Pragmatic Trial of Messaging to Providers About Treatment of Hyperlipidemia (PROMPT-Lipid)

NCT04394715

Provider Consent Form

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CONSENT 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 Hyperlipidemia (PROMPT-Lipid)

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: 2000027852

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 rates of best practices in the treatment of patients with hyperlipidemia.
- 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 of Cardiology or Internal Medicine at an outpatient practice 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 includes adult outpatients at very high risk for atherosclerotic cardiovascular disease (ASCVD), defined as a history of a major ASCVD event and an LDL-C greater than 70 mg/dL on their most recent lipid profile, with or without other high-risk features such as diabetes and chronic kidney disease. We are looking for 100 provider participants across 4 study sites to be part of this research study.

Who is paying for the study?

This study is being funded by Amgen, 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 containing guideline-based recommendations that is built into the EPIC electronic medical record to improve the management of hyperlipidemia among outpatients at very high risk for future ASCVD events. Our primary outcome will analyze the proportion of patients with intensification of lipid lowering therapy after 90 days. Secondary outcomes will look at the achieved LDL-C at 6 months, and the proportion of patients with an LDL-C less than 70 mg/dL and less than 55 mg/dL.

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 containing guideline-based recommendations for all of your eligible outpatients with hyperlipidemia 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 is at very high risk for ASCVD, displaying the most recent cholesterol values and the patient's current lipid lowering therapy. There is also a link to the full treatment guidelines for hyperlipidemia, including an option to obtain continuing medical education (CME) credits. These guidelines may be inappropriate for any specific patient. They are not based on a comprehensive or individualized assessment, but on limited indicators. A clinical assessment of your patient will be required before prescribing medication. A link to an order set will be available should you wish to change the patient's current therapy.

The alert will fire once per patient, followed by a one hour lock out feature so that you cannot receive another alert within this one- hour time frame. However, should you open the patient's order entry page outside of this window, the alert will fire again.

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.

At the bottom of the alert is an option to accept or dismiss the alert. If you choose to dismiss the alert, a drop-down menu will appear that will ask you to select a reason for dismissing the alert (i.e. the alert may not be relevant to your patient, or clinical reasons preclude you from intensifying your patient's lipid-lowering therapy).

We will also ask you to complete a pre- and post- study survey to assess your knowledge and level of comfort with the ACC/AHA guidelines for hyperlipidemia as well as to assess overall provider approval and acceptance of the alert regarding usefulness, user friendliness, and overall user experience. This will help us understand how to improve the alert in future

iterations. Each questionnaire will be fully electronic and should take no more than 20 minutes to complete.

We anticipate that you will see alerts for approximately 12 months so that we can collect data on 2500 outpatients across all 4 sites.

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 lipid lowering therapies. 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 hyperlipidemia. 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 hyperlipidemia 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?
During the 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. We will also collect information from you during pre- and post-study surveys that assess your knowledge and familiarity with ACC/AHA guidelines for hyperlipidemia and, should you be randomized to the intervention group, your overall opinion and experience with the alert.

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 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