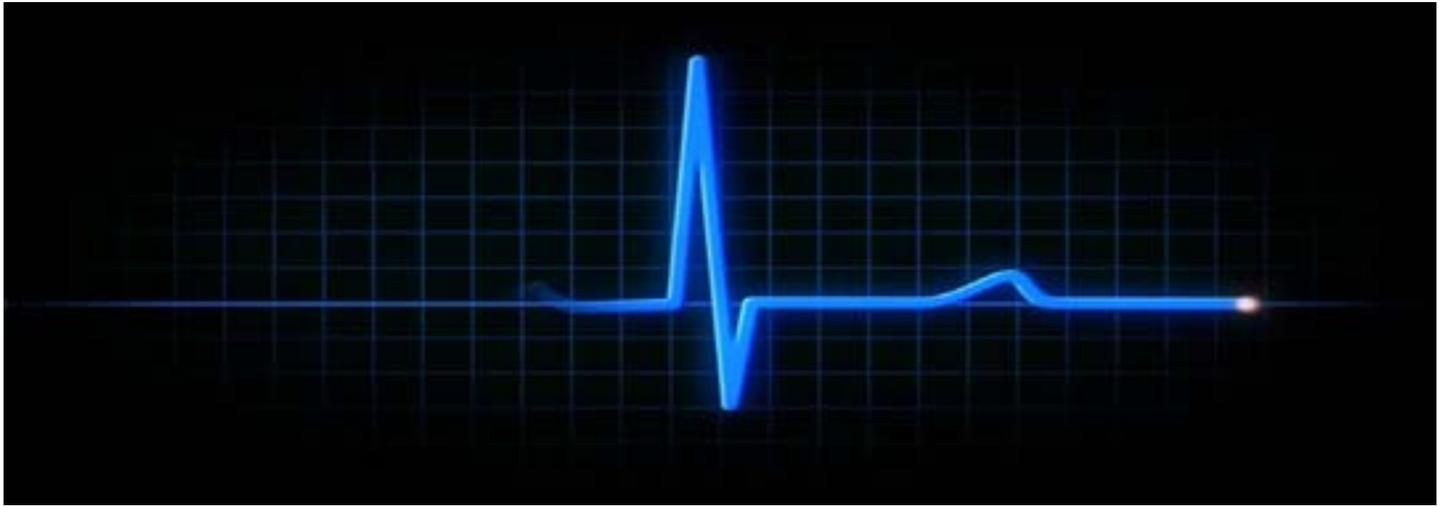


The Pitt Men's Study



New MACS Protocol Yield Results

With the beginning of the new wave on October 1st, the Pitt Men's Study added two new tests to the MACS protocol in an effort to gather information on the heart health of Study participants. As the MACS continues to pave the way in assessing the collateral impacts of HIV infection, the study turns its focus to heart health. An electrocardiogram (ECG or EKG) will be conducted on Study participants at their clinic visits to obtain information on the electrical activity of the heart. In addition, Study participants will also be asked to wear a

small device called a ZIO Patch which records a continuous ECG over a 14-day period. We believe that by conducting these two similar but distinct tests we will be able to collect valuable information on the impact of HIV on heart health and on heart health in general.

Based on early results, we also believe that the information collected during testing may be valuable to Study participants. During the first two months of testing, we have identified two individuals with abnormal ECGs that warranted an immediate follow-up

and referral for treatment. During that same period, the ZIO Patch detected an abnormal heart rhythm in six additional PMS participants who were referred into care. In all eight cases these tests provided our men important information that they were unaware of.

Please note that ECG and ZIO Patch testing will continue only through March 31, 2017.

Those who have missed an appointment are encouraged to call and resched-

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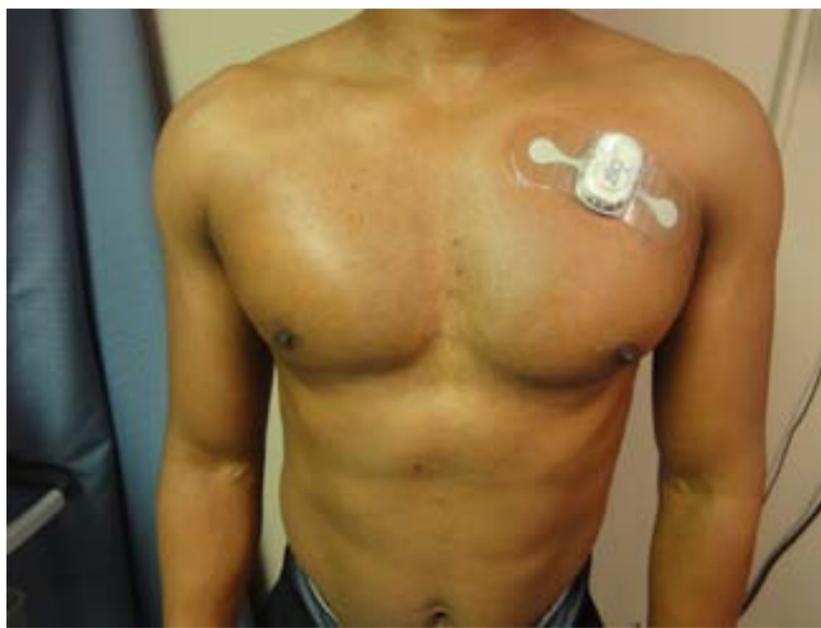
Inside the Issue

- **Cover** PMS staff discuss how new testing helps our study continue to grow, and how it might also help you.
- **Page 2** Learn about the future of the study, as well as what new tests may come as the study continues to evolve.
- **Page 3** You want me to wear this thing for how long? We answer all of your questions about the EKG and ZIO Patch testing that we are conducting.
- **Page 4** Dr. Charles Rinaldo, PMS principle investigator, offers his sincere thank you to study participants and your tremendous efforts.

ule; this includes men who have not been seen for some time. We hope that those who have an upcoming appointment will take advantage of these new tests. And if you recently had an appointment but opted not to do one or both tests, just know that you can still do them if you change your mind - they do not have to coincide with your

MACS appointment. **If you would like to make an appointment, call 412-624-2008 or 1-800-987-1963.**

Thanks in large part to a diverse cohort of HIV+ and HIV- men, the Pitt Men's Study has played



an unequalled role in the study of the natural history of HIV infection and AIDS over the past 30 years. Over the past decade and a half the Study has expanded this research to assess how HIV infection affects long-term participant health in areas including lipid metabolism, heart health, kidney health, aging and bone fracture, and co-infection with other diseases such as

hepatitis. This additional testing is just one more way that the study hopes to examine—and improve—the health of people around the world.

Change in the Air

As the Pitt Men's Study continues to evolve, it is collaborating with other institutes within the National Institutes of Health (NIH), one of which is the National Institute Heart, Lung, and Blood Institute (NHLBI). The NHLBI has given the study a grant to do the ECGs and ZIO Patches that are described in the newsletter. This is just a beginning, however.

In the next reporting period (which begins April 1, 2017) we will be doing pulmonary function tests (PFT) as part of the MACS visit. Many of our MACS men have done PFTs with Dr. Alison Morris' lung studies conducted at Montefiore Hospital, but this has been done on only a subset of our men, and the NHLBI would like to obtain data on as many of our men as possible to better examine the lung health of the cohort.

A PFT involves breathing in deeply and then exhaling forcefully and as completely as possible through a tube. This measures how well participants' lungs work and is used to diagnose lung conditions such as COPD (aka emphysema) and asthma. The PFT will be done in our clinic and may add about 45 minutes to the MACS visit. You will receive more detailed information about exactly how the testing will be done prior to your next appointment. There will be additional reimbursement for your time and effort.

Another test that is being considered starting

in October 2017 is a transthoracic echocardiogram (aka "echo") which is basically an ultrasound of your heart. This allows technicians to observe the size and structure of your heart as well as how it beats and pumps blood. Conditions that an echo can reveal include an enlarged heart, thickened ventricles, congestive heart failure, damage from heart attacks, heart valve problems such as mitral valve prolapse, congenital heart defects, and blood clots and tumors.

As part of an echo one lies on an exam table and a technician applies a gel to your chest. This gel helps transmit sound waves to your heart and back. A transducer, a wand-like object, is then moved around on your chest and transmits sound waves which allow images of your heart to be observed on a screen and recorded. We do not know for sure yet if echos will be offered, but we will let you know once a final decision is made and a protocol is developed.

We are very excited to add these new tests as the different institutes within the NIH offer us grants to do research. They allow us to learn even more about your health and how HIV and aging affect it. It's part of our commitment to you and your health. These tests do add time to your visits, and we appreciate that you make the time to help us with this valuable research.

EKG and Zio Patch FAQ's

What is an ECG?

You may already have had an ECG, possibly during a physical exam or prior to a surgical procedure. The ECG measures electrical impulses from the heart that help to determine if the heart is functioning normally. Electrodes, called leads, are placed on your chest, arms and legs while you lie on an exam table, and the ECG is recorded for a few seconds. This whole process usually takes 15 to 20 minutes. There is minimal risk to these procedures other than the minor discomfort of removing the leads.

What is a ZIO Patch?

The ZIO Patch is a relatively small device that works like a portable ECG. Like the ECG it too measures the electrical impulses of heart. But unlike the ECG which measures the heart's electrical impulses at a single point in time, the ZIO Patch measures these over a period of time, ideally 14 days. This enables us to detect problems that may be intermittent and would not be detected by the short ECG performed in the clinic. When the 2 weeks are done, you simply return the patch for analysis in an addressed, postage-paid mailer that we give you.

You want me to wear this ZIO Patch for how long?

Ideally, two weeks, but the average length of time that men have kept the ZIO Patch on is about seven days. Our goal is for men to wear it as close to two weeks as possible, but if it comes off early, even a few days of data are useful to the study and potentially helpful to you.

Can I delay doing the ECG and the patch? I'm going to the beach on vacation tomorrow. I'm short on time today, and I don't want the patch on my chest when I'm sunbathing.

You do not have to do the ECG or have the patch applied at your visit. You can return to the clinic at a later date to have it applied, but you must do this by March 31, 2017. Our NIH grant only allows us to do these tests until that date.

I'm young. Why is it important for me to do these tests?

The strength of our Study is based in part on the participation of as many of our men as possible and

by having a wide variety of people. Also, heart conditions are not only present in older people. Young people may have a heart condition that they are not aware of because they feel no symptoms. Early detection and treatment of some conditions is desirable and can lead to better outcomes.

I work out regularly (or have a job that's physically demanding). Will the ZIO Patch stay in place?

As long as the ZIO Patch is not submerged in water, it can withstand exercise and sweating. Sweating may make it more likely to lose adhesiveness, but some participants have had success reattaching it with medical tape or Tegaderm. Even if the ZIO Patch comes off early, it will still provide very detailed data for participants about their heart rhythms during whatever duration it was worn and will help the study.

Can the results be shared with my doctor?

Yes. You will also get a report for your records.

Is there reimbursement for doing these tests?

Participants will be reimbursed \$25 on their WePay cards when they do the ECG, and they will get another \$25 for wearing the ZIO Patch.

I recently had an ECG (heart monitor). Can't you just use those results?

Unfortunately, no. To produce the best results, we need data that has been collected using the same equipment, methods, and standards. All of the MACS clinics across the country are equipped with the same ECG equipment, and all of the staff performing this test are trained to follow the same detailed, standardized methods.



A New Year's Note of Appreciation

The Pitt Men's Study, which is about to enter its 33rd year, is truly amazing. As part of the internationally renowned Multicenter AIDS Cohort Study (MACS), it continues to produce powerful information that positively impacts peoples' lives. It is a testament to the good will and generosity of its men, most of whom have stuck with this research for many years. I want to thank you for your dedication and faith in us. Without you we would not have been able to do this great work or continue in our mission to defeat this epidemic.

We know that there is a burden associated with being an active member of this study. It requires your time, effort and willingness to complete numerous questionnaires on highly personal issues, as well as your willingness to let us poke and prod you with any number of tests and measures. Please know that this is acknowledged and deeply appreciated by me, my staff, and all the MACS investigators at Pitt and across the country.

Recently we have increased this burden by adding electrocardiogram (ECG) and ZIO Patch testing of your heart beat and rhythm. We are preparing to launch a new study soon using echocardiograms that take sonographic pictures of your heart to make sure that the valves and blood flow are normal. We will continue to add other tests in the future including lung function testing starting in April 2017.

We bring on these additional studies with careful forethought and planning - including review and approval by our incredibly dedicated Community Advisory Board - and with the utmost care to keep your personal time and effort as manageable as possible. The new studies are an increasingly important addition to the core work that we have been doing to assess your health since 1984.

These additional tests and questionnaires also affect our staff who tirelessly strive to put these protocols into effect and to collect the data that we need with the least burden on you. Their superb work and partnership with you is an important part of the engine that keeps this study running.

We have worked hard to make an impact on your health and the HIV epidemic. Our illness and death rate dropped remarkably with the

advent of highly active antiretroviral therapy in the mid-1990s. Now that people are living longer with HIV, we need to understand how they age so that we can help them lead longer and healthier lives. We also need to study our HIV negative men, not only to compare them to those who are infected but to address their aging process as well. Your continued participation is critical to these ends.

We had no idea when we began in 1984 that our research study would be ongoing and so important today, more than 30 years later. There is still much work to. The gratitude of all of us at the Pitt Men's Study and all of the people whose lives are positively affected by its work knows no bounds.

You are the heart and soul of this study - only with your help will we succeed in winning this fight against HIV/AIDS in our lifetime.

Best wishes for a prosperous and healthy new year,

Charles Rinaldo, Ph.D., Principal Investigator, for the staff and investigators of the Pitt Men's Study

The Pitt Men's Study

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If you are overdue for an appointment, we welcome you calling us at 412-624-2008 or 1-800-987-1963. If you've already had an appointment since October 1 and opted not to have these new heart tests, they are still available - please call us. The NIH study allows us to offer these heart tests through March 31, 2017.