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iPrEx has its interim review

The Chemoprophylaxis for HIV Prevention in Men (iPrEx) study received its regularly scheduled review by its Data Safety Monitoring Board (DSMB) in Washington, DC on November 3, 2009. This independent expert board reviews iPrEx data at regular intervals to ensure that the study is being conducted as it should and that the health and wellbeing of volunteers are always protected.

The board that reviewed iPrEx consists of clinical research experts, statisticians, and other representatives of the international academic research community, including reviewers from the United States, Peru, South Africa, Brazil, Thailand, and India. The DSMB found that iPrEx is being conducted according to plan and recommended that the study continue.

Because of the outpouring of support at our eleven sites, iPrEx now has enough volunteers enrolled to meet the study outcomes. As a result, iPrEx finished the enrollment phase of the study in December 2009. The successful completion of volunteer screening and enrollment is due to the outstanding efforts of iPrEx study personnel and – most of all – to the selfless contribution of more than 2,400 volunteers enrolled in this study. Everyone involved in iPrEx should be congratulated for their excellent work. Please keep it up!

Letter from iPrEx Protocol Chair

We have much to celebrate in the last quarter of 2009!

The study team spent at least 6 months of intensive effort preparing for the interim review of the independent multinational Data Safety and Monitoring Board (DSMB). The data managers worked long hours to review and clean all of the data, which included more than 400,000 forms. The iPrEx statistical center submitted reports to the DSMB containing several hundred pages of information. The resulting DSMB review concluded that iPrEx continues to play a pivotal role in HIV prevention, addressing the needs of communities of men who have sex with men. They also concluded that the study is proceeding well and should continue - a huge success. The iPrEx study also met a key milestone late last year: completing enrollment on December 17th, 2009. The completion of enrollment reflects the success of all 11 study sites in the United States, Ecuador, Peru, Brazil, South Africa, and Thailand. The study cohort is truly global in scope, involving men and transgendered women living on four continents and speaking 5 languages (English, Spanish, Portuguese, and Thai). iPrEx is old and young people, men and women, rich and poor, working together to find out if Truvada® can protect a diversity of people who are vulnerable to acquiring HIV. While most prevention trials focus on one or two continents, iPrEx has been successful around the world. More than 70 members of that global iPrEx team met in San Francisco in November for our 2nd annual Investigators Meeting. The teams presented their successes and challenges and reviewed laboratory information related to drug level testing, immunology, virology, and metabolism. We also heard from behavioral scientists regarding pill-taking behaviors, which lie at the heart of our study.

We heard about the qualitative research and behavioral interventions being pioneered in the iPrEx study, and from David Halperin, a Professor of English at the University of Michigan and a renowned scholar of social theory, who asked “how to be gay?” in a quite entertaining and provocative manner.

The meeting opened with the “Voices of Hope” film, which highlights the work of the global iPrEx team to create a new model of prevention research that fully engages communities as partners to discover new ways for people to protect themselves. As we all participate, a strong and diverse community, our iPrEx community, is born. By coming together, we learn to protect each other and ourselves from HIV, and to stand together against all that hurts us.

Robert M Grant, MD, MPH
Protocol chair, iPrEx



iPrEx Interim Analysis / Open Report



Dave Glidden, PhD,

is the Study Statistician for iPrEx. It's Dave's responsibility to review and prepare thousands of pages of data from the study to help us answer the question of whether a pill a day might be able to help stop HIV infection. iPrEx Update asked Dave Glidden to explain the recent independent interim analysis of iPrEx by the Data Safety Monitoring Board (DSMB).

What is an interim analysis?

An interim analysis is a detailed look at a study's progress. The recent iPrEx interim analysis reviewed the study enrollment, profiled its participants (age, site of enrollment, sexual behavior), looked at how well participants are doing at taking the pill, examined any side effects reported in the study, and looked at how many people in the study have become HIV-positive since iPrEx began.

Who reviews this interim analysis?

The iPrEx interim analysis is reviewed by an expert committee appointed by the study's sponsor, the United States National Institute of Health (NIH). These reviewers are totally independent and are not involved in the study in any way. The committee has members from the United States, Thailand, South Africa, Peru, Brazil, and India. They have expertise in HIV, ethics, and statistics. Their top priority is ensuring that iPrEx study participants are protected from any harm.

What is the interim analysis used for?

The analysis tells this expert board whether the iPrEx study is proceeding as it should and protecting the safety of the study participants.

What are the major findings of the committee report?

The independent committee found that the study is proceeding according to plan, and that enrollment and retention rates in the study are on target. They also found that iPrEx had recruited enough participants to meet its objectives and that the study could close the recruitment and enrollment phase.

This means we should have data from iPrEx by late 2010.

An Investigator's Perspective:

Principal Investigator for Desmond Tutu HIV foundation, University of Cape Town, South Africa:

HIV Prevention Research in MSM in a country with a generalized epidemic

The Desmond Tutu HIV Foundation (DTHF) in Cape Town has been enormously honored and very excited to be the only site to host the iPrEx study in Africa.



Linda Gail-Bekker, PhD

Many of our participants face multiple social problems and competing priorities, however, including poverty, unemployment, limited housing and crime, which challenge both meaningful engagement and participant retention. Good, MSM-friendly services are almost non-existent in these communities – again, presenting both challenges and opportunities. Through iPrEx, DTHF has been able to offer services as well as much valued respect, recognition and advocacy in these communities. The realities of our volunteers' lives mean our team has also had to be very innovative in their recruitment strategies. As gay-friendly internet networks are not viable in these communities, word of mouth, recruiter networks, and informal social events have played a much more important role in our outreach. These networks, based on trust and consistency, take time to build to the point where they are effective and the research team is able to feel confident that recruits are enrolling with a solid understanding of commitment and informed consent. Through ongoing efforts, the research team has been able to promote a sense of belonging among recruits and a team spirit which may be the beginning of the altruism that often drives men to volunteer in large numbers in other parts of the world. The DTHF team has been gratified at the way Cape Town MSM have stepped up and pledged their commitment to the prevention fight.

Notwithstanding a liberal Constitution that recognizes same sex relationships and a city that has welcomed gay and lesbian people, the DTHF team has experienced both challenges and opportunities in implementing an HIV prevention trial in men who have sex with men (MSM) in a country with a generalized, predominantly heterosexual HIV epidemic. Some of the challenges have included stigmatization associated with taking part in an HIV clinical trial, with some potential participants concerned about associating with HIV service providers or fearing that neighbors might suspect that they were HIV-positive. With high national rates of HIV, the team has struggled to find uninfected individuals eligible for the trial. In the communities we have tapped for recruits, up to 1-in-4 adults are infected by HIV. In some ways, this made messaging on grass roots, in-the-field level easier -- because the individuals we recruited truly felt the urgency of finding new prevention methods and the potential value of their participation in a clinical trial.



News from the iPrEx Study Sites



San Francisco, USA

The San Francisco site was thrilled to reach our recruitment goal of 140 men on December 11, 2009. Hooray! Reaching that goal involved a collaborative effort, and was especially complemented by a heroic final screening push that included local events hosted by our resident diva, the fabulous Garza, and a series of community forums held in partnership with a local HIV prevention organization, STOP AIDS. Retention continues to be high at our site, and we are incredibly grateful for the dedication of all of our volunteers. Almost one-third of our volunteers participated in focus groups and in-depth interviews talking about their experiences with pill-taking. From their insights, we are identifying new ways to support taking the pill, including developing an enhanced client-centered counseling approach and other novel strategies. We are in the process of planning several retention events in the spring, including a volunteer appreciation party and a public screening of the iPrEx video.



Boston, USA

Now that enrollment has closed, our site will switch gears and focus on retention for the 87 participants enrolled here. We are currently planning a “mixer” social event to include iPrEx participants and those involved in other Fenway studies, such as our current vaccine trials. As one iPrEx volunteer put it, “It would be fun to meet other men who volunteer, to talk about why we do it, to meet other guys who care!” We plan on coordinating this with a screening of the “Voices of Hope” video that we found so inspiring when some of our staff saw it in San Francisco. Our clinical staff is also focusing on quality improvement of our internal processes. We are looking forward to working with our participants in the year ahead!



Chiang Mai, Thailand

The PIMAN Center organized a volleyball and cheerleader competition on World AIDS Day, December 1st, 2009, in cooperation with Chiang Mai Provincial Public Health Office. Among the audience were university students and iPrEx participants who campaigned for World AIDS Day. The PIMAN Center currently provides counseling and HIV testing (VCT) services of for MSM in Chiang Mai.



An Interview with Global iPrEx video, “Voices of Hope”

Director, Miguel Bernal

A new video all about the iPrEx study, Voices of Hope, takes viewers on a moving journey to all 11 iPrEx study sites to get a first-hand, behind-the-scenes look at one of the largest international HIV prevention studies ever conducted among men who have sex with men.



Lima, Peru

INMENSA was out in force at the IV Latin America and the Caribbean Community Forum on HIV/AIDS and STD (November 21st - 23rd, 2009). iPrEx peer recruiters participated in the pre-forums with representatives from 17 countries from the region. Topics included human rights and universal access to prevention services, care, support and treatment of HIV / AIDS for gay men, transgendered women, and other MSM in the region.

iPrEx's information stand at the Forum's Global Village was one of the busiest and most colorful, providing information about the iPrEx site in Lima and distributing educational materials for the public and for specific communities, especially gay and transgender. Also at the Forum were Dr. Robert Grant, iPrEx Protocol Chair and Dr. Javier Lama, iPrEx Protocol co-Chair, who participated in a debate on clinical research in vulnerable populations at high risk of acquiring HIV infection.

For World AIDS Day, INMENSA collaborated with the community-based organization Dignidad to organize an HIV/AIDS Prevention Concert before 4,000 attendees at one of the largest parks in the city of Lima. The nationally televised show, which brought together many of Peru's top performers, included six hours of musical entertainment, along with frequent messages on HIV prevention and the importance of clinical research.





Voices of Hope is the work of Lima-based filmmakers Miguel Bernal and Ximena Barra and iPrEx Communications and Community Relations Director Pedro Goicochea. The film tells the compelling story of how pre-exposure prophylaxis may work to block HIV infection, how a major clinical study operates and, most memorably, what draws volunteers and keeps them involved in the multi-year effort.

Viewers at the film's recent San Francisco premier shared these comments with iPrEx Update: *"It reminds me what we are working for. 'Voices of Hope' is an inspiration for anyone who feels fatigued by the work we're doing. It will re-charge your battery and give you strength to move ahead."*

"It's a wonderful explanation of PrEP and iPrEx, and the volunteers are so inspiring. I highly recommend it."
"This film captures the global nature of iPrEx like nothing I've seen before."



We sat down with filmmaker Miguel Bernal to ask about his experience with the iPrEx team:

What did you want to accomplish with this video?

We wanted to draw an honest portrait by focusing on the social and human sides of iPrEx. We worked without scripted dialog or fixed scenes, which means we had to trust the spontaneous responses that emerged from more than 130 interviews. Thanks to the support of Bob Grant and Pedro Goicochea, and the sincere responses of everyone we interviewed, the video took on a life of its own, and we were able to capture the human and social face of this incredible project.

Was it difficult to tell the iPrEx story?

It was a pretty complicated process. Each interview added a piece to a large and very challenging puzzle. It was not until we were done and began to replay all of the interviews, in four different languages, that we saw how the pieces fit together. The hardest part was deciding what not to include. We could do a second iPrEx video with the answers, opinions, and emotions that we had to leave behind!

You traveled to four continents (South America, North America, Africa, and Asia) to make this video. What impressed you most about iPrEx and its participants?

One of the things that most stayed with us is how a common goal can unite different cultures and people throughout the world. There is a single spirit across the different iPrEx sites. We felt like we were visiting members of a single family living in different cities of the world. Another thing that caught our attention was the response of the study personnel and, above all, of the iPrEx participants. Their statements revealed a deep caring and hope for the project. The emotion that came through in these interviews made us feel grateful to be part of this effort to find new solutions to the HIV pandemic.

Miss Amazonas Gay

Mark Aurigemma **A View from the Judge's Table**



More than a few iPrEx Update readers may have dreamed at some point about being a beauty queen (perhaps you still do!). But how many of us ever imagine what it would be like to sit at the judge's table? I know I hadn't until my friends at Selva Amazonica bestowed this incredible honor and responsibility on me at the year's Miss Amazonas Gay pageant in Iquitos, Peru. This annual event rivals any international pageant, and has become a must-see event in this vibrant jungle city. The gowns, musical acts and production numbers are beyond imagination... as is the amount of preparation the contestants undergo.

Sixteen candidates are selected for the honor of vying for the Miss Amazonas Gay title from a field of 100 entrants, and those lucky sixteen spend the next three months practicing the usual pageant requisites such as poise and congeniality, while also learning about iPrEx, HIV prevention, and clinical research. Every contestant is an ambassador for HIV prevention and iPrEx.

As for being a judge, I can only say that, while it was as fun as you might imagine, it was far from easy. Every one of these contestants was remarkable and inspiring. Miss Amazonas Gay - long may she reign!



Coming
in the next issue of
Global iPrEx Update:
**Retention
at the sites!**

1st quarter 2010 · Number 3
Visit the Global iPrEx website:

www.globaliprex.net

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iPrEx Update

iPrEx is sponsored by the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID) of the US National Institutes of Health (NIH) and co-funded by the Bill & Melinda Gates Foundation. Study medication is donated by Gilead Sciences. This study is under the United States Food and Drug Administration (FDA) investigational new drug (IND) number 71,859.