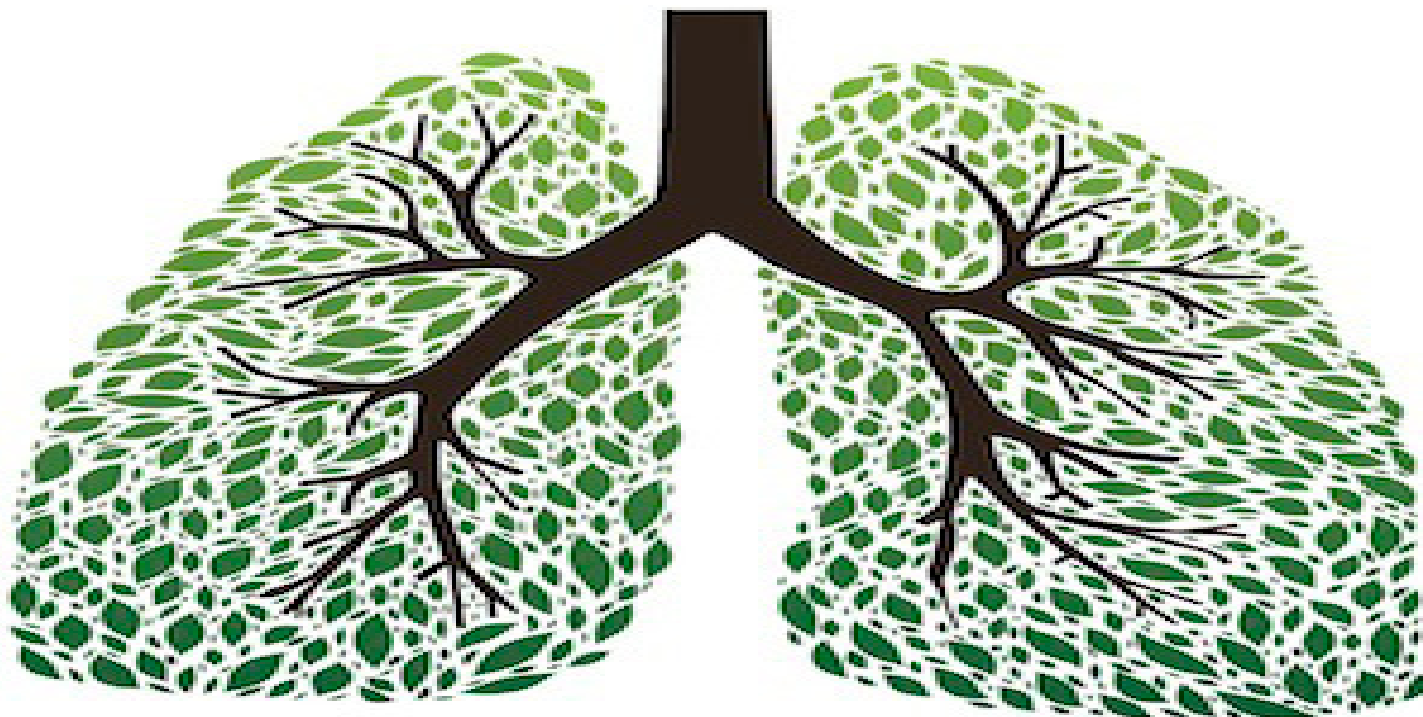


The Pitt Men's Study



BLOW!

Thanks to a whopping amount of funding (think millions of dollars) the MACS is continuing its partnership with the National Heart, Lung, and Blood Institute. At your last visit, you

participated in a new heart study. This newsletter gives you a preview of the “L” in NHLBI and the lung study that we will offer you the chance to participate in this time around.

Inside the Issue

- **Page 2** Lung disease plagued HIV patients in the early days of the epidemic. Learn how that has changed (and how it hasn't) and what the MACS is doing about it.
- **Page 3** Turn here to learn the ins and outs of the new study, its effect on you, and ways to participate.
- **Page 4** Am I done yet? As the MACS adds more testing to your visits, we share our new effort to get you out on time.
- **Page 4** We have a new PA at the clinic, and we can't wait for you to see the ways that she's giving Bill a run for his money as the PMS resident performer.
- **Pages 5-7** Thanks to you, our heart studies were a resounding success. Find what we learned, and how to get involved if you haven't already.
- **Page 8** We know it's a long survey, but we hope you'll flip here to read why we ask all of those questions about aging.

HIV and Lung Disease

In the early days of the HIV epidemic, lung diseases—*pneumocystis* pneumonia, tuberculosis, and Kaposi sarcoma, to name a few—plagued HIV and AIDS patients as their leading cause of mortality. Luckily, these diseases have disappeared with the ART era, and HIV+ people now live normal lives many years after infection. Yet, it seems that HIV+ patients have not yet completely escaped the shadow of lung diseases. A growing body of research shows that long-term HIV and ART therapy is still associated with increased risk for lung disease, mainly COPD.

worse over time—marked mainly by difficulty breathing, coughing, and wheezing. COPD is caused by narrowing of airways and decreased surface area of the small air sacs in the lungs, or alveoli, which slows the intake of oxygen and the export of carbon dioxide. There is no cure for COPD, but treatment and lifestyle changes can slow the progression of the disease and help people to breathe better and stay active.

As part of our new study, we will ask you to complete pulmonary function testing at this visit. Pulmonary function tests (PFTs), include spirom-



Smoking is the main cause of COPD, but HIV infection/ART therapy is associated with increased incidence of COPD *even among groups of people who have never smoked*. To investigate the cause of this, the Pitt Men's Study, as part of the Multicenter AIDS Cohort Study (MACS), has teamed up with the National Heart, Lung, and Blood Institute to launch the largest study of lung function in HIV. The study will attempt to examine the risk factors, biomarkers (blood levels and proteins), and causes of lung disease.

Emphysema (now more commonly referred to as chronic obstructive pulmonary disease or COPD) is a progressive disease—meaning it gets

etry and Carbon Monoxide Diffusion Capacity (DLco). Spirometry is a measure of the volume and flow of air into and out of the lungs, where DLco is a measure of the rate that gases transfer across the lung and into the blood.

Without the help of our participants, studies like this would not be possible. It is because of your effort and dedication that the MACS has changed the world of HIV treatment and continues to be a leader in HIV research. We cannot thank you enough for your efforts to this point, and we hope that you will read on to learn more about how these changes will affect your visit, and how you can help us help you.

PFT FAQ's

What does this study involve?

Namely, this study involves forced spirometry and diffusion capacity for carbon monoxide (DLCO). Forced spirometry measures the flow of air from your lungs; for this testing you will be taking deep breaths and then exhaling as hard and fast as possible. Further, you will conduct this test before and after inhaling albuterol, which will open up your airways. For the DLCO test, you will inhale a very small amount of carbon monoxide (along with a mixture of other gases) then hold your breath for ten seconds. This test measures how well gas flows from the lungs into your blood. We will also have you answer two questionnaires to obtain a better sense of the lung function that is normal for you.

This study does require one additional tube of blood. For those of you who may elect to do this testing on a different day from your usual appointment, the extra tube of blood must be drawn on the same day that you undergo PF testing.

Finally, you will have the option to provide additional samples: a saliva sample, a stool sample, and a tongue scraping. The tongue scraping should not be painful, and the stool sample may either be collected during your visit or at home. Declining to provide any of these other samples will not affect your participation in the PFT study.

How long will it take?

We estimate that the PF testing and additional surveys will take between 45 minutes to 1 hour to complete. Obviously, some participants will finish faster than others will. The amount of time it will take you to complete the testing depends largely your ability to listen well, follow directions, and stay on task. By coming prepared to listen to instructions and respond to feedback, you will help us to serve you and your fellow participants in a timelier manner.

What risks are involved if I participate?

All the procedures involved in this study are routine and involve very low-level risks. However, PF testing does require quite a bit of effort, and you may feel tired afterward. Additionally, some people experience coughs or lightheadedness during testing.

Who can join the study?

This study is open to all MACS participants who come to their appointments between April and October. We determine final eligibility by a short questionnaire conducted on the day of your visit.

How does this benefit me?

As with the cardiac testing we offered at your last appointment, this study will provide information about your health that may be valuable and that we can share with your doctor. Further, you may help us to improve the health of others in the future. Finally, you will be compensated \$75 for your successful completion of testing.

The Pitt Men's Study

P.O. Box 7319, Pittsburgh, PA 15213

(412) 624-2008 (800) 687-1963

<http://pittmensstudy.com/>

Charles R. Rinaldo, PhD
Principal Investigator

Ken Ho, MD
Medical Director

Faster Appointment? Yes, Please!

Many of you have noticed that the MACS has added more and more testing to your visits. Between surveys, longer questionnaires, and more tests, study visits have grown longer. We at the clinic truly cannot express how much gratitude we have for your continued efforts, and your hard work to accommodate these increasing burdens on your energy and time.

With pulmonary function testing adding about an hour to visits in this wave, we have been brainstorming ways to reduce visit time. At the Chicago site of the MACS, they have adopted a system of emailing some of the surveys to participants *before* their visits. Researchers at this site have expressed how well this has worked for them, and how much their participants have appreciated the ability to get some things done ahead of time and then be paid for them when they come in for their visit.

We at the Pitt Men's Study would like to adopt the same strategy for our busier clinic days. We would like to email you both the behavior survey (the sex and drug questions that you do on your own at the clinic) and the aging survey. **Completing both of these surveys ahead of time will save 30-60 minutes at your next appointment.**

We will be trying this strategy on our busier days before considering adopting this method for all of our participants. If we see you on our busy days (namely Saturday's), we will call you a few days before your appointment, asking if you would like to complete these surveys ahead of time. We will also give you instructions about how to do so.

As always, completing these surveys ahead of time (or at all) is not required for your participation in the study. This is just one way we have found to shave some time from your visits. We thank you again for all of your help over the years, and we look forward to seeing you at your next visit!

PMS Welcomes Carling Lellock, PA-C

The PMS clinic hopes you will all join us in welcoming our newest staff member: Carling Lellock, PA-C. Aside from bringing a hard-working and upbeat attitude, Carling has been instrumental in implementing some of the new procedures you may undergo at your next visit.

Carling grew up in the small town of Punxsutawney, PA (and assured all of us that Groundhog day celebrations are over-rated) before moving to the city to attend the University of Pittsburgh. However, Carling's first stint at Pitt lasted just one year; at the end of her freshman year she elected to transfer to Duquesne University's five year entry-level physician assistant program, the first program of its kind in the nation.



While Carling completed her degree to become a PA, she likely would have been a performer in another life. You may notice at your next appointment that Carling rather enjoys speaking in song.

Continued on Page 5

PMS Extends EKG and Heart Monitor Studies

Our first collaboration with the National Heart, Lung and Blood Institute (NHLBI) was a great success, so much so that the study decided to extend offering EKGs and heart monitors for another reporting period (Wave) to men who have not yet done these tests.

Anyone who missed his visit last Wave (October 1, 2016 through March 31, 2017) is eligible to participate in this study. Also, those who were here last Wave and opted out of one or both of these tests is eligible to do them this time around. The tests will be offered until September 30, 2017. Volunteers receive \$25 for the EKG and an additional \$25 for the heart monitor.

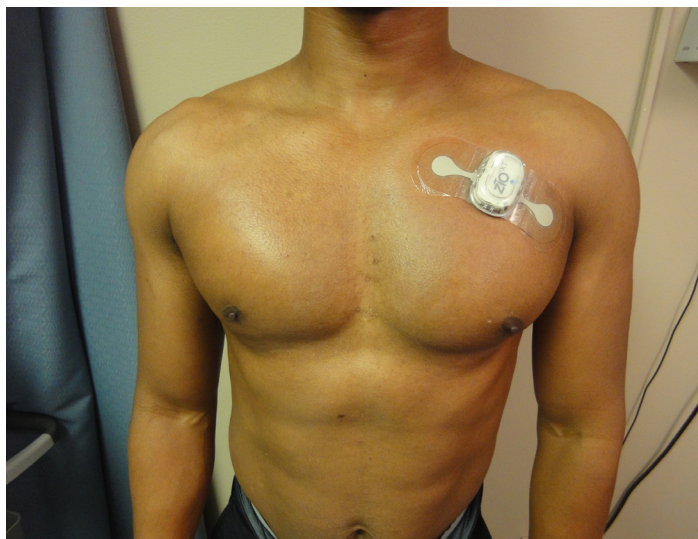


Continued from Page 4

She also boasts talents of professional-level hula hooping and “really fast spelling,” not to mention her infectious personality and high energy.

Carling also brings a wide swath of experience. She began her career in urgent care at Med Express, where she practiced clinically before moving to a corporate position in which travelled the country to help on-board new physicians and mid-level clinicians. From Med Express, Carling moved to the Slippery Rock area to work in endocrinology at Sharon Regional Hospital. Most recently, Carling worked in hepatology at Montefiore Hospital, where she met our other full-time PA, Lisa Graham.

We hope that Carling’s return to Pitt will be much longer than the first (and that we won’t lose her back to Duquesne with the rest of our part-time PAs!). Carling has been a very welcome addition to the clinic; we hope you will all enjoy her as much as we have!



If your last appointment with us was before October 1, 2016, give us a call at 412-624-2008 or 1-800-987-1963 to schedule an appointment and to take advantage of one or both of these tests.

If you were here between October 1, 2016 and March, 31, 2017 but opted out of one or both of these tests, you can still take advantage of them either (1) at your next appointment if it is before October 1, 2017 or (2) by calling 412-624-2008 or 1-800-987-1963 to arrange a special appointment if you’ve already been here since April 1, 2017.

EKG and Heart Monitor Studies a Success

As of the end of our last reporting period, 95% of men seen at the Pitt Men's Study had an EKG as part of their visits and 77% wore a small heart monitor called a ZIO Patch. These numbers compare very favorably with the other MACS sites. If you look at the numbers for all sites, 94% of MACS subjects had an EKG and 72% wore the ZIO Patch. Way to go Pittsburgh!

But there are more important things to brag about. There were a number of significant findings in Pittsburgh as a result of these tests, and some of our men were referred into care and are now on medication or have had pacemakers implanted. Many of these men were asymptomatic.

"I had no idea that my heart was stopping for up to 9.8 seconds at a time."

"I had no idea that my heart was stopping for up to 9.8 seconds at a time," said a 57 y.o. study volunteer. "The only way I found out was by agreeing to wear that heart monitor, and I'm really grateful that I did."

Another participant who wore the ZIO Patch heart monitor said, "It was a really good thing that I did it and found out [that I needed a pacemaker]."

Both the EKG and the ZIO Patch measure electrical impulses from your heart to help determine if your heart is functioning normally. During an EKG electrodes called "leads" are placed on your chest while you lie on an exam table. After the leads are placed, the technician records your heart's electrical activity for a few seconds. The whole process can take as little as ten minutes.

While the EKG records your heart's activity at one moment in time, the ZIO Patch records it 24/7. Therefore, the patch may pick up irregularities that are intermittent and did not occur during

the EKG. The ZIO Patch is small and is held on your chest by an adhesive. One can wear it for up to 14 days, but some of our subjects needed to remove it sooner. Even if worn for only a few days, we get important data and volunteers may learn something useful about their health.

If you are a MACS volunteer and missed the opportunity to participate in these tests, there's still time. See the next article about the extension of this heart study through September 1, 2017.

As the Pitt Men's Study and the MACS continue to move into the era of monitoring the aging process of our men, we will offer more additional tests like the EKG and ZIO Patch. We are currently offering pulmonary function testing and may offer echocardiograms in the near future. We hope that you'll continue to participate in the Pitt Men's Study and enroll in as many of these extra tests as you can. Together we can make a better future for all of us.

"The most important factor in the success of the MACS is the outstanding support of you, our volunteers, for as long as an extraordinary, astounding 30 years," said Dr. Charles R. Rinaldo, Ph.D., principal investigator of the Pitt Men's Study. "Recently, our new ECG and heart monitor studies have yielded amazing results, most importantly showing previously undetected, serious heart disorders in some of our volunteers."

"The MACS is evolving into a study that is uniquely positioned to provide crucial data not only about HIV but also diseases that commonly impact people living with HIV such as heart disease, lung disease, liver disease, and cancer. This contribution will hopefully lead to discoveries that will help all people (HIV positive and HIV negative) lead longer and healthier lives."

-Dr. Ken Ho, PMS Medical Director

DIVERSITY – IT’S WHAT MAKES THE PITT MEN’S STUDY TICK

By Bill Buchanan

You’ve probably noticed that we do a lot of extra studies any more: CAT scans of the heart, kidney studies, MRIs of the brain, and more. Such things have become an increasingly important part of what we do, and we appreciate you taking the time and effort to do them.

But I thought the Pitt Men’s Study was an HIV research project. Why all this interest in my heart, brain, kidneys and such? Don’t you study HIV anymore?

We still do many extensive and cutting edge studies of HIV with the hope that what we learn will lead to better treatments, a preventative vaccine, and a cure. We’ll never stop doing that until this virus is defeated. And what we learn may also have an impact on other virus-driven diseases like cancer and autoimmune disorders like rheumatoid arthritis, inflammatory bowel disease, multiple sclerosis, and lupus.

But we have a very good reason to look at the overall health of our volunteers - as our cohort ages we have the opportunity to study how aging affects men’s health in a way that other studies can’t because of the vast wealth of data and samples we have collected since 1984. And we need to study the aging process on all our men – young and old, positive and negative, whatever racial or ethnic background, sexually active or inactive, newer recruits or “old-timers” like me. Studying the vast diversity of men in our study gives us a rich and detailed look into men’s health, a look that will hopefully generate a lot of great ideas on how to keep us all healthier longer.

In particular, with the advent of effective therapies against HIV we entered an era in which infected men could expect to live a more or less normal life span. However, we now know that either the virus or the medications used to control it (and, more than likely, a combination of the two) affect men’s cardiovascular systems, kidney function, breathing, thinking and more. By studying all of our men, both HIV-infected and HIV-uninfected, we can parse out these effects and hopefully make some significant findings that will benefit everyone’s health.

“The most important factor in the success of the MACS is the outstanding support of you, our volunteers, for as long as an extraordinary, astounding 30 years.”

*-Dr. Charles Rinaldo Jr., Pitt Men’s Study
Principal Investigator*

As Dr. Rinaldo, our principal investigator, said elsewhere in this issue, “Recently, our new ECG and heart monitor studies have yielded amazing results, most

importantly showing previously undetected, serious heart disorders in some of our volunteers.

We have an amazing opportunity to learn so much of such great value for so many. And we can’t do it without YOU. As Dr. Rinaldo also said earlier, “The most important factor in the success of the MACS is the outstanding support of you, our volunteers, for as long as an extraordinary astounding 30 years.”

Thanks for keeping your appointments and doing those extra studies when we ask. And if you haven’t been here in a while, give us a call at 412-624-2008 or 1-800-987-1963. We’d love to find a way to keep you active in the study in some way, large or small. Every bit helps – and the clock is ticking.

Understanding Patterns of Healthy Aging in Gay and Bisexual Men

HIV/AIDS continues to have an enormous effect on the lives of older gay and bisexual men.

A remarkable milestone in the fight against AIDS occurred in 2016, when over half of all people living with HIV in the United States were over the age of fifty. This means that HIV has now become a disease of aging!

Although this wonderful news is something to be celebrated, as usual with HIV, it also means that we have new challenges for which we did not have time to prepare. Because no one thought that it would be possible at the start of this epidemic that HIV could become a problem faced by men in later life, no one thought to study how best to take care of people affected by or infected with HIV as they age. We are pledging to do so with this new study.

If you choose to participate in this sub-study you will probably notice that the questions that we are asking you are very different from those that you are used to in the MACS. The new questions we want to ask you will identify and measure your strengths and the resources that you are tapping into as you age. To the best of our knowledge, this is the first research project to do so.

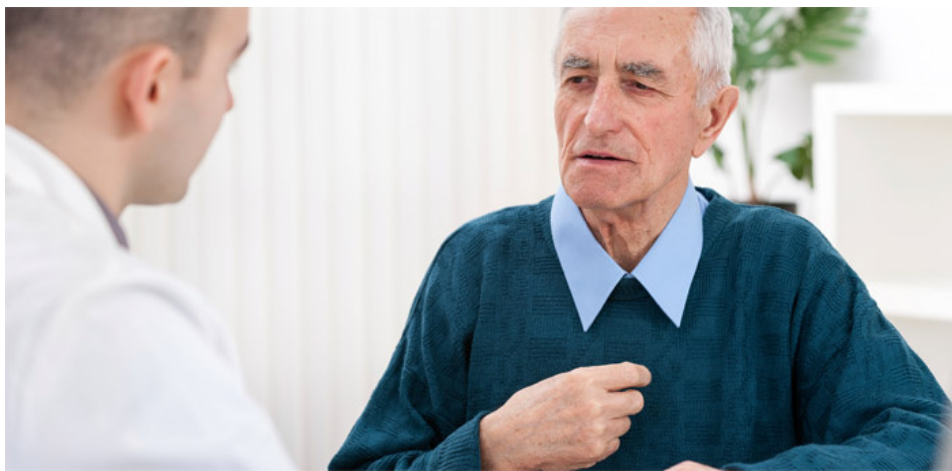
We hope to learn a bit about how you have struggled and overcome adversity, how you have maintained your physical health over the years, and how you and the people close to you have

maintained your mental health. Perhaps most importantly, we want to see how you are not simply surviving life with HIV but living life, to the fullest extent of your ability.

We encourage you to participate in this study. The men in the MACS are the experts that know more about dealing with HIV/AIDS, about aging and about aging successfully than any other group of people in the world. You are the real

experts and we hope that by sharing your experiences with us, that the lessons that you teach us will benefit future generations of aging gay/bisexual men.

To learn more about this research study see either Dan Rzewnicki or Bill Buchanan, your clinic coordinator, at your next visit. You may also contact Ron Stall (rstall@pitt.edu) the Principal Investigator of the study.



MULTICENTER AIDS COHORT STUDY

M**C****S**