to usual care in optimizing GDMT for HFrEF. Using a baseline average GDMT optimization score of 2.4 and standard deviation of 1.5 as calculated for the population of patients with an OPS of 5 or less at VA Greater Los Angeles, we estimated a sample of 300 patients to have 83% power to detect 25% improvement in GDMT optimization scores for the intervention (standard deviation assumed 1.9 for the intervention arm). Given the target sample size of n = 300 total patients, the sequence was generated using permuted blocks of size 6 to ensure that an equal number of patients were randomized to panel management and usual care, maximizing efficiency (power).

The dashboard data was exported at baseline. To evaluate study outcomes, the VA dashboard will be exported again to a secure Excel file 6-months after the last participant received the intervention. The primary analysis will be performed using ANCOVA with baseline adjustment for age and OPS which should improve the power to detect a difference between treatment arms. Semi-structured survey data will be captured by clinicians for only intervention patients. No interim analyses are planned. Longer term secondary evaluations will be evaluated at year 1 and 2.

2.11. Study status

The DASH-HF study was registered on http://clinicaltrials.gov on August 11, 2021. The DASH-HF study completed enrollment and randomization of 300 participants on September 17, 2021. 150 patients

received the intervention over a 12-week period with half-day panel telehealth clinics based on clinician availability. Table 2 describes participants' baseline characteristics. The intervention was initiated on September 17, 2021 and completed on December 15, 2021. Results will be disseminated in 2022.

3. Discussion

The DASH-HF study is designed to evaluate the utility of identifying patients on suboptimal HF therapies using the existing VA dashboard and utilizing a telehealth intervention to improve care and outcomes. Prior quality improvement initiatives have evaluated strategies on implementing HF guidelines into practice, including audit and feedback process measures [12,27], tracking performance measures such as HF-related readmissions [20,28,29],or inpatient initiation of GDMT for patients hospitalized for HF [30].

The Registry to Improve the Use of Evidence-based HF Therapies in the Outpatient Setting (IMPROVE-HF) was the first large-scale outpatient QI trial for HF that incorporated various structured interventions including clinical decision support tools and chart audits with feedback [27]. The trial resulted in significant improvements in 5 of 7 prespecified quality measures [27], however, the outcomes did not capture changes to target dosing of GDMT and the trial was not randomized with a control group for comparison. The Care Optimization Through Patient and Hospital Engagement Clinical Trial for HF (CONNECT-HF) was a randomized hospital and post-discharge quality improvement intervention that focused on clinician education and audit and feedback [12]. The study found no significant difference in its primary outcomes, which included a HF composite score that incorporated use and dosing of GDMT. Similar results were observed in the Patient Centered Care Transitions in Heart Failure (PACT-HF), designed to test the effectiveness of HF post-hospitalization transitional care services [31].

| Table 2 | |
|----------|-----------|
| Pocolino | Charactor |

| Базение | Charac | teristi | cs. |
|---------|--------|---------|-----|
| | | | |

| Intervention (<i>N</i> = 150) | Usual Care (N = 150) |
|--------------------------------|--|
| 71 (64–78) | 73 (65–79) |
| 2 (0.01%) | 2 (0.01%) |
| | |
| 49 (38%) | 43 (33%) |
| 74 (57%) | 82 (63%) |
| 5 (4%) | 2 (1%) |
| 2 (2%) | 2 (2%) |
| | |
| 0 (0%) | 1 (1%) |
| | |
| 92 (83–97) | 91 (81–97) |
| 4.7% | 4.7% |
| | |
| 19 (13%) | 18 (12%) |
| 22 (15%) | 24 (16%) |
| 38 (25%) | 36 (24%) |
| 31 (21%) | 32 (21%) |
| 22 (15%) | 21 (14%) |
| 18 (12%) | 19 (13%) |
| | |
| 102 (68%) | 99 (66%) |
| 118 (79%) | 120 (80%) |
| 44 (29%) | 44 (29%) |
| 16 (11%) | 17 (11%) |
| | |
| 15 (10%) | 15 (10%) |
| 15 (10%) | 18 (12%) |
| 16 (11%) | 14 (9%) |
| 16 (11%) | 17 (11%) |
| 125 (111–134) | 119 (107–135) |
| 69 (59–77) | 69 (58–79) |
| 75 (66–85) | 74 (67–85) |
| 187 (158–222) | 188 (157–225) |
| | 1161 (W = 150) 71 (64-78) 2 (0.01%) 49 (38%) 74 (57%) 5 (4%) 2 (2%) 0 (0%) 92 (83-97) 4.7% 19 (13%) 22 (15%) 38 (25%) 31 (21%) 22 (15%) 18 (12%) 102 (68%) 118 (79%) 44 (29%) 16 (11%) 15 (10%) 15 (10%) 15 (10%) 16 (11%) 69 (59-77) 75 (66-85) 187 (158-222) |

These studies demonstrate the need to develop novel interventions beyond the post-hospitalization period to engage in the care of HF patients. The Electronically Delivered, Patient-Activation Tool for Intensification of Medications for Chronic Heart Failure with Reduced Ejection Fraction (EPIC-HF) assessed the utility of a digital health intervention delivered directly to patients leading up to their cardiology clinic visits and found enhanced use and dosing of GDMT, although there was a nonsignificant increase in emergency room department visits and hospitalizations in the intervention group [18]. Another recent study incorporating a remote, algorithm-driven medication optimization program managed by patient navigators under supervision of a pharmacist, nurse practitioner, and heart failure cardiologist resulted in improved GDMT for HFrEF patients [19].

DASH-HF will add to the evidence base by using the existing VA dashboard to identify HF patients with the largest gaps to GDMT and proactively target this group for the intervention. Our study will evaluate the effectiveness of telemedicine panel management clinics in this patient population and highlight major systems challenges. The study will also help describe limitations and barriers to GDMT optimization among this patient population. The Coronavirus disease 2019 (COVID-19) pandemic has led to a marked overall increase in the use of telehealth services [32]. If successful, this study may serve as a key pilot trial that leverages telehealth services and dashboard data to target patients who may be at highest risk for HF-related hospitalizations and mortality due to suboptimal HF therapies.

4. Conclusion

DASH-HF is a unique, pragmatic, randomized quality improvement study designed to evaluate the effectiveness of an existing VA dashboard to identify and close treatment gaps in GDMT for HFrEF. The study will provide important data on strategies to identify patients without optimal GDMT using clinical informatics and provide insight on supplementing traditional care with proactive telemedicine panel management clinics.

Disclosures

Dr. Fonarow reports consulting for Abbott, Amgen, AstraZeneca, Bayer, Cytokinetics, Edwards, Janssen, Medtronic, Merck, and Novartis. There are no disclosures for other authors.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The data that has been used is confidential.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2022.106895.

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