Spring 2018

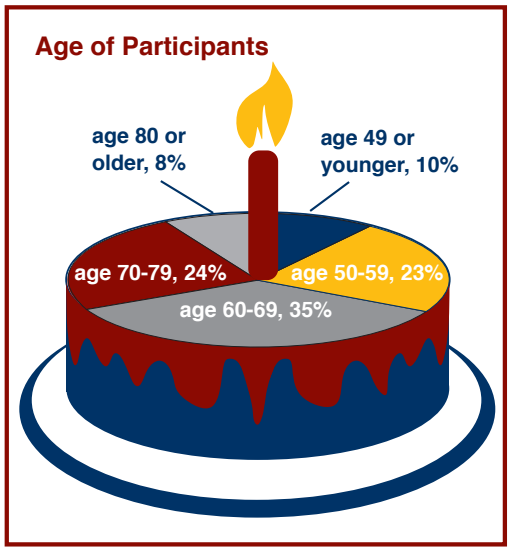
THE BEAT

News and information for participants in the PRE-DETERMINE Study

Baseline data offer a glimpse of PRE-DETERMINE study participants

More men than women. A wide range in age. Geographically far-flung. And, of course, committed to advancing research on the prevention and treatment of heart disease.

That's the picture of PRE-DETERMINE study participants that emerges from a look at the information provided on the initial study questionnaires, as well as feedback from participants during conversations and other correspondence with study staff. There will, of course, be few results available until the end of the study regarding major risk factors for sudden cardiac death. But the data collected at the start of the study provide an interesting snapshot of the PRE-DETERMINE study population.



Of the 5,956 participants, 76% are men and 24% are women. Ten percent of participants are younger than age 50, 23% are in their 50s, 35% are in their 60s, 24% are in their 70s, and 8% are 80 or older. The youngest participant is 24 and the oldest is 93! One in 7 participants identify themselves as belonging to a racial/ethnic group other than non-Hispanic white. Participants reside in 48 U.S. states and 5 Canadian provinces.

One-third of participants have never smoked, 52% have quit smoking, and 14% currently smoke. Thirty-seven percent of participants exercise vigorously at least 3 times per week, while 42% rarely or never do.

At study entry, 91% of participants had had a prior heart attack; 79% had had coronary angioplasty with or without stent placement; and 33% had had coronary artery bypass surgery. Three-quarters of participants had a history of high blood pressure, and nearly one-third had diabetes. Most participants were taking aspirin or another anti-clotting medication (95%), a cholesterol-lowering statin (90%), and/or drugs to control blood pressure.

Although not formally asked to provide their reasons for joining PRE-DETERMINE, many participants have told study staff that they are enthusiastic about contributing to research on heart disease.

From the PRE-DETERMINE Study Investigator

Dear PRE-DETERMINE participant,

As you know, the purpose of the PRE-DETERMINE Study is to identify risk factors for sudden cardiac arrest resulting from heart rhythm disturbances in people with a history of coronary artery disease or myocardial infarction (heart attack). Participants were enrolled at cardiology clinics throughout North America and are being followed by the Clinical Coordinating Center at Brigham and Women's Hospital in Boston, Massachusetts every 6 months via mail or phone to complete a brief health questionnaire. Thanks to your continuing commitment to completing these questionnaires, the study is well on its way to achieving its goal.

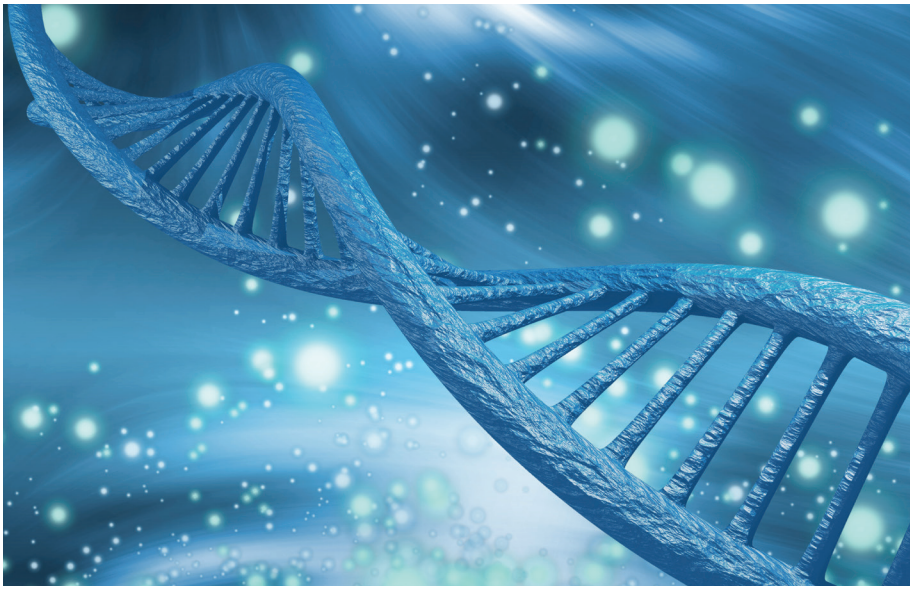
My colleagues and I are extremely pleased to report that we have successfully asked the National Institutes of Health (NIH) to continue to fund the PRE-DETERMINE Study. In giving us the green light to continue the study for several more years, the NIH praised the high level of commitment demonstrated to date by study participants; the careful design and progress of the study; and the scientific impact of the eventual results. The study is expected to provide findings that will be important in identifying new strategies to prevent sudden cardiac death.

If you have any questions about the study, please let us know (see our contact information on page 4). Thank you for making the study a success!

Christine M. Albert, MD, MPH
Professor of Medicine
Harvard Medical School
Brigham and Women's Hospital

Important information about sharing of genetic data in PRE-DETERMINE

We are excited to announce that we recently received funding from the National Institutes of Health (NIH) to expand our planned genetic analyses, which were previously limited to selected genes linked to abnormal heart rhythms. This new funding will support genome-wide genotyping, a procedure that will allow us to study all or most of your genes at the same time. This will open up an exciting opportunity to discover previously unsuspected genes that might elevate risk of life-threatening arrhythmias and/or other complications from coronary heart disease. Often the genes that are ultimately found to cause disease are not those that were initially considered.



Database of Genotypes and Phenotypes (dbGaP)

The type of genetic analysis that we will be performing in PRE-DETERMINE is also performed in many other studies funded by the NIH. In 2006, the NIH created a centralized database called Genotypes and Phenotypes (dbGaP), which stores and shares genetic information from multiple studies for the purpose of identifying and understanding genes linked to a variety of medical conditions, such as heart disease and cancer, as well as other human characteristics, such as height, blood pressure, and smoking status. Because the genome-wide genotyping in PRE-DETERMINE will be supported by the federal government, the NIH is requiring us to submit our genetic testing results to dbGaP so that these data can be shared with other researchers. The goal is to maximize what can be learned from the genetic data.

> "The goal [of dbGaP] is to maximize what can be learned from the genetic data."

We do not think that sharing your genetic information with the dbGaP database will result in further risks to your privacy and confidentiality. The genetic data will be sent to the dbGaP database with only your code number attached. Your name, year of birth, address, or other directly identifiable information will not be given to dbGaP. There are also many safeguards in place to protect the information stored in dbGaP. In addition, the NIH restricts access to qualified researchers who can prove a scientific use for the data. More information about dbGaP can be found at www.ncbi.nlm.nih.gov/gap.

Allowing your genetic data to be included in dbGaP is up to you. You can decide not to allow your information to be placed in this database. If you have questions about—or wish that your data be excluded from—dbGaP, please call us at 877-718-8003 or e-mail us at predetermine@research.bwh.harvard.edu. You can also write to us at PRE-DETERMINE Study, 900 Commonwealth Avenue, Floor 3, Boston, Massachusetts 02215. Regardless of your decision, you will still remain a valued participant in the PRE-DETERMINE Study.

Q&A

Q. Why is it important to complete and return the study questionnaire every 6 months?

A. Maintaining frequent contact with study participants allows us to learn of new health events shortly after they happen. Timely reporting makes it easier to recall the dates and other details of health events and increases our chances of obtaining relevant medical records.

Q. What are the options for returning the questionnaire?

A. You may choose to return the questionnaire via postal mail or call us to complete it over the phone—whichever is easiest for you.

Q. Should I still complete the questionnaire if my cardiac health has not changed within the last 6 months?

A. Yes! Even if your health has not changed, please continue to fill out and return the study questionnaires. If we do not receive your questionnaire in the mail, we may follow up with you over the phone.

Q. Why are the same health questions asked on each questionnaire?

A. We are looking to see if you have experienced any new cardiac events since the last time you returned a questionnaire. If you already reported a particular event on a previous questionnaire, you need not report that event again.

Q. Why do you ask for the name and telephone number of a contact person?

A. In a long-term study such as PRE-DETERMINE, we occasionally lose touch with study participants when they move or have other changes in their status. We will write or telephone your contact person to ask for your current address or phone number only if we cannot reach you after multiple attempts. Contacts are an excellent resource to ensure important study data are collected in a timely fashion. Please take a moment to remind your contacts that you are participating in the PRE-DETERMINE Study and that we may need to contact them in the future for research purposes.

Q. How long will the study last?

A. The study is expected to continue for 4 to 5 years or longer. We will continue to contact you via mail or phone every 6 months to assess your current health status during this time. Thank you for your continued participation and dedication to this important study!

Q: What is the benefit of participating in this study?

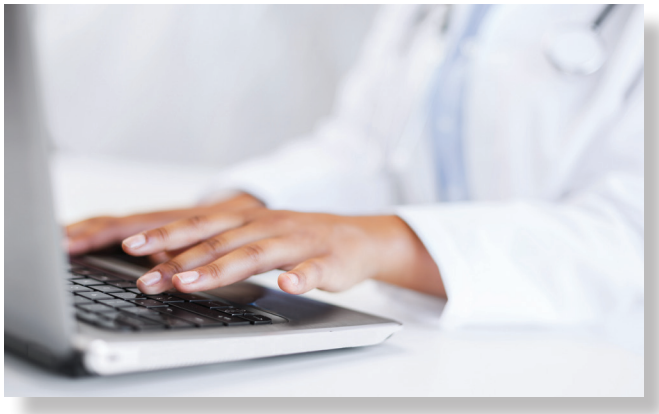
A. Although there are no direct benefits to you for taking part in PRE-DETERMINE, the information collected will increase medical knowledge about the continuing health of people with abnormal heart function after a heart attack and may help to identify new strategies to prevent sudden cardiac death.

What motivated you to join PRE-DETERMINE?

For a chance to be featured in a future newsletter, please let us know what motivated you to join the study by sending an e-mail to predetermine@research.bwh.harvard.edu or mailing a short note to the postal address in the box on page 4—and consider including your photo (tell us where the photo was taken). (Please note that high-quality digital photos, sent as JPG attachments to e-mails, are preferred and that no photo will be published without the written consent of the participant. Published photos will include first name, last initial, and state of residence.)

Use of Medicare claims data in PRE-DETERMINE

Medicare (more formally, the Centers for Medicare and Medicaid Services) routinely collects information about Medicare-funded medical care received by certain U.S. citizens. (Most Medicare recipients are aged 65 years or older.) To increase the completeness of the information that we collect on study questionnaires about your health, the PRE-DETERMINE team plans to work with study investigators based at the Harvard School of Public Health in Boston, Massachusetts, to search the Medicare database for information related to the health outcomes followed in the PRE-DETERMINE Study. Such information includes medical diagnoses from hospitalizations, emergency room visits, and outpatient visits, as well as the names of tests, procedures, and prescriptions funded by Medicare. **Please note that the Medicare information does NOT include test results or actual medical records from doctors' offices and hospitals**. If we wish to obtain and review test results or medical records from doctors' offices and hospitals for study purposes, we will contact you directly to request your permission, just as we do when you report a new diagnosis on your study questionnaires.



The Medicare data will add to the information that you provide on study questionnaires regarding new medical diagnoses and treatments received during the course of the study. The combined information will enhance our ability to understand important health outcomes pertaining to heart disease. Many large studies regularly use Medicare data to supplement information on study health outcomes.

To obtain your information from the Medicare database, we will locate you in this database by identifiers such as your date of birth, zip code, and if you provided it to us, your social security number. We will not obtain or use your Medicare beneficiary ID number. **As always, we are committed to protecting your privacy. All data obtained from Medicare will be held strictly confidential and used only for PRE-DETERMINE Study purposes.**

If you have questions about—or wish to be excluded from—this part of the PRE-DETERMINE Study, please call, e-mail, or write to us (our contact information is directly below). Of course, you will still remain a valued participant in the PRE-DETERMINE Study.

ICD Request

If you have an implantable cardiac defibrillator (ICD) or plan to receive one, we will be contacting you (if we have not done so already) to request your permission to obtain important information on heart-rhythm disturbances identified and treated by your ICD. An ICD is often able to treat a rhythm disturbance without a noticeable shock; thus, you may be unaware that you have experienced such a disturbance. To collect all essential data from your device, we will ask your permission to contact your cardiologist and/or electrophysiologist to obtain records from device interrogations conducted during routine follow-up visits and hospitalizations. In addition, if your ICD is being remotely monitored, we will ask your permission to collect records directly from the ICD manufacturer, a process that would require us to provide your device's unique serial number to the manufacturer. Information from ICDs will be critical in allowing the PRE-DETERMINE Study to identify patient characteristics that increase the risk for heart-rhythm disturbances.

PRE-DETERMINE STUDY
900 Commonwealth Avenue, Floor 3
Boston, Massachusetts 02215
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Fax: 617-277-0198
E-mail: predetermine@research.bwh.harvard.edu
Web: www.pre-determinestudy.org