Dashboard Activated Services and tele-Health for Heart Failure (DASH-HF) Study

Statistical Analysis Plan

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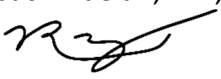
Signature: 
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2 Abbreviations and Definitions

ACE	angiotensin-converting enzyme inhibitor
ADHFD	Academic Detailing Heart Failure Dashboard
AKI	acute kidney injury
ARB	angiotensin II receptor blockers
ARNI	angiotensin receptor neprilysin inhibitor
HF	heart failure
HFrEF	heart failure with reduced ejection fraction
LVEF	left ventricular ejection fraction
MRA	mineralocorticoid receptor antagonist
SGLT2i	sodium-glucose cotransporter-2 inhibitor

3 Introduction

3.1 Preface

The TELEhealth and Dashboard Activated Health Services outreach (TELE-DASH) study is a pragmatic randomized controlled trial of a quality improvement (QI) intervention of a prospective panel management intervention to optimize medical treatment for Veterans with heart failure with reduced ejection fraction (HFrEF) compared to the receipt of usual VA health care services over a 6-month period of observation. The study will incorporate the existing VA Academic Detailing Heart Failure Dashboard (ADHFD) to target actionable patients with gaps in performance measures for guideline-directed medical therapies (GDMT). Patients with HFrEF are optimally managed by cardiovascular specialty clinics. Typically, patients are referred to cardiology or heart failure (HF) clinics from primary care, emergency department, or post-hospitalization clinicians and scheduled into clinic grids. These patients may be lost to follow-up, not referred without prior HF hospitalization, or clinicians may miss opportunities to optimize GDMT for HFrEF. GDMT includes Class I indicated medications from the following classes: beta blockers (BB), angiotensin-converting enzyme inhibitor (ACE), angiotensin II receptor blockers (ARB), angiotensin receptor neprilysin inhibitor (ARNI), mineralocorticoid receptor antagonist (MRA), sodium-glucose cotransporter-2 inhibitor (SGLT2i). [1–3] The intervention is designed around prospective panel management clinics led by clinicians using impromptu patient telephone calls or electronic communications with existing responsible clinicians.

3.2 Scope of the analysis

The analyses will evaluate the effectiveness of proactive panel management clinics in optimizing the receipt of GDMT for patients with HFrEF compared to usual care at 6-months post-intervention for the final participant. The goal is to demonstrate that panel management clinics are more effective than usual care in optimizing care for patients with HFrEF that may been lost to follow-up or not referred for HF evaluation and treatment.

4 Study Objectives and Endpoints

4.1 Study Objectives

The purpose of this study is to measure the effectiveness of proactive panel management clinics to optimize GDMT relative to usual care. The study will also evaluate secondary outcomes that signify improved outcomes such as reduced hospitalizations and mortality. The study will also evaluate clinician time per intervention relative to usual cardiology or HF clinic structure.

4.2 Endpoints

4.2.1 Primary outcome

The primary outcome is active prescription of HFrEF therapies as summarized by the change in GDMT optimization potential score (Table 1) at final evaluation. The optimization potential score ranges from 0-10. Scores of 0 indicate a high potential for further optimization. The scoring system is defined in as follows:

Table 1: Guideline-Directed Medical Therapy Optimization Scoring System

	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

As an example, a patient on target doses of beta-blocker and ARNI would receive 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 presents of an ARNI a total of 4 points to reflect the complexity of titration.

4.2.2 Secondary outcome

The secondary outcomes of the study will include the following at final evaluation:

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 any cause hospitalization
    b. Total number of primary HF hospitalizations
    c. Proportion of patients with any hospitalization
    d. Proportion of patients with any HF hospitalization
3. Number of deaths
4. Clinician time spent per patient from opening chart to end of patient-specific intervention and documentation.
5. Health service efficiency
    a. Number of patients reviewed or contacted per half-day clinic
    b. Number of medication adjustments (stop, start, titration) per half-day 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
6. Qualitative evaluation of patient surveys who received the intervention.

5 Study Methods

5.1 General Study Design and Plan

This is a randomized, pragmatic QI study designed to evaluate the effectiveness of proactive panel management to close gaps in evidence-based care for patients with HFrEF. We will use the VA's ADHFD to generate a list of actionable patients with HFrEF and left ventricular ejection fraction (LVEF) ≤ 35%. After identifying a cohort of HFrEF patients from the ADHFD, we will randomize individual patients on the actionable list to usual VA care or a novel proactive panel management clinic. Clinicians will be trained on how to use the dashboard information to identify opportunities for optimization based on detailed chart review. The proactive panel management intervention will use clinicians to perform an electronic chart review and call patients impromptu at their discretion to evaluate HFrEF management and opportunities to optimize GDMT. Each panel management clinic is staffed by a single cardiovascular clinician or trainee with cardiology (PI) supervision. All patients will receive chart review or telehealth notes brought to the attention of primary care and cardiology clinicians. Patients randomized to the intervention will only receive one chart review during a half-day panel management clinic with follow-up of any laboratory results or diagnostic tests as required and referral to HF or general cardiology clinic as deemed appropriate. The control arm consists of the usual delivery of health services with routine scheduled appointments for primary care or cardiology.

Outcomes will be assessed at 6-months from the last patient to receive the intervention. The study is powered to detect superiority of the intervention compared to usual care in optimizing GDMT for HFrEF. Treatment assignment is based on 1:1 randomization using fixed blocks (size=6) to assure an equivalent number of patients randomized to the intervention and usual care. Patients are randomized after a list of 300 actionable patients are generated from the ADHFD. Study participant numbers will be assigned to the list of patients sorted by optimization scores in Excel. The supervising statistician (AA) will generate concealed randomization assignments by participant identification numbers. The randomization assignments will be merged with baseline study dataset and exported as password protected Excel and PDF documents. Study investigators will divide the intervention arm into lists of 10 to 15 per half-day clinic. Patients not receiving chart review or phone call attempts will be reassigned to future panel management clinics until all patients receive the intervention. Patients that did not answer phone calls will receive chart review notes for primary care and cardiology clinicians and not be reassigned to future panel management clinics.

Study participants do not require informed consent as determined by the VA IRB review. Patients will receive all accepted standards of care and medications approved by the Food and Drug Administration for HFrEF indications. The VA Subcommittee for Research and Safety found an absence of any declared research-laboratory-based biohazards and granted exemption from continued review. The study will evaluate the effectiveness of the QI intervention, telephone/telemedicine panel management clinics, to more rapidly implement evidence-based care for patients with HFrEF. Patients in the usual care arm will be unaware they are part of the control group for the RCT. Intervention patients nor study staff are blinded to usual care or intervention assignments. Patients that receive the intervention will be informed this is a pilot quality improvement effort with informal consent before proceeding to the clinical interventions. Intervention patients may refuse to participate after being contacted by phone in the intervention.

Study enrollment is based on the inclusion and exclusion criteria used to filter the ADHFD list. A list of actionable patients with HFrEF will be exported for randomization. The GDMT optimization score will be automated for each patient on the extracted list (**Table 1**). A sample of 300 patients will be selected with the lowest GDMT composite scores. Once the final sample of the study is determined, patients will be randomized to usual care or the intervention. Intervention patients will be divided into smaller lists of 10 to 15 patients. These smaller

lists will be assigned to proactive panel management clinics. Clinicians staffing the intervention clinics will review ADHFD data, review the electronic health record (EHR) and decide whether to proceed to evaluate and recommend treatment over the phone to patients directly. If clinicians did not have sufficient time to review all patients on their clinic list, they will be redistributed to future intervention clinics. Intervention clinics will be held until each patient assigned the intervention has a chart review or attempted telephone contact. A failure to contact a patient will trigger a letter to a patient or electronic communication to their primary care or cardiology clinician.

Prior to each ADHFD telehealth clinic (half-day clinic lasting 4 to 4.5 hours), clinicians will be sent a secure email that will include a password-protected Excel document of 15 patients with exported clinical summary data from the ADHFD. Clinicians will be instructed to chart-review patients and decide if an opportunity exists to further optimize the receipt of GDMT. Clinicians will also be given a document providing guidance on the sequence of GDMT optimization based on latest guidelines and VA policies (Supplement S1 GDMT Guidance Document). If a patient does not qualify for further optimization (i.e. chart documentation of prior intolerance, patient preference), a short note in the electronic health record (EHR) will document the chart review and inform the primary care clinician that based on chart review, no opportunity currently exists but they may consider further GDMT titration in the future. If a patient appears to have an opportunity for further titration, the clinician is encouraged to call the patient to see if they are available to discuss their HF care. If the patient agrees, a telehealth visit will take place over phone or switch to video. A formal telehealth cardiology visit will occur at the time of care. If the patient is interested but does not have time for a visit, a brief telephone note will be placed and a request for a future cardiology clinic visit will be requested. If a formal telehealth visit occurs, clinicians will be asked to inquire about key details around medication titration (**Supplement S2 Interview Guide**). The data from chart review and interviews will be documented on a password-protected Excel document (**Supplement S3** Clinician Documentation Form). Any medication addition or titration will have indicated laboratory labs ordered per usual care. Lastly, clinicians will also be asked to administer a short survey with each participant based on a template at the end of the call proactive phone call (**Supplement S2 Interview guide**). Primary care and regular cardiology clinicians will be notified of any changes in medication management in the EHR. The study's lead (BZ, AV) will be available by phone to answer questions or problems that arise during the clinic. Supervision of patient encounters by clinical pharmacists, medical trainees, or advanced practice nurse practitioners and study protocols will be BZ as the licensed and boarded general cardiologist.

5.2 Inclusion-Exclusion Criteria and General Study Population

This quality improvement (QI) initiative involves patients with heart failure with reduced ejection fraction (HFrEF) receiving care in the VA West Los Angeles (WLA). The criteria for eligible patients are:

Inclusion criteria:

- Facility: Greater Los Angeles, CA
- Division: All divisions within Greater Los Angeles
- Patient is eighteen years of age or older
- Patients has a primary diagnosis of HFrEF (last documented LVEF ≤35% per ADHFD algorithms)
- Patient has an estimated GFR greater than or equal to 30 mL/min
- Patient lacks at least one active prescription of a beta-blocker, ACE/ARB/ARNI, MRA, or SGLT2i
- There are no cardiology appointments in the upcoming 2 weeks.

Exclusion criteria:

- Patient is currently hospitalized at WLA

5.3 Randomization and Blinding

Patients will be randomized 1:1 to intervention and usual care groups with all patients randomized at one time; given the target sample size of n=300 total patients, the sequence will be generated using permuted blocks of size 6 to ensure that an equal number of patients are randomized to panel management and usual care, maximizing efficiency (power). The randomization sequence will be concealed from the clinicians until after randomization has already been complete. Post-randomization, study staff will not be blinded to allocation. GLA IRB exemption was granted for consent of the low risk, non-experimental intervention. The intervention does not allow for blinding of participants in the intervention arm.

5.4 Study Assessments

Data for analysis will be pragmatically ascertained through the variables available in the ADHFD. The ADHFD data will be exported at baseline. To evaluate study outcomes, the ADHFD will be exported again to a secure Excel file 6-months after the last participant receives the intervention. The ADHFD data includes age, race, hospitalization risk scores, number of VA hospitalizations in the past 12 months, vital signs (weight, blood pressure, pulse), laboratory values (potassium, creatinine, BNP, eGFR), active GDMT prescriptions, and upcoming appointments. Sem-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 1 and 2 year.

6 Sample Size

Assuming a baseline average GDMT optimization score of 2.4 for the included population and a standard deviation of 1.5, we estimate 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). The primary analysis will be performed using ANCOVA with baseline adjustment for age which should improve the power to detect a difference between treatment arms.

7 General Analysis Considerations

7.1 Timing of Analysis

The final analysis will be performed at 6 months after the last participant received the study intervention. For patients, who are no longer captured by the ADHFD at this time, study staff will abstract relevant data based on chart review.

7.2 Analysis Populations

All subjects randomized per intention to treat. Any deaths, hospitalizations that occur prior to receipt of the intervention will be included in the primary analysis.

Secondary outcomes assessment will evaluate patients that received the telephone intervention vs. did not receive any protocolized interventions.

7.3 Covariates and Subgroups

Covariates of interest include age. We will evaluate age dichotomized based on the median of the trial participants and continuously in regression models. Race is categorized as White, Black, Hispanic, Asian, American Indian or Alaska Native. Heart rate will be used to dichotomize patients ≤70 and systolic blood pressure ≤ 120 mmHg. Renal function will be dichotomized for subgroups of patients with eGFR ≥60 ml/min/ 1.73 m^2.

7.4 Missing Data

For data missing from the ADHFD required for the primary or secondary analyses, chart review will be used to identify the missing data. If a patient dies prior to the end of the trial, we will evaluate active medications prior death for the primary and secondary outcomes. No imputation of missing data is planned for the outlined analysis. Any imputation procedures would only be used for exploratory analyses.

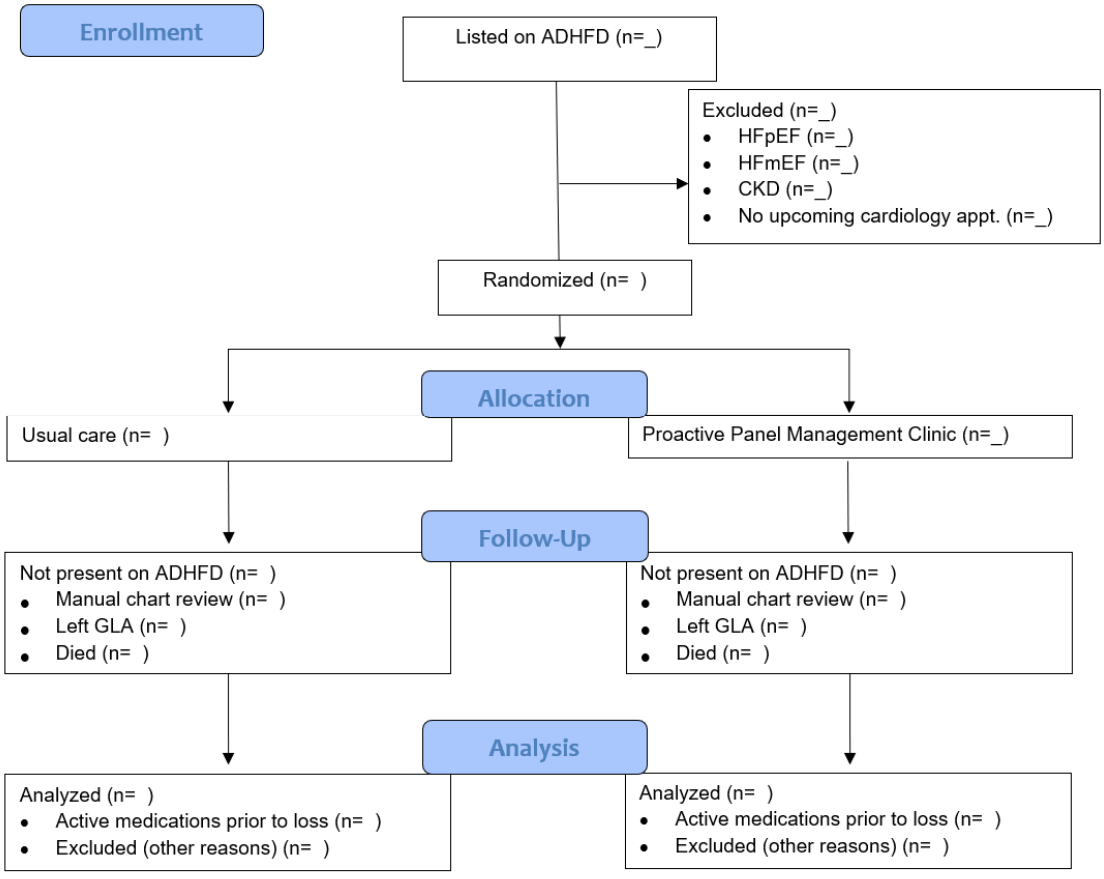
8 Summary of Study Data

All continuous variables will be summarized using the following descriptive statistics: n (non-missing sample size), mean, standard deviation, median, maximum and minimum. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical measures. All summary tables will be structured with a column for each treatment in the order (Control, Intervention) and will be annotated with the total population size relevant to that table/treatment, including any missing observations.

8.1 Subject Disposition

Participants will be included as active based on presents on ADHFD at baseline and at termination of the study. Participants missing on the final exported ADHFD file will undergo chart review to abstract study variables. Deaths or transfers to other VA healthcare systems will be abstracted for missing patients.

Figure 1: CONSORT Study Flow Diagram Template



8.2 Derived Variables

We created and utilized an optimization potential score (OPS) to quantify the extent of GDMT optimization. The OPS ranges from 0-10. Scores of 0 indicate a high potential for further optimization. The scoring system is defined as follows and represents the incremental steps a clinician would take to add-on or titrate therapies:

Table 1: Guideline-Directed Medical Therapy Optimization Scoring System

	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

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.

8.3 Protocol Deviations

No major deviations from the protocol are anticipated for this study.

8.4 Demographic and Baseline Variables

Variables obtained from the ADHFD are available in **Table 2**.

Table 2: Baseline Variables from the Academic Detailing Heart Failure Dashboard	
Name	*Legal name*
Last 4 Social Security	-
Age	*years*
Race	White, Black, Hispanic, Asian, American Indian or Alaska Native
Weight	*lbs*
Primary Care Clinician	Assigned
3M Hospitalization Risk	Percent
3M Hospitalization Rank	Percentile
Heart Failure Hospitalizations	Last 12 months for any VA hospitalization.
Last Heart Failure Discharge	Date
Current Inpatient Status	Yes/No
Recent ED Visit	Last 14 days
Most Recent Left Ventricular Ejection Fraction (LVEF)	Last 3 years based on natural language processing variable construction
Last LVEF Documented Date	Date
Blood Pressure	Most recent recorded in the last year
Blood Pressure Date	Date
Pulse	Most recent recorded in the last year
Pulse Date	Date
Weight	Most recent in last 3 years
Weight Date	Date
Potassium	Most recent in last year
Potassium Date	Date
Magnesium	Most recent in last year
Magnesium Date	Date
Serum Creatinine	Most recent in last year
Serum Creatinine Date	Date
BNP	Most recent in last year
BNP Date	Date
NT-proBNP	Most recent in last year
NT-proBNP Date	Date
Digoxin	Most recent in the last year
Digoxin Date	Date
Estimated glomerular filtration (eGFR)	Race stratified estimates
eGFR Date	Date
ACE/ARB/ARNI	Medication name and dose *last fill must cover preceding 6 weeks **active, suspended, hold or provider hold orders ***Current non-VA medication
Beta-Blocker	“
Aldosterone Antagonist	“
SGLT2i	“
Allergies	To above medications only
Next Primary Care Appointment	Clinic name, date, and time
Next Cardiology Appointment	Clinic name, date, and time
Next Appointment	Next appointment for any clinic within 2 weeks.

Table 3: Expected Baseline Characteristics Presentation Template		
	Control	**Intervention**
Patient Characteristics		
Age	*years*	
Female	*%*	
Race	%	
White	%	
Black	%	
Asian	%	
AI/AN	%	
Mean BP	mmHg	
Systolic >120 mmHg	%	
Mean Pulse	rate	
Pulse >70	%	
Median Weight	lbs	
Mean eGFR		
Medications		
ACE/ARB/ARNI	%	
ARNI	%	
Beta-Blocker	%	
MRA	%	
SGTLT2i	%	
Diuretic	%	
Measurements		
Median Weight (IQR)	lbs	
Mean Pulse (SD)	Beats per minute	
Mean BP (SD)	SBP/DBP mmHg	
Mean Potassium (SD)	mmol/L	
Mean eGFR	ml/minute	
Number of Hospitalizations past 12 months	count	

8.5 Treatment Compliance

For secondary analyses, treatment compliance will be estimated using the proportion of days covered (PDC) from VA pharmacy data for the 6 weeks prior to the study termination for each GDMT class of medications.

9 Efficacy Analysis

The analysis will evaluate differences between usual care and the intervention arm (intention to treat) in the receipt of active prescriptions for GDMT, hospitalizations, and mortality.

9.1 Primary Efficacy Analysis

The primary analysis will evaluate the effectiveness of the proactive panel management intervention compared to usual care using the OPS score 6-months after the last participant in the intervention arm receives the intervention. The difference in the OPS score between usual care and intervention will be estimated using a parametric ANCOVA with baseline OPS as a covariate as well as restricted cubic spline adjusting for baseline age. Age is specified as it may relate to the tolerance and probability of receiving more classes of medications.

9.2 Secondary Efficacy Analysis

The secondary efficacy analysis will include the difference in OPS score 6-months after the last intervention using an unadjusted parametric ANCOVA.

Additional secondary analyses include:

- Difference in rates of receipt of each class of GDMT using a two-sample proportions test Pearson's chi-squared test between intervention and usual care assignment.
  - ACE/ARB/ARNI
  - ARNI
  - Beta-blocker
  - MRA
  - SGTL2i
- Hazard ratio for heart failure hospitalization at final evaluation between intervention.

9.3 Additional Analyses

Number of patients that successfully received the intervention

Rate of appreciation for proactive phone communication from WLA Cardiology.

Rate of medication titrations per half day panel clinic vs. usual HF clinics for 10 clinics matched by week during the study period.

10 Safety Analysis

Clinicians involved with the intervention will report acute kidney injury (AKI) defined as 25% decrease in GFR from baseline on follow-up labs (1-week for MRA and 1-2 weeks for ACE/ARB/ARNI) after a successful medication titration within the intervention group. Laboratory alerts will be followed by pilot study clinicians. Hospitalization related to adverse medication event (e.g. symptomatic hypotension, AKI, hyperkalemia) related to the intervention. Difference in mortality between intervention and usual care.

10.1 Adverse Events

Specific adverse events of interest include symptomatic hypotension documented in the EHR. Hospitalizations related to heart failure will be captured during the study end using the ADHFD. If patients were removed from the dashboard at 6 months, a chart review will be performed to abstract missing data.

11 Reporting Conventions

P-values ≥0.001 will be reported to 3 decimal places; p-values less than 0.001 will be reported as “<0.001”. The mean, standard deviation, and any other statistics other than quantiles, will be reported to one decimal place greater than the original data. Quantiles, such as median, or minimum and maximum will use the same number of decimal places as the original data. Estimated parameters, not on the same scale as raw observations (e.g. regression coefficients) will be reported to 3 significant figures.

12 Quality Assurance of Statistical Programming

Code files for cleaning and analysis will be saved and dated for Stata 17.0 or greater. Co-investigators will evaluate baseline and outcome tables for anomalies. All output will include data and time, name of the code file that produced the analysis, and the author. Statistical reviewer will review trial raw and cleaned data, as well as Stata code and output files for all primary and secondary analyses.

13 References

1. McMurray JJV, Solomon SD, Inzucchi SE, et al. Dapagliflozin in Patients with Heart Failure and Reduced Ejection Fraction. *N Engl J Med*. 2019;381(21):1995-2008. doi:10.1056/nejmoa1911303

2. Packer M, Anker SD, Butler J, et al. Cardiovascular and Renal Outcomes with Empagliflozin in Heart Failure. *N Engl J Med*. 2020;383(15):1413-1424. doi:10.1056/nejmoa2022190

3. Maddox TM, Januzzi JL, Allen LA, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversig. *J Am Coll Cardiol*. 2021;77(6):772-810. doi:10.1016/j.jacc.2020.11.022

14 Listing of Tables, Listings, and Figures

15 Supplemental Material

S1: GDMT Guidance Document for LVEF ≤35%

I. Make a recommendation

Step 1: patient not at target ACE/ARB or beta-blocker

Initiate/titrate up ACE/ARB and/or beta blocker

- If signs of volume overload or HR<70 → ACE/ARB
- If signs of euvolemia, HR>70, atrial fibrillation history, ventricular ectopy → Beta-blocker
- Age < 75, systolic BP>120 mm Hg, HR >70, normal renal function → Start both

Tailored based on patient's profile and history.

Step 2a: Transition ACE/ARB to ARNI

- Initiate ARNI once patient is taking equivalent dosing to lisinopril 20 mg daily

Step 2b: Initiate and titrate up aldosterone antagonist

- If K < 5 (helpful for hypokalemia)
- Well tolerated in low BP patients
- Check labs 3-7 days within initiation. Repeat labs monthly for the first 3 months.

Step 2c:

Initiate SGLT2i – empagliflozin 10mg daily

- Initiate earlier if A1C ≥7% or GFR 25-60 mL/min/1.73m^2 refer nephrology for SGLT2i
- Otherwise, add to cornerstone beta-blocker and RAAS inhibitor, ideally when dosing is stable.

II. Discuss instructions and precautions

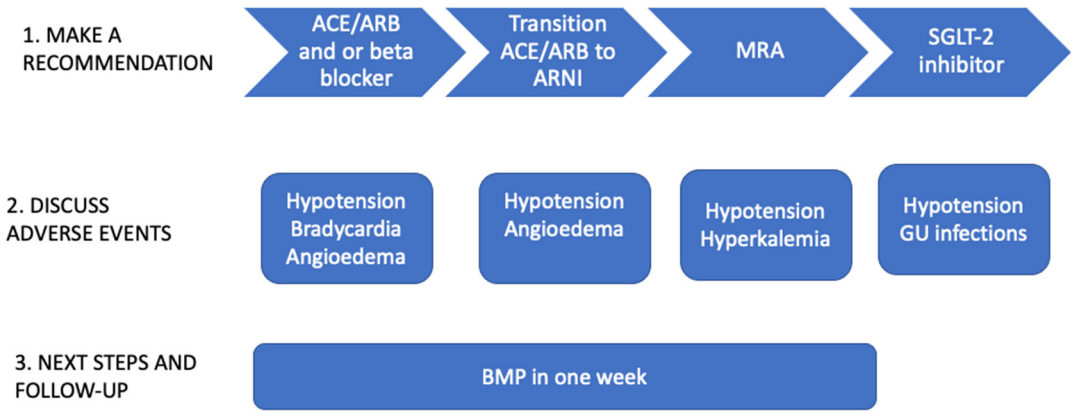
Symptomatic hypotension, genital yeast infections (SGLT2i)

III. Recommended follow-up

Labs, diagnostic imaging or studies, new consults, follow-up appointments

Strategies for intolerance/symptomatic hypotension

- Reduce non-GDMT antihypertensives, half diuretic dose with initiation of RAAS inhibitor or SGLT2i.
- Consider insulin reduction for history hypoglycemic events with SGLT2i.
- Space out administration times for medications
- Move RAAS inhibitors to evening to peak during sleep
- Lower morning doses relative to evening doses



S2: Interview Guide

Introduction

Hello, I am Dr. _____ calling from the West LA VA Cardiology. We are piloting an effort to proactively reach out to Veterans with heart disease to see how they are doing and improve their medical therapies for heart failure. Is now a convenient time to discuss your heart medications?

- ***Yes:*** Thank you. Do you have access to a smartphone or computer? May we convert this visit to video?
- ***No:*** May we request a follow-up phone, video, or in-person visit with our heart failure clinic?

Yes**:** Thank you. [RTC WLA-Cardiomyopathy Clinic]

No: Thank you for your time***.*** [Chart review note for PMD and last cardiology fellow/attending highlighting potential opportunity for further medication optimization]

Obtain history and assess functional NYHA class

1. How have you been feeling? Any change in [dyspnea/orthopnea/edema]?
2. What type of physical activities do you do regularly [walking, exercise, stairs]?
3. Do you know what medications you take for heart failure and how do manage your medications?
4. Have you had issues with any of heart failure medications in the past?
5. Do you check your home blood pressure and weights regularly? What are they?
6. Do you have issues with lightheadedness/dizziness or passing out?

Make recommendation

Optimization: I see that you might benefit from an increase in you _____ / I see that you might benefit from an additional medication _____/I see you may benefit from stopping one of your non-heart failure blood pressure medications. May we start that today and you can receive the medication in the mail or pick-up from your local VA clinic?

Hypervolemia: Increase diuretic regimen and refer for face to face visit within 1 week.

Discuss appropriate precautions with optimization

Dizziness, orthostasis, follow-up blood tests.
SGLT2i [genital yeast infections/hypoglycemia for IDDM]

Next steps

- Order medications
- Follow-up appointment
- Required labs
- BMP in one week (MRA), 1-2 weeks (ACE/ARB/ARNI)

Questions

Do you have any concerns related to medication change? Other questions?

Feedback

Thank you for your time. This was a call part of our pilot telephone heart clinic program. How would you rate your experience with the heart failure outreach today on a scale 1 to 10 (10 being very appreciated)? Any suggestions to improve the program?

S3: Clinician Documentation Form

Documentation survey which will guide clinician's chart review and patient conversation. The form will be password-protected and utilize checkbox and short answers for clinician ease.

Clinic Date	Clinician	Start Time	Homeless	Active Substance Use	Female	Last EF	Last cards appt	Last PCP appt
1/1/21	Ziaeian, Boback	13:55	x	x	x	35-40%	1/1/21	1/1/21

Phone Call Time	NYHA Class	No Response
9 minutes	III	x

Reasons for no GDMT titration				
Prior intolerance	**Prior adverse event**	**Patient declined**	**Patient concerned of side effects**	**Other**
x	x	x	x	Cost

Actions Performed						
Number of Rx adjusted	**Med adjustment**	**Labs ordered**	**Imaging / diagnostic tests**	**RTC**	**Patient Letter**	**Consults**
3	Amlodipine stopped	x	x	x	x	x

Feedback	End Time	Comments
9	1415	Straight to voicemail

Clinician Documentation form definitions	
Clinic date	Date today, (mm/dd/yy)
Clinician	Name of clinician (Last, First)
Start Time	Military time at onset of pre-chart
Homeless	Is the veteran currently experiencing homelessness?
Active substance use	Is the veteran actively using substances?
Female	Sex as categorized in EHR
Last EF	Most recent left ventricular ejection fraction on transthoracic echocardiogram, %
Last cards appt	Date of last cardiology clinic visit, (mm/dd/yy)
Last PCP appt	Date of last PCP visit, (mm/dd/yy)
Phone Call Time	Duration of successful phone or video visit
NYHA Class	Based on patient's symptoms and chart review, (1-3)
No response	Indication if no response after 2 attempts
Patient requests later appointment	Indication if patient is interested in further discussion, but busy at this time. Check and order RTC cardiology
Reasons for no GDMT	
Prior intolerance	History of symptomatic bradycardia or hypotension on GDMT
Prior adverse event	History of hospitalization or angioedema related to GDMT titration. History of yeast infection while taking an SGLT2i inhibitor
Patient declined	Patient declined additional or higher doses of medications in the past
Patient concerned of side effects	Patient is concerned of side effects of GDMT
Other	Other reasons cited by patients or on chart review in the comments
Actions Performed	
# medication adjustments	Number of medications adjusted after this visit
Medication adjustment detail	Description of medication adjustment
Labs ordered	If laboratory tests ordered as part of today’s plan
Imaging / diagnostic tests ordered	If imaging or diagnostic tests ordered as part of today’s plan
RTC	If "return to clinic" order placed to patient's cardiology clinic
Patient Letter	Letter mailed to patient regarding following up with primary care or cardiology regarding heart failure.
New consults	If new consults placed as part of today’s plan
Patient feedback	Self-reported experience of conversation and heart failure plan, on a scale of 1 to 10, where 1 means an awful experience and 10 means an exceptional experience
Time (end call)	Military time on completion of phone call
Comments	Noteworthy general observations not contained in fields regarding chart review or patient experience