What's New in the HPTN?

A Message from New HPTN Network Leadership Drs. El Sadr and Cohen

It is an exciting time for the HIV Prevention Trials Network and for HIV prevention in general. As we look to the future, we note a robust current agenda focused on some of the most critical research questions of our day. These ongoing studies will be the foundation that will allow us to focus a future agenda with an emphasis on pre-exposure prophylaxis (PrEP) and integrated strategies. In terms of PrEP, the HPTN has a strong portfolio; HPTN 066 will provide results on the pharmacokinetics of different regimens of Truvada and will inform the feasibility of an intermittent dosing regimen. HPTN 067 is assessing pharmacokinetic and behavioral issues associated with intermittent PrEP and HPTN 069 is examining newer antiretroviral agents for PrEP.

In terms of integrated strategies, the HPTN is currently conducting groundbreaking research in the U.S. and internationally. HPTN 065 (Test, Link, and Care-Plus or TLC-Plus) is an ongoing study in the U.S. which is evaluating the feasibility and effectiveness of a combination of interventions for prevention of HIV. HPTN 071 (PopART) is in development and will examine the impact of combination prevention strategy on HIV incidence at a population level. The study will be conducted in Zambia and South Africa. HPTN 068 is evaluating a structural intervention of cash transfers on prevention of HIV acquisition in school girls in South Africa and if found effective, will help inform future integrated prevention interventions in young women.

None of this would have been possible without the remarkable leadership provided by Drs. Sten Vermund and Quarraisha Abdool Karim and the many dedicated Network investigators. We are also thankful for the enormous commitment and dedication of the Operations Center, Network Laboratory, Statistical and Data Management Center, and the hard work of Unit and Site

Making Progress

HPTN at AIDS 2012

The HPTN is proud to announce that it has 19 posters and 5 oral presentations accepted at the 19th International Aids Conference in Washington, DC. A complete list of abstracts can be found on our website: HPTN Abstracts Accepted at XIX International Aids Conference.

HPTN will also host a satellite session on Sunday, July 22: Health Disparities, Hurdles and Hope: Ending the HIV Epidemic in the U.S. The session will explore the current landscape of the U.S. HIV epidemic, challenges in reaching and engaging at risk populations, exciting new evidence supporting new prevention interventions and research efforts that seek a better understanding of the epidemic and identifying new effective prevention interventions.

- Why the Domestic HIV Agenda Matters
- HIV and US Women: Understanding the Challenges
- Black MSM in the US: Addressing the Social and Cultural Contexts
- Looking Ahead: A Commitment to Fighting the Epidemic Panel Session

Wafaa El Sadr and Kenneth Mayer will serve as Co-Chairs for the
leaders. Most importantly, the input and support provided by the HPTN community advisory groups has been fundamental for our success. We look forward to working with all of you as we continue our journey towards an AIDS-free generation.

Wafaa El Sadr, Principal Investigator
Myron Cohen, Principal Investigator

The HPTN is pleased to announce that as of June 1, 2012, Drs. Wafaa El-Sadr and Myron Cohen assumed responsibility for the leadership of the Network. Dr. El-Sadr is professor of epidemiology and medicine at Columbia University’s Mailman School of Public Health and College of Physicians and Surgeons and Director of the International Center for AIDS Care and Treatment Programs (ICAP). Dr. Cohen is Associate Vice Chancellor for Global Health and Director of the Institute of Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill.

A Message from Outgoing Leadership

Six years as HPTN Principal Investigators, Drs. Sten Vermund and Quarraisha Abdool Karim have logged thousands of miles, attended numerous conferences and participated in hundreds of meetings and conference calls. Under their leadership great strides have been made in HIV prevention research with two large-scale HPTN studies. HPTN 052 demonstrated that treating an HIV-infected individual with antiretroviral therapy (ART) reduces the risk of sexual transmission of HIV to an uninfected partner by 96 percent. The landmark study was recognized by Science as the most important scientific breakthrough of 2011. Results from HPTN 043 (Project Accept) showed that adding community mobilization and support services to a mobile HIV counseling and testing program can improve community testing rates.

Drs. Vermund (SV) and Abdool Karim (QAK) share some of their career highlights:

What have you enjoyed about your tenure at HPTN?

QAK: Working with an outstanding team of dedicated, caring and committed colleagues and friends at the leadership and site level that always remain optimistic and enthusiastic about prevention science.

SV: When Quarraisha and I started our tenure in 2006, only five HPTN studies were ongoing (HPTN 037, 039, 043, 052, and 058). It seemed that momentum for U.S. domestic trials had diminished. Today we have a vibrant network reflecting the hard work, creativity and even lobbying efforts of our talented protocol teams and their leaders. HPTN 043, 052, 062, 063, 067, and 068 are international studies in the field and HPTN 071 is planned. HPTN 061, 064, 065, 066, 067, and 069 are domestic studies in the field or recently completed and HPTN 073 is planned. The vibrancy of the network is what is truly enjoyable.

What do you see as the greatest challenge for HIV prevention?

QAK: Translating the evidence to action that is customized and optimized for different epidemic settings to benefit the most affected populations.

Study Updates

HPTN 065 continues with successful operational execution. The financial incentive (FI) components, which encourage linkage of HIV+ individuals into HIV care and help those on ART to achieve and maintain a suppressed viral load, have completed a year of implementation with another year before the FI intervention ends. The efforts to expand HIV testing in hospital in-patient and emergency departments have been ongoing for a year, with two more years to completion. The prevention for positives component, which uses a computer-delivered counseling intervention designed to decrease risk behavior, is anticipated to begin in the summer of 2012.

As of June 12, 120 participants in Cape Town have enrolled in HPTN 067 (ADAPT), a Phase II study to determine the feasibility of intermittent dosing of Truvada® as pre-exposure prophylaxis (PrEP) to prevent HIV in heterosexual women and in men who have sex with men. A site in Bangkok enrolling men who have sex with men has begun screening for enrollment.

HPTN 071 is under development and will determine the impact of a community-level combination prevention package which includes home-based HIV testing and provision of HIV antiretroviral therapy (ART) to all HIV-positive individuals, regardless of CD4 cell count, on population-level HIV incidence.

HPTN 073 is also under development. It will evaluate oral pre-exposure prophylaxis (PrEP) initiation and adherence among at-risk black men who have sex with men (MSM) in the U.S. by combining a culturally-tailored adherence intervention implemented in local healthcare facilities.

Fem-PrEP Results

Lack of adherence to daily oral Truvada appears to be the cause for the inability to assess its efficacy.
Overcoming real or perceived stigma and discrimination that still prevents many people from knowing their HIV status and the ability to access appropriate prevention and treatment services. Balancing efforts to develop new technologies for HIV prevention while implementing existing tools and ensuring adequate funding to support efforts to stop the epidemic.

**SV:** Combining well-vetted methods for prevention into one coherent package of activities could, we believe, truly make a notable mark on epidemic trends. The challenge is not merely the efficient design of such studies (and later programs), but the mobilization of the resources to test this approach.

**What has been the biggest change over your years of work and research on HIV prevention?**

**QAK:** The change in the discourse in our response to the epidemic from helplessness to new hope in HIV prevention catalyzed by the prevention potential of antiretrovirals to stop the epidemic.

**SV:** The pessimism of the past decade has changed 180 degrees. We now recognize that tools such as male circumcision, antiretrovirals for prevention and behavioral efforts integrated with biomedical approaches can truly make a difference in the epidemic. We still have challenges in stigma, program expansion, quality of care, and political ennu to contend with, but the tools are now here to truly make a difference.

**Tell us about a person who taught you a lesson about the HIV epidemic.**

**QAK:** The late Dr. Reuben Sher, a South African immunologist who I was working with on leprosy when the first cases of AIDS were reported in the U.S. He immediately set up a health service for gay men in South Africa even though we had no idea what AIDS was or its cause. At a time when homosexuality was stigmatized Dr. Sher exemplified and embodied for me the importance of courage, compassion and respect that all health care workers and researchers should practice.

**SV:** My exposure to the epidemic began in New York City where I was influenced by the Montefiore Medical Center group of Drs. Ernie Drucker, Karen Hein, Jerry Friedland, Anat Feingold, Karen Kelley, Ellie Schoenbaum, Bob Klein and Peter Selwyn. Their efforts in the mid 1980s on behalf of drug users, adolescents, and men who had sex with men inspired me enormously as a pediatrician interested in adolescent and women's health.

**What are your greatest or proudest moments throughout your career/research?**

**QAK:** In my twenty-four years of undertaking HIV research, these past two years have to count as the greatest period—starting with the findings of CAPRISA 004, followed soon after by IPREX, HPTN 052, Partners PrEP and TDF-2. These studies collectively transformed thinking on reducing sexual transmission of HIV, bringing new hope to prevention science and totally changing the discourse in efforts to stop the HIV epidemic.

**SV:** My work dates back even longer than Quarraisha's (given my age!), and I remember the sense of mission in the late 1980s when my team documented the link of HIV with HPV-induced cervical pre-cancerous lesions in the first cross-sectional study to document the association without confounding factors. Subsequent PEPFAR-related studies focused on quality improvement (QI) of programs with colleagues Jeff Stringer, Moses Sinkala, Phil Ciampa, and Mohsin Sidat have also been most gratifying for me. Programs can improve remarkably when one has disciplined QI work extant.

**What lessons has your work life taught you?**

**QAK:** The importance of perseverance, courage and persistence.

**SV:** Quarraisha has captured it. I’d just like to add, paraphrasing Winston Churchill during WWII, “Never ever, ever, ever, ever, ever, ever give up!” I don't know whom I am paraphrasing here, but “one can get a lot done if one does not care who gets the credit.”

The panel determined that women at high risk of HIV or living with HIV, can continue to use all existing technologies for prevention, including male circumcision, female and male hormonal contraception, PrEP, and Truvada. The panel noted the importance of expanding access to these technologies and addressing barriers to uptake. The panel also emphasized the need for sustained commitment and funding to support ongoing research and implementation efforts.
HPTN 064 ISIS Results Released

Results from the Women’s HIV Seroincidence Study (ISIS) were released at the 19th Conference on Retroviruses and Opportunistic Infections in Seattle, Washington and generated a great deal of national media interest. The study indicated that the HIV incidence rate for U.S. women living in study communities is much higher than the national overall estimated incidence rate in the U.S. for black adolescent and adult women. The study found an incidence of 0.24% in black women, a rate that is fivefold higher than that estimated for black women overall by the Centers for Disease Control and Prevention (CDC). The rate noted in HPTN 064 is comparable to estimated HIV incidence rates in the general population in several countries in sub-Saharan Africa. Although black women constitute only 14 percent of the U.S. population, they account for 67 percent of all new HIV infections among women in the U.S.

“Despite prevention efforts in the past 30 years, the reality is that we still have ongoing HIV transmission in the U.S. that requires focusing prevention efforts,” said Study Chair Sally Hodder, MD, with the University of Medicine and Dentistry of New Jersey-New Jersey Medical School.

A total of 2,099 women, ages 18 to 44 years, were recruited for the study between May 2009 and July 2010. Eighty-eight percent were black, 12 percent Hispanic/Latina. Women were enrolled in 10 communities in six distinct geographical areas in the northeast and southeast regions of the U.S.; Atlanta, GA, Raleigh-Durham, NC, Washington D.C., Baltimore, MD, Newark, NJ, New York City, NY.

Eligibility areas within the communities were defined using the National HIV Behavioral Surveillance (NHBS) methodology, which combines U.S. Census poverty data with state health department HIV prevalence data and uses a standardized algorithm to identify census tracts or zip codes where there is a high risk of HIV transmission. However, in contrast to NHBS, ISIS used cohort follow-up as well as state-of-the-art laboratory methods to estimate the new HIV infection rate at all study sites.

Women without a prior positive HIV test living in areas with high HIV prevalence and poverty were eligible for enrollment and were interviewed about many key aspects of their lives including mental health, sexual behavior, history of sexually transmitted infections (STIs), domestic violence, social support, financial insecurity and health care utilization.

Yashika’s Story

Yashika Dickerson was homeless when she first met a member of the ISIS study. She had just lost her job and her mate of 12 years and was living in a shelter for women in Raleigh, NC. “I was broken in spirit and about to give up on life,” said Yashika. “When the study team arrived they were all smiles and immediately connected with the women in the shelter. They treated all of us with respect and dignity.” She says she decided to become a study participant after learning that ISIS could have a positive impact on the community. “I wanted to be part of something positive and meaningful.”

Meet a new HPTN Scholar: Chyvette Williams

Chyvette "Chevy" Williams from the University of Illinois at Chicago is a new HPTN Scholar who will be working on data from HPTN 037.

While growing up Chevy always had an interest in health-related fields, but knew she did not want to work in a hospital. While preparing to take the MCAT, Chevy was introduced to public health after attending a conference on health career opportunities at the University of Illinois at Chicago School of Public Health (UIC SPH). After becoming intrigued with public health’s focus on prevention and community, she applied to graduate school for an MPH at UIC SPH and then a PhD at Johns Hopkins University.

Chevy is very excited to be part of the HPTN Minority Scholars Program and plans to use the experience to nurture her research career in several important ways. First, she will have the opportunity to be integrated into the HPTN with premier HIV investigators through meetings and focused mentorship. Second, working with a nationally-respected project on HIV risk networks will help further develop her methodological skills in social
In appreciation for what she calls the “hope and rejuvenation” that ISIS provided her, Yashika wrote a poem of gratitude.

ISIS
You reached out to me and gave me hope,
you showed me
that somebody cared about my welfare,
by just being there…

You exemplified the meaning of ISIS,
which is Protector,
Goddess of women and children from which all beginnings arose,
Exceptionally wise with the knowledge and understanding to the highest
degree…

Universal Mother which made me believe and discover
that I could recover
from low self-esteem and always dismissing
the fact that I am a queen with every ounce of my being…

Your symbol means life
which I was slowly taking away from myself
by risking suicidal decisions to my health…

You educated and empowered me on the facts about HIV
and how 50% of the ones infected look like me…

You gave me an outlet in which I could speak and tell my story on how
things came to be
in my community…

You listened, intently, and gave me information
facilities, testing, counseling, even contacted me monthly
just to see how I was
Coping…

Even compensated me monetarily to show you valued my time and opinion,
treated us all with confidentiality, fairness, and equality…

“ISIS”
You revived my soul and rebirthed my spirit by nurturing
and releasing my captive mind
that longed to be freed…

And now, I can teach my seed,
and tell everyone how
ISIS has been immeasurably PRICELESS

What's New in Prevention?

HPTN 069 NEXT-PrEP Launches
HPTN 069, Novel Exploration of Therapeutics for PrEP (NEXT PrEP), is a Phase II, multisite study designed to evaluate the safety and tolerability of alternative drugs for pre-exposure prophylaxis (PrEP) to prevent HIV transmission in a population of at-risk men who have sex with men (MSM) in the United States. There are at least nine efficacy studies of PrEP either recently completed or currently underway in 15 countries involving over 20,000 individuals with diverse risk behaviors. All of these clinical trials evaluate PrEP using two drug formulations, either tenofovir disoproxil fumarate (TDF) or a fixed-dose combination of TDF/emtricitabine (FTC). Despite encouraging findings from several of these studies, some concerns

HPTN Researchers in the News

Bob Grant (HPTN 067) was recently named one of TIME Magazine’s 100 Most Influential People in the World for his work with pre-exposure prophylaxis (PrEP). Congratulations to Bob for being named to this prestigious list.

Tim Mastro was recently elected as a member of the American Epidemiological Society (AES), a select society that provides a scientific forum for senior epidemiologists. Congratulations to Tim for this well-deserved honor.

Salim Abdool Karim (HPTN 035) was appointed president of the South African Medical Research Council (MRC). The mission of the MRC is to improve the nation’s health and quality of life through promoting and conducting relevant and responsive health research. The HPTN congratulates Salim for his selection to this esteemed post.

Coming Soon

19th International AIDS Conference
July 22-27
Washington, DC

Hot Off the Press

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exist. TDF/FTC (trade name Truvada®) is used commonly in antiretroviral therapy (ART) regimens for treatment of HIV-infected individuals, and viral strains that are resistant to TDF and/or FTC exist and are transmitted in the community. In addition, although TDF with or without FTC is generally well-tolerated in both HIV-infected individuals and healthy volunteers using PrEP, concerns remain about long term side effects of these drugs, including possible kidney damage and loss of bone density. New HIV prevention options remain critical. HPTN 069 (NEXT-PrEP) will use regimens that include the following antiretroviral drugs alone or in combination drugs: maraviroc (MVC), emtricitabine (FTC), tenofovir disoproxil fumarate, and matching placebos. Participants will be randomized to one of four arms including a Truvada® arm.

The study will enroll four hundred men from the U.S. at sites in the following locations: Baltimore, MD; Boston, MA; Chapel Hill, NC; Cleveland, OH; Los Angeles, CA; New York City, NY; Philadelphia, PA; Pittsburgh, PA; San Francisco, CA; San Juan, PR; Seattle, WA; Washington, DC. Sites are encouraged to enroll young adult MSM (aged 18-25) and/or MSM of color. The study is expected to last approximately two years.

**Truvada Recommended for HIV Pre-exposure Prophylaxis**

In May, a committee of U.S. Food and Drug Administration (FDA) advisors recommended that the agency approve the use of once daily oral Truvada® for use as pre-exposure prophylaxis in men who have sex with men, HIV serodiscordant couples and other individuals at risk for acquiring HIV through sexual activity. The FDA is expected to make a final decision by September 14. If approved, Truvada® would become the first antiretroviral drug marketed to healthy people to protect against HIV infection. Gilead Sciences Inc. has marketed Truvada® since 2004 as a treatment for people who are infected with the virus. The medication includes two antiretroviral drugs, tenofovir and emtricitabine. Since Truvada® is already on the market to manage HIV, some doctors have prescribed it “off label” as a preventive measure. Full FDA approval would allow Gilead Sciences to formally market its drug for PrEP.

Research on PrEP is a high priority for the HPTN and the Network extends its congratulations to all the study teams, investigators, study participants, Gilead Sciences, Inc. and funders for their efforts in achieving this milestone. The announcement offers hope and a new option for protection from HIV in populations at risk.

**FDA Approves Home HIV Test Kit**

Americans are one step closer to being able to test themselves in the privacy of their own home for the virus that causes AIDS. In May, an FDA advisory panel voted in favor of approving the OraQuick In-Home HIV Test.
Using a simple mouth swab, the test produces results within 20 minutes. The FDA has already approved other HIV test kits designed to be used at home, but they require a blood sample and must be sent to a laboratory for development.

The number of new HIV infections in the U.S. has remained steady at about 50,000 for the past twenty years. The government estimates that nearly a quarter million people are unaware that they are infected. The new easier to use HIV home test has the potential to increase the awareness of those that are infected and therefore reduce the number of people who unknowingly spread the virus.

In the Community

HPTN 061: Navigating Peer Health
Peer health navigation (PHN) was one of the main components tested in the HPTN 061 (BROTHERS) study. Years of research has shown that when clients work with trained and culturally matched “peers” to help them navigate our complex health care system, they achieve better health outcomes. The approach has worked for cancer and HIV treatment. The goal of the HPTN 061 study was to determine if PHN among black men who have sex with men (BMSM) would aid in preventing HIV infection.

In HPTN 061, peer health navigators (PHNs) helped participants identify and prioritize their goals for living a healthier life and overcoming challenges to meeting those goals. Depending on the participant’s needs, PHNs provided health education, facilitated connections to health services, and connected study participants to appropriate community based organizations for long-term case management, among other activities. It was expected that peer health navigation would help those infected with HIV receive more care, and lower the risk of HIV infection for those who were uninfected.

What PHNs discovered is that they needed to address the basic needs of participants, such as employment, housing, mental health and social support before they could address issues more directly related to HIV. Without an income or a stable place to stay, getting regular health care was often less of a priority for participants, or very difficult to achieve. PHNs assisted participants with resume writing, online job services, and referrals to agencies that assist with criminal record expungement, while also establishing relationships with service providers and accompanying participants to their appointments to model how to communicate with providers.

Each of the seven study sites developed its own PHN implementation strategy. Much of that strategy was dictated by the unique socio-economic


Want to Read More?

HIV Prevention Trials Network
http://www.hptn.org/index.htm

HPTN 046
http://www.hptn.org/research_studies/hptn046.asp

HPTN 052
http://www.hptn.org/research_studies/hptn052.asp

HPTN 064
http://www.hptn.org/research_studies/hptn064.asp

HPTN 065
http://www.hptn.org/research_studies/hptn065.asp

HPTN 067
http://www.hptn.org/research_studies/hptn067.asp

HPTN 068
http://www.hptn.org/research_studies/hptn068.asp
and cultural differences of each site. Sites frequently referred participants to mental health services, primary health care, employment assistance, treatment for sexually transmitted infections (STIs)/HIV, substance abuse counseling, housing assistance and education (GED) programs.

PHNs wanted to make sure that the lessons they learned in HPTN 061 not be lost with the end of the study and worked as a team to describe the HPTN 061 PHN perspective in a document titled: The experience of providing peer health navigation to black men who have sex with men at risk for HIV, including insights for future implementations. The document describes the first-hand experiences of PHNs at each site, with sections on the impact of the economy, most frequent referrals, clinical supervision, transitioning participants out of the study and recommendations for improvement of PHN. The PHN perspective documents the process of actually conducting PHN in HPTN 061, in contrast to the theory of PHN, and provides a starting point for further exploration of defining, conceptualizing and implementing PHN in future studies.

A Closer Look

Network Profile Spotlights
In this edition of Prevention Now, we begin a new feature to spotlight the hardworking people who make our research possible.

Shauna Wolf

Shauna started working as a Senior Research Specialist with the HIV Specialty Laboratory at Johns Hopkins University in March 2011. Shauna studied Clinical Science at Edinboro University of Pennsylvania and worked at different hospitals and reference labs in Ohio before moving to Maryland.

As the HPTN has grown with an increased number of protocols, the NL had to increase its size and was looking for an experienced Medical Technologist who also had HIV and Laboratory Data Management System (LDMS) background. Shauna handles specimens coming in from all the study sites, coordinating them as they move through the other labs for ARV, STD and incidence testing. She performs additional specialized HIV testing, and help sites with LDMS queries. Those who work with Shauna compliment her attention to detail, enthusiasm and willingness to take on new challenges. She received high praise for her sample coordination and organizational skills managing the numerous samples for HPTN 043. She is currently learning the protocol process and will assist with new HPTN protocols such as HPTN 071.

Shauna came to her first HPTN annual meeting last year and is excited to return. She also went on her first study close-out visit to Tanzania and Zimbabwe. “It was a great experience getting to see how the international sites function and what our close-out visits entail. It gave me a clearer picture of what takes place and needs to get done at these sites.”

Shauna is originally from Ohio and currently lives in Baltimore. She enjoys working out and playing in the co-ed leagues that Baltimore offers, such as kickball, soccer and flag football.

Scott Rose
Scott has been a Senior Clinical Research Manager working in the HIV Prevention field for 10 years. Prior to HPTN, Scott worked for a pharmaceutical company on the development of FTC (emtricitabine). Scott says making the switch from a for-profit to non-profit changed his life by enabling him to have more robust and meaningful contact with site staff and participants. “I became tired of always chasing the bottom line. I like the HIV prevention focus and the desire to make a difference. I had a friend that worked at HPTN and she recruited me for HPTN 039. It turned out to be a perfect fit.”

Scott says his greatest joy is being a part of the process of affecting people’s lives in meaningful ways thanks to the relationships he has forged and the many projects he has worked on including HPTN 033, 036, 039, 056, 058, 067 and 073 in addition to CHAVI. Part of what Scott enjoys about his work is the chance to work with a wide variety of people in different countries and experience different cultures.

If he wasn’t at HPTN Scott says he would likely be a practicing physician in the country. “I would be living the quiet life, who knows, perhaps deep in the savannah of Zambia.”

When not traveling for work or in the office, Scott enjoys spending time with his wife Ginger and their four young children.