COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD
CAMPUS BOX F-490 TELEPHONE: 303-724-1055 Fax: 303-724-0990

Protocol #: 17-1249
Project Title: A clinical trial of an **E**lectronic health record-leveraged, **P**atient-centered, **I**ntensification of **C**hronic care for **H**eart **F**ailure (**EPIC-HF**) patient engagement video and medication options checklist
Principal Investigator: Larry A. Allen, MD., MHS
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I. Hypotheses and Specific Aims:

Aim I: Pilot test the screening, enrollment, intervention, and data collection to be used in the Electronic health record-leveraged, Patient-centered, Intensification of Chronic care for Heart Failure (EPIC-HF) trial.

- *Hypothesis 1:* Pilot testing of the feasibility and acceptability of study procedures—using survey tools and qualitative interviews—will lead to important modifications prior to conduct of the full trial.

Aim II: Assess the effectiveness of a pre-clinic patient activation video and in-clinic medications checklist to improve medication prescribing for patients with heart failure with reduced ejection fraction (HFrEF), the EPIC-HF intervention**.**

- *Hypothesis 1*: Compared to usual care, EPIC-HF will increase the number of HFrEF medication optimizations, without compromising secondary outcomes, including safety and healthcare provider satisfaction.
- *Hypothesis 2*: Compared to usual care, EPIC-HF will increase participant activation, control preferences, and adherence to their HFrEF medication regimen.

II. Background and Significance:

II.A. HFrEF treatment regimens are increasingly complex
While decades of scientific discovery have created multiple efficacious treatment options for patients with heart failure with reduced ejection fraction (HFrEF), this progress has simultaneously created complicated medication regimens. While the introduction of two new classes of medications in 2015 (i.e. ivabradine [Corlanor] and sacubitril/valsartan [Entresto]) illustrates the ongoing potential to enhance treatment options for patients with HFrEF, it also demonstrates how novel medications tend to be studied on top of existing treatment regimens. Thus, breakthroughs have generally added complexity to existing care; better treatment translates to more medications for clinicians to prescribe and for patients to take.[1] Further complicating this scenario, HFrEF frequently occurs in the setting of multimorbidity (patients with HFrEF have an average of 4.5 other major diseases),[2] and optimal management of these patients often includes medications for atrial fibrillation, coronary artery disease, diabetes, chronic obstructive lung disease, etc. Without efforts to match the level of patient support to the complexity of their medical regimens, novel therapies will likely have diminishing returns for improving patient outcomes.[3]

II.B. HFrEF medication use in the real world is suboptimal
As the NHLBI's Strategic Initiative Plan states, "A widely acknowledged 'quality gap' exists in which proven effective preventive and therapeutic strategies are not consistently followed, a function of both patient behavior and provider practice."[4] This is true for HFrEF. While beta-blocker (*β*B) and angiotensin converting enzyme inhibitor / angiotensin II receptor blocker (ACEi/ARB) prescribing exceeds 90% in eligible Americans, they are rarely uptitrated to optimal doses, despite the known

benefits and relative safety of dose maximization.[6] Meanwhile, prescribing of aldosterone antagonists (AldA, spironolactone and eplerenone) and combination hydralazine plus isosorbide dinitrate (hydral-ISDN) remains below 50% among eligible patients.[7] Uptake of sacubitril/valsartan and ivabradine has been much slower than anticipated. Medication nonadherence further undermines the potential benefit of HFrEF therapies.[8]

II.C. Provider-focused decision support dominates but is limited
Scientific research and quality initiatives to improve the use of HFrEF medications have primarily focused on healthcare providers.[9] However, clinical inertia and competing demands on clinician's time are real. Worse, quality metrics and value-based purchasing have not yet created significant "skin in the game" for providers. Providers hold the keys to prescribing yet have little direct incentive to do the hard work of medication optimization.

II.D. Patient-focused approaches require engagement
Existing patient education efforts have focused largely around self-care regarding diet, exercise, and adherence.[8] Learning techniques are typically passive, most often with printed reading materials. Formal educational initiatives based on these approaches, when tested in randomized trials, have generally been ineffective in improving clinical outcomes.[12,13] Much less has been done to *engage patients in decisions about medication prescribing*. Given the algorithmic nature of HFrEF treatment regimens and that >80% of Americans with HFrEF have reasonable health literacy,[14] the basic principles of HFrEF medication prescribing are not beyond comprehension of most patients. These principles of medication optimization follow a simple cycle:

A) identify one HFrEF medicine that is not at goal dose;
B) initiate the drug or intensify the dose;
C) monitor for side effects;
D) repeat approximately every 2 weeks towards recommended maximal doses, as tolerated.

A growing body of evidence suggests that patients are far more likely to understand and adhere to medication regimens that they have participated in creating.[15,16] Encouraging patient engagement also forces important personalized discussions with clinicians around choices in HFrEF medication prescribing. Finally, patients are more likely to cognitively weigh short-term side effects against the potential of long-term health benefits if they better understand the overall goals of therapy and have participated in prescribing decisions.[17]

II.E. A culture of shared decision making facilitates patient engagement in prescribing
Since the landmark publication of the Institute of Medicine's 6 domains of healthcare quality in 2001[18]—which includes patient centeredness—shared decision making has increasingly been accepted within American medicine.[19] Shared decision making asks that clinicians and patients share information with each other and work toward patient-centered decisions about treatment. Shared decision making incorporates the perspective of the patient, who is responsible for articulating values, goals, and preferences as they relate to his or her health care. Shared decision making also incorporates the perspective of the clinician, who is responsible for narrowing the diagnostic and treatment options to those that are medically reasonable and fit within the patient's values framework.

III. Preliminary Studies:

III.A. Decision Aids for Cardiovascular Devices
Dr. Allen and colleagues have extensive experience in developing, testing, and implementing patient decision aids for implantable cardioverter-defibrillators (ICD), left ventricular assist devices (LVAD), transcatheter aortic valve replacement (TAVR), and stroke prevention in atrial fibrillation (AF). These tools have been well accepted by a range of stakeholders (patients, clinicians, and health systems) and appear to improve patient knowledge, activation, and decision quality (COMIRB 13-1970).

III.B. HFrEF Experience
Dr. Allen and co-investigators have are well versed in issues around HFrEF medication prescribing. They have collaborated on HFrEF medication research regarding guideline recommendations, health literacy, nonadherence, and monitoring/safety. Dr. Allen and

many of the co-investigators also remains active clinically and administratively in the care of patients with HFrEF, which imbues them with both an academic and real-world understanding of the many challenges faced by patients and providers when attempting to treat HFrEF optimally and implement tools into the care setting.

IV. Research Methods

A. Outcome Measure(s):

Pilot Outcomes: The primary purpose of the pilot is to assess the feasibility of the study procedures and intervention. Therefore, we will use interview guides and observations to assess the length of study procedures for patients, the logistics of delivering intervention, and the complications that could occur. Through this, we will modify the study procedures accordingly (e.g. understand flow of care at various clinics participating in recruitment, confirm appropriate delivery of the intervention, remove survey measures for excessive length, etc). Please note: Any changes made to the study materials or procedures will be submitted as an amendment and approved by COMIRB before implementation in the main trial.

Trial Primary Outcome: For the trial, the **main measure of effectiveness will be a comparison of the number of HFrEF medication optimizations** (i.e. dose changes for *β*B, ACEI/ARB/sacubitril, AldA, ivabradine, and hydral-ISDN) between the EPIC-HF intervention arm and usual care arm. This will be assessed through review of medication prescribing at baseline, 1-month following intervention delivery, and 1 year after enrollment.

Trial Secondary Outcomes: A number of additional secondary measures will be collected through patient surveys at baseline and 1-month following intervention delivery, and will be compared between the EPIC-HF intervention and usual care. See Table 1 for survey measures collected.

Table 1.

Surveys to be completed at baseline	Surveys to be completed at follow-up (1 month)
Patient Activation Measure, 13-item (PAM)	Patient Activation Measure, 13-item (PAM)
Patient Assessment of Care for Chronic Conditions Survey (PACIC)	Patient Assessment of Care for Chronic Conditions Survey (PACIC)
Control Preferences Scale (preferred)	Control Preferences Scale (preferred)
REALM-R literacy	Heart Failure History (shortened version)
Heart Failure History	Intervention/Education Use
Subjective Numeracy	
Demographics	

B. Description of Population to be Enrolled:

PATIENTS: For the pilot and the trial, adult patients with HFrEF from UCHealth Metro, North, and South will be enrolled.

Patients will be identified by either a) LVEF <=40% on their most recent cardiac imaging study or b) a clinical diagnosis of HFrEF. Co-investigators (Drs. Allen, Khazanie, Oldemeyer, Huang, Matlock, and other cardiology and primary care providers who are on this protocol) have a clinical relationship with the majority of the UCHealth HFrEF population, directly or through clinical colleagues. Following IRB approval and then using the automated lists of patients with HFrEF, patients will be screened, recruited, and enrolled in the study by the project manager and research assistants.

Inclusion criteria:

1. Most recent cardiology imaging study showing LVEF <=40%

2. A plan for ambulatory clinic appointments in the UCHealth system

Exclusion criteria includes:

1. Under 18 years of age
2. Non-English speaking (decision tools and study assessments are in English only)
3. Unable to consent (this would include patients with conditions such as moderate-to-severe dementia)
4. Prisoners
5. Patients who are enrolled in hospice (increasing curative medications is often not appropriate in these patients)
6. Patients who are expected to live < 6 months as documented in the patient's chart by treating clinician.
7. Continuous IV inotropic support (e.g. dobutamine or milrinone)
8. GFR < 15 mL/min or chronic renal disease
9. Patient has an LVAD in place
10. Patients who have neither an email address nor a phone to which text messages may be sent
11. Patients who are listed as status Ia, Ib, or II for heart transplant
12. Patients who are being formally evaluated for either an LVAD or a heart transplant
13. Patients who have been classified as having stage D heart failure

CLINICIANS: For both the pilot and trial, we will enroll clinicians who care for HFrEF patients in the study for semi-structure interviews to understand the feasibility and acceptability of the intervention and trial procedures. This could include any clinician w pho sees HFrEF patients and/or is the provider of a patient enrolled during the pilot or trial period.

C. Study Design and Research Methods

Pilot: For the pilot, we will conduct all trial procedures with a small group of HFrEF patients and clinicians at the 3 main sites (see below for trial details). During this process, we will conduct semi-structured interviews with the patients at baseline and/or post-intervention follow-up to obtain their viewpoints on the study procedures and intervention. Similarly, we will conduct semi-structured interviews with involved clinicians. Clinicians will be identified by study personnel as anyone who treats HFrEF patients and/or had a patient enrolled in the pilot. Clinicians will be recruited over email, phone or in person. Clinician verbal consent will be obtained. Interviews may be audio recorded and transcribed. This will contribute to the feasibility assessment and potential modifications to the trial protocol. Any changes made to study procedures or materials will be submitted to COMIRB for approval prior to use, with the exception of the patient checklist, which will be iteratively developed based off of feedback received from the pilot.

Trial:

Screening: The electronic health record will be queried for eligible patients. Health Data Compass will be used to generate lists of patients for whom LVEF is <=40% or for whom a diagnosis of "systolic heart failure" has been applied in the last year. Cardiology and primary care clinic schedules as well as inpatient cardiology services may be screened to further enrich screening. Patients on these lists will then then be screened to confirm the last imaging test shows an LVEF of <=40% and assess upcoming clinic appointments.

Recruitment: We will prospectively enroll patients for this study. Recruitment and consent will be conducted at each site by research personnel. Patients will primarily be recruited in-person during a clinic visit or hospitalization. For some patients, research personnel may call prior to the appointment to see if they would be willing to hear about the study during/after their appointment; these patients will then be consented in person at the appointment. In order to increase representativeness of patients who live in rural areas, and thus may travel to the main study cites for appointments

infrequently, study personnel have requested a waiver of written consent. Study procedures in their current form require two visits to the study cite within one year—this waiver of written consent would allow us to enroll patients for whom traveling to the study site more than once a year might be burdensome or infeasible. In these instances where written consent is not possible to obtain, study personnel will conduct verbal consent with the patient over the phone prior to their clinic appointment at one of the study sites. All in-person consent and enrollment will occur at the clinic or hospital.

Baseline Data Collection: Patients will complete the baseline survey at time of enrollment. Baseline medical record data will also be collected by study personnel.

Randomization: Patients will be randomized to one of two arms:
ARM 1: a best practices standard care control arm (*control*),
ARM 2: the EPIC-HF intervention (*engagement tools*)

Randomization will occur using a computer generated system that chooses which of the 2 arms the patient will be put into. This will be used for all participants and tracked by study personnel.

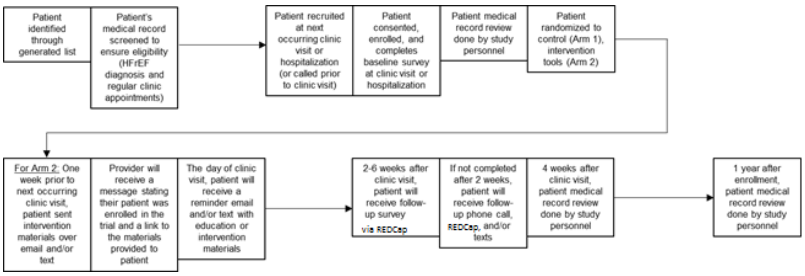
Control and Intervention Activities: Enrolled subjects in the control arm will complete baseline and 1 month post-clinic visit surveys, but will not receive further communications from the study team in order to preserve usual care. Clinicians seeing patients in the control arm have access to multiple heart failure management tools provided through Epic; these will not be modified.

Subjects in the EPIC-HF intervention arms will receive intervention materials. These are A) a 3-minute, animated patient-engagement video (https://goanimate.com/videos/0DjaQSN_Nexk?utm_source=linkshare&utm_medium=linkshare&utm_campaign=usercontent) and B) a 1-page a heart failure medications options checklist. Patients will receive these materials through either the MyHealthConnection portal, an email address, a cell phone text, and/or mail as preferred and agreed to by the subject at the time of study enrollment. Patients will receive a repeat reminder within 24 hours of their clinic appointment. For the texting component of this study, the secure research-to-patient texting service Call-em-all will be utilized. Call-em-all has a strict privacy policy that includes both physical and electronic security measures (such as security systems and password protections), and has been used by healthcare facilities for patient-facing activities (both research and clinical) before (https://www.call-em-all.com/how-we-help/healthcare). Only members of the study team will have access to the texting service; only patients who explicitly elect to be contacted by text message after they have consented to participate in the study will be contacted by this method. Information about both texting and emailing options is included in the consent form.

Clinicians seeing patients in the intervention arm will receive notification from the study team that their patient is enrolled in the study with exposure to intervention materials (e.g. Epic inbox alert with URL to video and medication options checklist).

Follow-up Data Collection: 2-6 weeks following the clinic appointment, all study subjects will be sent a follow-up survey via REDCap (or by telephone or mail if requested). Participant email addresses will be collected upon enrollment and entered in to REDCap, which will be used to both house the follow-up survey and send participants a link to the survey via a secure, HIPPA complaint connection. For non-responders, 2 subsequent reminders will be sent via REDCap and up to 2 follow-up phone calls or texts will be made to the participant if the survey has not been completed. Participating patients will be mailed a $25 gift certificate for completing the follow-up survey.

Medical record data will be collected by study personnel at 4 weeks after participants' clinic appointment and at 1 year from the time of enrollment. Pharmacy data to assess prescription fills will also be collected. Data for prescriptions filled are automatically obtained through Surescripts as part of routine clinical operations (~15% from UCHealth pharmacy and ~85% from non-UCHealth pharmacy).



Qualitative Activities: In order to understand some of the context that surrounds patient and provider interactions, we intend to audio-record the second clinic appointment for a subsample of participants. These participants will also be asked to participate in an interview, wherein study personnel will listen back to the audio from the recent clinic appointment and ask patients about their thoughts and opinions during specific points of the interaction. These interviews will take place between 2-4 weeks after the patients' recorded appointment, in a quiet and private room in a university building on the University of Colorado, Anschutz, campus. These qualitative activities will allow us to: 1) delve deeper in to any barriers preventing patients from utilizing the intervention checklist their appointment; 2) understand how the checklist is used during the appointment; and 3) elicit patient perspectives and opinions around the quality and structure of discussions around their medications. Consent will be elicited at enrollment; however, patients will be given the option to opt out of participating in the qualitative piece if they are contacted, while still being able to participate in the survey portion of this study.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

Patients: The study team believes that this project poses minimal risk to all subjects involved. The engagement video and medication options checklist do not make specific suggestions about medication prescribing beyond suggesting that patients and their clinicians look for additional opportunities to follow existing evidence-based, guideline-recommended medical therapy. While initiation and intensification of indicated medications can lead to side effects and other risks, nothing that is encouraged is outside of standard of care; the purpose of the study is to encourage patient-provider discussion and ultimate movement towards recommended therapies within existing clinical encounters designed to do this. Data collection from participants includes questions and medical record review that primarily relates to their known disease management; no deeply personal questions will be asked, and only limited demographic data will be obtained. Audio-recordings of both the clinic appointment and the subsequent interview will be kept on a secure server on the University network that only study participants have access to; only information from the clinic appointment audio-recording that is relevant to the study will be discussed during the interview. There is always a risk that participants may feel uncomfortable discussing aspects of their heart failure or medication plan with the research team; to mitigate this, participants will be informed of their right to refuse to answer any question they do not wish to answer, and may terminate participation in the study at any point (and that should they decline to participate, answer a question or withdraw this will not affect their medical care). There is also the risk that patients may be uncomfortable having their clinic appointment audio-recorded; in order to mitigate this risk, patients selected for the qualitative activities will be contacted prior to their appointment to affirm that they are still comfortable with having their appointment recorded, and will have the option of declining to participate in this portion of the study, while still being able to participate in the rest of the study.

Clinicians: Clinicians may feel uncomfortable discussing how they talk about medicine prescribing with their patients or may feel burdened by the interview. However, we will remind clinician participants that they can always refuse to answer any question and their participation is always voluntary. Additionally, clinicians may feel uncomfortable with changes to their clinical work flow. We will try to mitigate this risk by keeping open and clear communication and give clinicians access to

intervention materials, as well as early notification that their patient is enrolled in the study. We will work to understand and mitigate any burden of the trial during our pilot interviews with clinicians.

Data: Data collection and storage has been planned to appropriately protect participant confidentiality. All patients will be given a unique identification number, and study data and identifiable information will always be kept separate. REDCap, the COMIRB-preferred system, will be used to store all survey and enrollment data, and the University's secure server will be used to store clinic audio files, interview audio files, transcripts and notes; access to both REDCap and the secure server will be limited to study personnel only. All paper documents will be stored in a secure and locked file cabinet in a secure and locked office building – again, all study data paperwork will be stored separate from paperwork with identifiable information (i.e. signed consent forms) and be accessible to study personnel only.

E. Potential Scientific Problems:

Could EPIC-HF exacerbate disparities?
Of concern is that an Internet or cell phone-based patient engagement tool around prescribing will differentially benefit patients by age, race/ethnicity, education, and socioeconomic status. While these concerns are real, growing evidence suggests that the "digital divide" is shrinking,[54] and in some cases is even working to counteract disparities in access. The EPIC-HF intervention will be designed with these concerns in mind, including best practices and novel approaches to limit disparities. For example participants will indicate at enrollment their preferred mechanism of contact. Subgroup analysis of outcomes will focus on pre-specified groups with lower perceived ability to access the intervention components. Finally, major efforts are being made to move the nation towards meaningful use of EHRs, irrespective of these concerns; our study helps figure out how the uptake of EHRs can be used to further help a wide range of patients.

Might patients in the control arm be exposed to the EPIC-HF intervention?
Because of patient-level randomization across sites, providers caring for usual care patients are likely to be exposed to intervention patients simultaneously. This may lead to diffusion of medication prescribing changes triggered by intervention patients to usual care patients, thus reducing the differences in the primary endpoint and biasing towards a null result. Given the mostly patient-centered focus of the intervention, we feel this threat is low. Additionally, the primary goal is to scientifically isolate patient engagement effects. Finally, with the randomized phased roll out of the intervention by the 3 main sites within UCHealth, we can look for short-term trend differences by sites using stepped-wedge methodology.

F. Data Analysis Plan:

Pilot: Interview notes will be compiled and typed. The notes will be analyzed for key, recurring themes in order to assess for changes that should be made in the study protocol. The findings from the qualitative feedback will be integrated with the other feasibility findings to determine adjustments to the main trial. They will be discussed in study team meetings with a goal of modifying the intervention and study protocol to increase feasibility, acceptability, and helpfulness for the subsequent fully-powered effectiveness trial. An audit trail (detailed description of the research process) will be maintained to document the analytic process and changes made to the study protocol.

Trial: Basic demographics of the participants will be summarized quantitatively in a way that characterizes the study participants but cannot be traced to individuals.

HFrEF medication dose optimizations (initiations and intensifications) at 1-month and study end will be obtained from the Epic electronic health record and summarized as a count.

Analyses of effectiveness for the primary outcome of dose optimizations will use a repeated measures mixed model. This strategy allows for partially incomplete data (e.g. missing follow-up or one of the patient/caregiver pair) and relaxes missing data assumptions to missing at random conditional on observed data. Prior to these analyses, we will contrast the participants in the arms of the study, identifying any patient/site characteristics that are unbalanced. If more than 3-5 variables are identified, we will develop a propensity score for the likelihood of being in the intervention phase as a secondary analysis. Each analysis model will include an indicator variable for the intervention phase, indicators for each of the sites and the variables identified above.

Quantitative questionnaire data will be scored and summarized according to the methods previously validated and published for each questionnaire. Significance for differences between quantitative statistics will be determined using Chi-square tests.

We will use the following measures:

- Prescribed dose optimizations: Number of initiations and dose intensifications of HFrEF medications.
- Patient Activation Measure: To measure patient activation, we use the 13-item Patient Activation Measure (PAM) developed by Hibbard et al.
- Feasibility: To evaluate feasibility, we will explore participation rates and adherence to the study protocol. Additionally, we will collect information on how the patient and providers perceived the usefulness of the materials, through qualitative interviews conducted during the pilot phase.
- Patient Assessment of Care for Chronic Conditions Survey: Patient perceptions of medical care will be assessed using the Patient Assessment of Care for Chronic Conditions Survey (PACIC) developed by Glasgow et al.
- Control Preferences Scale (preferred): We will measure the participants' preferred role in decision making using the validated Control Preferences Scale.
- Proportion of Days Covered (PDC): Prescription fills compared to the ideal, expressed as a percent of days covered.

Sample Size: The primary outcome of dose optimizations is used to guide study size. Based on data review from a sample of ambulatory patients with HFrEF seen at University of Colorado Hospital as well as prior work characterizing ambulatory HFrEF care in Denver (Dr. Allen's K23),[13] the average number of dose adjustments over a year period is approximately 0.5 (0.6 SD); most dose adjustments occur around the time of hospitalization for decompensation. We assume at least half of patients in the intervention will involve the video and Option Grid in their clinical encounters, and that half of them will experience an average of 1 additional medication optimization. In summary, we surmise that 25% of patients randomized to EPIC-HF realizing additional medication optimization is clinically significant and possible. Assuming a Poisson distribution for the outcome as a count, with a 2-sided alpha of 0.05, a 1-year mortality rate of 15% among ambulatory HFrEF patients,[53] and a drop-out rate of 10%, with comparison of each intervention arm to the control, study of 255 patients should allow for reasonable power (>80%) to assess the primary endpoint as well perform hypothesis testing around secondary measures and predetermined subgroup analyses. Due to experiences from other studies of a large dropout rate with this patient population (due to death, withdrawal, and lost to follow-up from severe illness and/or lack of return to UCH medical center for care), we will allot for enrollment of 315 patients.

For the pilot trial, we will enroll no more than 60 patients and clinicians spread between North, South, and Metro/Central.

G. Summarize Knowledge to be Gained:

Pilot: By understanding how a sample of patients engage with and react to the intervention materials, the pilot study will illuminate barriers to implementation of the intervention, as well as any critical flaws with the materials.

Trial: By formally testing, on a multi-site level, the effectiveness of the intervention, we will help inform how best to support patients and providers navigate the complexities of HFrEF prescribing, and whether increased patient engagement around their medication plans leads to improved provider prescribing habits.

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