A Cluster Randomized *PR*agmatic Trial Aimed At Impr*O*ving Use Of Guideline Directed *M*edical Therapy In Out*P*atien*T*s With *H*eart *F*ailure: *PROMPT-HF*

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Funding Information and Disclosures

JH, TO, JM are employees of AstraZeneca. RJR is a consultant for Alexion, AstraZeneca, Boehringer Ingelheim, Janssen, Johnson & Johnson, PhaseBio, and Portola. RD does executive teaching for Sanofi Consumer Healthcare. SEI has served on clinical trial committees and advisory boards for Boehringer Ingelheim, AstraZeneca, and Novo Nordisk. He has served as a consultant to Merck, Pfizer, Lexicon, vTv Therapeutics, Esperion and Abbott and has delivered lectures supported by Boehringer Ingelheim and AstraZeneca. TA is consultant for Sanofi-Aventis, Amgen, Cytokinetics. He has research funding from Boehringer Ingelheim, AstraZeneca, Cytokinetics, and Relypsa. NRD works under contract with the Centers for Medicare and Medicaid Services to develop and maintain performance measures used for public reporting and pay for performance programs. He reports research grants and consulting for Amgen, Astra Zeneca, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Cytokinetics, Novartis, SCPharmaceuticals, and Vifor. The remaining authors have nothing to disclose.

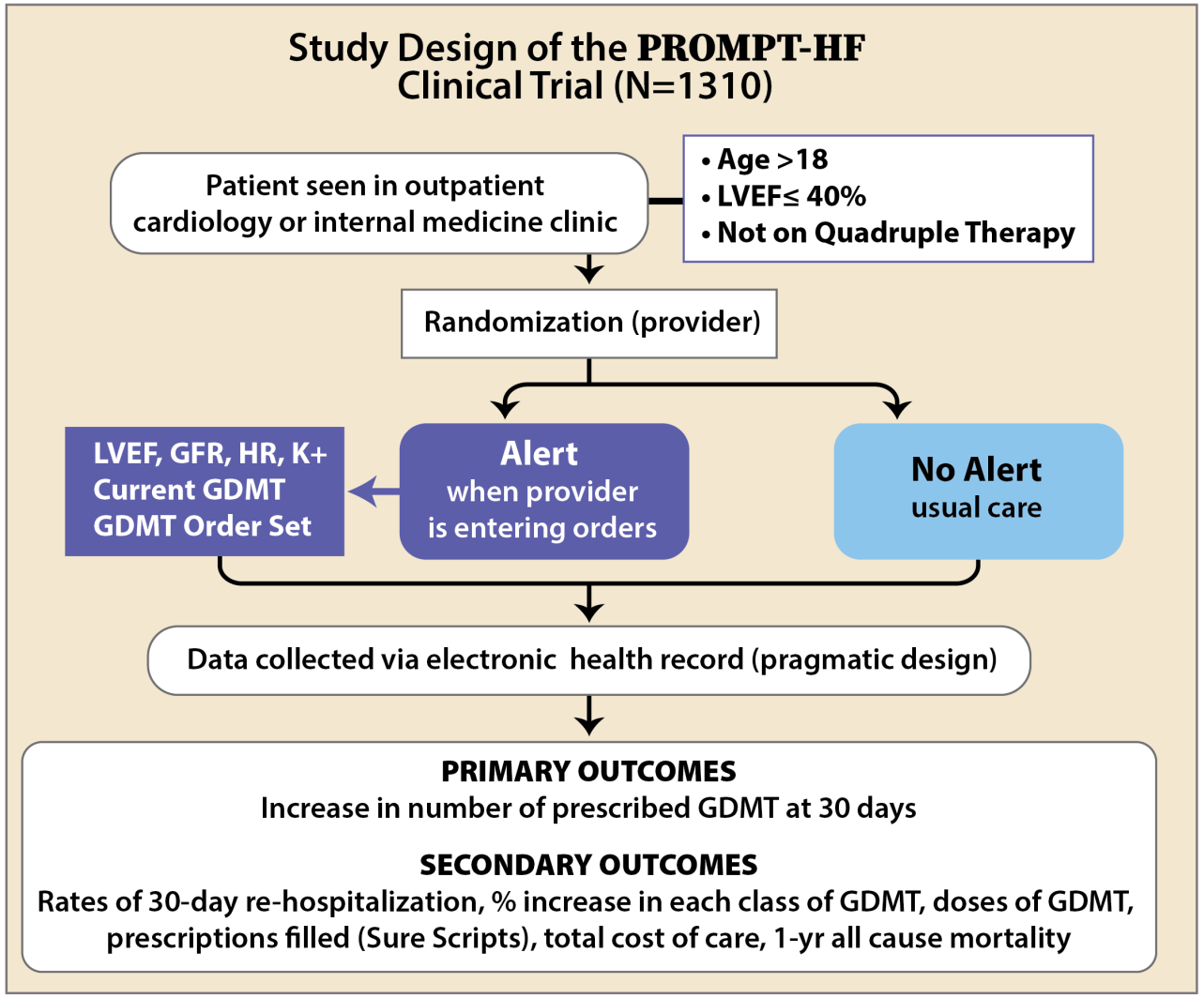
Background

- 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

The ***PR***agmatic Trial ***O***f ***M***essaging to ***P***roviders about outpatient ***T***reatment of ***H***eart ***F***ailure (***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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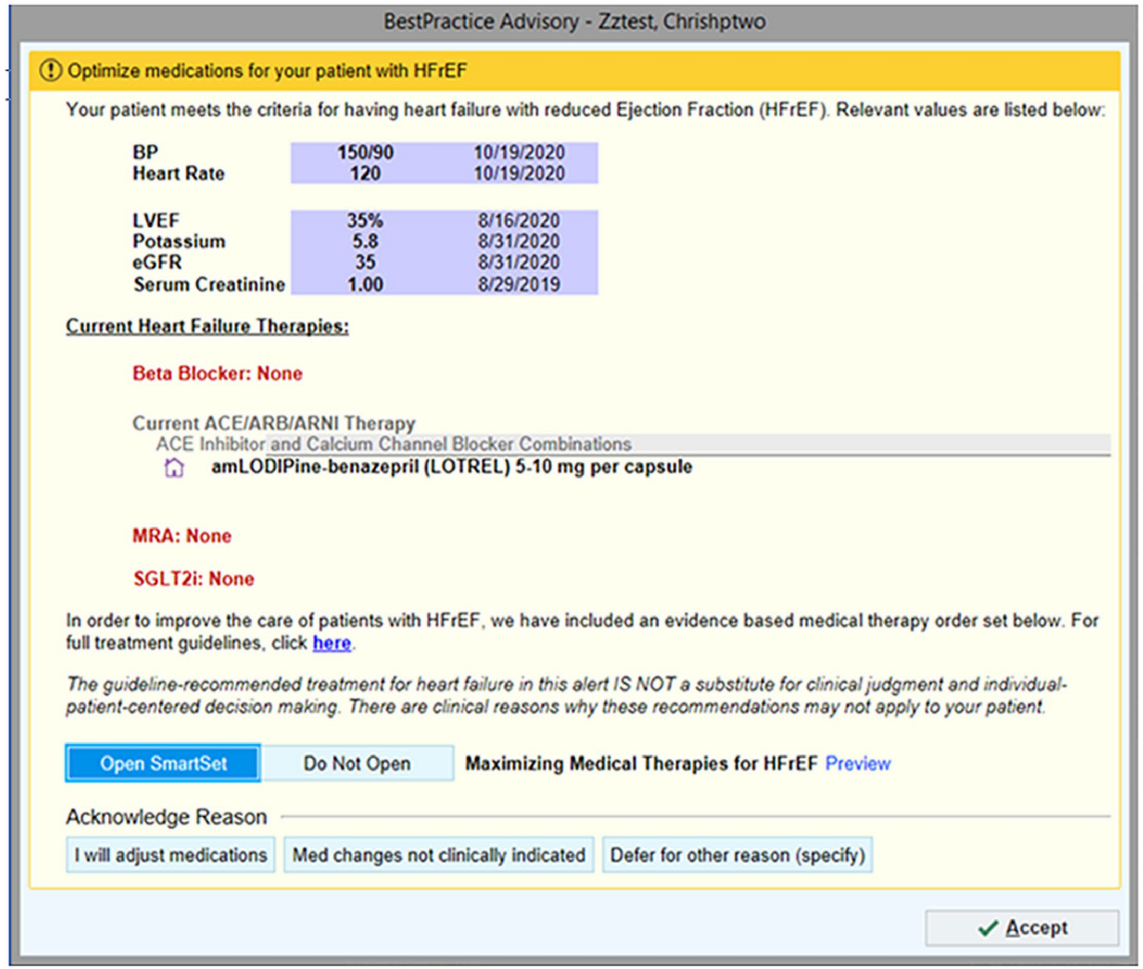
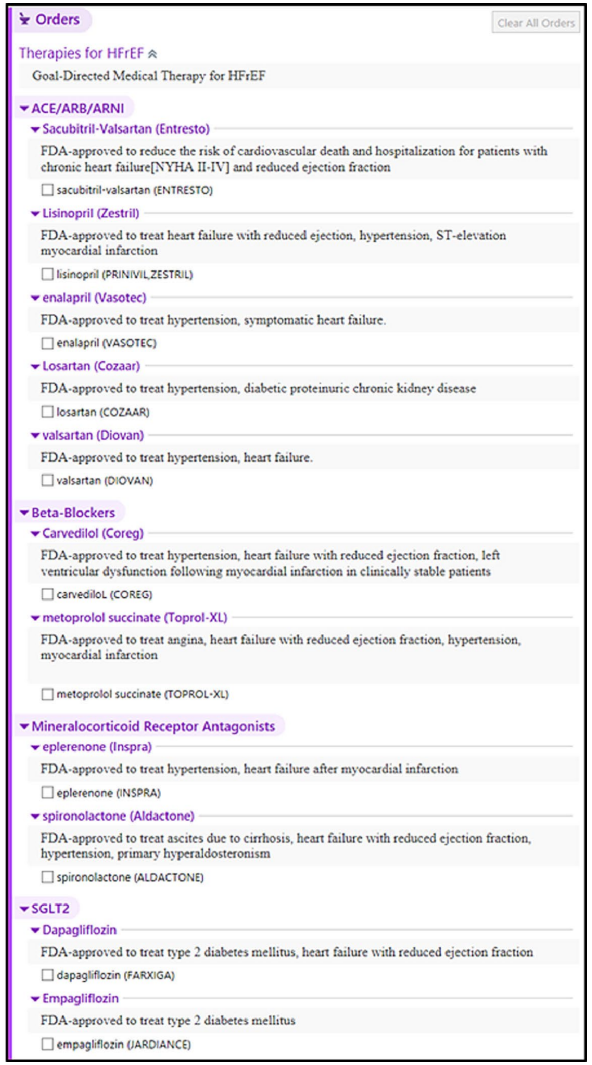
Alert Arm





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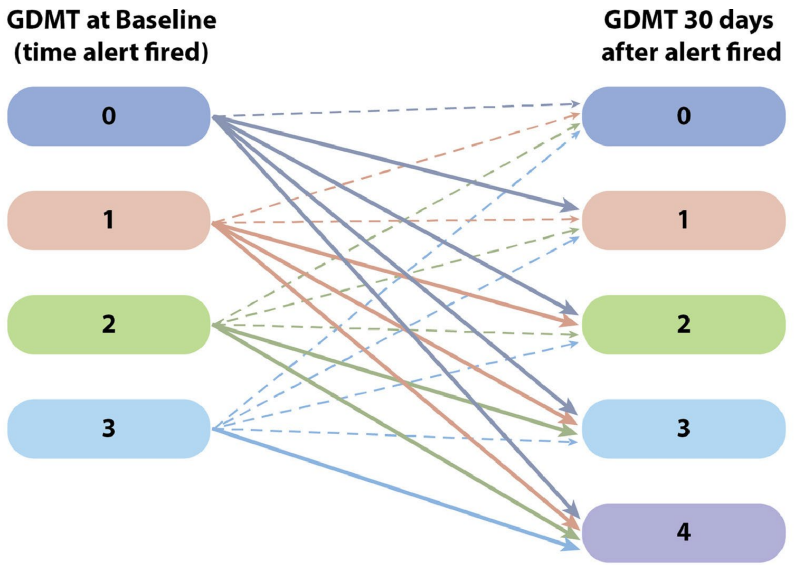
Primary Outcome: Addition of GDMT Class



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

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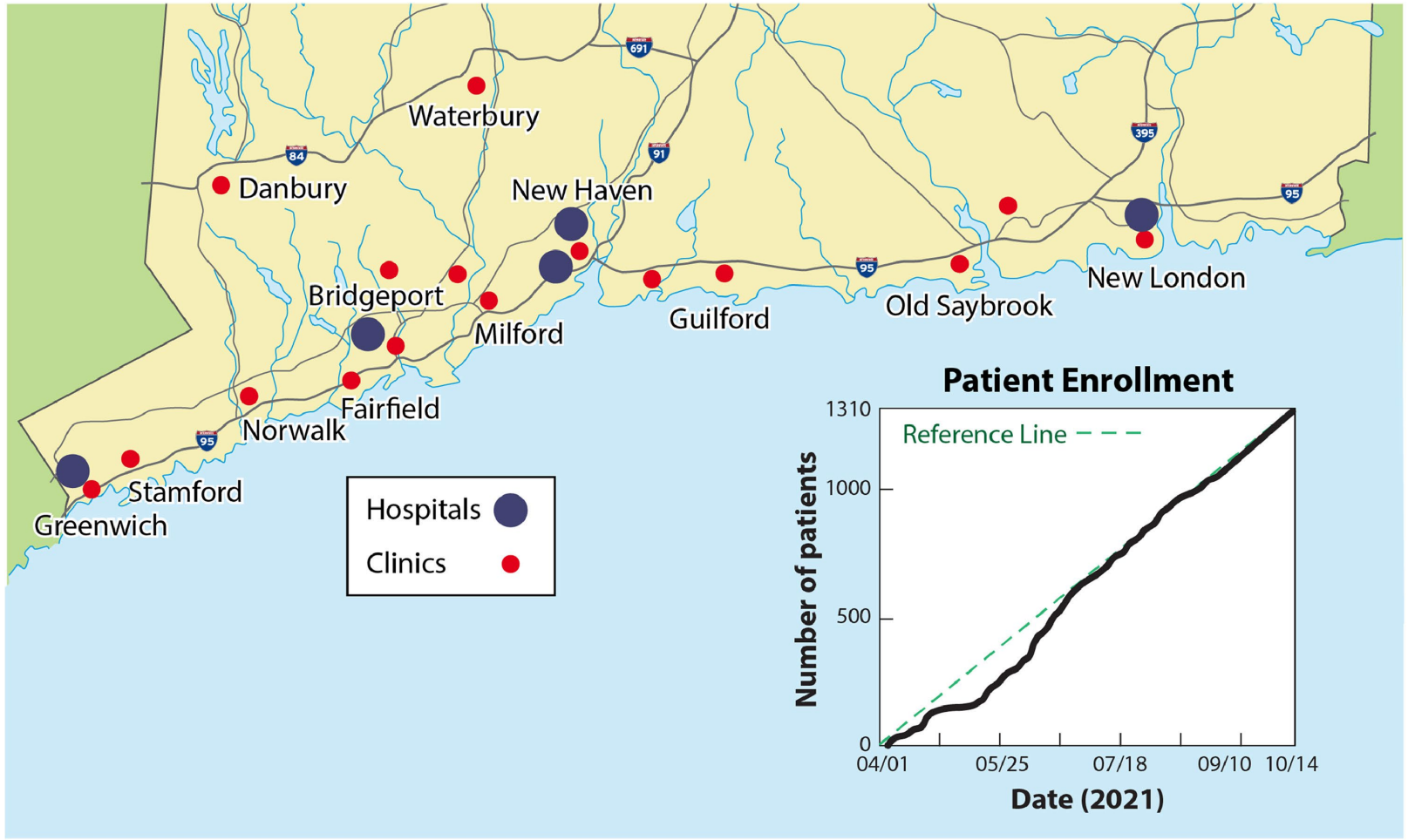
Sample Size and Power Calculations

- 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 $\alpha=0.05$ 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

Embedded EHR-Based Pragmatic Clinical Trial



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CTRA Clinical and Translational Research Accelerator

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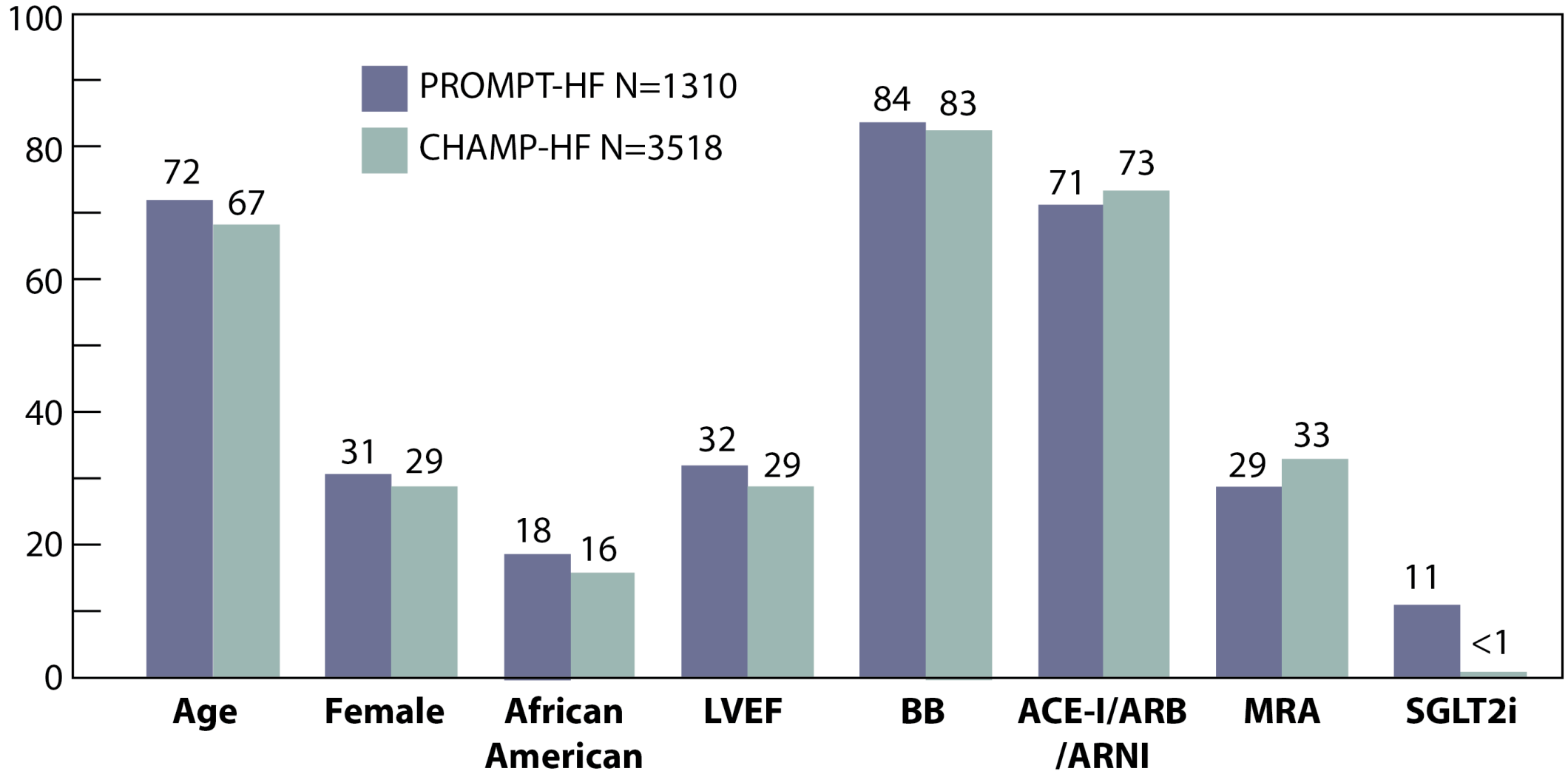
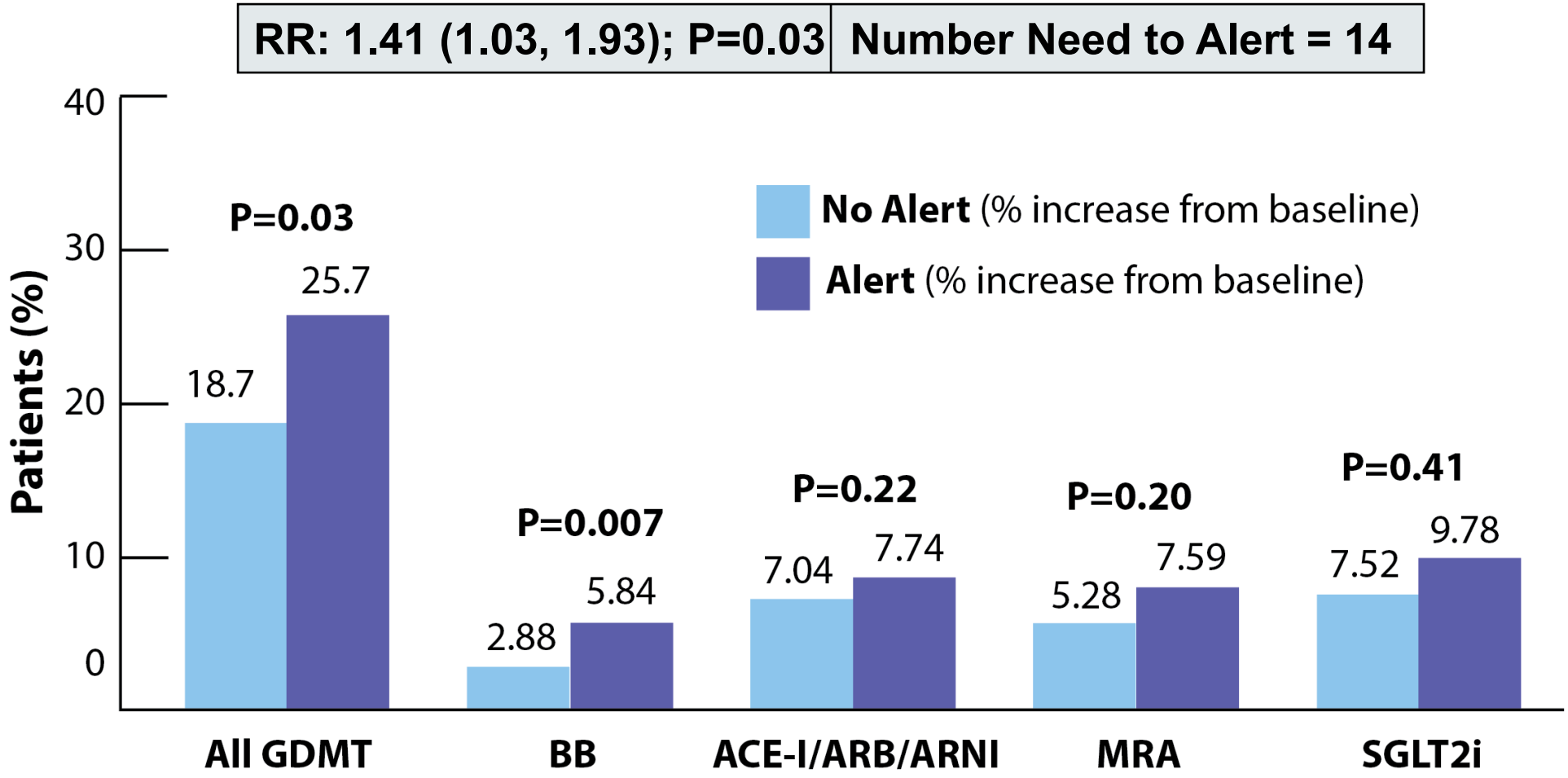
Baseline Characteristics



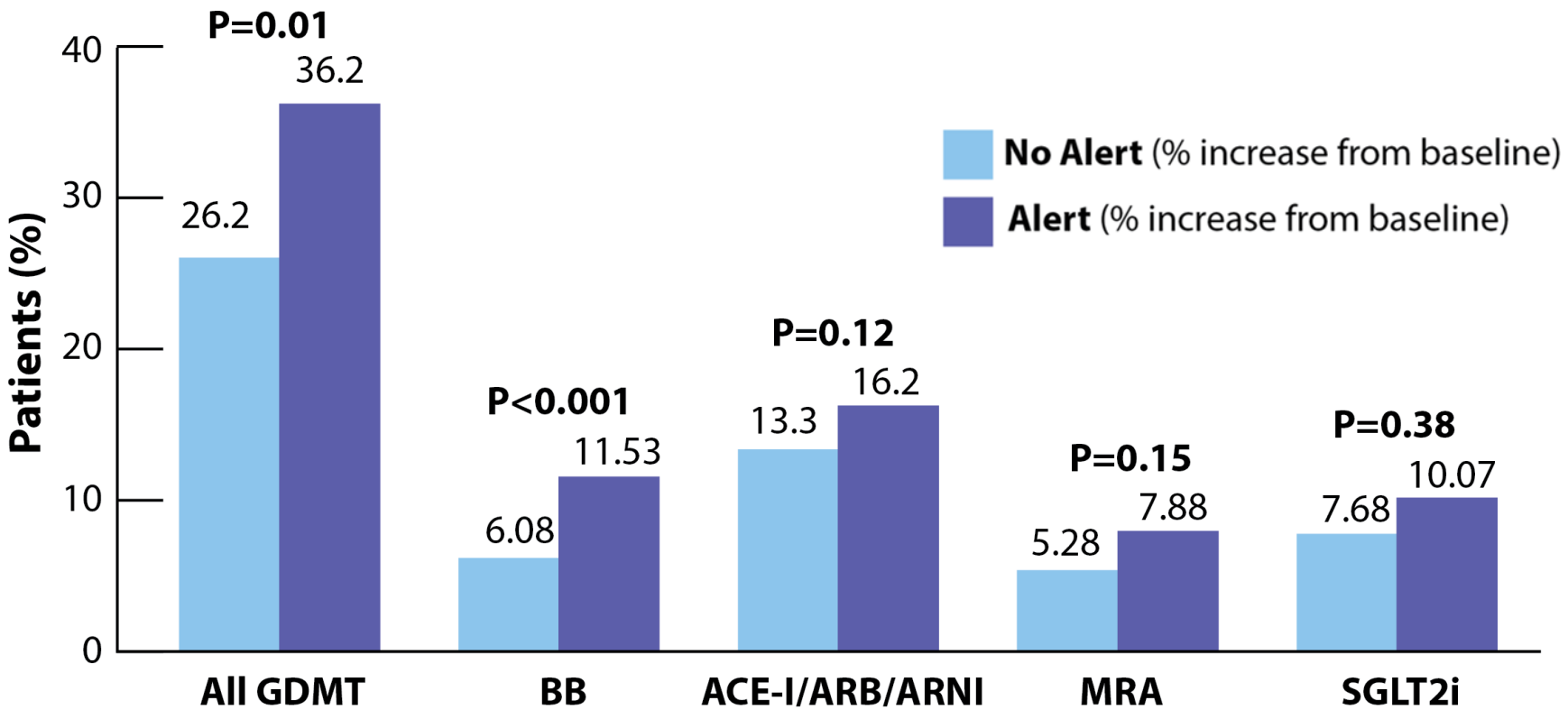
Stephen Greene et al. JACC 2018; 72(4):351-366.

Primary Clinical Endpoint: Additional GDMT Class



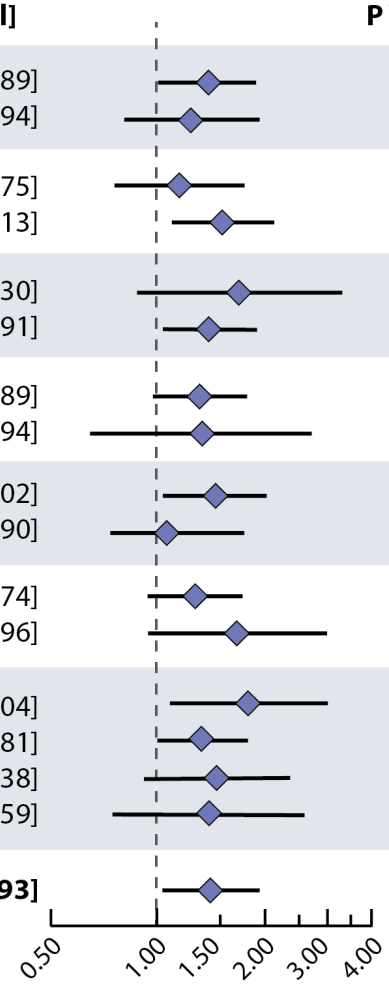
Secondary Clinical Endpoint: +GDMT Class/↑Dose

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



Pre-Specified Subgroups

Subgroup	No. of Patients	RR [95%CI]	Interaction P Value
Age ≥ 65 yr	937	1.39 [1.01, 1.89]	0.86
Age < 65 yr	373	1.24 [0.79, 1.94]	
Female	402	1.15 [0.75, 1.75]	0.09
Male	908	1.53 [1.09, 2.13]	
Black	237	1.70 [0.87, 3.30]	0.67
Non-black	1073	1.40 [1.03, 1.91]	
LVEF ≥ 20%	1157	1.31 [1.01, 1.89]	0.41
LVEF < 20%	139	1.24 [0.79, 1.94]	
Cardiology	981	1.45 [1.04, 2.02]	0.65
Non-cardiology	329	1.05 [0.58, 1.90]	
Medicare/Medicaid	1117	1.27 [0.93, 1.74]	0.20
Other	193	1.57 [0.94, 2.96]	
GDMT: 0	80	1.81 [1.08, 3.04]	0.71
GDMT: 1	286	1.34 [0.99, 1.81]	
GDMT: 2	570	1.47 [0.91, 2.38]	
GDMT: 3	374	1.39 [0.75, 2.59]	
Overall	**1310**	**1.41 [1.03, 1.93]**	



Limitations

- 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

Full Results Now Avalible Online

We Thank The Participants of PROMPT-HF

Questions or Comments
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