Fippinger Foundation Reaffirms Partnership, Funds Crucial Nicotine “Patch” Study

Continuing a longstanding partnership with Women’s Health Research at Yale, The Grace J. Fippinger Foundation is providing new support for a much needed study to determine whether transdermal nicotine replacement, the “patch,” works as well in smoking cessation for women compared to men.

This is a critical question in women’s health. Smoking is the leading preventable cause of illness and death, and the patch is the most common smoking cessation aid used in the United States. Yet most studies of this therapy have not examined outcomes by gender, and the few studies that have analyzed outcomes by gender show lower rates of quitting success for women.

“The mixed evidence has become a persistent source of controversy in clinical care, and the resolution of this issue will directly inform public health policy. Thanks to the Fippinger Foundation’s renewed support, Women’s Health Research at Yale will be able to finally determine smoking cessation outcomes with the patch for women versus men,” said Dr. Sherry McKee, Associate Professor of Psychiatry and Director of the Yale Specialized Center of Research on gender-sensitive treatments for tobacco dependence.

This is the foundation’s fifth grant to our Center since our partnership began in 2005 with a grant for operating support for research and public outreach. Other grants have supported important pilot studies to begin:

- exploring whether there are gender differences in military veterans’ readjustment to civilian life – helping secure U.S. Department of Veterans Affairs funding for a national study by the VA and WHRY.
- discovering the particular way that diet-induced obesity begins in women, first steps to explain why women are at higher risk for disease when overeating leads to obesity.
- evaluating a new approach to treating substance abuse in patients with co-occurring trauma, expected to be more effective in women but beneficial to men and women.

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Women’s Health Research at Yale generates research findings that transform the scientific community’s understanding of women’s health, answer important questions, and advance knowledge to improve well-being for all.

To learn more, visit our website:

➤ www.yalewhr.org

e-mail us:

➤ WHResearch@yale.edu

and join us on social media:
JOIN THE SOCIETY OF FRIENDS

Consider a donation to Women’s Health Research at Yale in celebration of a birthday, a special occasion, or to honor someone in your life.

Our Society of Friends ensures the future of Women’s Health Research at Yale.

Gifts are welcome at all levels.

To make an online gift visit www.yalewhr.org or mail your gift to Women’s Health Research at Yale

Educational and outreach activities are made possible through the generous support of

The Community Foundation for Greater New Haven
The Grace J. Fippinger Foundation
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Women’s Health Research at Yale was founded in 1998 with initial funding from The Patrick and Catherine Weldon Donaghue Medical Research Foundation.
Using Video Games to Prevent HIV Infections
WHRY Pilot Study Part of “Serious Games” Trend

Tapping into the enormous popularity of video games among young people, a team of Yale researchers is developing a mobile-based game aimed at reducing HIV infections among a particularly at-risk population: young black women.

This Women’s Health Research at Yale-supported project, called PlayitSafe, is part of a new wave of video games called “serious games.” These games are designed to be fun to play while disseminating information to address major challenges like climate change, war, obesity and disease prevention.

In our case, the message involves the high-priority public health goal of reducing and preventing transmission of the human immunodeficiency virus (HIV) and other sexually transmitted infections (STI) among black women ages 18 to 24.

According to the U.S. Centers for Disease Control and Prevention, after men who have sex with men, young African-American women have the next highest rate of acquiring new HIV infections and STI.

It is not that young black women engage in risky behavior more than young women in general. In fact, even though the levels of risk behaviors (unprotected sex, not testing for HIV, and multiple partners) among young black women are lower or comparable to the levels reported for women overall, young black women still face a higher risk of HIV infection, according to Kimberly Hieftje, Ph.D., Associate Research Scientist in Medicine and Co-Principal Investigator on this WHRY-funded project.

The risk is higher for young black women because HIV is more prevalent in their communities, Hieftje said. With HIV infection rates higher than in the general population, very few or even one encounter involving unprotected sex can more often result in HIV infection for a young black woman than for other young women, according to Hieftje.

“So it’s not behavior that’s the issue – it’s the environment. A lot of young black women, just like young women in general, assume their partners are monogamous. But living in an environment in which HIV prevalence is high, this assumption can be more dangerous,” Hieftje said.

“The whole idea behind creating the video game is empowerment – for women to know the risk, to ask their partner to be tested for HIV, and to protect themselves by insisting on condom use,” she said.

The video game project is funded through a 2013 WHRY Pilot Project Program grant that teams Hieftje with Lynn Fiellin, M.D., Associate Professor of Medicine.

Hieftje, an avid video game player, earned her doctorate in health behavior at Indiana University in 2009 and came to Yale to conduct research on promoting healthy behaviors, with an emphasis on electronic media. Fiellin earned her medical degree from Yale in 1996 and has been an HIV clinician ever since. Early on, she developed a research focus on treatments for substance use disorders, as the use and injection of illicit drugs is a major risk factor for HIV infection.

Fiellin is the founder and Director of Yale’s play2PREVENT initiative and Hieftje is a prominent member of this interdisciplinary laboratory. It brings together health scientists, community leaders, educators and video game technologists to develop

(Continued on page 4)
video games focused on advancing the health, well-being and social intelligence of children, teens and young adults.

The play2PREVENT team includes industry leaders such as Ben Sawyer. He is co-founder of the Serious Games Initiative, a federally sponsored project, and a founder of Digitalmill, a video game consulting firm in Portland, Maine, that is among the leading proponents of serious games. Sawyer originated the Games for Health Conference, an annual event supported by the Robert Wood Johnson Foundation, drawing the best minds in game development and health care to advance game technologies for improving health and the delivery of care. Fiellin also regularly consults with Alex Seropian, a video game developer who co-founded the mobile game company Industrial Toys and is one of the initial founders of Bungie Software Products Corporation, which developed the hugely popular Marathon, Myth and Halo video game series.

Before obtaining the WHRY grant, Fiellin and Hieftje began collaborating in 2009 on development of an initial video game, aimed at teen girls and boys ages 11 to 14, to reduce risk behaviors associated with sex, alcohol and drugs that may lead to HIV and other sexually transmitted infections.

This iPad-based video game, called PlayForward: Elm City Stories, lets players create their own virtual characters, or avatars. The game is meant to be played as either a girl or boy character, and is designed to be gender-sensitive. As the game progresses, the character goes through life and faces a series of challenges he or she must overcome, making choices with risks and benefits. These risks and benefits are shown to the player, and the character experiences the consequences and risks of the choices. Having gained this knowledge, the player can choose to take a different path, with a different result.

Initial Game Now in Clinical Trial

The goal in making this game both informative and appealing to teens was to create interactive narratives about living a healthy life. So the game is more about recognizing risk than about HIV.

Hundreds of teenagers from New Haven, Hamden and Bridgeport are now enrolled in a clinical trial to test the game’s effects on decision-making concerning risks. This is the same kind of rigorous testing that must be conducted before a new medication can be approved. If the test shows the game can increase healthy decision-making among teens, the research team plans to make it available for use in schools nationwide.

Early on, Fiellin and Hieftje realized that the research that went into developing the teen game lent itself to creating a game aimed at young black women. They recognized, however, that they could not simply tinker with the teen game to make a version appealing to young black women. It had to be a whole new design. “A 24-year-old woman is very different from a 14-year-old boy,” Fiellin said.

Input of Young Black Women is Key

To understand the differing needs and perspectives, the investigators formed partnerships with the New Haven Family Alliance and the University of Bridgeport to recruit young black women interested in providing input to guide the development of the video game. They held two focus group meetings in New Haven and one in Bridgeport.

The young black women in the focus groups play a major role in steering the research team’s

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development of the game.

“We’re really building this intervention with their eye,” Hieftje said. “It has to ring true, or no one will play the game.”

Going into the project, the investigators figured they would create a video game for use on Facebook, the online social network, on a computer. The young women in the focus groups nixed that idea immediately. Facebook, the women told the investigators, is good for staying in touch with family and people from the past. But they said it would not be a good option for this video game.

The women in the focus groups – representative of the intended audience – include married women, working mothers, single women and students, all with demanding schedules. The game, the women said, had to allow for quick play – 3 to 4 minutes – preferably on a mobile device while on a break.

“We had to rethink how we were going to make this game,” Hieftje said, adding that the team is now considering Instagram, the free, online photo/video sharing social network platform, as the vehicle for the video game.

Working with the women in the focus groups, team members created paper prototypes – combining elements of card and board games – in which women create characters and navigate challenges that mirror their social situations.

WHRY Support Vital to Game’s Development

The investigators plan a second round of focus group meetings to refine the concept before creating a working paper prototype. With the prototype completed and play-tested, Fiellin and Heiftje plan to seek a much larger grant from the National Institutes of Health this fall to develop the digital version of the video game. Once the game is developed, the team will recruit young black women for a clinical trial of the game, followed by the game’s introduction to the intended population.

“The NIH, the Robert Wood Johnson Foundation, the Gates Foundation, they’re all interested in this game technology for public health. But they really need to see pilot data,” Fiellin said. “That’s why this Women’s Health Research at Yale project is such an incredible opportunity for us to create something that will really move this along.

“This allows us to bring a first form of a product to funders,” she said. “This is really important pilot work.”

HIV Among African-American Women

- Black youth represent more than half (57 percent) of all new HIV infections among young people ages 13 to 24—underscoring the need to reach a new generation with effective HIV prevention messages.
- Young black women are more affected by HIV than young women of other races.
- The rate of new infections among young black females ages 13 to 24 is six times that of young Hispanic females, and 20 times that of young white females.
- Comparing 2008 to 2010, new HIV infections among black women decreased 21 percent, however, black women account for 13 percent of all new HIV infections and the majority (64 percent) of all new infections among women overall.

Source: U.S. Centers for Disease Control and Prevention, February 2014 Fact Sheets
A Yale Undergraduate Asks the Question: 

Does WHRY Do More than Research?

Monique Arnold, Yale College Class of 2015 and WHRY’s communications intern, turns the tables on our communications coordinator, Dan Jones, to inquire about his observations on our Center’s four key initiatives.

Q: Let me get the obvious question out of the way: Why does the Center focus on women’s health and gender differences rather than just health?

A: Great question. Across the entire spectrum of health conditions, there are differences in how women and men experience disease. These differences can be in risk, onset, prevalence and/or response to treatment. And we’ve just begun to scratch the surface of uncovering gender differences and finding out how and when they affect health outcomes. I frequently see surprise – even shock – when I explain that, historically, women often have not been included in clinical trials and studied adequately. The fact that this troubles many of the people I meet in the course of my work is a good sign – indicating that the public supports women’s health research and embraces the need to explore gender differences in research.

Q: What’s the typical reaction when someone hears that you coordinate WHRY’s communications? Does it seem most people know what we do?

A: Most people in the general public who I meet – especially women, but men too – are genuinely interested in what we do. They usually want to know what the latest findings say about a particular health concern – whether it’s breast cancer, or diet and its relationship to heart disease, or hormones and memory – a whole range of topics. I often emphasize that our work doesn’t end with the research we do. We initiate and fund research, and then translate findings into practical benefits for improving health and healthcare, plus we have a strong commitment to training new generations of women’s health researchers, and connecting with the community through educational outreach.

Q: WHRY’s pivotal research support method is the Pilot Project Program. How does this fit into the Center’s strategic initiatives?

A: Through the Pilot Project Program we provide “seed” funding to Yale researchers to launch highly inventive studies on a whole range of health concerns, some specific to or more prevalent in women, and others affecting both genders, but with differences between genders. When scientists apply for a large research grant from the National Institutes of Health or other funders, they have to have feasibility data showing their project will lead to a health benefit. For the projects we fund, the feasibility data doesn’t exist yet. Our funding allows investigators to generate preliminary findings they can use to obtain larger grants to further their work.

WHRY Investigators:
- Were awarded – more than $4.5 million for pilot studies
- Have obtained – more than $52 million in external grants
- Return on investment – nearly 1,200 percent

The incredible success of this program means the generation of enormous new knowledge to tackle women’s health challenges and improve health for women and men.

(Continued on page 7)
A: I am constantly reminding myself to emphasize that our pilot studies represent only one of our four strategic initiatives to advance women’s health and gender-specific medicine. We have three other equally important strategic initiatives but they are sometimes overlooked.

Strategic Initiatives
- Collaborating through Interdisciplinary Research Cores
- Sharing information with the community
- Training new women’s health researchers

Q: How are WHRY’s interdisciplinary research cores different from the pilot projects?

A: While the Pilot Project Program funds studies on a variety of particularly important health concerns and gender differences, our Research Cores bring together Yale’s leading scientists to develop research programs promoting interdisciplinary and inter-institutional collaborations. Working as a team, these collaborators explore emerging questions and develop new prevention and treatment strategies, focusing on gender differences and using gender-specific approaches. Currently, our two cores focus on women and addictive behaviors, and women and trauma.

Q: Why these areas, specifically?

A: Addictive behaviors represent an extremely important area of women’s health for several reasons. Historically, addiction research has focused primarily on men. However, increasing addictive behaviors in women, such as the recent increase in misuse of prescription painkillers, require that we understand gender-specific aspects of these behaviors. With smoking, for example, women are more adversely affected than men, and it’s harder for women than men to quit. These kinds of differences matter, and our cores generate gender-sensitive prevention and treatment research to improve outcomes for women.

The same can be said for research focused on women and trauma. Women who experience trauma are more likely than men to develop Post-Traumatic Stress Disorder (PTSD) and for a longer time. Up to now, research on violence and other trauma affecting girls and women focused mostly on domestic violence and abuse in childhood, while trauma in men has been studied primarily in relation to war experiences. This is changing, as unprecedented numbers of American military women have returned from combat in Afghanistan and Iraq. We are collaborating with the U.S. Department of Veterans Affairs on a nationwide study involving these veterans — to determine whether there are gender differences in how female and male combat veterans readjust to civilian life. Our women and trauma core studies the disabling effects of traumatic experiences by gender across a variety of underlying causes.

Q: Another of the strategic initiatives is connecting with the community through the sharing of new research findings and health information through educational outreach. Why and how does the Center do this?

A: In communications, it is essential to anticipate and stay ahead of change, and serve a diverse audience. By that I mean our Center provides information through all sorts of digital media, and publishes a newsletter you can hold or read online.

WHRY communicates via
- Website, Eblasts & Newsletter
- Facebook, Twitter, YouTube,
- Yale Media (YaleNews, press releases)
- External Media (Newspaper, TV, Radio)

(Continued on page 8)
We think it is important to use multiple forms of media to reach all age groups, women and men, scientists and lay people – all those interested in learning about what we do and supporting our work, whether they are right here in New Haven, or across the country, or on the other side of the world.

Q: You’ve just launched a redesigned website with a new Heart Health Q & A. Can you tell me more about this feature?

A: Yes, it’s a website feature that provides useful information about cardiovascular health related to the latest news on research in this high-priority area. Cardiovascular disease is the biggest cause of mortality among women and men.

The Q & A is a collaborative effort by our Center and the OhioHealth Healthcare System, a great example of our Center’s inter-institutional collaborations. In this new feature, we answer very timely questions about heart health and what you eat, or cholesterol-lowering medications, or how quickly your cardiovascular health improves after quitting smoking—whatever arises as we survey the latest scientific news about cardiovascular health. The latest installment is available on our website homepage. We’re already receiving great feedback.

Q: How is the health information that WHRY provides different from what you get from mainstream media?

A: News reports usually take a snapshot approach to the latest research finding. Our approach is to go beyond explaining the importance of the research to tell a story about how the scientists found what they did, the origins of their hypotheses, and the direction in which the finding might be leading them—as anticipated, or, as in many cases in research, in unexpected directions. Our belief is that those who understand how scientific research unfolds will be better equipped to filter information about health research and make more informed decisions about their own health. Moreover, people who can sort through complicated, sometimes confusing scientific information are more likely to support research that leads to practical improvements in health and health care—and that’s what we are all about.

Q: The final strategic initiative is training the next generation of researchers. Why is this necessary? What is the goal?

A: Two decades might seem like a long time. That’s how long it has been since a federal requirement to consider the inclusion of women in clinical trials went into effect. The modern movement to study women’s health and gender differences got started in the 1990s. But scientific research typically moves at a very slow pace—and we are still at the beginning of discovering and understanding research findings involving women’s health and gender differences, and translating such findings into improved health and health care. To borrow a phrase that our Director, Dr. Mazure, expresses in one of our videos, “You can’t see the whole picture with one eye closed.”

We’re not going to really advance medical care or policy with respect to women’s health—or men’s health—if we don’t look for and understand gender differences in disease and treatments. It’s very clear that, as a nation, we will need new generations of biomedical researchers who will routinely consider gender in the design and conduct of their investigations. We’re mentoring promising researchers who will do just that in their careers. (Continued on page 9)
Supporting Tech-Savvy Research Can Save Women’s Lives

How many of us know a young person who loves to play video games? Everyone, right! So why not use this passion for public good? That’s exactly what a team of WHRY-funded investigators are doing – developing a video game for preventing the spread of Human Immunodeficiency Virus (HIV) among young black women – a population that is particularly at risk for infection. You can find out more about our Pilot Project Program research to develop this video game in the article that begins on page 3.

This kind of highly innovative science and technology is the norm for our Center, and you can be a part of it. In fact, we are asking you to join us right now – so we can meet our 2013 Annual Appeal goal.

For the third consecutive year, a generous Friend of our Center who wants to remain anonymous will match your donations dollar for dollar – up to $10,000 – as incentive to get us to our goal. The closer we get to the June 30 end of our fiscal year, the more important each gift becomes.

Please give now to enable scientists like Drs. Fiellin and Hieftje, who are creating the video game, to improve the lives of the girls and women we know and love – in our families, communities – everywhere.

Every gift counts.

Thank you for all of your support!

Reminder to Yale College Alumni

Your Class Gifts Can be Designated to Women's Health Research at Yale

WHRY is a program within Yale University School of Medicine. Yale University is a 501(c)(3) non-profit organization.

For information on any aspect of making a gift, please contact Ramona Gregg. ramona.gregg@yale.edu • (203) 764-6600
Faculty News...

Samuel Ball Named Head of National Center on Addiction and Substance Abuse

New Yale Research & Policy Program Planned

Samuel A. Ball, Ph.D., Professor of Psychiatry and Director of Research for our Yale junior faculty Scholars program, has been named president and chief executive of The National Center on Addiction and Substance Abuse (CASA).

A nationally known expert on addiction, Dr. Ball will oversee an expanded effort by CASA to study all addictions and addictive behaviors. CASA was established in 1992 at Columbia University. Ball will maintain his faculty affiliation with Yale, and will establish a CASA program at Yale for research and policy development focused on substance use and behavioral addictions (including gambling, food, sex, and the internet). Women’s Health Research at Yale will collaborate with the Yale CASA program on research related to gender.

As research director of our Yale Scholars program, Building Interdisciplinary Research Careers in Women’s Health (BIRCWH), he works closely with our Director, Dr. Carolyn M. Mazure, in training and mentoring junior faculty scholars for careers conducting interdisciplinary research on addictive behaviors in women, and developing new gender-specific prevention and treatment strategies. Dr. Mazure is the Principal Investigator for the BIRCWH Scholar program, funded by the National Institutes of Health Office of Research on Women’s Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism.

Dr. Ball also serves as assistant chair and director of faculty development programs for Yale’s Department of Psychiatry.

Council News...

YaleWomen Blogs About WHRY
Filling the Gender Gap in Research

As Chair of YaleWomen, WHRY advisory Council member Ellen Gibson McGinnis, J.D., is connected to a global network of alumnae interested in the advancement of women. Recently, she began blogging on the YaleWomen website, focusing on the “gender gap” in various areas of society. In a March 4 blog post, she pointed to a Bloomberg news article on a report that reinforces what our center has been saying for 16 years about the need to pay attention to gender in medical research. Ellen began her post with this excerpt from the article: “Scientists continue to neglect gender in medical research, endangering women’s health by focusing on males in studies that shape the treatment of disease, a report found.”

She explained how she was “stunned” several years ago when she first heard our Director talk about the historical underrepresentation of women in clinical trials, and our Center’s mission. Ellen soon joined our advisory Council. “It’s hard to overstate the importance of [WHRY’s] work, and the other day we got more evidence that it is still needed,” Ellen concluded.

Press Notes...

Message on Gender Differences Gains Traction in Mainstream & Trade News

It’s great to see the media—including a premier broadcast news program and the pharmaceutical trade press—acknowledge that gender differences matter and deserve much more attention. Council member Ellen Gibson McGinnis’ blog post came after CBS’ “60 Minutes” aired a segment February 9, “Sex Matters: Drugs Can Affect Sexes Differently,” focusing on gender differences, starting with drug development. “And drugs are just the
beginning,” reported correspondent Lesley Stahl, adding that gender differences have been found in pain receptors, liver enzymes, even the wiring of the brain. “More and more,” Stahl said, “scientists are realizing that the differences are dangerously understudied.”

Then, in early March, a global news service of the pharmaceutical industry published an article, “It’s a Man’s Man’s Man’s World—What’s Needed for Better CVD Drugs for Women,” making a case for the need to include more women in cardiovascular drug trials and analyze results by gender.

“We have to continue building awareness and be mindful of gender as we test pharmacologic drugs,” the article reported.

FDA Seeks Input on Addressing Sex Differences in Drug, Biologics & Device Research

One of Dr. Pamela Scott’s primary goals as Director of Research and Development in the U.S. Food and Drug Administration’s Office of Women’s Health is to advocate for the inclusion of women in clinical trials of drugs, biologics, and medical devices, and for analyses of the results by sex. With a staff of three and no regulatory authority, she has a difficult task.

Progress has been made since the FDA issued a guidance encouraging the study and evaluation of sex differences in 1993, and issued regulations requiring analyses for sex difference in drug approvals in 1998. But the FDA is now seeking input on how it can help ensure more progress, especially in the collection, analysis and communication of data on sex differences discovered in clinical trials.

Scott outlined FDA’s role in addressing sex differences in research on drugs and devices to a packed audience on April 10 as part of our BIRCWH/SCOR Women’s Health Seminar Series.

The FDA held a public hearing April 1 on a recent status report on the collection, analysis, and availability of demographic subgroup data in applications for medical product approvals. The agency will accept comments until May 16, and the input will inform an FDA action plan, expected in August, to identify further steps to assure FDA-regulated products are tested in ways that serve women and men across the demographic spectrum, including elderly patients and patients with various racial and ethnic backgrounds.

Interest is increasing in Congress. The Ranking Members of the House Energy & Commerce and Health Subcommittee asked the Chairs of those committees to hold a hearing to examine progress on the inclusion of women and minorities in health research. “Health disparities between men and women persist – in conditions such as depression and cardiovascular disease,” wrote Congressmen Henry Waxman of California and Frank Pallone Jr. of New Jersey. “And there are still many conditions that disproportionately affect minority populations, such as diabetes and HIV/AIDS.”

Connecting with the Newest Generation: Fairfield 6th-grader Wins Women’s History Essay Award

As Fairfield, Conn., 6th-grader Oliver Kleinberg puts it, “I have really enjoyed learning about [WHRY Director] Carolyn M. Mazure and the impact she has had on women’s health issues.” He was among this year’s winners of an annual 6th-grade National Women’s History Month essay contest.

Students submit essays on “Important Women in Connecticut’s History and How Their Contributions to the State and Nation Affect Me.” Parents Liz and Howie Kleinberg encouraged their son to profile someone he was not familiar with, and they were thrilled with his choice. “To say you’ve had an impact on Oliver is a tremendous understatement,” Howie Kleinberg wrote to Dr. Mazure.

Oliver’s essay recounted Dr. Mazure’s establishment of WHRY. “As a boy,” he wrote, “I never thought about specific diseases that affect women.” Because of Dr. Mazure’s work, “women around the world should feel much better knowing that people are putting so much work and time” into advancing women’s health. Congratulations Oliver – WHRY’s newest and youngest ambassador!
Heart Health Q&A
Providing useful information on the latest cardiovascular health news.

www.yalewhr.org