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Leon H. Charney Division of Cardiology

Building Electronic Tools To Enhance and Reinforce CArdiovascular REcommendations for Heart Failure (BETTER CARE-HF):

A Pragmatic Cluster-Randomized Trial to Improve Heart Failure Care

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NIH Pragmatic Clinical Trials Collaboratory
Grand Rounds
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- No relevant disclosures
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Educational Objectives/Outline

- Describe gaps in evidence-based care for patients with heart failure
- Review the BETTER CARE-HF Study for the development of an effective electronic health record tool to improve prescribing
  - Development and qualitative pilot-testing
  - Cluster-randomized trial
  - Follow up studies
  - Current ongoing pragmatic, multi-center trial

Heart failure is a major public health issue

Over 6 million Americans

Over $30 billion in expenditures

A leading cause of hospitalization

High mortality (40-60% at 5 yrs)

Virani, et al. Circulation 2020
Dharmarajan, et al. JAMA 2017
Bytyci, et al. Anatol J Cardiol2015

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Mineralocorticoid antagonists (MRA) are life-saving, but under-prescribed in HFrEF

- Approximately **65-75%** of patients eligible for MRA are not prescribed this life-saving medication.
- Closing this treatment gap could save **over 20,000** lives per year in the United States.

Greene, et al. JACC 2018
Fonarow, et al. Am Heart J 2011
Mukhopadhyay, et al. BMC Cardiovasc Disord 2022

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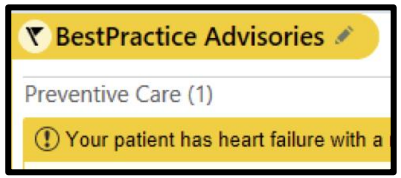
Electronic health record (EHR) tools are low-cost, scalable, and can improve prescribing

- When developed for other medications, EHR tools have shown modest effectiveness (4.4 percentage points in a metanalysis).
- However, there is **wide variability** in EHR tool development and design.
- The optimal delivery and timing of EHR tools is **unknown**.

Kwan, et al. BMJ 2020

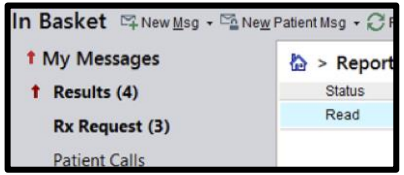
Two EHR tools: Alerts and Messages



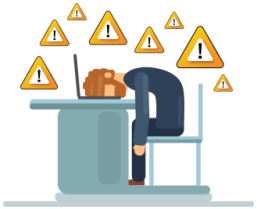
- Single patient at a time
- During clinical encounter
- Could disturb workflow
- Could cause “alert fatigue”

Alerts

Messages



- Multiple patients at once
- Seen between encounters
- Does not disturb workflow
- Could cause “burnout”



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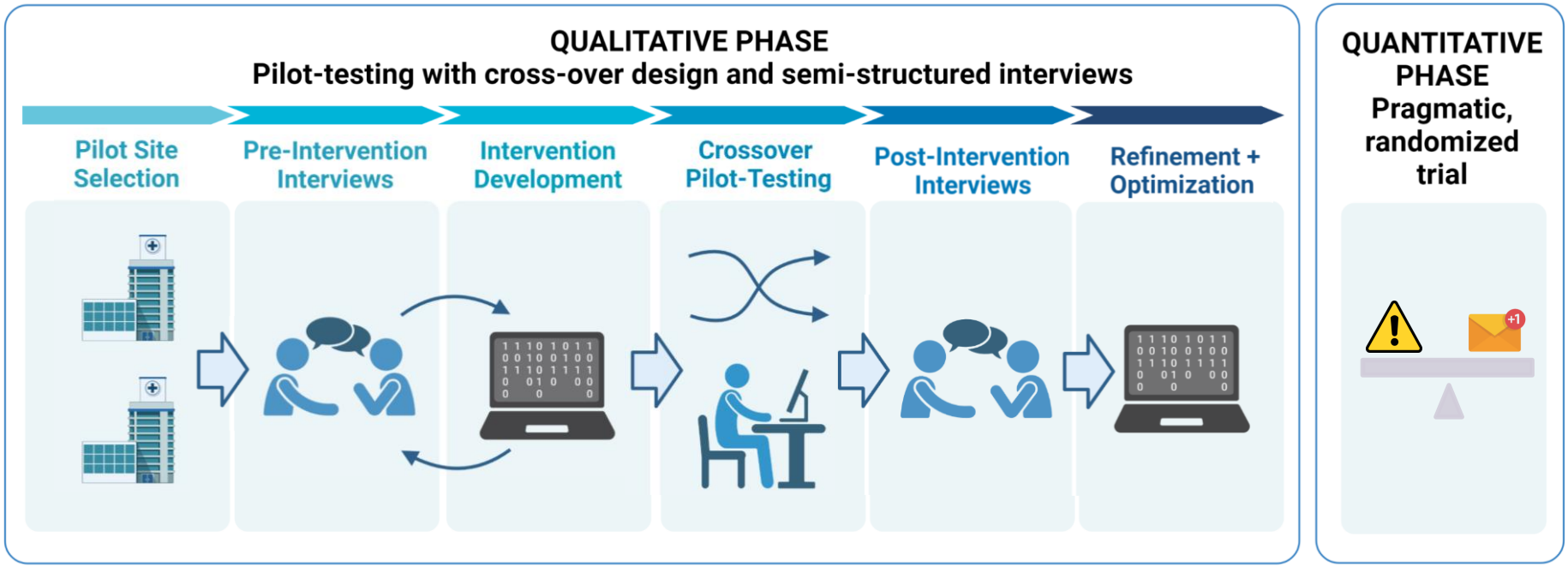
BETTER CARE-HF Hypotheses

- Among patients with HFrEF who are evaluated by a cardiologist in the outpatient setting, an alert or a message will improve prescribing of MRA as compared to usual care.
- An alert will also be more effective than a message at improving prescribing of MRA.

Mixed Methods Study Design



Mukhopadhyay, et al. Am Heart J. 2023

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Qualitative Phase: Theories and Frameworks Inspiring EHR Tool Development

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Cognitive Load and Nudge Theories

Cognitive Load Theory

- "Split attention effect"
- "Transient information effect"

Nudge Theory

- "Default option"
- "Positioning"
- "Social influence" (illusion of being monitored)

Mukhopadhyay, et al. Am Heart J. 2023

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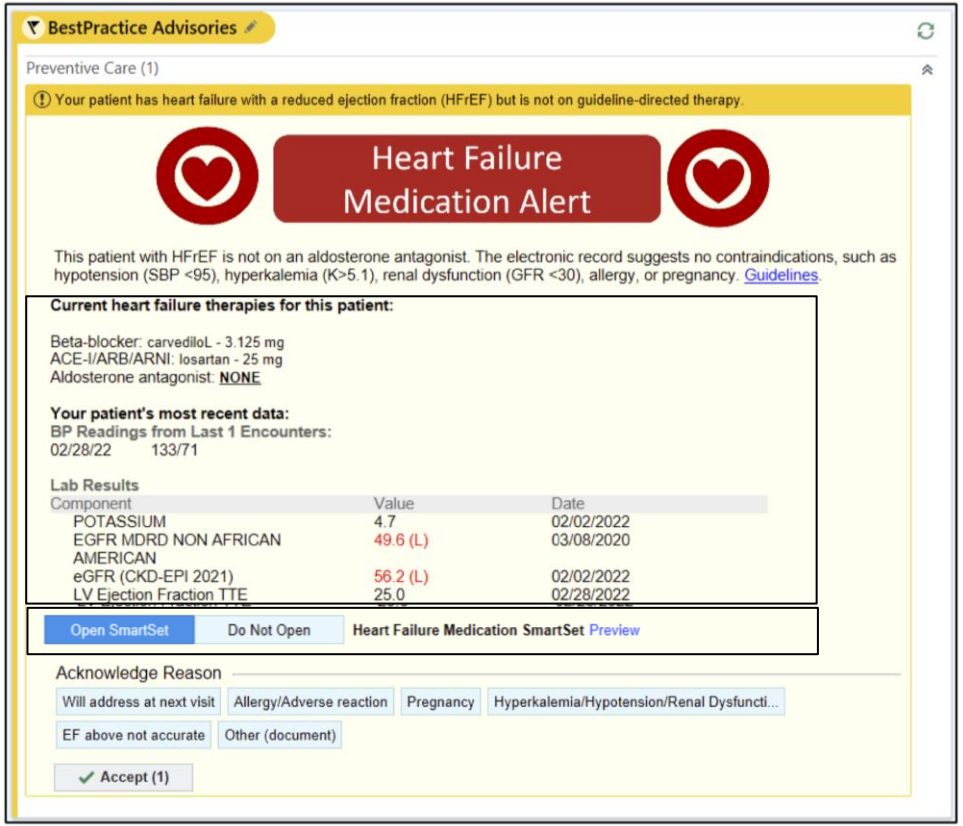
Applying theories to the EHR alert

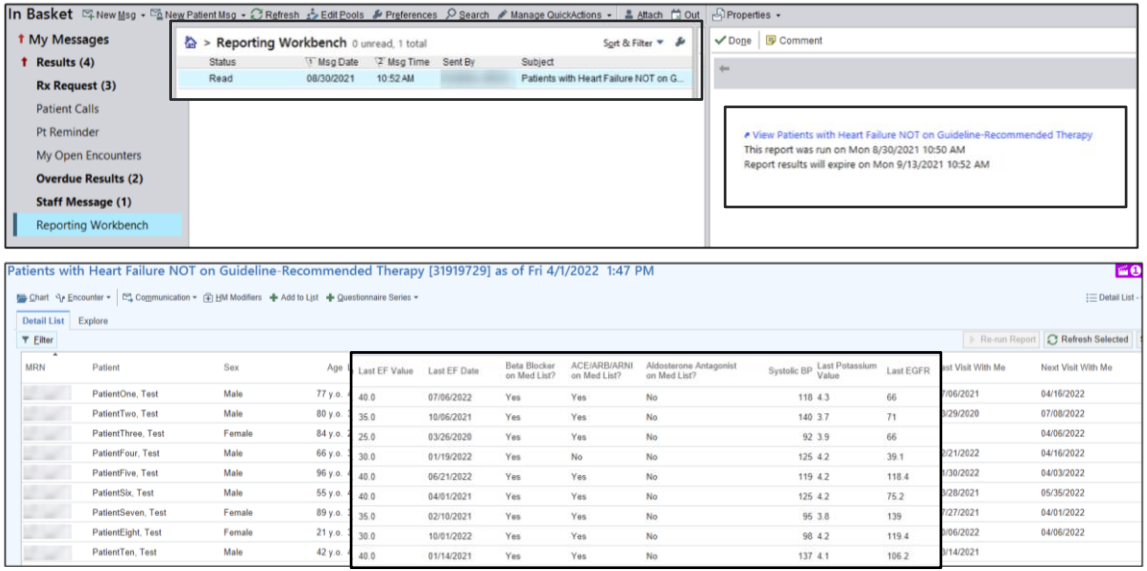
- **Positioning:**
  First alert visualized at the top of the chart
- **Split attention effect:**
  Multiple components of patient's data all in one place
- **Default option:**
  Pre-selected order set



Mukhopadhyay, et al. AHJ 2023

Applying theories to the EHR message

- **Transient information effect:** Information stays in EHR inbox until deleted
- **Social influence:** There is an illusion of being monitored (although we did not actually monitor!)
- **Split attention effect:** Multiple components of patient's data all in one place



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Mukhopadhyay, et al. AHJ 2023

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Guiding Framework: The 5 Rights of Clinical Decision Support

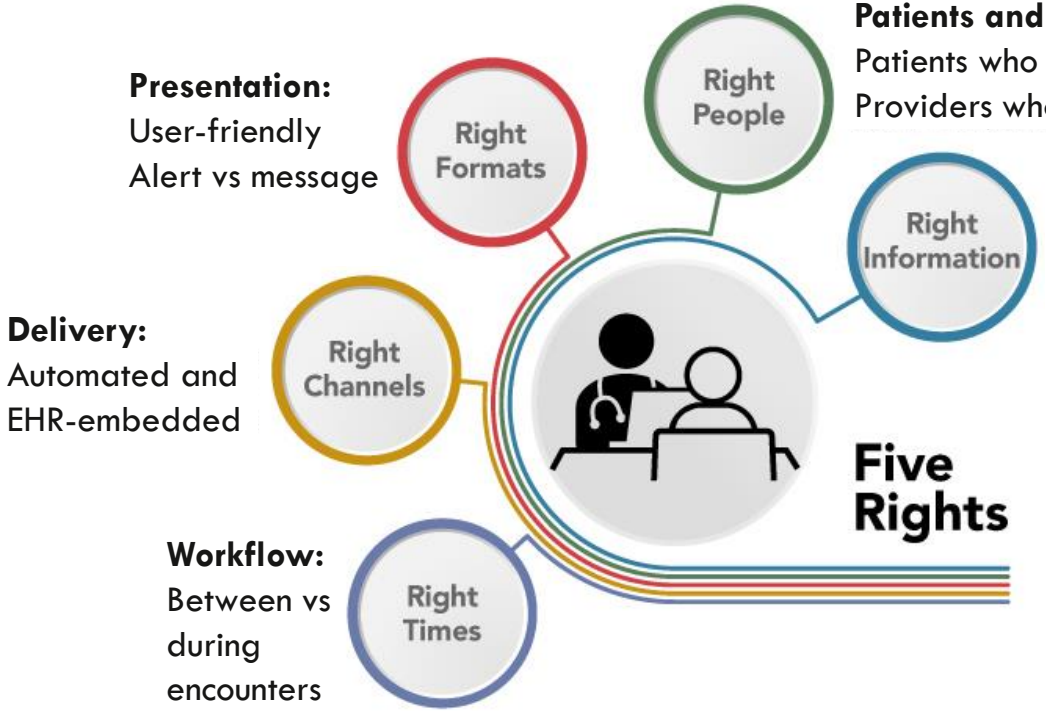
Patients and providers:
Patients who could benefit from MRA ("selective")
Providers who make MRA decisions

Presentation:
User-friendly
Alert vs message

Content:
Evidence-based
Patient-specific ("tailored")

Delivery:
Automated and
EHR-embedded

Workflow:
Between vs
during
encounters



Sirajuddin, et al. J Healtch Inf Manag, 2009

Participants for pilot-testing and interviews

11 cardiologists participated in pilot-testing and qualitative interviews

Characteristic	Number (%) or mean (std)
Age	
• 31-50 years	7 (64)
• 51-70 years	4 (36)
Gender	
• Female	3 (27)
• Male	8 (73)
Years in Practice	
• 0-5	2 (18)
• 11-20	3 (27)
• >20	3 (27)
Subspecialty Training	
• None/General	6 (55)
• Electrophysiology	3 (27)
• Interventional	1 (9)
• Advanced imaging	1 (9)
Estimated percent of patients with HFrEF	
• 0-25%	9 (81)
• 26-50%	2 (18)
Clinic sessions (half-day) per week	6.4 (2.6)
Patients seen per clinic session	14.5 (2.8)
Cardiologist is primary person making decision for MRA prescription	11 (100)

Mukhopadhyay, et al. Am Heart J. 2023

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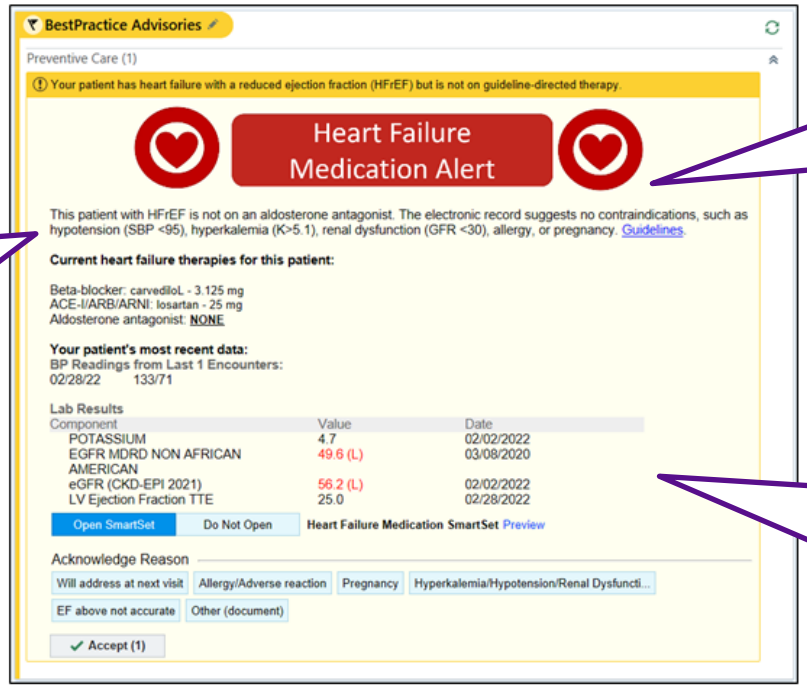
Pilot-testing and user interviews lead to intervention improvements

RIGHT INFO
"I'd like having a little bit more information about the contraindications… the criteria… [for example] not just hyperkalemia but hyperkalemia greater than 5.2"

(A) Best Practice Alert (BPA) displayed at time of visit for single patient



RIGHT FORMAT
"If you do want people to be aware of it, then it has to be more prominently displayed"

RIGHT INFO
"Sometimes you're so busy, and you're so rushed that you can't get all this information in your head at once… I like it because it's right there, and brings it right to mind."

Mukhopadhyay, et al. Am Heart J. 2023

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Pilot-testing and user interviews lead to intervention improvements

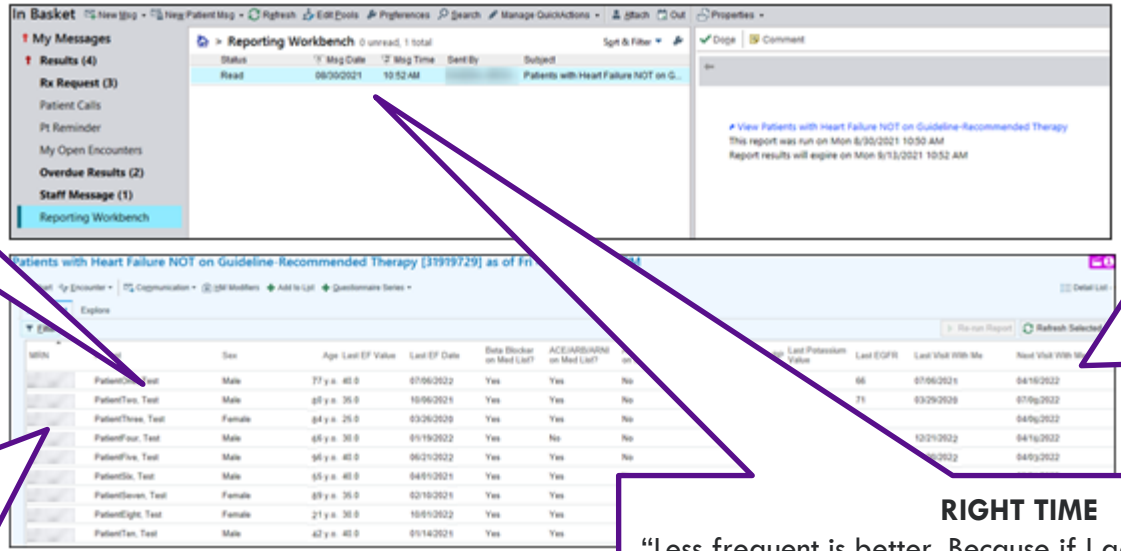
RIGHT PESON

"One of my patients is in the list with TTR amyloid. Amyloid patients should be dropped"

RIGHT FORMAT

"I basically just ignored them because there were so many patients on the list… the in-basket message was very good, but I think it's probably too much… it was a huge list."

(B) In-Basket Message sent between visits with list of patients



RIGHT INFO

"I think you need the date when the patient's coming in… somebody's coming on this date, and then I'll look at it, but otherwise, I'm not going to try to figure out when this patient's coming in."

RIGHT TIME

"Less frequent is better. Because if I get it every two weeks, I'm going to get enough where I just start ignoring it."

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The importance of guiding theories, frameworks, and pilot-testing

- We made several modifications to the EHR alerts and messages in response to pilot-testing.
- Guiding frameworks and pilot-testing are **critical** to designing an electronic intervention.

Pragmatic, Cluster-Randomized Trial

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We conducted a trial to test the EHR tools

Cluster-randomization by cardiologist
(60 per arm)

All patients seeing same cardiologist were assigned to the same arm.

Alert
for a single patient at the time of visit

Message
for multiple patients in between visits

Usual Care
(no alert or message)

The study was conducted across over 60 practices

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Patient Inclusion and Exclusion Criteria

Inclusion Criteria	Excluded if MRA Contraindicated	Additional Exclusion Criteria
• Age ≥ 18 • Seen in outpatient cardiology practice • Most recent EF ≤ 40% • Not already prescribed MRA therapy	• Hypotension (SBP < 90 mm Hg) • Hyperkalemia (most recent K > 5.0 mmol/L) • Kidney disease (GFR ≤ 30 mL/min/1.73m^2 • Documented MRA allergy or intolerance	• Ventricular assist device • Cardiac amyloid • Hospice

Selected Group of Patients
Reduced "Alert Fatigue"

Amrita Mukhopadhyay, MD

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Study Setting

Amrita Mukhopadhyay, MD

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Outcomes

Primary outcome

- New MRA prescription during study period

Secondary outcome

- Prescription of new BB, ACEI, ARB, or ARNI

Statistical Considerations

- Sample size
  - In order to detect at least a 10 percentage point difference between each two-way comparison with 80% power and two-tailed alpha = 0.05, with Bonferroni adjustment, we required 1,503 patients, which we estimated would require a 6 month study period.
- Pre-specified, intention-to-treat analysis
  - Generalized linear mixed effects model with binomial distribution, log link function, and random intercept by cardiologist to account for clustering at the provider level.

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Patient Characteristics (N=2,211)

Median age: 73 years	Sex: 71% male	Race: 69% White	Ethnicity: 11% Hispanic
Insurance: 69% Medicare	Background BB therapy: 80%	Background ACEI/ARB/ARNI: 74%	Seen by General or HF: 75%

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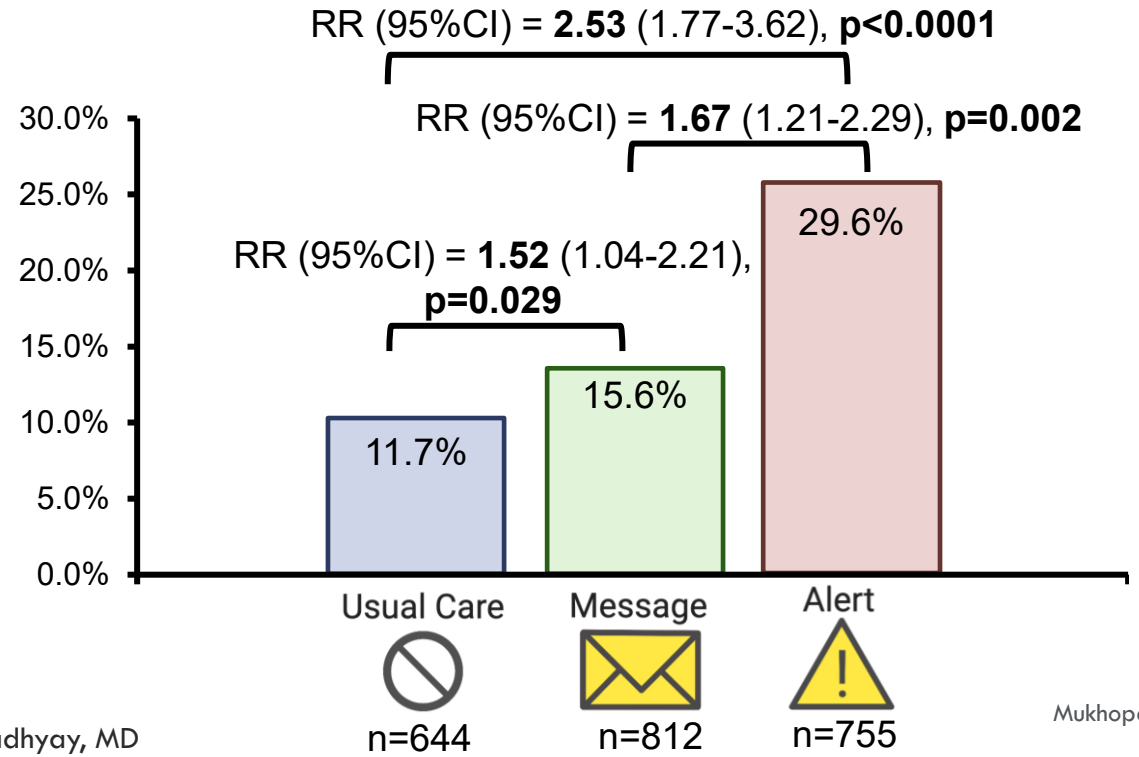
Primary Outcome

Percent of MRA-eligible patients with newly prescribed MRA



Number of patients needed to result in one prescription:

Alert: **5.6**

Message: **25.6**

Mukhopadhyay, et al. JACC 2023

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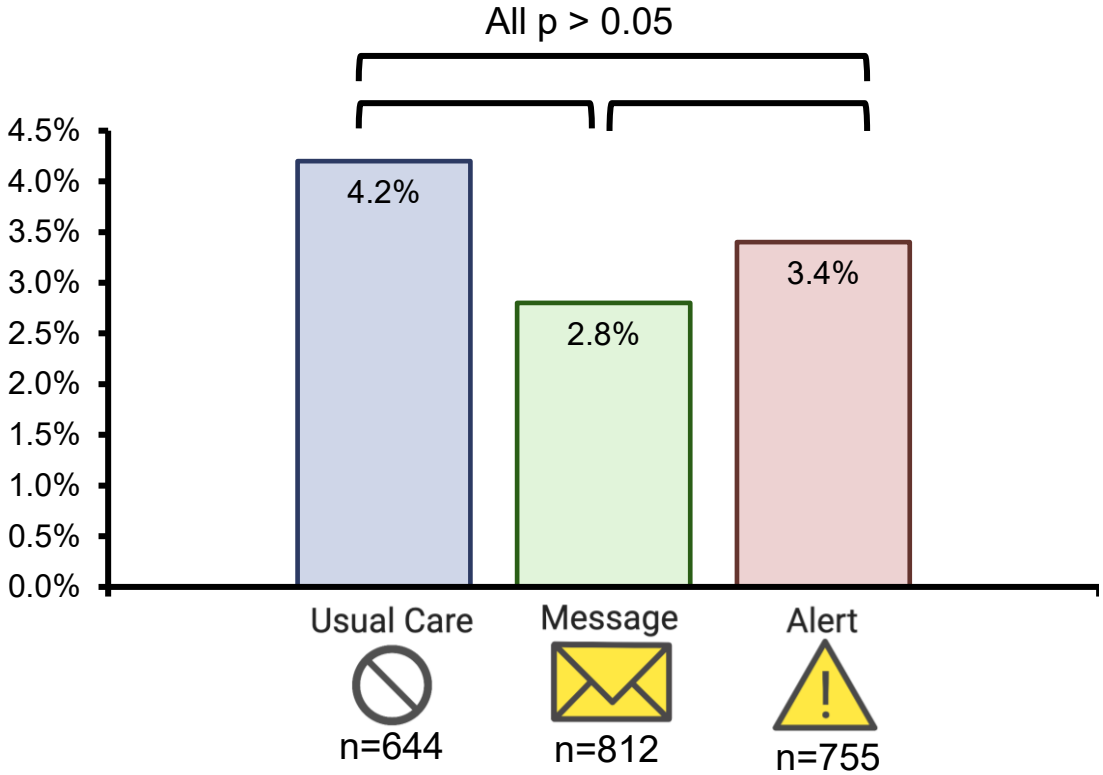
Secondary Outcome

Percent of patients with newly prescribed BB, ACEI, ARB, or ARNI



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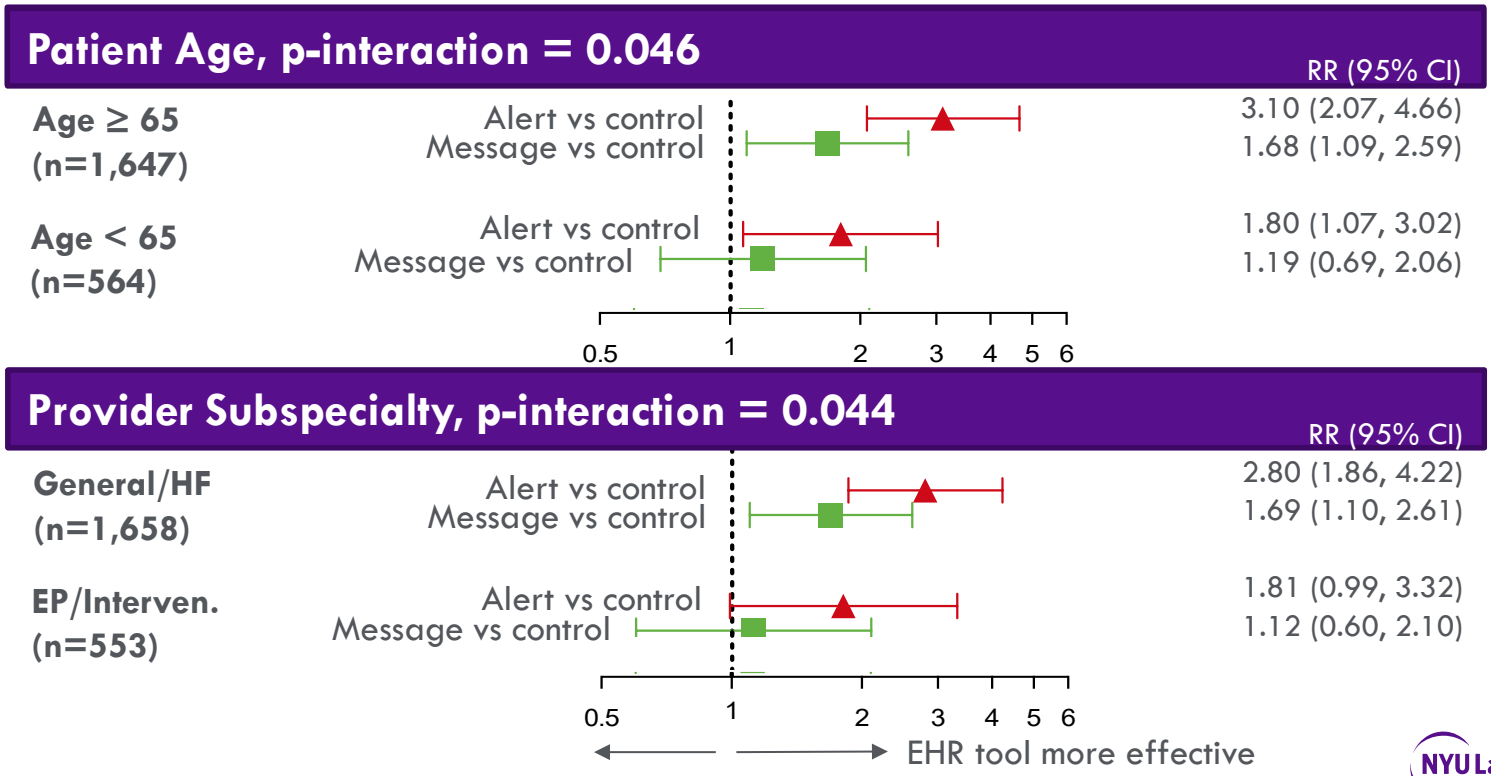
Pre-Specified Subgroup Analysis



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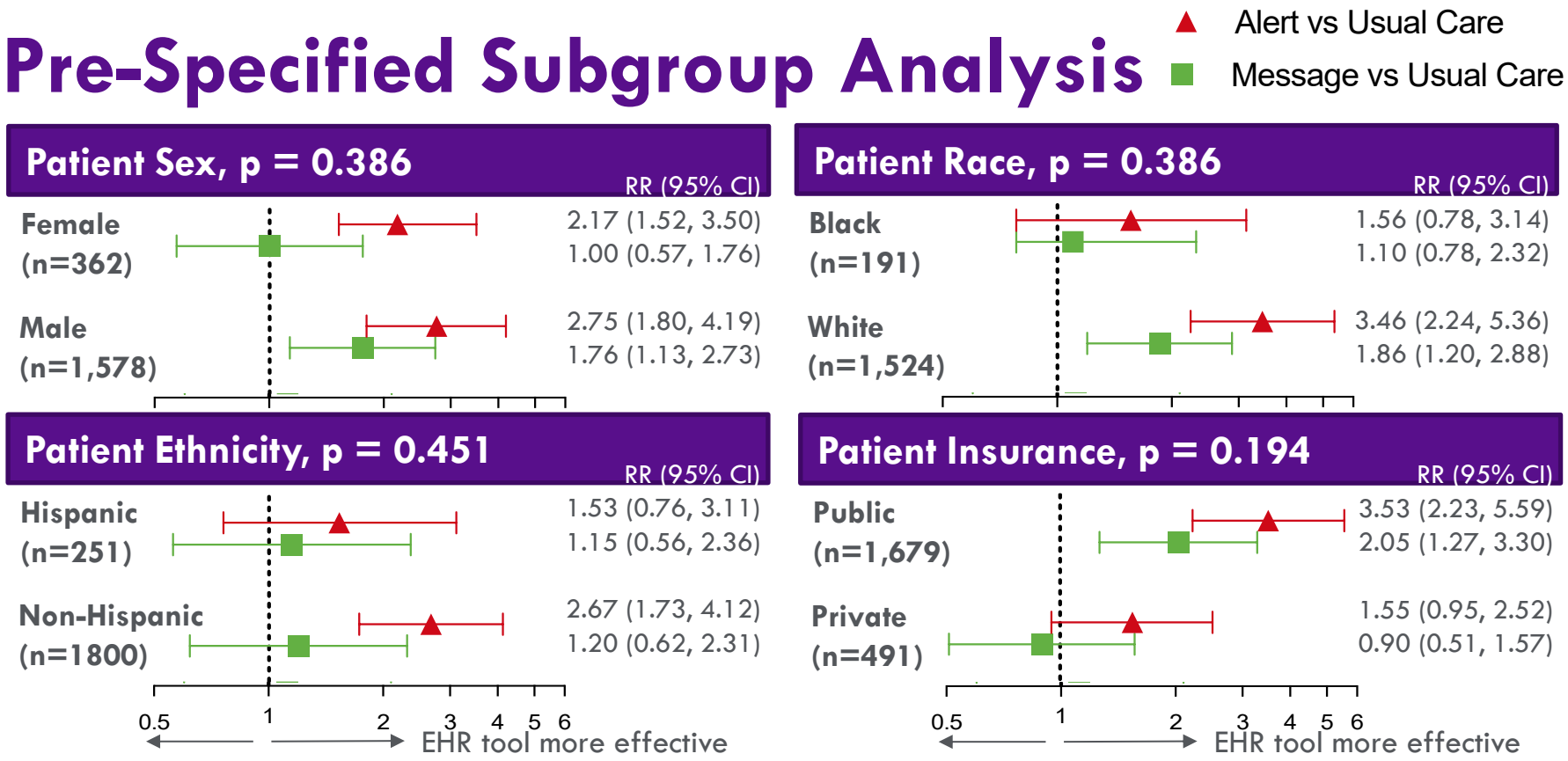
Pre-Specified Subgroup Analysis



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Limitations

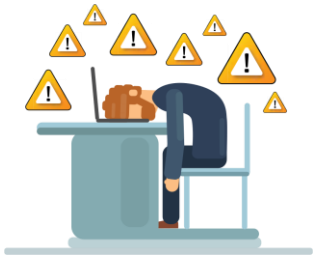
- Generalizability
- Targeted to cardiologists
- Specific and selective for MRA
- Sustainability and interaction with other decision support tools is unknown

Well-designed EHR tools could save lives!

- An automated, EHR-embedded, tailored, and selective alert delivered at the time of visit **more than doubled** prescribing of MRA as compared to usual care.
- If the amount of improvement in MRA prescription seen in our study was achieved nationally, we could save an estimated >3,500 lives per year (and even more hospitalizations)!
- But is this generalizable across physicians and practice settings?

Despite EHR tool effectiveness, busy physicians may still be hesitant

- Too many EHR tools can cause fatigue/burnout.
- Concerns about **workload** and time costs may hinder uptake in busy practice settings.
- Conversely, EHR tools that **save time** and reduce cognitive load may be more beneficial in busy practices.



Fletcher, et al. BMC Primary Care 2023

Does cardiologist workload modify the effectiveness of our EHR tools?

Cardiologist Visit Volume Subgroups

- Total number of visits seen during the study period by the cardiologist
  - High-volume = upper tertile
  - Non-high volume = lower two tertiles

Sensitivity Analysis

- Average number of visits seen per half-day session by the cardiologist

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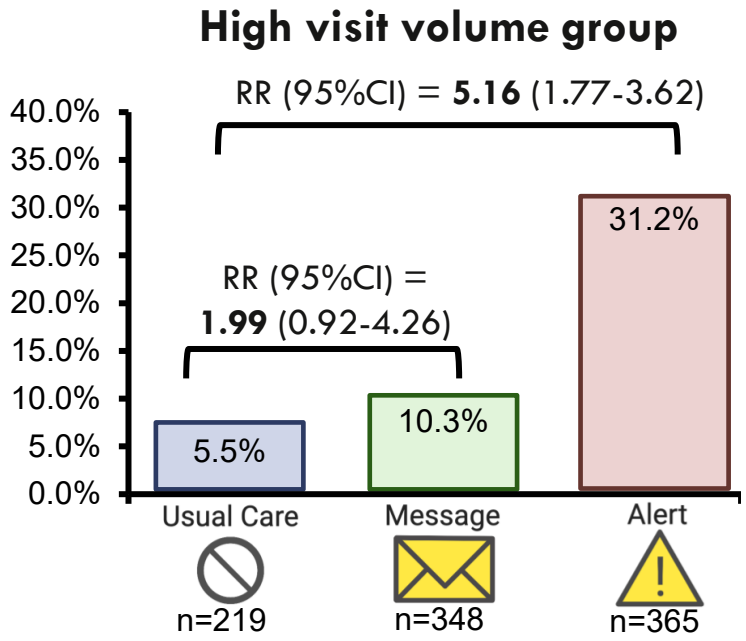
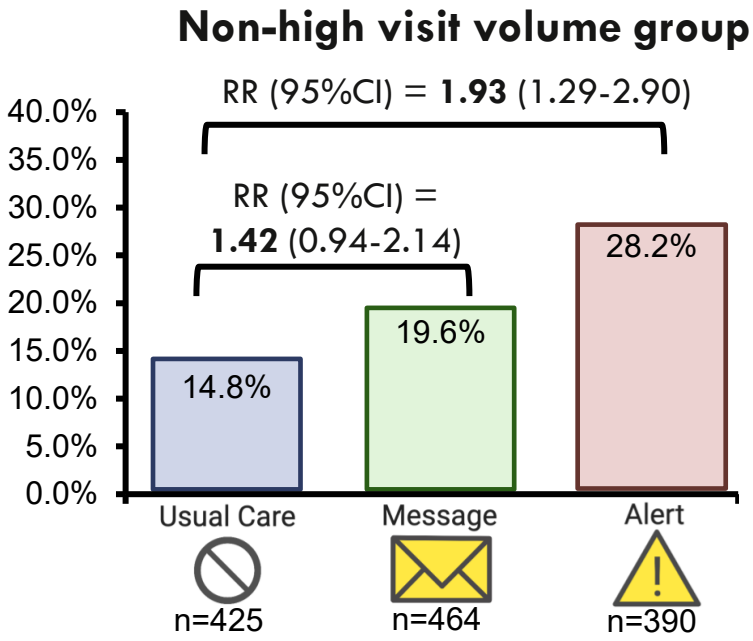
Primary Outcome Stratified by Visit Volume

Percent of MRA-eligible patients with newly prescribed MRA





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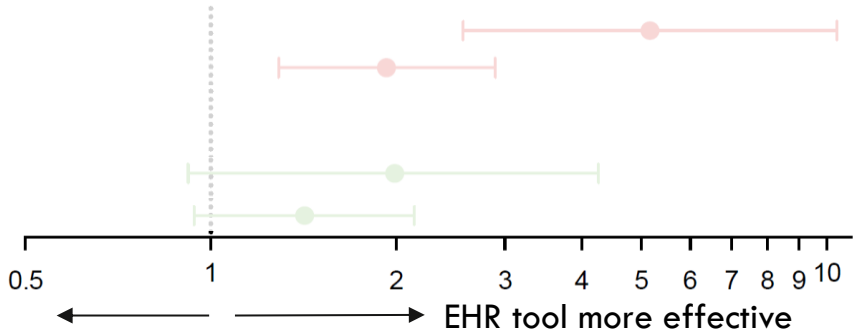
Subgroup Analysis for Primary Outcome

Percent of MRA-eligible patients with newly prescribed MRA

Subgroup	RR (95% CI)	p-interaction
Alert vs Usual Care		
- High-volume group	5.16 (2.57, 10.38)	0.02
- Non-high volume group	1.93 (1.29, 2.90)	
Message vs Usual Care		
- High-volume group	1.99 (0.92, 4.26)	0.46
- Non-high volume group	1.42 (0.94, 2.14)	



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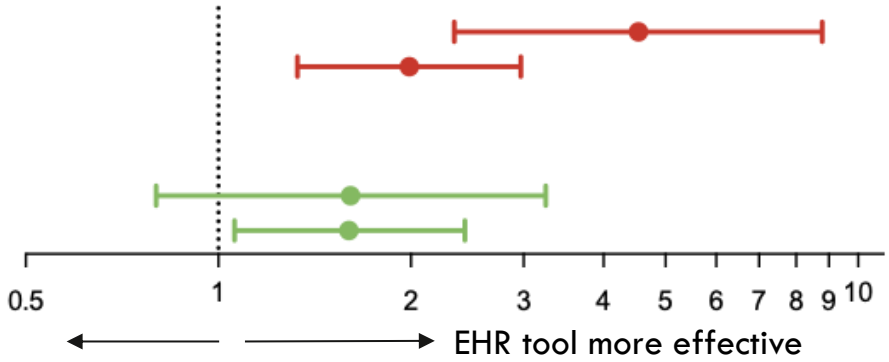
Sensitivity Analysis for Primary Outcome
(Visit volume defined as average # visits per half-day session)

Subgroup	RR (95% CI)	p-interaction
Alert vs Usual Care		
- High-volume group	4.54 (2.34, 8.79)	**0.04**
- Non-high volume group	1.99 (1.33, 2.97)	
Message vs Usual Care		
- High-volume group	1.61 (0.80, 3.25)	0.99
- Non-high volume group	1.60 (1.06, 2.43)	



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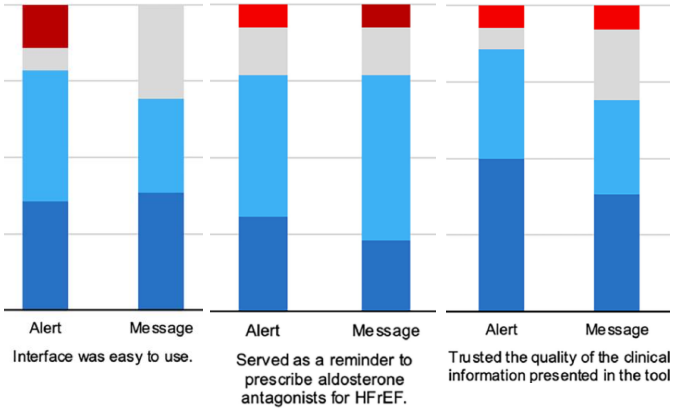
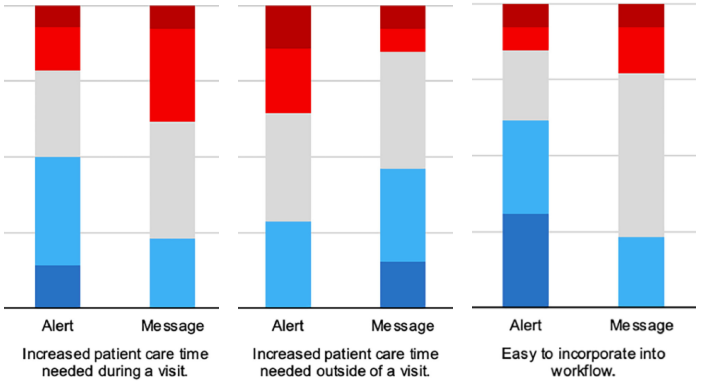
Post-Trial Survey (N= 27 Cardiologists)

- Overall, cardiologist perceptions were favorable towards both EHR tools.



- With some notable differences when asked about workflow.



Maidman SD, et al. Am Heart J 2024

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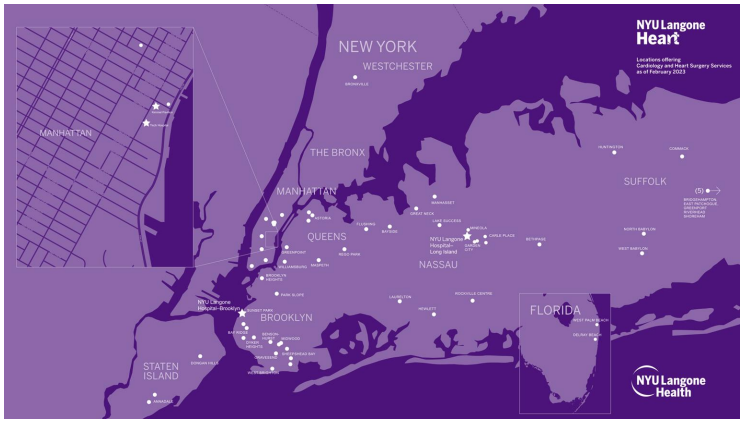
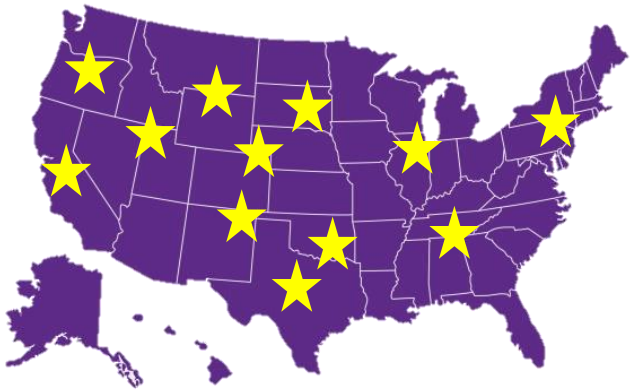
Will our alert work at other institutions?

- We are conducting multi-center trial to assess the effectiveness of the alert across 3 high-volume health systems around the country

Just because it worked here…



May or may not mean it will work here…



We are looking for more institutions to join us!
(please reach out if interested)

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Current Progress, Resources, and Support

- With Epic support, we have built tools for standard alert implementation across sites
- Our team has also built tools for standard, de-identified data extraction across sites
- NYU Grossman School of Medicine is currently serving as the single IRB for this study
- Our team provides technical support, and will conduct all statistical analysis for this work
- Currently, one site is live and two others will go live in the coming weeks
- We want to partner with you! Amrita.Mukhopadhyay@nyulangone.org

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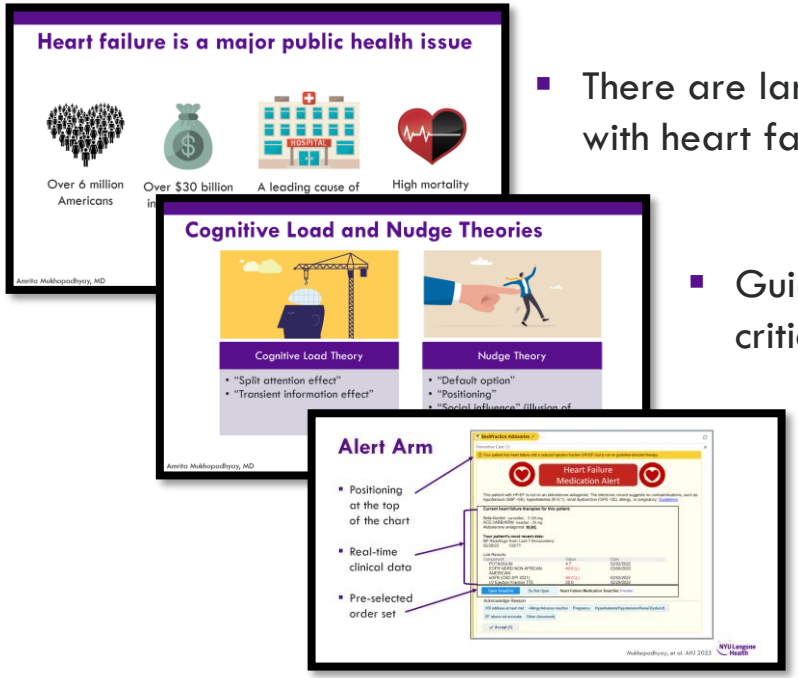
Learning Points



- There are large gaps in evidence-based care for patients with heart failure.
- Guiding theories, frameworks, and pilot-testing are critical for successful development of EHR tools.
- Well designed EHR tools can improve prescribing of life-saving therapies.

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Thank you!

We thank NYULH administrative leadership, physicians, and patients

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