First Year of Gen 3 is Great Success!

The examination of the Third Generation (Gen 3) of the Framingham Heart Study (grandchildren of original participants) began in April, 2002. The response of the Gen 3 volunteer participants to join the Study and attend clinic has been tremendous, even throughout a long, snowy winter. We are especially interested in having as many brothers and sisters as possible in each family come in for the exam. So, if you are in the Offspring Study, you can help by encouraging all your children to participate. If you are already a participant in Gen 3, please tell your brothers and sisters about our Study. The enrollment period will run through December, 2004. When your enrollment form arrives, please fill it in and return it immediately. For information, please contact Maureen Valentino at 800-854-7682.

Gen 3 were invited to attend a forum on October 29, 2002, at the Sheraton Framingham Hotel. On that night 400 participants listened to presentations from a panel comprised of Framingham Heart Study staff members, as well as Dr. Claude Sanfiant, Director of the National Heart, Lung and Blood Institute, and Dr. Aram Chobanian, Dean, Boston University School of Medicine, followed by questions and answers. See inside for excerpts from this evening of open dialogue.

Cardiovascular CT Scan for Offspring and Gen 3

One of our exciting new studies is the Cardiovascular CT (computer tomographic) scan which many Offspring participants as well as their children who are enrolled in Gen 3 have had or will have. The CT test requires only about 30 minutes of a participant’s time and, to date, over 800 participants have completed it.

The CT test is able to detect and measure the amount of calcium deposited in coronary arteries of the heart and the aorta, the main artery of the body. A calcium deposit in the coronary artery is a marker of atherosclerosis (i.e., buildup of fat, cholesterol and other abnormal substances in the arteries). Heart attacks almost always originate from atherosclerosis in the coronary arteries. Dr. Christopher O’Donnell, Director of the CT study, says, "For the first time we are able to directly detect atherosclerosis in the coronary arteries before a heart attack occurs."

The main purpose of the research CT scans is to detect calcium in the heart arteries and the aorta; therefore, not all of the body is being scanned and other medically important findings may not be identified. However, in the past few months, several scientific researchers have reported that medically important “incidental findings” can still be identified while examining CT scans for artery calcium.

Because Framingham Heart Study physicians and our radiology collaborators at Massachusetts General Hospital want to provide information to our participants that may be important to their health, in February 2003 we began reviewing all previous and current CT scans. Should there be any medically important “inciden- tal” findings, you and your physician will be contacted. Barbara Ingelse is calling eligible participants now for spring and summer CT Scan appointments. This scan is done at the Mais General Hospital Waltham Imaging Center and transportation will be provided if needed. For information please call Barbara at 508-935-3451.

If you are a participant in the Framingham Offspring Study, you may be selected to have a cardiovascular magnetic resonance imaging (MRI) test. The MRI test provides a powerful, non-invasive way to detect abnormalities of the structure of the heart and athero-
The Third Generation will allow us to look at familial patterns of risk factors such as blood pressure and lipids, as well as tobacco use. It has become clinically apparent, hopefully to give us an opportunity to intervene and prevent overt clinical disease.

Dr. Philip A. Wolf, Principal Investigator, Framingham Heart Study

The Episcopal Studies of the Framingham Heart Study is one of the most important developments in our 54 year history. Let me tell you a little about the context that precipitated the third generation. It is the leading cause of death and disability in our society. It was felt that if we could take a large population and follow it for a period of time, perhaps we could gain some insight into the causes of cardiovascular disease. Under the auspices of the US Public Health Service, the National Heart Institute, the National Heart, Lung, and Blood Institute, the Framingham Heart Study began in 1948. Initially, we enrolled 5,209 men and women from Framingham who were between 30 and 62 years of age. Our first participants were their grandparents. They came in for exams that were similar to the exams that we perform today, which included medical history, ECG, a routine examination, and an electrocardiogram. And they have been invited back every two years since that initial visit back in 1948. Right now we are in the midst of our 27th cycle of exams on the original study group.

Our study opened its doors for a second time in beginning in 1971. We began recruitment of the Offspring Generation, a second study group of 5,124 children and spouses of the original study participants. The Offspring generation is the group to which you and I belong. Our generation is the third generation. Our exams are very similar to those of the original study and we recently finished their 7th exam cycle. By following these two generations simultaneously—recruitment and analysis and analyzing the data, we have learned a great deal about many of the causes of heart disease, the things we call risk factors for heart disease. This information has been used to identify risk levels, low levels of HDL cholesterol, diabetes smoking and obesity and other risk factors for heart disease. The Framingham Heart Study has become a family tradition and we are now recruiting a third generation of participants. The Offspring Generation is the group of 5,124 children and spouses of the original study participants. The Offspring generation is the group to which you and I belong. Our generation is the third generation.

Dr. Daniel Levy, Director, Framingham Heart Study

On behalf of all the clinic staff, I want to tell you how much we really enjoy working with all the participants of the Framingham Heart Study. I have heard many times this evening about the importance that our participants have placed on being involved in the studies and contributing to our work. As a participant of the Framingham Heart Study, you will be given ongoing clinical care for your entire life. We will be measuring your height and weight and will be asking you questions about your family and your exercise habits. We will be doing some tests you may have already had done in your own doctor's office such as an electrocardiogram or ECG. We will also be measuring your height and weight and will be asking you questions about your family and your exercise habits. We will be measuring your height and weight and you will be given ongoing clinical care for your entire life. We will be measuring your height and weight and will be asking you questions about your family and your exercise habits. We will be doing some tests you may have already had done in your own doctor's office such as an electrocardiogram or ECG.
Q: Will any willing, interested Third Generation member be accepted? Will any Third Generation people be turned away?
A: You must be 20 years old and have at least one parent and one grandparent in the Study to be enrolled as part of the Third Generation. Our exam is scheduled to go through December of 2004. We will enroll 3500 Third Generation participants between now and the end of 2004.

Q: After the exam, do we get the results of the exam and how long does that take?
A: It takes about six weeks for you to get results from us. You will receive a letter noting any concerns that were raised from your physician exam. We also send a letter to your designated physician which includes the measurements of the two blood pressures taken by the physician in clinic, a copy of your ECG and the interpretation of the ECG by our Heart Study clinic physician, and a list of any medical issues that were raised during your visit. A copy of your lung function tests will also be forwarded to your doctor. The results of tests that are used for research purposes only are not ordinarily forwarded. However, if there is an abnormality of any significance on the echocardiogram (the ultrasound of your heart), it will be forwarded to your physician.

Q: During the examination, if there is a critical problem discovered, what happens?
A: The Framingham Heart Study is a research facility so we do not provide any direct medical care. We would discuss any issue that is identified at the clinic visit with you. If it is an urgent or emergent problem, we will ask for your permission to call your physician while you are still at our Heart Study clinic to get his or her input as to how to proceed. If it is a less urgent issue, we will discuss it with you in person, send you a follow-up letter and also send your physician a letter indicating our concern.

Q: If I am on a cholesterol lowering medication, can I participate?
A: Absolutely.

Q: Can I participate if I am pregnant?
A: Pregnancy is associated with some changes in blood cholesterol levels and perhaps vascular function so we have asked that women come in approximately six months after their babies are born.

Q: In the 1940s, the community wasn’t very diverse and I was wondering now how you address diversity with the Study?
A: When the Framingham Study began in 1948, the community was very different from the community today. To better reflect this diversity, in 1995, we began the Omni Study, which is a minority recruitment study within Framingham. The Omni Study has African-American, Asian-American, Native American and Hispanic representation. There will be recruitment of children of the Omni Study who will attend exams that are very similar to those of the Gen 3 Study. The Framingham Heart Study now reflects far better the diversity of the community.

Q: What is the age range of the Third Generation participants and what will their average age be? Also, is there a priority age group to be studied first?
A: Third Generation participants will be eligible if they are 20 years of age by the time of their exam. There is no upper age range. We are not giving any priority to people according to their age.

Q: What if you have already had an enrollment form sent to you but you lost, misplaced, or overlooked the form? Is there a way to check? Will we be contacted again if we did not reply?
A: If you lost or misplaced an enrollment form, you can contact our Participant Coordinator, Maureen Valentino, at the Heart Study (800-854-7682). She will be happy to send out an additional enrollment form.

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Q: The Heart Study mentions genetics as one of the objectives for the Third Generation. If a third generation person is adopted, does this affect participation in the Heart Study?
A: If one or both of your parents are members of the Offspring Study, and that means you have had at least one grandparent in the original Cohort, you are eligible for the Study. Whether you are adopted or not, you are welcome to join.

Q: Are there any medical conditions that make a person ineligible to participate in the Study?
A: No, there are not.

Q: I received an initial mailing from the Framingham Heart Study about six months ago but I haven’t been called to schedule a visit. When will I get that call?
A: We don’t send all the enrollment forms out at the same time. The entire enrollment process will go on until the end of 2004. If you are going to be in the Framingham area and have come from a distance, you are welcome to call Maureen Valentino (800-854-7682) and tell her that you are going to be in town. We will try very hard to accommodate your clinic visit at that time.

Q: Are Third Generation participants’ spouses included in the Study?
A: We are able to enroll only people with at least one parent in the Offspring generation and one grandparent in the original Cohort, and are unable, unfortunately, to accommodate spouses of people who are eligible for the Third Generation.

Q: Can I participate if I am pregnant?
A: Absolutely.

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Q: Have we had a number of questions about places to get more information about the Study; is there a website where I can find out more about the Framingham Heart Study?
A: Our website is www.nhlbi.nih.gov/about/framingham/index.html. You will find information about the history of the Study and exam content. We also include information that details the research milestones of the Framingham Heart Study and also information for researchers who might have questions about the Heart Study.

Q: Will we be given guidelines or information on better health habits?
A: The Framingham Study is an observational study and not an interventional study, so we do not provide any guidelines or treatment.

Q: What should I do if there are some parts of the exam I am uncomfortable with?
A: At any point, if there is a part of the exam that you feel uncomfortable with, you are free to decline that part. We are eager to have you come in and participate, and all parts of the exam are voluntary.

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