An Electronically Delivered, Patient-Activation Tool for Intensification of Medications for Chronic Heart Failure with Reduced Ejection Fraction: The EPIC-HF Trial

Running Title: *Allen et al.; EPIC-HF: Patient-Activation Tool for HFrEF Prescribing*

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Abstract

Background: Major gaps exist in the routine initiation and dose up-titration of guideline-directed medical therapies (GDMT) for patients with heart failure with reduced ejection fraction (HFrEF). Without novel approaches to improve prescribing, the cumulative benefits of HFrEF treatment will be largely unrealized. Direct-to-consumer marketing and shared decision making reflect a culture where patients are increasingly involved in treatment choices, creating opportunities for prescribing interventions that engage patients.

Methods: The Electronically delivered, Patient-activation tool for Intensification of medications for Chronic Heart Failure with reduced ejection fraction (EPIC-HF) trial randomized patients with HFrEF from a diverse health system to usual care versus patient-activation tools—a 3-minute video and 1-page checklist—delivered electronically 1 week prior, 3 days prior and 24 hours prior to a cardiology clinic visit. The tools encouraged patients to work collaboratively with their clinicians to "make one positive change" in HFrEF prescribing. The primary endpoint was the percent of patients with GDMT medication initiations and dose intensifications from immediately preceding the cardiology clinic visit to 30 days, compared to usual care during the same period.

Results: EPIC-HF enrolled 306 patients, 290 of whom attended a clinic visit during the study period: 145 were sent the patient-activation tools and 145 were controls. Median age was 65 years, 29% female, 11% black, 7% Hispanic, median ejection fraction 32%. Pre-clinic data revealed significant GDMT opportunities, with no patients on target doses of beta-blocker, sacubitril/valsartan, and mineralocorticoid receptor antagonists. From immediately preceding the cardiology clinic visit to 30 days later, 49.0% in the intervention and 29.7% in control experienced an initiation or intensification of their GDMT (p=0.001). The majority of these changes were made at the clinician encounter itself and involved dose uptitrations. There were no deaths, and no significant differences in hospitalization or emergency department visits at 30 days between groups.

Conclusions: A patient-activation tool delivered electronically prior to a cardiology clinic visit improved clinician intensification of GDMT.

Clinical Trial Registration: URL: https://clinicaltrials.gov Unique Identifier: NCT03334188

Key Words: heart failure; quality; clinical trial; outcomes
Non-standard Abbreviations and Acronyms
GDMT: guideline-directed medical therapies
HFrEF: heart failure with reduced ejection fraction
EPIC-HF: Electronically delivered, Patient-activation tool for Intensification of medications for Chronic Heart Failure with reduced ejection fraction
EVBB: evidence-based beta-blockers
ACEI: angiotensin converting enzyme inhibitors
ARB: angiotensin receptor blockers
ARNI: angiotensin receptor neprilysin inhibitors
MRA: mineralocorticoid receptor agonists
H/ISDN: hydralazine/isosorbide dinitrate
DTCA: direct-to-consumer advertising
SDM: shared decision making
LVEF: left ventricular ejection fraction

Clinical Perspective

What is new?

- A 3-minute patient activation video plus a 1-page medication checklist delivered directly to patients with heart failure with reduced ejection fraction (HFrEF) before a visit with a cardiology clinician resulted in a 19% absolute increase those who had their guideline-directed medical therapies (GDMT) intensified.
- The majority of these intensifications involved dose increases of beta-blockers.

What are the clinical implications?

- Clinical inertia accounts for some portion of underuse of GDMT in HFrEF.
- A brief tool delivered to patients electronically before the visit encouraging patients to ask about opportunities to enhance their medical therapy led to improved GDMT.

Introduction

Advances in medicine have revolutionized the care of patients with heart failure with reduced ejection fraction (HFrEF). Multiple medications—evidence-based beta-blockers (EVBB), angiotensin converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB), angiotensin receptor neprilysin inhibitors (ARNI), mineralocorticoid receptor agonists (MRA), hydralazine/isosorbide dinitrate (H/ISDN), and ivabradine—have been shown to improve cardiac function, quality of life, and survival for patients with HFrEF.[1-4] Current HFrEF clinical practice guidelines recommend the use of these medications in combination and at target doses that have been shown to be beneficial in clinical trials, i.e., GDMT. Unfortunately, multiple studies have shown that prescribing of GDMT in routine clinical practice is suboptimal.[5-8] While EVBB and ACEI/ARB are usually prescribed, few patients receive target doses.[5] Meanwhile, a minority of patients receive MRA and ARNI.[5]

Gaps in the prescribing of GDMT are likely due to a variety of factors. While patient intolerance and physiological factors related to HFrEF or other comorbidities account for some portion of submaximal GDMT,[9] clinical inertia is common. Achieving GDMT demands polypharmacy, iterative dose escalation, and active monitoring of patient symptoms, vital signs, and blood chemistries.[3] Furthermore, clinicians have few ambulatory quality measures for GDMT and payers' remuneration for clinic visits are relatively independent of prescribing. Consequently, continuation of current medical therapy is often the path of least resistance. Traditional quality improvement interventions designed to improve GDMT, such as clinician reminders, have been met with limited success.[10-12] Without novel approaches to improve prescribing, the cumulative benefits of HFrEF treatment will be largely unrealized.

Both direct-to-consumer advertising (DTCA) and shared decision making (SDM) are promising strategies for improving prescribing of GDMT for HFrEF. Patients increasingly cite DTCA from pharmaceutical companies as the motivator for asking clinicians for drug information or new prescriptions,[13, 14] and the majority of clinicians say exposure to DTCA prompts higher quality discussions between clinician and patient about treatment options.[15] However, industry-based DTCA is generally limited to therapies still on-patent, may be hampered by real or perceived biases, and does not provide a global view of treatment options for a disease. At the same time, SDM—a communication process by which patients and clinicians work together to make optimal health care decisions that align with patient values and preferences—has become increasingly recognized as a key component of patient-centered care.[16] Formal patient decision aids can support SDM;[17] however, existing patient decision aids tend to focus on treatment decisions identified by a clinician, rather than directly prompting patients to identify treatment opportunities themselves.

In this context, we developed EPIC-HF[18] which incorporates aspects of DTCA and SDM. The EPIC-HF intervention utilizes a patient-activation tool that combines a 3-minute video with a 1-page medication checklist. This study used an randomized control trial design to test the effectiveness of this patient-activation tool delivered before a cardiology-based clinic appointment to encourage patients to independently ask about opportunities for medication optimization, in turn prompting their prescribing clinicians to appropriately intensify GDMT.

Methods

The EPIC-HF trial (ClinicalTrials.gov Identifier: NCT03334188) is an American Heart Association-funded, Heart Failure Strategically Focused Research Network study designed to

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test the implementation, effectiveness, and safety of the EPIC-HF intervention. The study was a randomized clinical trial with patients randomized 1:1 to receive the intervention or usual care. A detailed description of the rationale, intervention development, and trial methods were previously published.[18] In order to protect participant personal health information, data for this study are available from the corresponding author only upon reasonable request. Many of the supporting materials used in the study are present in the previously-published rationale, or are available upon request.

Patients and Setting

The EPIC-HF trial was conducted across the UCHealth system, involving patients with HFrEF and their cardiology clinicians. UCHealth services approximately 3.5 million individuals from 3 regions of the state (northern Colorado, southern Colorado, and metro Denver). The health system includes 6 cardiology clinics with a mix of academic and private-practice community-based delivery models and vary in size, demographic composition of patients served, and capture of urban, suburban, and rural populations. All UCHealth facilities use a single instance of the Epic electronic health record (Epic Systems, Verona, WI).

Enrollment occurred from January 2018 to January 2020. Subjects were required to be 18 years and older, have a left ventricular ejection fraction (LVEF) of <=40% on their most recent cardiac imaging study, and a history of HF. Due to the nature of the intervention, patients also had to be English-speaking, have cognitive capacity to engage in a prescribing discussion, and have either an active email address or a smartphone with texting capabilities. Patients with an estimated glomerular filtration rate <15 mL/min, listed for transplant, or enrolled in hospice were excluded. Prisoners and pregnant women were also excluded. During screening, 699 patients were initially identified through an automated list using field-coded LVEF measures in the

electronic health record who also had a clinic visit with a cardiology clinician in the UCHealth system. Of these, 306 provided written informed consent, either in-person or by phone, and were enrolled (**Figure 1**). Screen failures were older and less likely to be seeing an advanced heart failure specialist, but otherwise were similar by gender, race/ethnicity, and LVEF. To be included in the study, patients needed to make a clinic visit following enrollment since delivery of the intervention required a patient-clinician interaction and because the pre-clinic medication data required for the outcome analysis was only available for patients that made a clinic visit. A relatively small number of enrolled patients (8 study and 8 control) were excluded because they did not make a clinic visit during the study period. There were no significant differences in baseline characteristics between the 8 study patients and 8 control patients who were excluded. All phases of the study procedures and personnel were approved by the Colorado Multiple Institutional Review Board.

Intervention

The EPIC-HF patient-activation tool included a 3-minute video combined with a 1-page checklist. The design and pilot testing of the tool was previously published.[18] In addition to following prior standards[19] and incorporating extensive multi-stakeholder input into a user-centered design, development combined aspects of DTCA and SDM. The result was a novel intervention designed to address real-world informational needs, time constraints, and interactions found in most clinic appointments, while challenging clinicians to step out of the mindset of "not rocking the boat". Using a "flipped classroom" model, the EPIC-HF tool was designed for electronic delivery before the visit and then asks the patient to use the information provided to engage their cardiology clinician in a conversation during the clinic visit. The final

tool provided the flexibility for the patient and clinician to discuss as few or as many changes to the medication plan as appropriate for that patient at that time.

The short-animated video was electronically delivered to patients as a URL hyperlink that explains in lay terms the benefits of GDMT intensification, gaps in prescribing, reasons for clinical inertia, and rationale for patients engaging in prescribing discussions. The 1-page tool is a list of drug classes, each with associated medication names (generic and brand) and target doses for each medication (https://patientdecisionaid.org/heart_medications/). The checklist allows patients to fill in their current medications and dosing, and contrast optimal GDMT against their current medication regimen. Patients were encouraged to bring the checklist to the visit to promote a conversation about changing at least "one thing" to optimize medication management. GDMT was based off of the most recent American Heart Association / American College of Cardiology[1, 2] and European Society of Cardiology[4] guidelines for the diagnosis and treatment of heart failure. At enrollment, patients were given the choice of whether they would like to receive the materials by email, text message, or both. Their next upcoming cardiology-based ambulatory clinic visit was identified by automated notifications to the study team generated by the electronic health record. The time between enrollment and the clinic visit was naturalistic, determined by usual clinical care, and variable for each patient. Intervention delivery occurred at 3 time points for all patients: 1 week, 3 days, and 24 hours prior to the next cardiology clinic visit. A brief note regarding the intervention materials and their delivery to the patient was sent through the electronic health record to clinicians 24 hours prior to the clinic visit for intervention patients; no such notification was sent to clinicians before a control visit.

Outcomes Measures

The primary effectiveness endpoint was the percent of patients with a GDMT intensification

from immediately preceding the study-qualifying cardiology clinic visit to 30 days later. GDMT intensification was defined as 1) initiation of EVBB, ACEI/ARB, ARNI, MRA, H/ISDN, or ivabradine, 2) a switch from ACEI/ARB to ARNI, or 3) dose intensification of these medications. Secondary outcomes included intensification type (initiation versus dose up-titration), intensification timing (at the clinic visit versus those occurring in the days to weeks after the visit), and total intensifications. Medication data was extracted from the electronic health record through review of medication reconciliation data, medication orders, and clinical notes. Safety was assessed by comparing the rate occurrence of emergency department visits, non-elective hospitalizations, and death at 30 days between the study and control groups. A survey was administered either electronically or mail to study patients, usually the day after the clinic visit, to collect self-reported use of the intervention.

Analysis

The percent of subjects with a GDMT intensification, and other dichotomous secondary outcomes, were compared between the control and intervention group using a 2-sided Fisher's exact test. Risk ratios for the outcome were calculated from a log binomial model; risk ratios were calculated rather than odds ratios for ease of interpretation, as this study does not meet the rare outcomes assumption where the odds ratio approximates relative risk. Region-level effects were accounted for through the inclusion of region as a fixed effect (i.e., indicator variables for region in the model). Clinician-level clustering within region was tested through random effects but did not improve model fit and was not included in the final models. Number of intensifications was compared using a Poisson model, also with a fixed effect for site. The number of intensifications was confirmed to fit the Poisson distribution through an examination of within-group means and variances, and a test of the overdispersion parameter in a negative

binomial (NB) model; the overdispersion parameter in the NB model was estimated to be zero

for both count outcomes, and therefore we proceeded with the Poisson model for these outcomes.

Primary and secondary analyses did not have any missing data, as one month of follow-up data

was able to be obtained on 290 all patients from the electronic health record. Missing

demographic information was excluded from **Table 1**. All analyses were performed in SAS

version 9.4.

Results

Cohort Characteristics

Overall 290 patients completed a cardiology clinic visit, 145 randomized to intervention and 145

to control (**Figure 1**). Overall, median age was 65 years, 29% were female, 11% were black, 7%

were Hispanic, median LVEF was 32%, 134 patients were from the academic metropolitan-

Denver region, and 171 patients from the community-practice regions in northern and southern

Colorado. Cardiology clinic visits involved 56 physicians and 17 advanced practice providers.

Brain natriuretic peptide and serum creatinine levels were lower in the intervention group;

otherwise, there were no significant differences between intervention and control patients (**Table

1**).

Pre-Clinic Visit Medications

At the start of the clinic visit, there were many potential opportunities for GDMT maximization

(**Figure 2**). No subject was simultaneously receiving target doses of EVBB, ARNI, and MRA.

GDMT Intensification

From the start of the qualifying cardiology clinic visit to 30 days later, 49.0% of patients in the

intervention group and 29.7% of patients in the control group experienced an intensification of

their GDMT (p=0.001, RR(95% CI)= 1.6 (1.2, 2.2)) (**Figure 3, Supplemental Table I**). When counting multiple intensifications over the 30 days, there were 0.61 intensifications per patient in the intervention group versus 0.36 intensifications per patient in control (p=0.002, Incidence Rate Ratio (95% CI)= 1.7 (1.2, 2.4)) (**Table 2**). The vast majority of these changes, including the effect of the intervention, were reflected by dose intensifications; initiation of medications was much less common, and switch to ARNI was rare and not different between intervention and control. Intensification of loop diuretics and digoxin (not considered part of GDMT intensification) were less frequent than changes to EVBB or ACEI/ARB/ARNI (**Supplemental Table I**). The most common dose intensification, and where our intervention showed the strongest effect, was among beta blockers; median(IQR) carvedilol dose increased from 18.75 (12.5, 25.0) to 37.5mg (25.0, 50.0) and median(IQR) metoprolol succinate dose increased from 50 (25, 100) to 75mg (50, 150) (**Supplemental Table II**).

Safety Events

No patients died between the cardiology clinic visit and 30 days. Numerically there were more non-elective hospitalizations and emergency department visits in the intervention group than the control group, but this was not statistically significant. Detailed chart review showed that the majority of these events were not related to hypotension, syncope, bradycardia, worsening heart failure, acute renal failure, or hyperkalemia (**Table 3**).

Intervention Delivery, Use, and Patient Impressions

Survey results of patients in the intervention group showed gradual loss of exposure from tool delivery to tool viewing to tool use, noting that more than half of patients reported reviewing the materials and more than a third of patients reported bringing the checklist to the cardiology clinic visit (**Figure 4**).

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Discussion

In this randomized, controlled trial of patients with HFrEF and an upcoming regularly-scheduled cardiology clinic visit, delivery of a patient-activation tool consisting of a 3-minute video and 1-page checklist before the visit was associated with a 19% absolute increase (1.6 RR) in GDMT intensification over the subsequent month. The majority of these increases occurred during the clinic visit itself and mostly involved dose intensification of previously prescribed generic medications. Patient medical records reported relatively low serious adverse events in this population, which were not significantly increased with the use of the intervention. This relatively simple patient-activation tool was deployed in the routine care of patients, suggesting opportunities for broader validation and dissemination.

The findings of our study expand upon prior research on GDMT prescribing and optimization. Consistent with a number of HFrEF registries,[5-8, 20] the vast majority of patients enrolled had multiple potential opportunities to improve GDMT. Consistent with prior research documenting clinical inertia,[21] we also showed that among those in the usual care group, less than a third of patients experienced any change to their HFrEF prescribing. Real-world use of optimal GDMT has been suboptimal due to a combination of patient and clinician factors. At the patient level, medications for HFrEF often do not produce immediate improvements in symptoms, and many are associated with short-term side effects. Out-of-pocket costs for newer on-patent medications can be a burden.[22] Also not surprisingly, patient adherence initiatives have had relatively little impact on clinical outcomes.[23-25] On the clinician level, limited clinic time, complexity of care, and the need for extensive patient medication education, make keeping medication doses at the status quo a practical option. Clinical inertia can become a necessity if uptitration is met with patient skepticism and uncertainty.

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The EPIC-HF intervention bridged these gaps between patients and clinicians. Unlike many prior trials designed to influence GDMT use through clinician notifications,[10, 11, 26, 27] and patient education,[23] the combined DTCA, SDM, and flipped-classroom approach engaged and activated patients prior to the clinical encounter and increased GDMT use more effectively. Others have reported successful mechanisms for improving GDMT use, but few studies have employed randomized controlled study design that remove the healthy user effects and treatment selection bias that naturally accompany GDMT intensification.[28]

Our results help counter the common argument, often from clinicians, that lack of GDMT intensification is an appropriate response to physiological limitations or drug intolerance.[9] In the closely monitored GUIDE-IT trial, medication adjustments were made in only 54.6% of qualified visits.[29] The most common reasons in GUIDE-IT for not adjusting were "clinically stable" and "already at maximally tolerated therapy;" yet at 6 months, only 16% achieved optimal GDMT. In our study, a simple tool activating patients to ask their clinicians about opportunities for GDMT intensification resulted in substantial increase in GDMT use. It is clear that not all patients should have GDMT increased; but the data here make it clearer that a good portion of them should at least try. The need for iterative dose escalation and active monitoring of patient symptoms, vital signs, and blood tests does not constitute intolerance, nor does it constitute a reasonable excuse not to deploy these high-value therapies.[30] With recent positive trials of sodium glucose transport 2 inhibitors,[31, 32] and stimulators of soluble guanylate cyclase,[33] and possibly myosin activators,[34] the options for, and thus gaps in, GDMT are growing. Innovative and pragmatic approaches to care will be required to reap the majority of benefit these advances offer.

Engaging patients in their healthcare treatment decisions and creating patient-clinician partnerships have emerged as major priorities in American health care. The 2001 publication of the Institute of Medicine's 6 domains of healthcare quality includes patient centeredness. Since that time, multiple healthcare organizations have called for engagement of patients in treatment decisions. These include Patient Centered Outcomes Research Institute's research agenda,[35] as well as Medicare national coverage decisions requiring the use of patient decision aids prior to implantable cardioverter-defibrillator and left atrial appendage occluder device placement.[36, 37] Furthermore, a growing body of evidence suggests that successful strategies to improve medication use do not place the onus for change on merely one party, but rather involve patient, clinician, and healthcare system working collaboratively.[38] Our trial and the EPIC-HF intervention were grounded in this principle, which may partially explain its success.

Perhaps as important as its patient-focus is the user-centered, pragmatic design of the EPIC-HF trial and intervention. Based on experiences with clinical operations and care delivery for patients with chronic HFrEF, this tool was designed using input from patients and caregivers, as well as physicians, advanced practice providers, nurses, pharmacists, hospital administrators, and experts in implementation science. This trial not only tested the EPIC-HF video and checklist, but it also leveraged years of work around field-coded LVEF, automated alerts around upcoming appointments, and patient-centered design following International Patient Decision Aid Standards. Our intervention is not solely a video and checklist, but requires the presence of timely, automated delivery that is seen by patients, clinicians, and the health system as not overly burdensome. A recent report from the Pew Research Center found that 81% of all Americans now own a smartphone, and the majority use the internet regularly,[39] such that we were able to deliver the intervention electronically. The success of the EPIC-HF tool is likely a combination

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of a variety of factors—video, checklist, notification to the clinician—which were all integrated into existing workflows using familiar technologies.

The study has a number of limitations. First, we did not measure intolerance and contraindications to GDMT. However, these are often vague and subjective, and absolute cut offs for heart rate, blood pressure, and creatinine elevation are not well defined. What we found is that if patients and clinicians are asked to try, GDMT can be intensified more often, and safely. Second, randomization occurred at the patient-level rather than the clinician- or site-level. This opens the potential for contamination, as clinicians who see intervention patients may subsequently be more active in prescribing and titrating medications for patients in the control arm. However, this would bias the result towards the null. Third, only cardiology specialists were included in this study, given that within the UCHealth system most HFrEF prescribing is managed by specialists. As such, the external validity of the tool for patients whose HFrEF is managed primary care clinicians is less certain. Finally, the use of a single, regional health system may further limit the generalizability. However, UCHealth is a diverse system spanning a range of local care approaches, and care was taken to over-enroll under-represented patient groups where possible. Further, the study tools can be modified for future use in a larger number of contexts: we have discussed the possibility of translating the video to a paper, comic-strip style format, which could then be delivered to patients who do not have access to, or the ability to use, a smartphone or email address. In total, we believe the insights gleaned from this study are likely to apply to a broad range of settings. At a minimum, the pragmatic approach should be further tested in different clinical contexts.

Conclusion

A myriad of medications can improve clinical outcomes in patients with HFrEF, but they remain widely underutilized. The EPIC-HF intervention improves suboptimal GDMT prescribing in HFrEF patients by using principles of DTCA and SDM. The result is a practical, yet novel tool that encourages collaboration between patients and clinicians, while still leaving room for the variability in clinical encounters and patient-clinician relationships. The positive results of the EPIC-HF trial beg for validation in other populations with HFrEF and suggest an approach that may be used in other chronic diseases that benefit from combination therapy.

Sources of Funding

Conflicts of Interest Disclosures

Supplemental Materials

Supplemental Tables I – II

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Table 1. Patient characteristics.

	Control Median(IQR) or %(N) n=145	Intervention Median(IQR) or %(N) n=145
Age, years	64 (55-72)	66 (58-74)
Female	29.7% (43)	28.3% (41)
Race		
Black or African American	11.3% (16)	10.0% (14)
White	85.1% (120)	85.0% (119)
Another race or multiracial	3.5% (5)	5.0% (7)
Hispanic or Latino ethnicity	6.3% (9)	8.0% (11)
Employment		
Employed	31.5% (45)	32.6% (46)
Retired	41.3% (59)	51.1% (72)
Unemployed	27.3% (39)	16.3% (23)
Insurance		
Medicare, Tricare	49.0% (71)	50.4% (73)
Medicaid	15.9% (23)	14.5% (21)
Private	33.1% (48)	33.1% (48)
None	2.1% (3)	2.1% (3)
Income		
Less than or equal to $20,000	22.8% (31)	17.9% (24)
$20,001--$40,000	22.8% (31)	12.7% (17)
$40,001--$60,000	11.0% (15)	14.9% (20)
$60,001--$80,000	19.9% (27)	21.6% (29)
Greater than $80,000	23.5% (32)	32.8% (44)
Single relationship status	41.0% (59)	38.6% (56)
Can receive text messages	59.3% (86)	53.1% (77)
Systolic blood pressure, mmHg	110 (102-124)	112.5 (104-124)
Diastolic blood pressure, mmHg	70 (62-80)	70 (64-78)
Pulse, bpm	74.5 (65.5-83)	72.5 (68-80)
LVEF, percent	32.5 (27-37.5)	32.5 (25.2-37.5)
BNP, pg/mL	266 (126-728)	161.5 (90-444.5)
Serum creatinine, mg/dL	1.1 (0.9-1.4)	1.0 (0.9-1.2)
Serum potassium	4.3 (3.9-4.6)	4.2 (4.0-4.5)

BNP=brain natriuretic peptide; BPM=beats per minute; LVEF=left ventricular ejection fraction
Data from day of cardiology clinic visit or closest to that day but not after.

Table 2. Total guideline-directed medical therapy intensifications per patient from pre-clinic visit to 30 days later.

	Treatment mean(sd) intensifications N = 145	Control mean(sd) intensifications N = 145	Estimate (95% CI) incidence rate ratio	p-value
Number of GDMT intensifications (initiation or dose increase EVBB, ACEI, ARB, ARNI, MRA, H/ISDN, or ivabradine)	0.61 (0.73)	0.36 (0.61)	1.7 (1.2, 2.4)	0.002
Number of all intensifications (including GDMT plus initiation or uptitration of loop diuretic or digoxin)	0.63 (0.73)	0.38 (0.62)	1.7 (1.2, 2.3)	0.002

ACE-I=angiotensin converting enzyme inhibitors; ARB= angiotensin receptor blockers; ARNI= angiotensin receptor neprilysin inhibitors; EVBB=evidence-based beta blocker; GDMT=guideline-directed medical therapy; H/ISDN=hydralazine/isosorbide dinitrate; MRA=mineralocorticoid receptor agonists

P values from Poisson model with fixed effect for clinic.

Table 3. Safety outcomes.

	Treatment N = 145	Control N = 145	p-value	Relative Risk
Deaths at 30 days	0	0	-	-
Unplanned hospitalization at 30 days	6 (4.1%)	4 (2.8%)	0.75	1.5 (0.4, 5.1)
Emergency department visit without hospitalization at 30 days	9 (6.2%)	5 (3.4%)	0.41	1.8 (0.6, 5.3)
Death, hospitalization, or emergency department visit at 30 days	15 (10.3%)	9 (6.2%)	0.29	1.6 (0.7, 3.6)

Hospitalizations and emergency department visits analyzed as yes/no per patient. Only 1 of 10 patients had 2 hospitalizations, and 1 of 14 patients had 2 emergency department visits. No patients had both a hospitalization and emergency department visit. P values using Fisher exact. Relative risk from log-binomial model with fixed site effect.

Figure Legends

Figure 1. Consort diagram.

Figure 2. Baseline medication prescribing pre-clinic visit.

"Isosorbide" includes isosorbide dinitrate and mononitrate (hydralazine was assessed separately)

Figure 3. Medication intensification from pre-clinic to 30-days later, stratified by treatment

assignment (further details in Supplemental Table I).

Figure 4. Survey results following patient-activation tool delivery and cardiology clinic visit.

Screened

(most recent echo LVEF <=40% and scheduled cardiology visit)

N = 699

Ineligible

N = 202

- LVEF >=40% on review (N = 5)
- Does not speak fluent English (N = 3)
- Has neither email account nor smartphone (N = 46)
- Lacks cognitive capacity to consent (N = 1)
- Physician objects to approaching patient (N = 152)
    - Deemed not ideal candidate (N = 138)
    - Conflict with another research study (N = 4)
    - Other (N = 10)

Eligible

N = 497

Refused

N = 191

- Not interested in study (N = 181)
- Other (N= 10)

Consented and randomized

N = 306 (153 control, 153 intervention)

Intervention

N = 153

Did not attend clinic

N = 8

- 1 withdrew
- 7 never had qualifying clinic visit

Control

N = 153

Did not attend clinic

N = 8

- 1 died
- 7 never had qualifying clinic visit

Analyzed

N = 145

Analyzed

N = 145

Alive at 30 days

N = 145

Alive at 30 days

N = 145
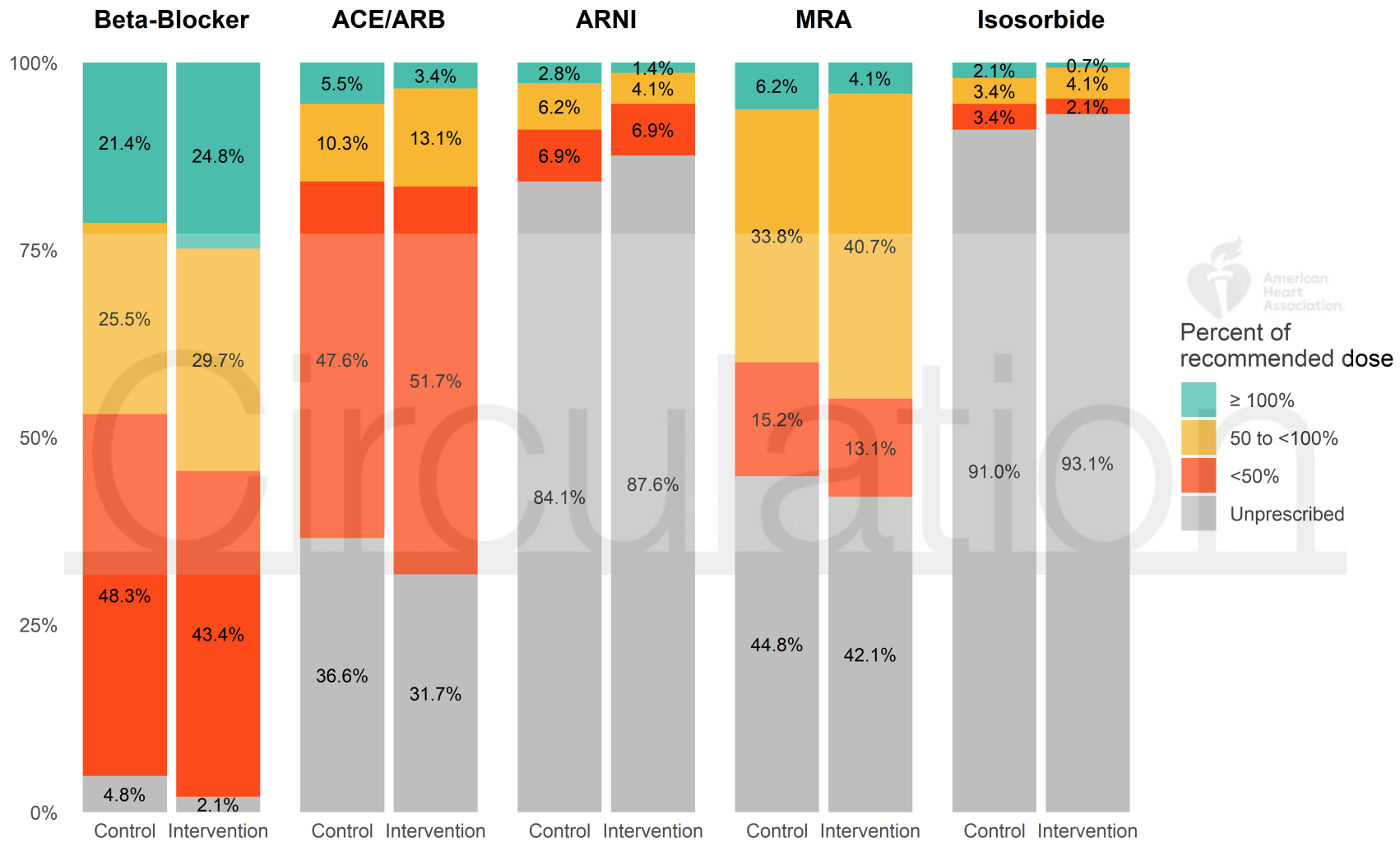
Primary outcome: Initiation or intensification of GDMT

100%

75% — 70.3%

51.0%

50%

25% — 29.7%

49.0%

0%

Control   Intervention

Initiation/ intensification categories

Key heart failure medication added

100%

75%

93.1%   89.7%

50%

25%

0% — 6.9%   10.3%

Control   Intervention

ACE-I or ARB replaced with ARNI

100%

75%

97.9%   97.2%

50%

25%

0% — 2.1%   2.8%

Control   Intervention

Key heart failure medication uptitrated

100%

75%

78.6%   60.7%

50%

25% — 21.4%

39.3%

0%

Control   Intervention

Additions/ uptitrations by heart failure medication

Additions

25%

0% — 1.4%   0.7% 2.8%   2.8% 1.4%

Cont Int   Cont Int   Cont Int   Cont Int

Beta blocker   ACE-I   ARB   ARNI

25%

0% — 2.1% 3.4%   0.7%   0.7% 0.7%   0.7% 1.4%

Cont Int   Cont Int   Cont Int   Cont Int

Aldosterone antagonist   Ivabradine   Hydralazine   Isosorbide
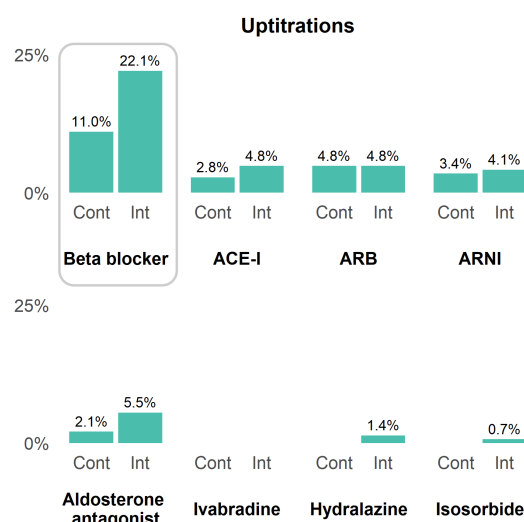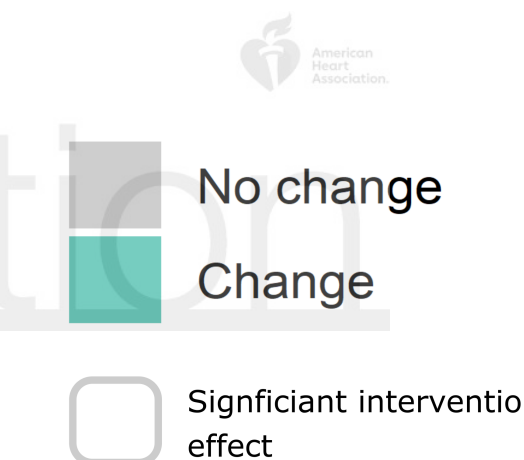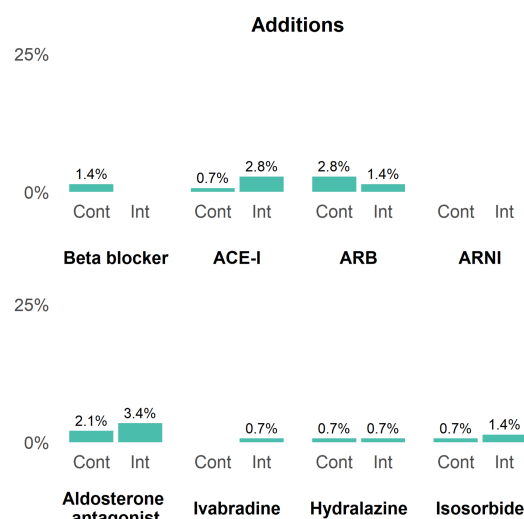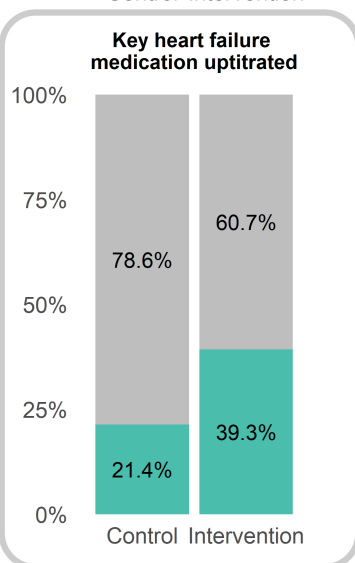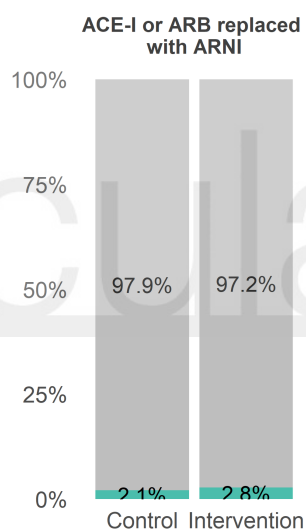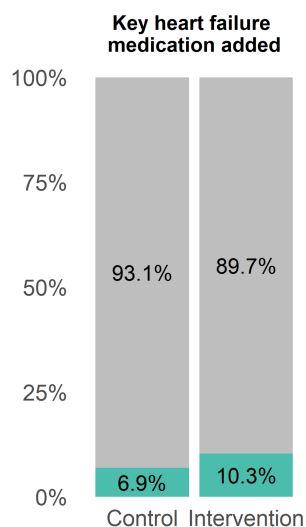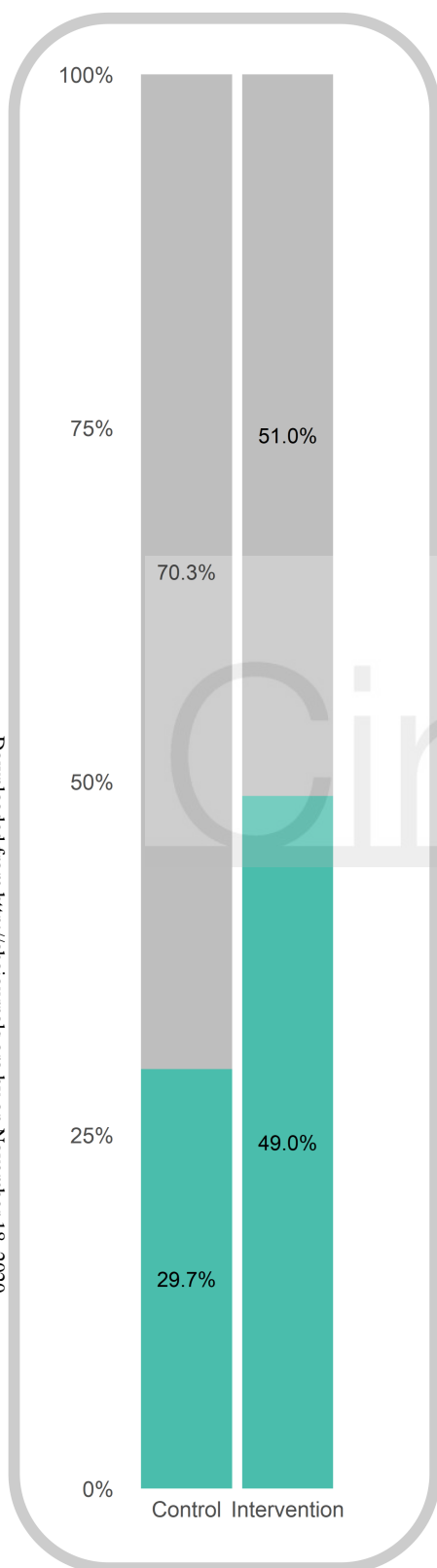
No change

Change

Signficiant intervention effect

Uptitrations

25%

11.0%   22.1%

0% —   2.8% 4.8%   4.8% 4.8%   3.4% 4.1%

Cont Int   Cont Int   Cont Int   Cont Int

Beta blocker   ACE-I   ARB   ARNI

25%

0% — 2.1% 5.5%   1.4%   0.7%

Cont Int   Cont Int   Cont Int   Cont Int

Aldosterone antagonist   Ivabradine   Hydralazine   Isosorbide

145 intervention patients were sent the survey

126 (87%) responded to the survey

5 did not respond

67% (81/121) reported receiving the video

1 did not respond

91% (73/80) of those reported reviewing the video

1 did not respond

74%

(53/72) found the video helpful in understanding their medical plan

71%

(51/72) found the video helpful in discussing their medicines with their doctor

7 did not respond

70% (83/119) reported receiving the checklist

0-2 did not respond to items

89% (74/83) of those reported reviewing the checklist

78%

(56/73) found the checklist helpful in understanding their medical plan

67%

(48/72) found the checklist helpful in discussing their medicines with their doctor

82%

(61/74) brought the checklist to their appointment

73%

(52/73) talked about checklist with doctor at their appointment