HF Update:

Use of Digital Health In Patients with HF

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Disclosures

- AHA Strategically Focused Research Network
- ESC Young Investigator Research Grant
- Bayer-Vascular Canadian Cardiovascular Society grant
- Roche Diagnostics
- Takeda
- BMS-Pfizer

Agenda

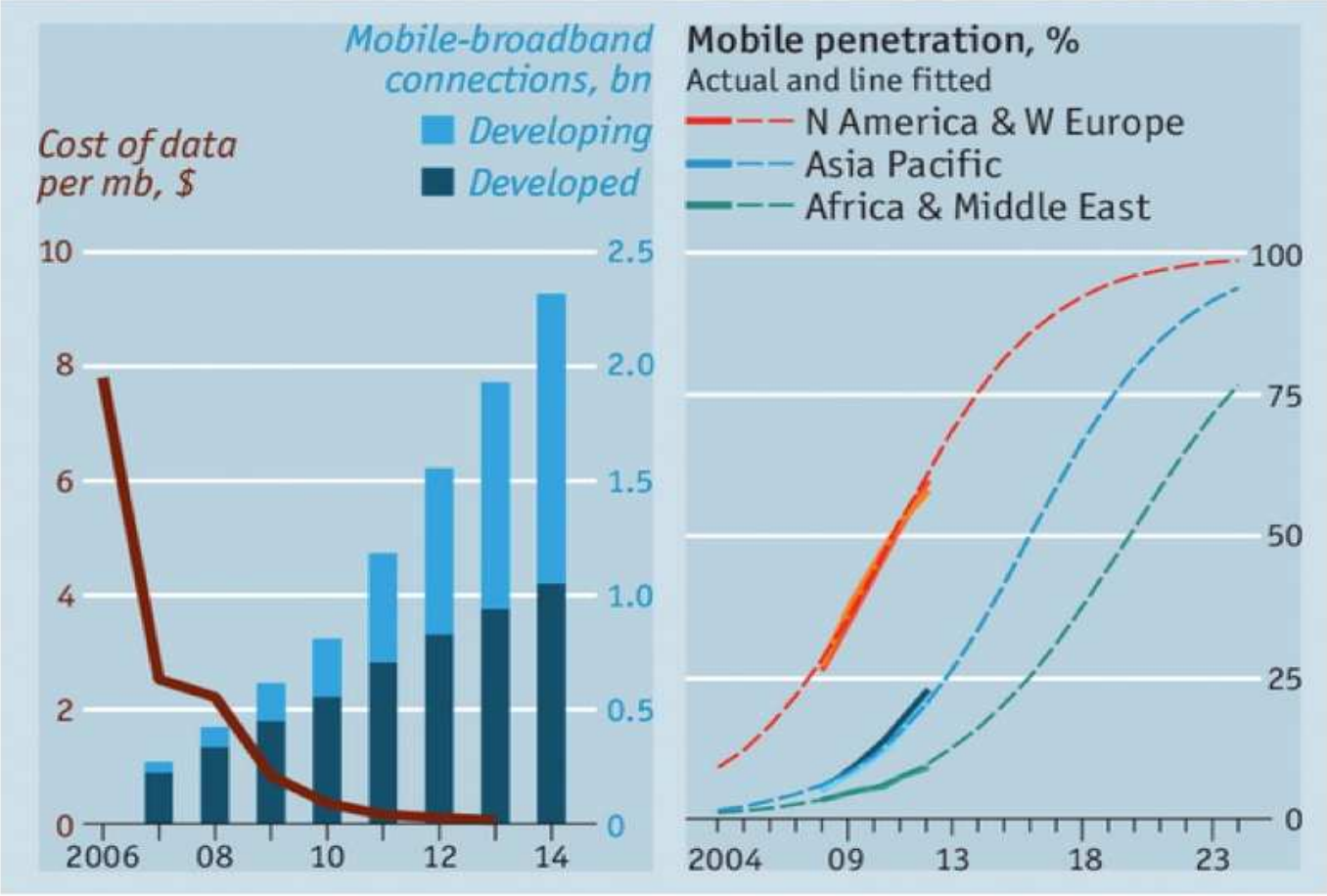
- Introduction of digital health in clinical research
- Three different technologies
  - Voice-based technology
  - Physical activity
  - Electronic Health Records
- Challenges and opportunities

Introduction of Digital Health in Clinical Care for Heart Failure

Introduction

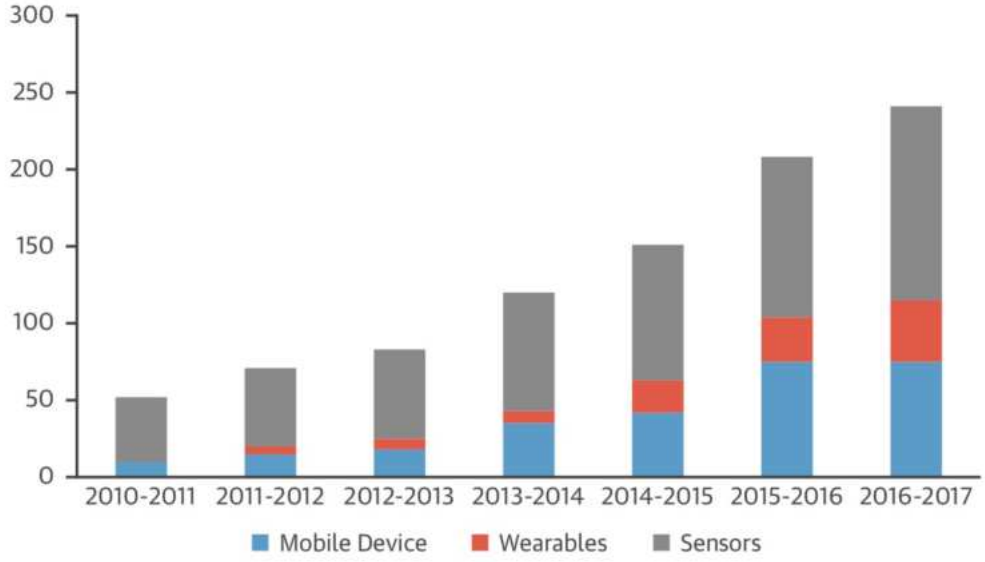
- Healthcare industry, until recently has been largely excluded from the advances in digital health
- Availability of powerful yet low-cost computing + funding from government and industry resulted in major advances in the use of digital technologies
- Facilitate healthcare delivery + optimize clinical trials

Sharma A et al, JACC 2018



Economist 2018

FIGURE 2 Use of Digital Health Technologies Within Clinical Trials

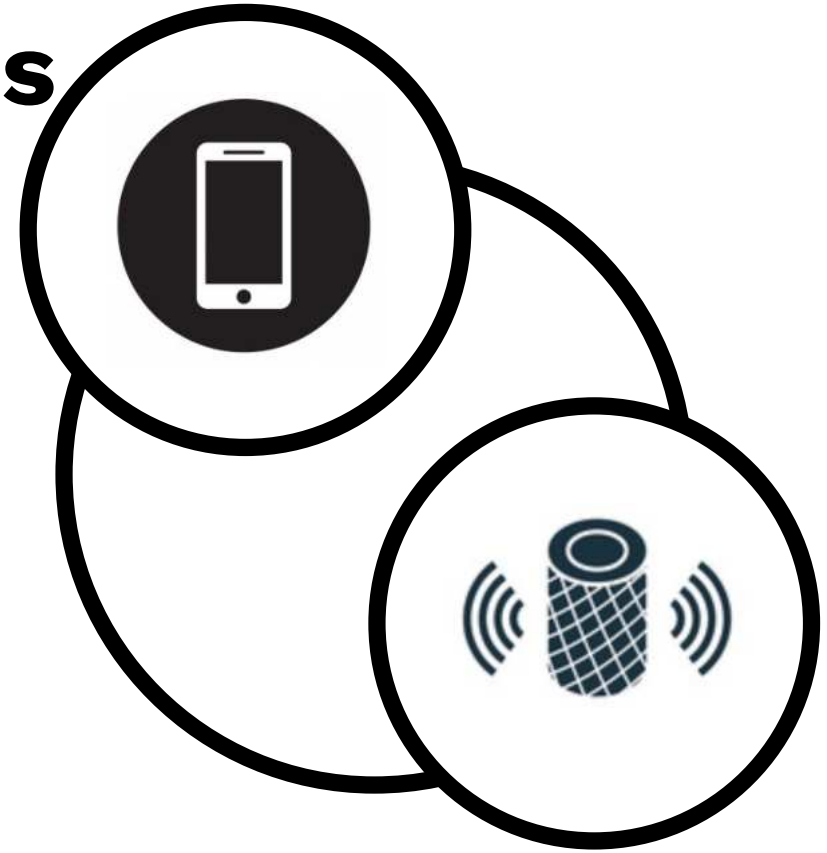


Data reflect the number of initially registered trials on clinicaltrials.gov per year (accessed March 20, 2017). Posted entries are defined based on investigator description of proposed devices used.

Sharma A et al, JACC 2018

Digital Technologies

Several emerging technologies
that will disrupt clinical trials



Voice Technology For Data Collection

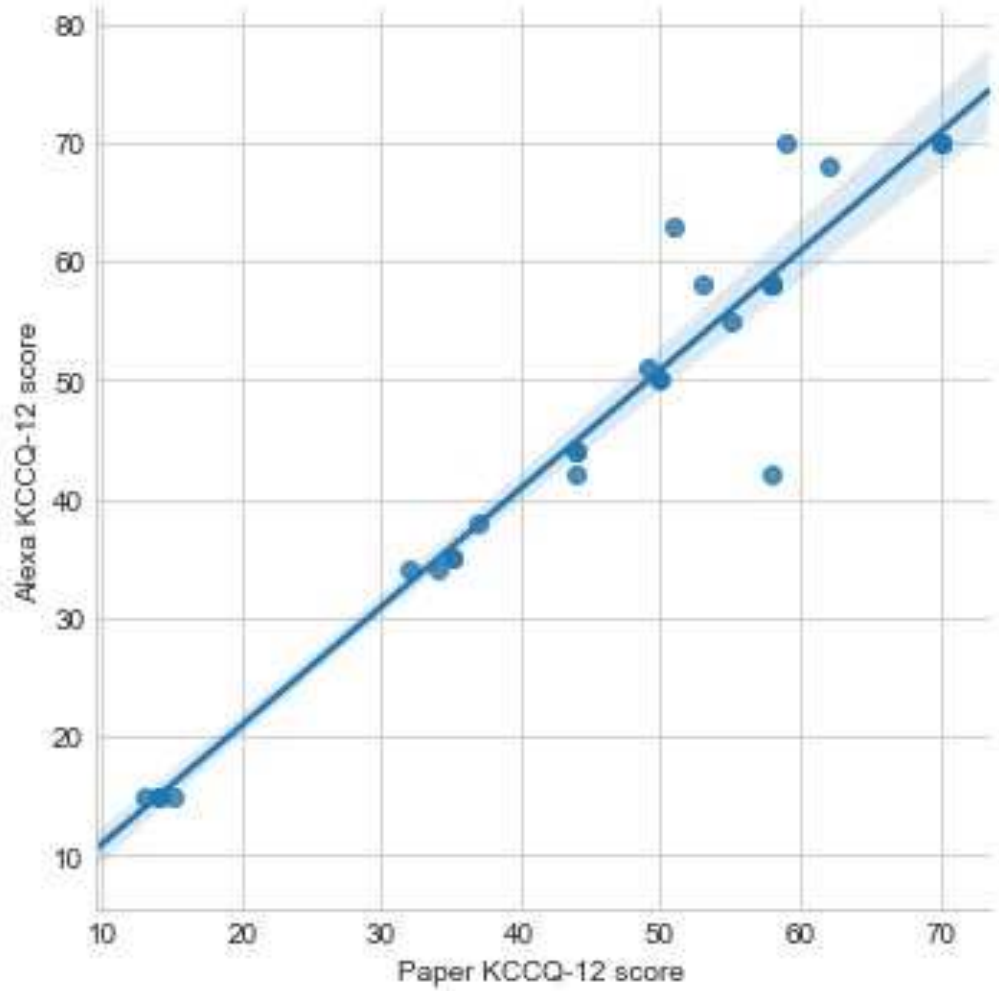

amazon
amazon

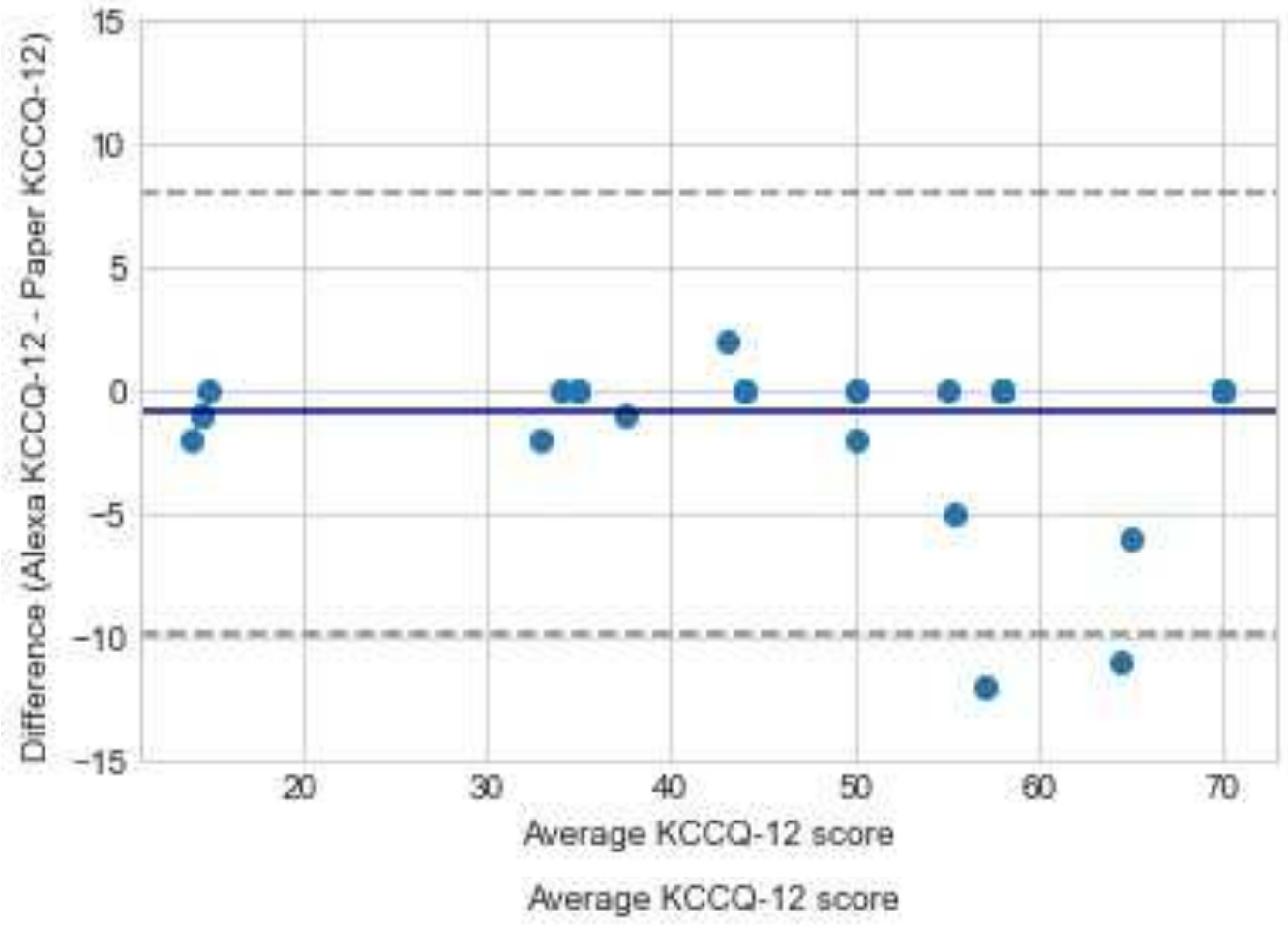
Kansas City Cardiomyopathy Questionnaire (KCCQ-12)

The following questions refer to your **heart failure** and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.

Activity	**Extremely** Limited	**Quite a bit** Limited	**Moderately** Limited	**Slightly** Limited	**Not at all** Limited	Limited for other reasons or did not do the activity
a. Showering/bathing	O	O	O	O	O	O
b. Walking 1 block on level ground	O	O	O	O	O	O
c. Hurrying or jogging (as if to catch a bus)	O	O	O	O	O	O
	1	2	3	4	5	6

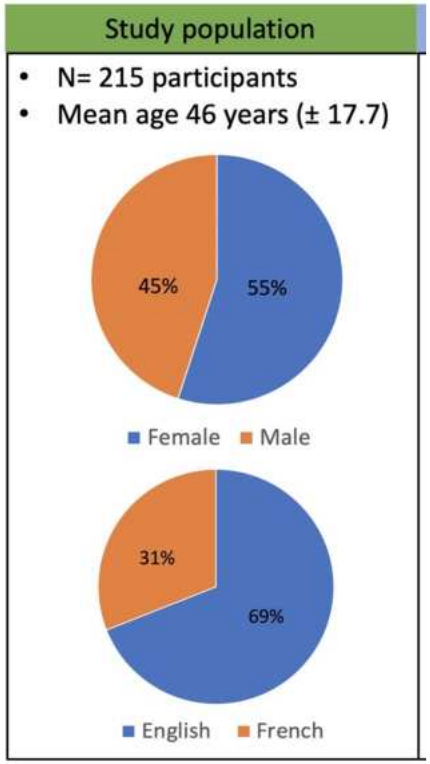

Alexa KCCQ-12 score
Paper KCCQ-12 score
10
20
30
40
50
60
70
80



Average KCCQ-12 score

Impact of COVID-19: Can These Technologies be Pivoted ?

VOICE-COVID Study



CI confidence interval; IQR Interquartile range; PPE personal protective equipment

Eur Heart J Digit Health, Volume 2, Issue 3, September 2021, Pages 521–527, https://doi.org/10.1093/ehjdh/ztab055

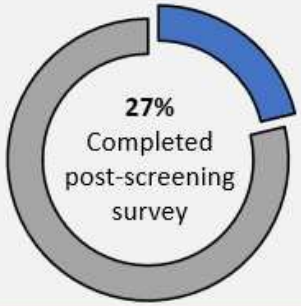
Attitudes About Artificially Intelligent Interactive Voice Response Systems Using Amazon Alexa in Cardiovascular Clinics: Insights from the VOICE-COVID-19 Study

Study population

VOICE-COVID-19 Study

Prospective evaluation of Amazon Alexa for SARS-CoV2 screening

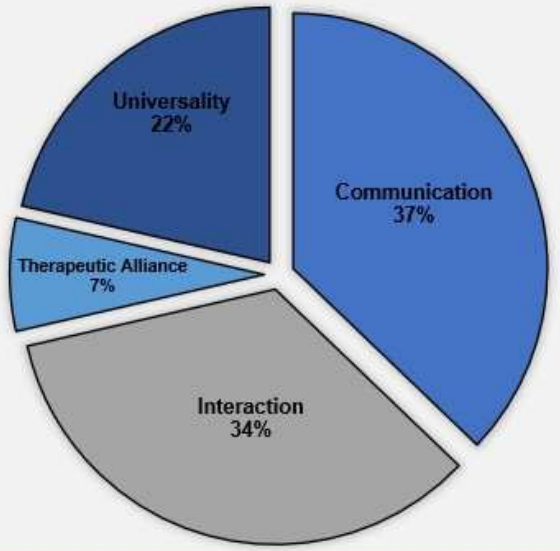
215 People screened with Amazon Alexa



Thematic Analysis of Attitudinal Variables Associated with the Use of Amazon Alexa

- The use of AI-IVR systems may improve cost efficient health service delivery and facilitate research tasks.
- Four identified themes affect acceptability: communication, interaction, universality, and therapeutic alliance.
- The most prevalent attitude related to the device's ability to produce and receive communicate.
- Demographic related subgroup differences are unclear, requiring further research.

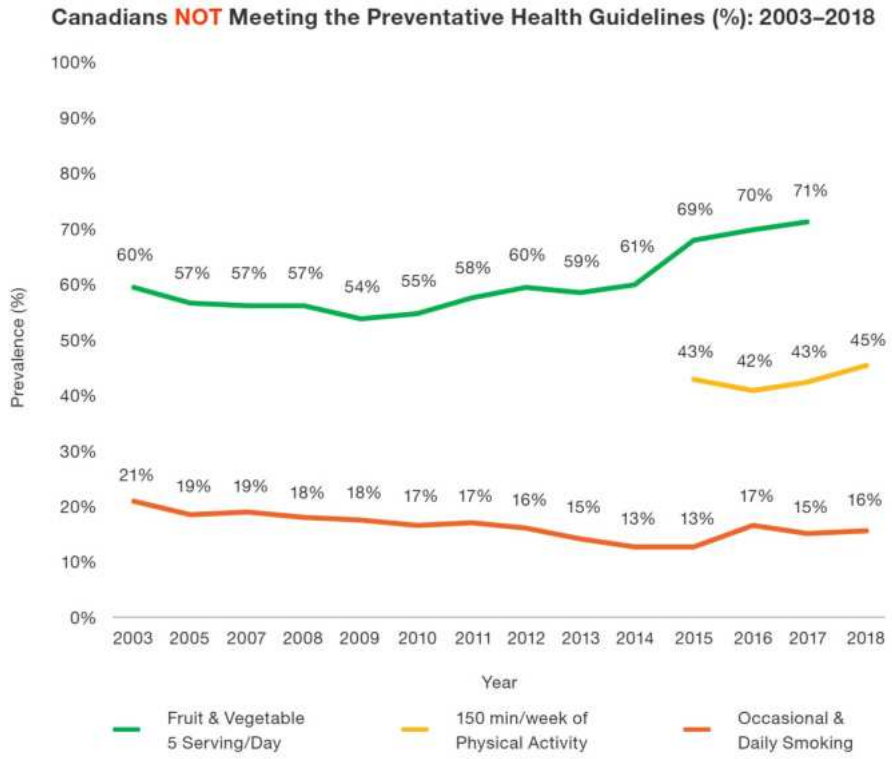
ATTITUDINAL THEMES AFFECTING ACCEABILITY



Communication is the most prevalent concern affecting the acceptability of AI-IVR systems for research purposes. AI-IVR optimization may facilitate health service delivery and research data capture.

Physical Activity

Problem We Are Trying To Solve



Healthy Futures: The Need For Action, 2020

A mobile health intervention to increase physical activity in patients with heart failure and diabetes: The TARGET-HF-DM trial

Background and Objectives

- Regular physical activity is essential to optimal cardiovascular health
- Improves outcomes and quality of life in heart failure
- Improves glycemic control and reduces complications in diabetes
- The health impact of behavioral recommendations such as regular exercise is limited by poor long-term adherence
- Digital health interventions (mHealth) provide novel platforms to improve health behaviors but have not been rigorously tested in patients with chronic diseases
- The TARGET-HF-DM study was designed to test the efficacy of a mobile health intervention in patients with both HF and DM on Physical activity Medication adherence

Design: Patients

- TARGET-HF-DM was a ***pragmatic multi-center randomized controlled trial*** at 6 clinical sites in the United States

- ***Broad Entry Criteria***:
- Both symptomatic heart failure (regardless of EF) and diabetes (requiring medical treatment)
- Not participating in formal supervised exercise program (such as cardiac rehabilitation)
- No significant non-cardiac impairments to physical activity
- Smartphone

Sharma A, et al. American Heart Journal 2018

Design: Intervention

- 1:1 randomization to mHealth intervention or usual care
- Both groups received step counter and weekly text reminder to wear it
- mHealth group received feedback and incremental personalized activity goals (based on prior week's activity) sent by text 3x/week
- 3 months of active intervention followed by 3 months of additional data collection

- ***Primary Endpoint:***
  - Change in mean daily step counts from baseline to 3 months

- ***Secondary Endpoints:***
  - Change in HRQOL (KCCQ OSS) from baseline to 3 months
  - Change in NT-proBNP from baseline to 3 months
  - Change in Hemoglobin A1C from baseline to 3 months

- ***Exploratory Endpoints:***
  - Change in mean daily step counts baseline to 6 months ("stickiness")
  - Change in metabolomic profiling from baseline to 3 months

Statistical Models

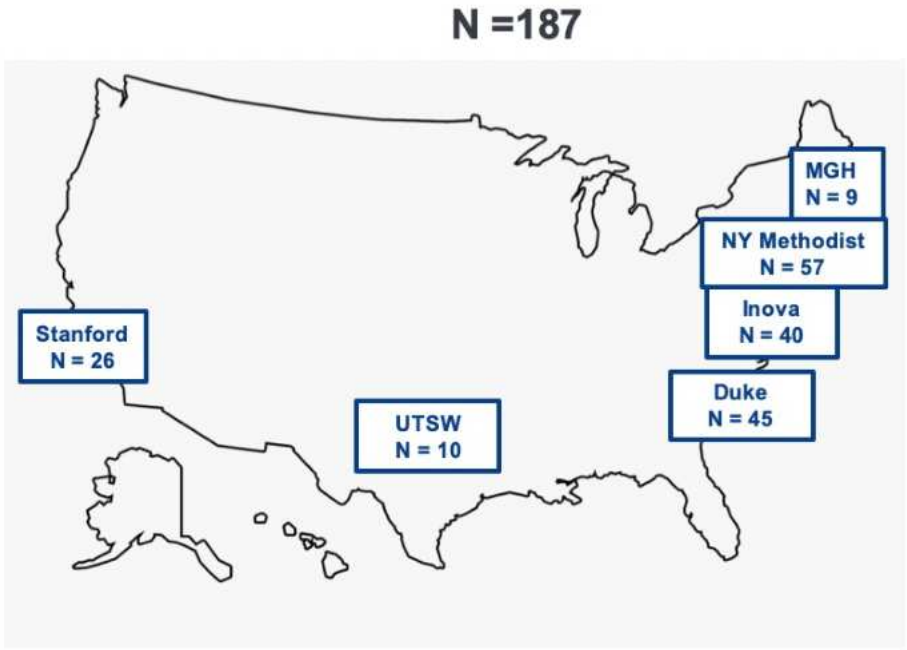
- Changes over time assessed using generalized linear regression model adjusted for baseline measures
- To account for missing or non-physiologic step count data, the primary analysis was limited to patients who had
  - Non-missing data at both baseline and month 3
  - Data were considered non-missing if at least 2 days of data/week were available and within defined physiologic range (200-20,000 steps)

Baseline Demographics

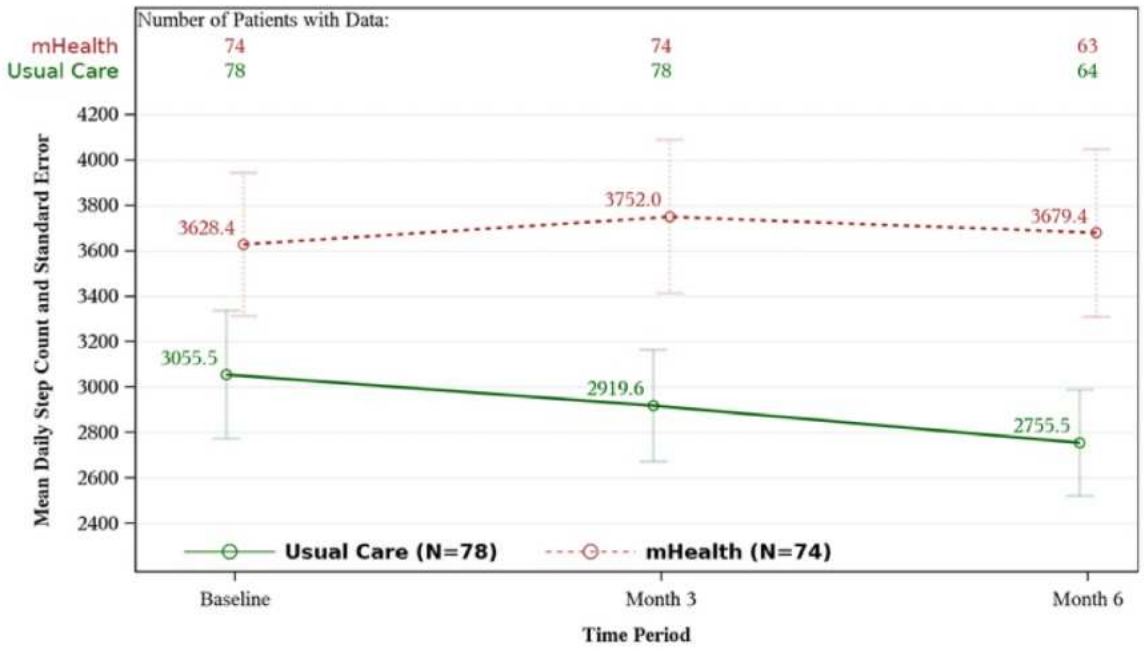
- 35% Women
- 47% African-American
- 10% Hispanic
- Age 59 years

- HFrEF (EF ≤ 40%) = 66%
- NYHA class II = 80%

- Diabetes = 100%
- Atrial Fib = 33%
- NT-proBNP = 1309 pg/mL



Primary Outcome



Change in daily step count baseline to month 3:

between group difference of 313 steps/day

95% CI 8, 619
p = 0.04

	mHealth	Usual Care	Treatment difference (95% CI)	P value
Change in mean daily step count (steps/day)	151	-162	313 (8, 619)	0.04
Change in KCCQ OSS	6.6	1.1	5.5 (1.4, 9.6)	0.009
Change in mean NT-proBNP (pg/mL)	-41 pg/mL	24 pg/mL	-65 pg/mL	0.20
Change in HbA1c (%)	0.13 %	-0.02 %	0.15 %	0.44

Strengths

- Multi-center
- High enrollment of under-represented populations
- Pragmatic design using consumer technology
- Concordance between step counts, QOL, and metabolic signals

Limitations

- Modest sample size
- Unblinded
- Missing step count data (although generally similar to other mHealth studies)
- Limited follow-up duration

Electronic Health Records To Nudge Use of GDMT

Electronic Alerts to Improve Heart Failure Therapy in Outpatient Practice: A Cluster Randomized Trial

Original Investigations

Lama Ghazi, Yu Yamamoto, Ralph J. Riello, Claudia Coronel-Moreno, Melissa Martin, Kyle D. O'Connor, Michael Simonov, Joanna Huang, Temitope Olufade, James McDermott, Ravi Dhar, Silvio E. Inzucchi, Eric J. Velazquez, ... SEE ALL AUTHORS

J Am Coll Cardiol. Apr 03, 2022. Epublished DOI: 10.1016/j.jacc.2022.03.338

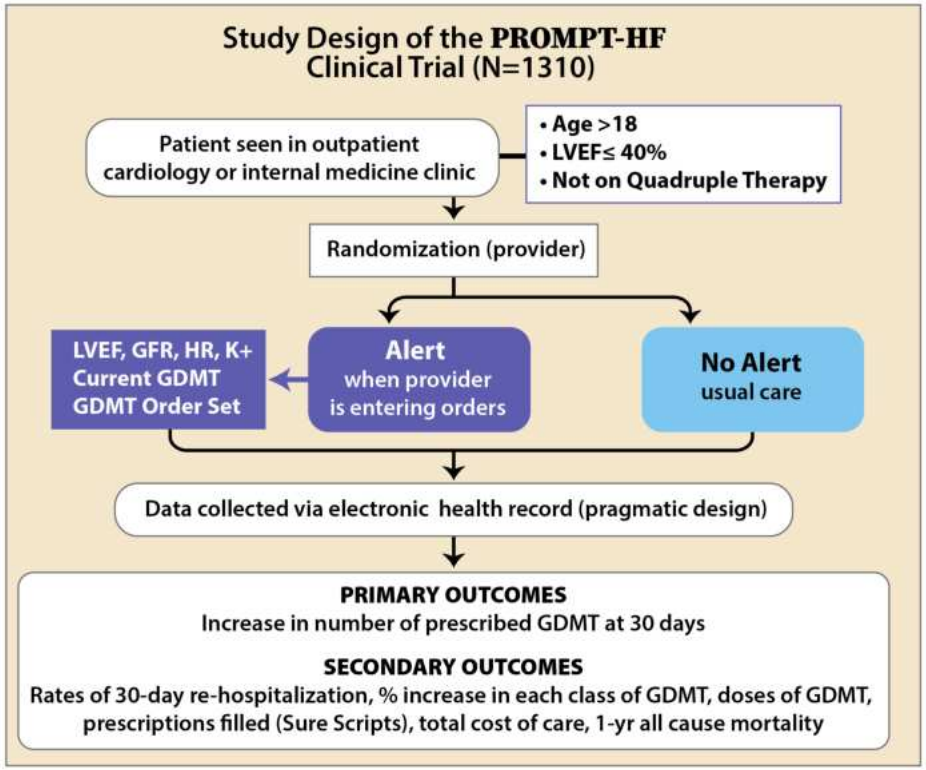
Background

- GDMT improves clinical outcomes in HFrEF but remains pervasively under-prescribed
- Efforts to optimize GDMT are abundant and resource intensive but limited evidence supports their use
- The electronic health record (EHR) may be used to target and individualize GDMT recommendations
- This approach is easily scalable and a low-cost way to accelerate high value care

Study Hypothesis

PROMPT HF was designed to test the hypothesis that **timely** and **targeted** alerting of recommendations about medical treatment of HFrEF tailored to the patient would lead to **higher** rates of GDMT prescription compared to usual care

Study Design



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BestPractice Advisory - Zztest, Chrishptwo

Optimize medications for your patient with HFrEF

Your patient meets the criteria for having heart failure with reduced Ejection Fraction (HFrEF). Relevant values are listed below:

BP	150/90	10/19/2020
Heart Rate	120	10/19/2020
LVEF	35%	8/16/2020
Potassium	5.8	8/31/2020
eGFR	35	8/31/2020
Serum Creatinine	1.00	8/29/2019

Current Heart Failure Therapies:

Beta Blocker: None

Current ACE/ARB/ARNI Therapy

ACE Inhibitor and Calcium Channel Blocker Combinations

amLODIPine-benazepril (LOTREL) 5-10 mg per capsule

MRA: None

SGLT2i: None

In order to improve the care of patients with HFrEF, we have included an evidence based medical therapy order set below. For full treatment guidelines, click here.

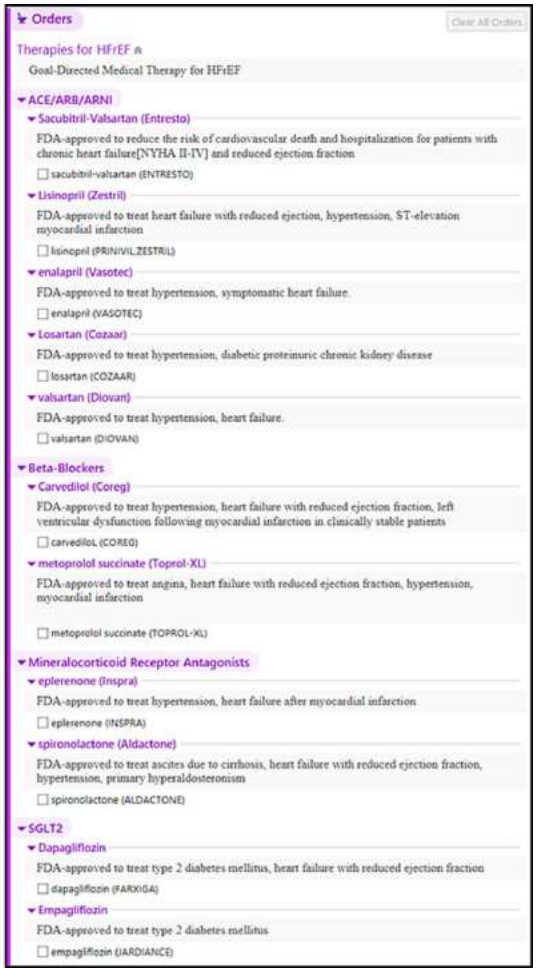
The guideline-recommended treatment for heart failure in this alert IS NOT a substitute for clinical judgment and individual-patient-centered decision making. There are clinical reasons why these recommendations may not apply to your patient.

Open SmartSet | Do Not Open | **Maximizing Medical Therapies for HFrEF** Preview

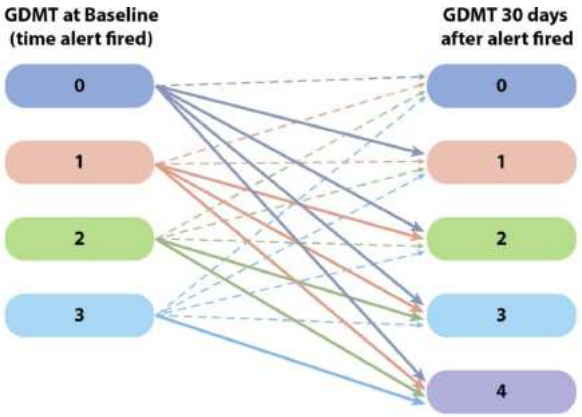
Acknowledge Reason

I will adjust medications | Med changes not clinically indicated | Defer for other reason (specify)

✓ Accept



Primary Outcome

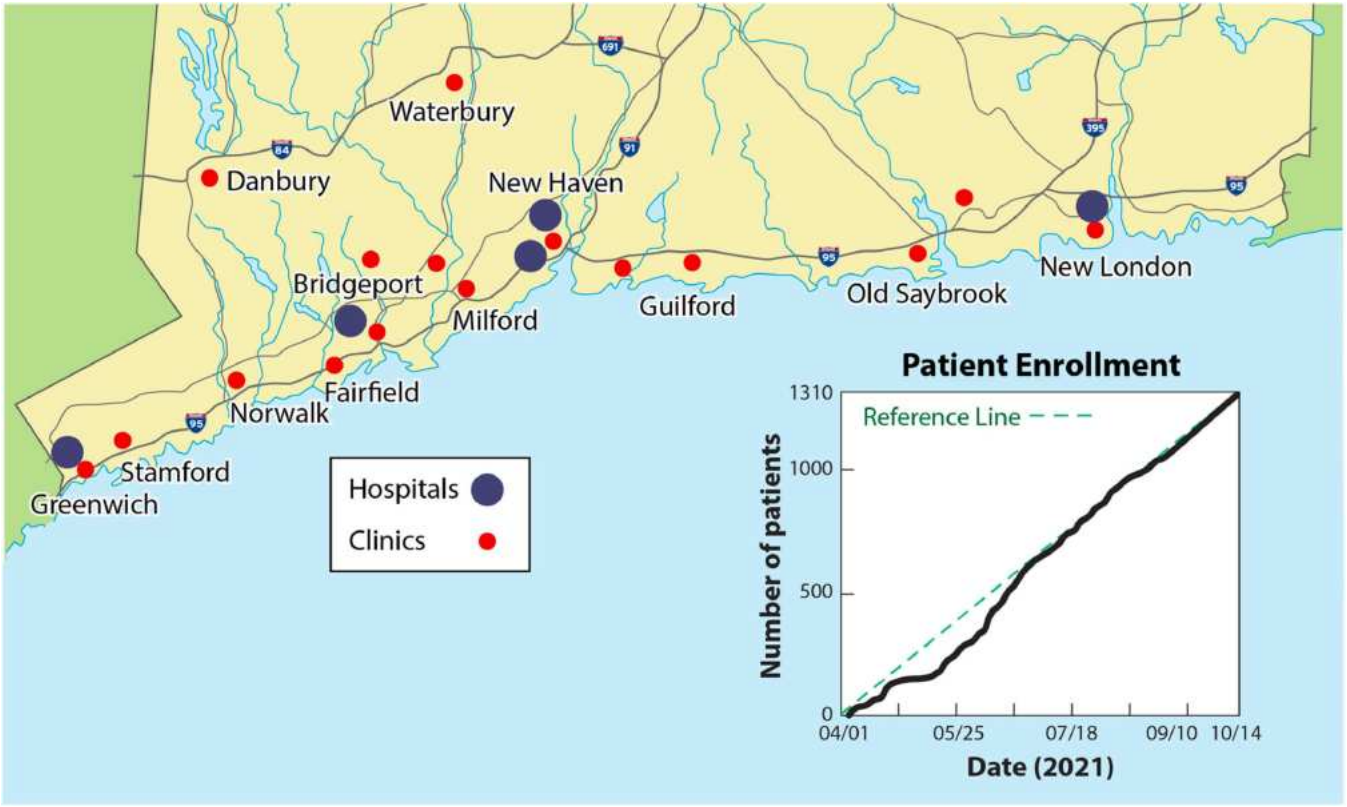


Scenario	Evidence-based medications at randomization	Evidence-based medications 30 days post-randomization	Outcome present (increase evidence-based medications)
1	ACEi + beta blocker	ARB + beta blocker	No
2	ARB + MRA	ARB + SGLT2i	No
3	ACEi	ACEi + SGLT2i + beta blocker	Yes
4	ACEi + MRA	ARNi	No
5	ARB + MRA + SGLT2i	ARB + MRA + SGLT2i + beta blocker	Yes
6	ACEi	ARNi	No

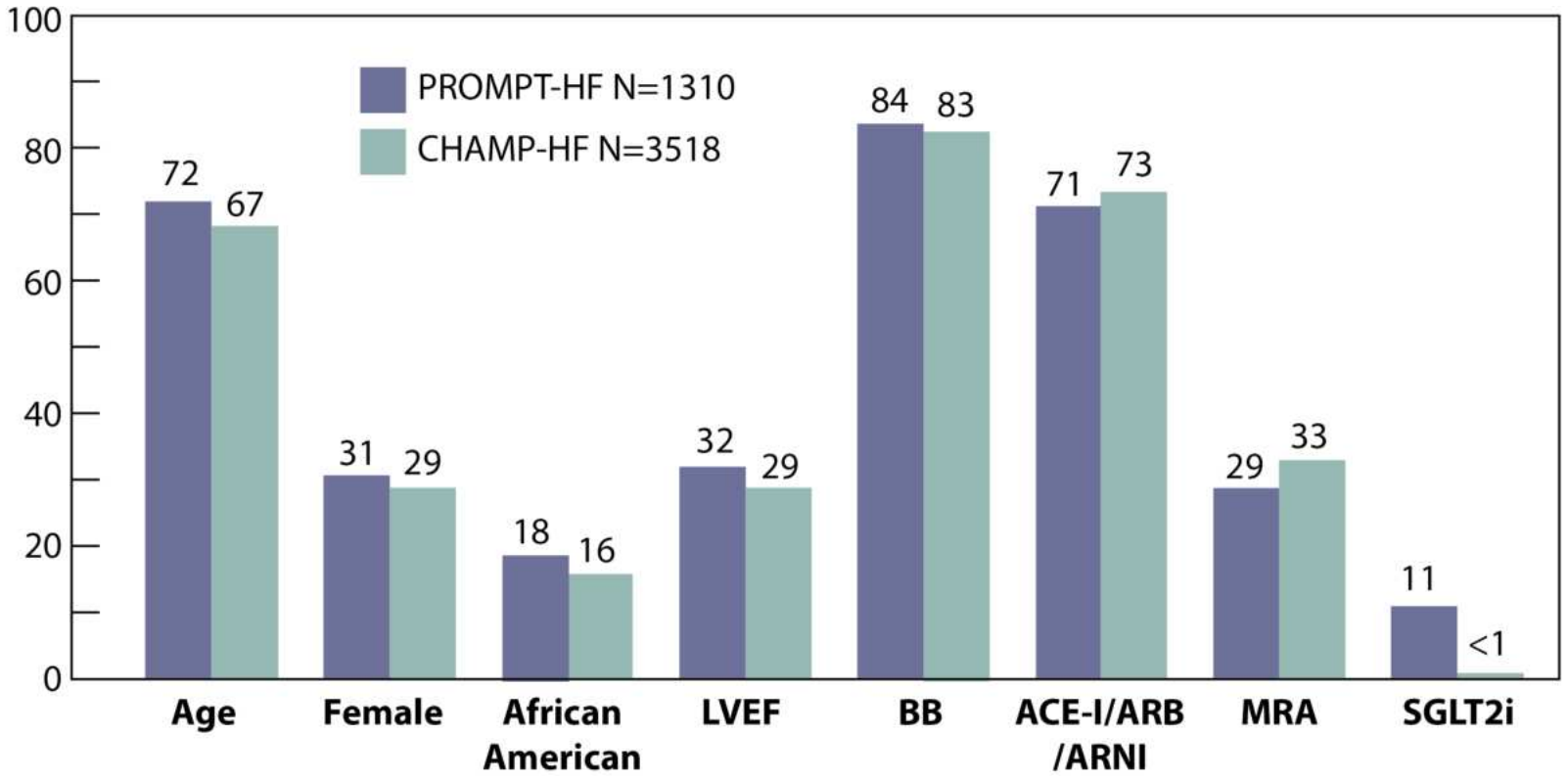
Sample Size

- Absolute increase of 10% in proportion of patients on an additional class of GDMT at 30 days
- Sample size of 1310 achieved 91% power to detect a 10% difference between study arms at α=0.05 and ICC of 0.05
- Primary outcome examined association between intervention and outcomes using generalized linear models adjusting for prespecified baseline characteristics and accounting for clustering at provider level

Trial Locations

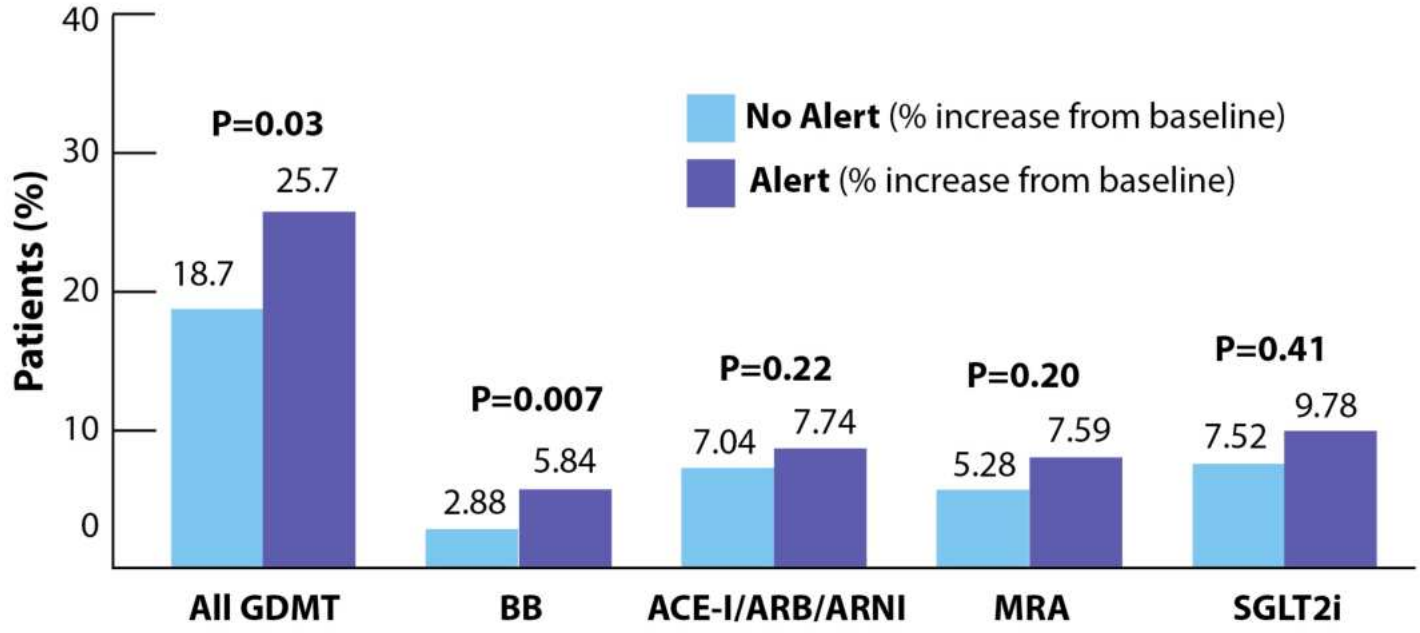


Baseline


100
80
60
40
20
0
PROMPT-HF N=1310
CHAMP-HF N=3518
72
67
31
29
18
16
32
29
84
83
71
73
29
33
11
<1
Age
Female
African American
LVEF
BB
ACE-I/ARB /ARNI
MRA
SGLT2i

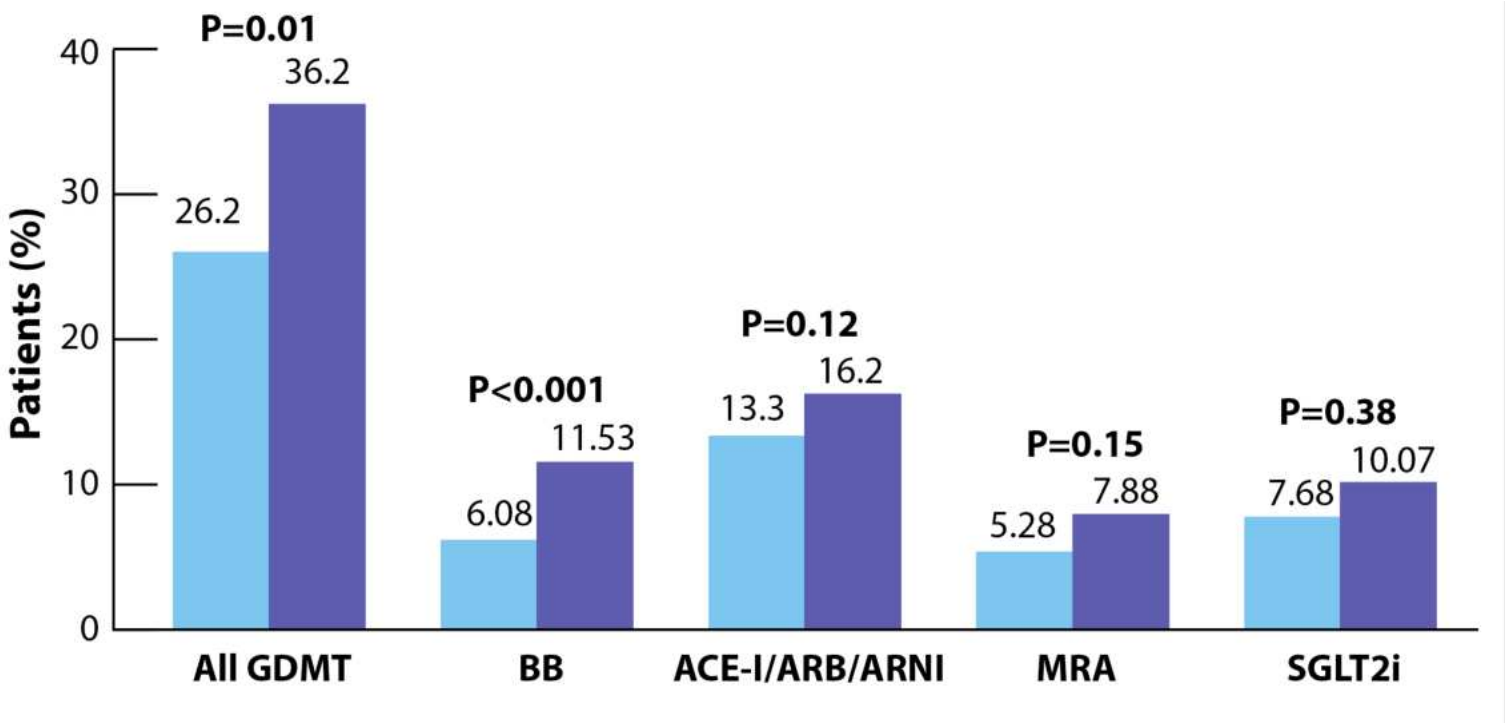
Primary Clinical Endpoint: Additional GDMT Class

RR: 1.41 (1.03, 1.93); P=0.03 Number Need to Alert = 14



Secondary Clinical Endpoint: +GDMT Class/↑Dose

RR: 1.39 (1.08, 1.79); P=0.01 Number Need to Alert= 10



Considerations

- Results from Single Health Care System
- Only Included High Volume Clinicians
- Tested in Outpatient Setting; Inpatient Trial Ongoing
- Tested within the Epic® EHR
- Increase in Dose was Secondary Outcome
- Impact Beyond 30 Days Subject of Future Study

Conclusions

- A personalized alert triggered via the EHR during office visits led to significantly higher number of HFrEF patients on appropriate GDMT
- This low-cost tool can be rapidly embedded into the EHR at integrated health care systems and lead to widespread improvements in the care of heart failure patients

Emerging discussion around digital technologies

Thank you very much!