Pragmatic Trial of Messaging to Providers About Treatment of Heart Failure (PROMPT-HF)
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Provider Consent Form
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CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

YALE-NEW HAVEN HOSPITAL
YALE-NEW HAVEN HOSPITAL: SAINT RAPHAEL CAMPUS
BRIDGEPORT HOSPITAL
GREENWICH HOSPITAL

Study Title: Pragmatic Trial of Messaging to Providers About Treatment of Heart Failure (PROMPT-HF)

Principal Investigator (the person who is responsible for this research):
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Phone Number: 203 785 7191
Human Investigation Committee (HIC) Protocol Number: 2000027014

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to evaluate the efficacy of automated electronic alerts built into the EPIC electronic health record to improve the use of evidence-based medical therapies in the treatment of patients with heart failure with reduced ejection fraction (HFrEF).
- Study procedures will include: possible exposure to an informational alert that is generated when opening the order entry screen in an eligible patient's medical record.
- There are some risks from participating in this study. Potential risks are minimal, and include disturbance to workflow and development of alert fatigue.
- The study may have no benefits to you. However, your patients may benefit from alerts due to closer monitoring of their condition and increased use of best practices by their providers to treat their condition.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you to take part in a research study because you are a practicing physician at a Cardiology or Internal Medicine outpatient clinic associated with one of four teaching hospitals within the Yale New Haven Health System and see a high number of outpatients who meet our inclusion criteria. This inclusion criteria for patients includes adult outpatients seen at an eligible clinic with a diagnosis of heart failure (defined by a left ventricular ejection fraction of ≤ 40%) and are in the Yale Heart Failure Registry. We are looking for 100 provider participants across outpatient clinics associated with our 4 study sites to be part of this research study.

Who is paying for the study?

This study is being funded by Astra Zeneca, however, this is an investigator-initiated study and the Yale study team has full jurisdiction over all aspects of study design, conduct, analysis and publication.

What is the study about?

The purpose of this study is to determine the efficacy of an automated electronic informational alert built into the EPIC electronic medical record versus usual care (no alert) to improve the care of patients with HFrEF. This alert informs providers of the presence of HFrEF in their patients, lists current evidence-based medications that the patient is prescribed, and links to an order set with additional evidence-based medications that a provider can prescribe. Our primary outcome will analyze the proportion of patients with an increase in evidence-based medical therapy for HFrEF after 30 days post-randomization. Secondary outcomes will look at the percentage of patients on each evidence-based medication class, the percent of filled prescriptions , one-year all-cause mortality, 30-day all-cause hospital admission rate, all-cause 30-day ED visits, and 6 month total healthcare costs.

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen: You will be randomized to one of two study groups.

If you are in the control group, you will continue with the usual care of your patients and you will not see our informational alerts.

If you are in the intervention group, you will receive an informational alert for all of your eligible outpatients with HFrEF upon opening of the order entry screen in your patient's medical record. This alert is a "pop-up" that will notify you that the patient has a diagnosis of HFrEF, will display the patient's current LVEF, and list the patient's current evidence-based medical therapy. Evidence-based medical therapy classes (four drug classes) will be displayed in the alert. If the patient is taking a recommended medication, the name of the drug and the dose will be displayed next to the class. If patient is not taking a medication belonging to one of the evidence-based medical therapy classes, a "None" will be displayed. There is also a link to the best available guideline-recommended treatment for heart failure. A link to an order set with recommended evidence-based and FDA-approved therapies for HFrEF patient will be available should you wish to change the patient's current therapy. It is important to note that these guidelines may be inappropriate for any specific patient. They are not based on a comprehensive or individualized assessment, but on limited indicators. The order set will not include any drug class the patient is already on and it will not include a drug class if the patient has a documented contraindication/allergy to it. A clinical assessment of your patient will be required before prescribing medication. You will be able to dismiss the alert and indicate your reason for doing so if you feel the alert is inappropriate for your patient.

The alert will fire once per patient, during the first encounter in which your patient is eligible, and only when the chart is open to enter orders. It is important to note that you are not obligated to take any action in response to this alert. This is an informational alert containing general, rather than individualized, guideline-based information, and you may choose to ignore the alert or use the information presented at your own discretion. This alert or the information presented does not substitute for any clinical consultation or clinical judgement, and the guidance contained within the alert is not a clinical recommendation, but a general guideline; these guidelines may be contraindicated for your patient.

We anticipate that you will see alerts for approximately 12 months so that we can collect data on 1330 outpatients across all 4 sites.

Following an alert, please use the following language with your patients about possible drug therapy changes: “The hospital is testing a new program where physicians are alerted of recommendations that have been shown to be effective in treatment of heart failure. I would like to discuss some of the recommendations with you, would you like to talk about that? Would you consider a change in your treatment?”

What are the risks and discomforts of participating?
This is a minimal risk study but may involve unforeseen risks. No PHI will be collected on providers who participate in this study. However, limited data will be collected on providers regarding behavior, such as rates of prescribing or modifying medical therapy for heart failure. However, this data is being collected in aggregate and will not be linked to specific individuals. Further, no clinician will be linked with any specific outcome. Data will be stored on a secure server that is only accessible to the study team.

Additional risks to you as a provider may include a disturbance to workflow, however we designed the alert to maximize the chance that it appears at the most relevant place in a provider’s workflow.

Finally, alert fatigue is a demonstrated phenomenon whereby more frequent alerting may lead to reduced attention to alerts overall. However, by rigorously studying the efficacy of alerts in randomized trials, we can better understand which alerts are truly effective and which can be discontinued such that alert fatigue can be reduced.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?
There are no direct benefits to you from participation in this study.

How can the study possibly benefit other people?
This study may provide benefit to the patients who are subjects of the study as a consequence of their provider being informed of the presence of their heart failure and current evidence-based therapy. The study may also provide a greater societal benefit regardless of the outcome for participants. Positive results may lead to a broader adoption of this alert system that will have been shown to improve treatment for HFrEF patients, while negative results may lead to less enthusiastic adoption of an ineffective alert that would otherwise contribute to alert fatigue.

Are there any costs to participation?
You will not have to pay for taking part in this study.

Will I be paid for participation?
You will receive payment for your time in completing a pre- and post-study survey. You will receive $50 for completion of the pre- trial survey and $200 for the completion of the post-trial

survey paid to you in the form of a pre-paid Bank of America debit card. You will receive this payment regardless of how you may or may not interact with any alerts, and regardless of your randomization status. The Bank of America card will be mailed to you upon completion of the first set of surveys. In order to do this, your name, address, and telephone number will be shared with Bank of America. We advise you to read the disclosure documents included with your card. Once the card is received, you will be required to activate it over the phone using the instructions included with the card in order to receive the funds on the card. Please keep the card on you for the duration of the study, as all payments associated with your participation in this study will be loaded onto this card. You are responsible for paying state, federal, and other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What are my choices if I decide not to take part in this study?
You may choose to not participate in this study and continue to care for patients as usual.

How will you keep my data safe and private?
We will keep information we collect about you confidential. All data in this study will be stored on a secured central server within our research center and will only be accessible from within the Yale Intranet with multi-authentication security. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it.

All data that is collected from the electronic medical record will de-identified. A linking file will be retained in a separate location that will allow for future linking for the collection and merging of longitudinal data and for potential future studies.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

What Information Will You Collect About Me in this Study?
No PHI will be collected from you in this study. We will collect data on provider behaviors, particularly in regards to changes to medications as well as interactions with the alert itself (i.e. how often an alert is dismissed or how often providers visit the guideline site via the link provided within the alert). This data will be collected in aggregate and never linked to any specific clinician, nor will any clinician ever be linked to any specific outcome.

How will you use and share my information?
We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Principle investigator and other co-investigators
- Study coordinator and members of the research team

- The study sponsor, Astra Zeneca, will collect aggregate, de-identified data regarding general provider behavior and de-identified patient data
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?
By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes

What if I change my mind?
The authorization to use and disclose your information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Nihar Desai, Yale Physician's Building, 800 Howard Ave, Ste 2nd Floor, New Haven, CT 06519

If you withdraw your permission, no new information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

What if I want to refuse or end participation before the study is over?
Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind and withdraw from the study at any time.

Not participating or withdrawing later will not harm your relationship with this institution.

To withdraw from the study, you may contact the Principle Investigator (203-785-7191) at any time and tell them that you no longer want to take part.

If you do choose to participate, it is important to remember that you are not obligated to take any specific action as a result of the alerts you may see as part of this study. You may choose to ignore alerts as you wish.

What will happen with my data if I stop participating?
Data collected from your participation in this study will still be used for research purposes unless you request to withdraw the data from the study.

Who should I contact if I have questions?
Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at 203-785-7191.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date