PRE-DETERMINE

BRIGHAM AND WOMEN'S HOSPITAL

HARVARD MEDICAL SCHOOL

Winter 2014 Newsletter

What is the PRE-DETERMINE Study?

The PRE-DETERMINE Study is an observational (i.e. questionnaire-based) follow-up study of male and female participants over the age of 18 with a prior history of coronary artery disease or myocardial infarction (heart attack). Participants were enrolled at cardiology clinics throughout North America. After enrollment, all participants are 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.

The purpose of the study is to more accurately identify people who are at risk for developing sudden cardiac arrest from life-threatening heart rhythm disturbances and to learn new ways to prevent such tragic events from happening in the first place.

When you enrolled in the study, you provided a blood sample that will be analyzed. Genes and other biologic markers (such as proteins and fats) found in your blood are an important biological resource that could provide crucial answers to many critical health questions.

These samples will give us the ability to "look back in time" for possible disease markers present years before the onset of a life-threatening abnormal heart rhythm event. We hope to also identify genetic or biologic factors that protect against sudden cardiac arrest.

In order to put your blood sample to good use, long-term follow-up is essential so that we can appropriately document all cardiovascular health events that have occurred after you joined the study. This means that we will continue to contact you every 6 months to assess your current health status. This allows us to also identify factors that protect against cardiac arrest. Even if there has been no change in your health status, it is still important for us to know you are doing well.

Thank you for joining us in our efforts to fight heart disease, the leading cause of death in the United States. We cannot do this without you, and we are grateful for your time and efforts in making this study a success!

Thank You for Participating in the PRE-DETERMINE Study!

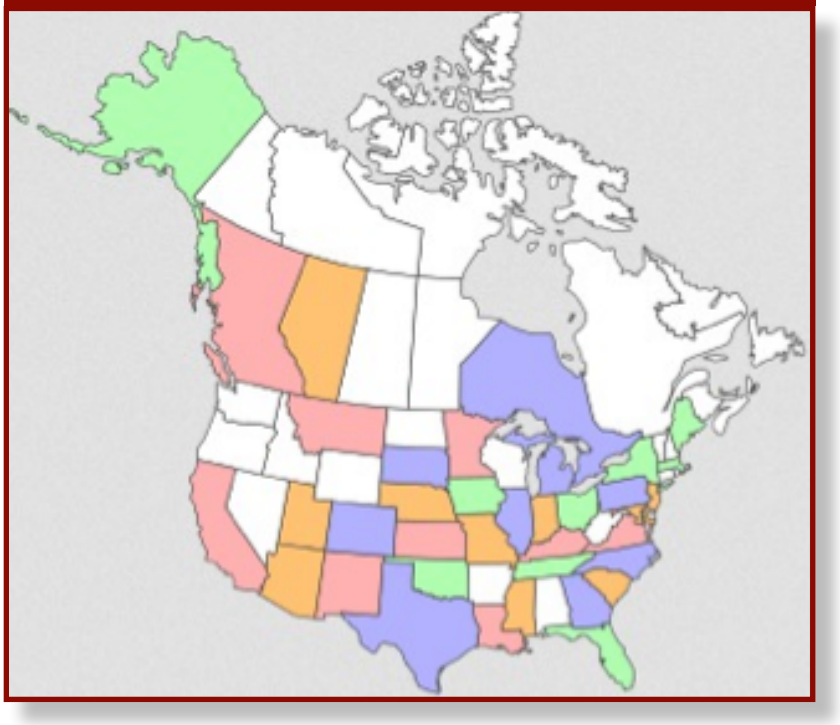
We would like to extend a huge THANK YOU to all of you who have donated your time and energy enrolling and participating in the PRE-DETERMINE Study.

We are pleased to announce that due to each of your efforts, we surpassed our initial enrollment goal of 5,300 participants, and are now following the health statuses of approximately 6,000 participants who signed up at our 136 sites throughout the United States and Canada.

Our participants come from as far north as Alaska and as far south as Puerto Rico. Below, you will find a map demonstrating where participants were enrolled in the study. The most participants were enrolled in Florida (10.2%), Ohio (7.3%), and New York (6.5%).

We are now entering into the most important stage of the study - the follow-up phase. During this time, we will continue to contact you every 6 months to follow your cardiovascular health status. We thank you for all your efforts during this crucial time.

PRE-DETERMINE SITES



Enrollment Percentages by State

- 0.05% - 0.6%
- 0.7% - 1.6%
- 1.7% - 3.9%
- 4% - 10%

Lowering Your Risk of Sudden Cardiac Death

Research has identified **4 key steps** that you can do to lower your risk of sudden cardiac death:

1. Don't start smoking; if you currently smoke, quit.
2. Maintain a healthy weight (BMI 18.5-25 kg/m2). If you are above your ideal weight, losing 5-10% of your body weight can reduce disease risk.
3. Exercise at a moderate level every day. A 30-minute brisk walk 5 days a week is enough for most people. Also, decrease sedentary pastimes, such as TV and computer time.
4. Eat a healthy diet. The best diet for preventing heart disease is:
   - Full of fruits and vegetables, whole grains, nuts and legumes, fish, poultry, and vegetable oils.
   - Low in red and processed meats, sugary beverages, sodium, and trans fat.
   - Limiting alcohol intake to 1 drink per day.

In a study among women, approximately 80% of sudden cardiac deaths may have been avoided through adherence to these lifestyle habits.

If you would like to learn more about healthy lifestyle changes and risk factors, please visit the nutrition center in the American Heart Association's website: www.heart.org. There are many wonderful resources regarding diet, physical activity, weight and stress management, and tips on quitting smoking.

Some Helpful Information

What is Sudden Cardiac Arrest/Sudden Cardiac Death?

The primary purpose of the PRE-DETERMINE Study is to find new ways to prevent death from sudden cardiac arrest. Sudden cardiac arrest is the leading cause of natural death in the United States, resulting in about 250,000 adult deaths each year. Sudden cardiac arrest is a condition in which the heart suddenly and unexpectedly stops beating due to a disturbance in the heart's normal rhythm called ventricular fibrillation. During ventricular fibrillation, the ventricles (the heart's lower chambers) do not beat normally. Instead, they quiver rapidly and irregularly. If this happens, blood stops flowing to the brain and other vital organs. Most people who have sudden cardiac arrest die from it—often within minutes. Sudden cardiac death is responsible for half of all heart disease deaths that occur in the United States.

What is an Implantable Cardioverter Defibrillator (ICD)?

Rapid treatment of sudden cardiac arrest with a defibrillator can be lifesaving. A defibrillator is a device that sends an electric shock to the heart to try to restore its normal rhythm. There are two types of defibrillators. The first is an external device, which is utilized by emergency personnel and bystanders to revive patients who have had a witnessed cardiac arrest. The second is a pager-sized metallic device that is surgically implanted in patients deemed to be high risk for cardiac arrest. The device is called an implantable cardioverter defibrillator (ICD) and is placed under the skin, usually below the left collarbone. One or two flexible, insulated wires run from the ICD through the veins to the lower chambers of the heart. The ICD continuously monitors the heartbeat and delivers extra fast impulses or electrical shocks to restore a normal heart rhythm when necessary.

In order for us to assess key risk factors that may play an important role in predicting sudden cardiac arrest, we ask all participants to report if they have had a cardiac arrest and/or have undergone surgery to have an ICD implanted, as well as received an electrical shock from their ICD during every 6-month follow-up period. To validate these reports, we ask for permission to obtain medical records from the event to be able to determine what may have caused this.

Frequently Asked Questions

Q. Where are you contacting me from?
A. We are contacting you from the study's coordinating center, located in Boston, Massachusetts. The coordinating center is based out of Brigham and Women's Hospital and is affiliated with Harvard Medical School.

Q. Why do you keep asking the same questions?
A. We ask the same questions every 6 months for validation purposes. If we were to change our questions regularly, we could not accurately compare the information you have previously provided. Please keep in mind that we are only asking if you have experienced any NEW health events since the last time you completed the questionnaire.

Q. Why would you send me a request to release records?
A. We send out a Release of Information (ROI) form if you reported experiencing one of the study endpoints, such as cardiac arrest or an ICD implantation. We do not have open access to your medical records. We require your written permission to access medical records that only pertain to an event that you report.

Q. Why do you need my medical records?
A. These records allow us to make sure our data is as accurate as possible. Medical records provide precise details given by medical professionals and help us validate events.

Q. Do you really need to contact me so often?
A. The purpose of maintaining close follow-up is to learn of new health events shortly after they happen, since it will be easier to recall specific details, as well as increase our chances of obtaining medical records pertaining to the event.

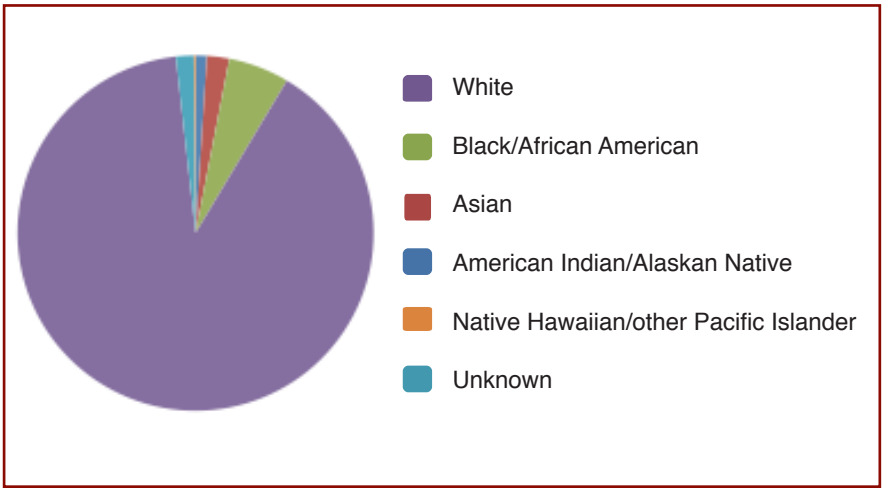
Our follow-up procedure is to mail questionnaires every 6 months. If we don't receive a response within 1 month, we will mail a short version of the questionnaire. If we don't receive either, we will call you to complete the questionnaire.

If your address is going to change or you know you won't be able to respond to the next questionnaire(s), please feel free to reach out to us at any time.

Q. Should I be taking any special medications for the study?
A. The PRE-DETERMINE Study is STRICTLY an observational study, which means that we do not ask you to take any supplements or medications. We also do not discourage you from taking anything you are already taking. Likewise, your participation in PRE-DETERMINE does not interfere with other studies in which you may be participating.

Q. Why do you want contact information for my next of kin?
A. We use the contact information for your family members and/or close friends if we are having trouble getting ahold of you. If you were to change addresses or phone numbers between questionnaires, we might call your contacts to get your updated contact information.

Our Participants



Ethnicity

5%	Hispanic/Latino
94%	Not Hispanic/Latino
1%	Unknown

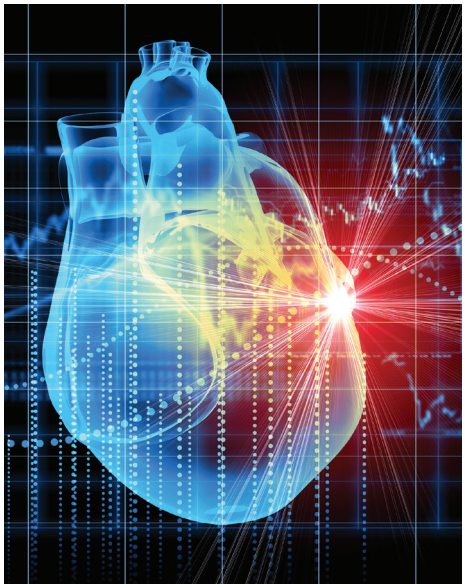
Race

1%	American Indian/Alaska Native
2%	Asian
6%	Black/African American
< 1%	Native Hawaiian/other Pacific Islander
89%	White
2%	Unknown

Gender

76%	Male
24%	Female

Study Updates



• Development of an online questionnaire

We are in the process of developing a web-based questionnaire that you can complete online instead of by mail. If you would rather complete the questionnaire online, please add your email address to the second page of the questionnaire.

• Cardiovascular events

We continue to follow up with any participants who report having surgery for an implantable cardiac defibrillator (ICD) or cardiac arrest and ask for permission to obtain medical records for these events.

• Implantable Cardioverter Defibrillator (ICD) Records

For participants who have received an ICD: within the next month or two, we will begin the process of collecting data regarding rhythm disturbances that your ICD may have identified and treated. Often the ICD is able to painlessly treat a rhythm disturbance without a shock. Therefore, you may be unaware that you experienced a rhythm disturbance. In order to collect all essential data from your device, we will be asking your permission to contact the doctor who currently cares for your ICD, usually a cardiac electrophysiologist. In addition, if your ICD is being remotely monitored, we will also ask your permission to collect relevant data directly from the device manufacturer.

Who We Are

We would like to introduce you to the PRE-DETERMINE research team at Brigham and Women's Hospital.

Our Principal Investigator, Dr. Christine Albert (first row center), started the PRE-DETERMINE Study in 2007 to identify new ways to prevent sudden cardiac death.

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