

Number **04**

GLOBAL
iPrEx Update

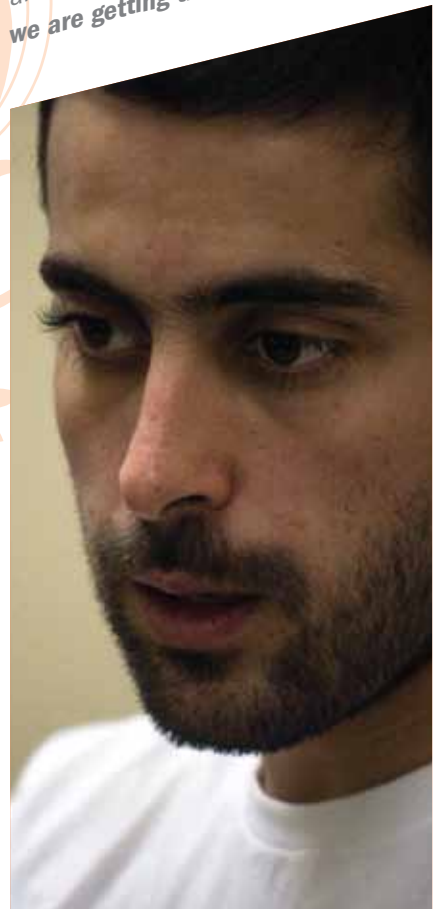
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**We are approaching the end
of the randomized phase in iPrEx**

The iPrEx teams are working really hard; clinical staff, data managers, retention teams, coordinators and investigators, hand in hand, to conclude the long way we have come together with participants attending their visits, with enthusiasm, and all of us wondering,

will it work?

This issue of the Global iPrEx Update addresses the efforts of the retention units at the study sites to keep up the spirit of hope, with imagination and creativity. **Thanks for your efforts, we are getting there!!!**



reflection on retention

Letter from iPrEx Protocol Chair

From the time our study began in mid-2007 to our last day of enrollment, December 17th, 2009, iPrEx has demonstrated that PREP trials can enroll briskly. One of the lasting lessons from this study will be that high risk populations of gay men, transgendered women, and other men who have sex with men are willing to enroll in HIV prevention trials around the world, including in Africa and Thailand. Growing epidemiological evidence shows the very high burden of HIV bourn by these populations in virtually every corner of the world. Whenever possible, HIV prevention research should address their needs and invite their participation. Of course, enrolling in an HIV prevention study is just the beginning of the journey. Keeping people interested and participating – what is known in study lingo as “retention” – is equally important. Efforts to keep iPrEx participants involved and retention rates high have stretched the imagination of the iPrEx site staff, producing activities that are range from the imaginative to the comedic to the Herculean. Since the best way to keep people’s attention is often entertain them, iPrEx sites have held movie screenings, drag shows, pageants, competitions, open houses and appreciation days. These and other activities are designed to engage our participants and the friends and family who support them and to support and reinforce good health in all of the iPrEx communities.

On the Herculean side, thousands of hours are spent keeping in touch with our participants, keeping track of people who change jobs or move but who still want to be part of the study, and occasionally even providing a bus ticket to bring people back for a few key visits. Visits to a participant’s home, (if they have given us permission to do so), can also help build stronger ties to the study and encourage participants to keep up with their visits. The movie “Voices of Hope” supports retention by emphasizing how much the diverse participants, researchers, and communities participating in iPrEx have in common, including a commitment to communicate and work together to stop AIDS. Trainings held in Lima and Iquitos Peru in mid-2009 brought all of the iPrEx sites together to share ideas and first-hand experiences about how to recruit and retain people in PrEP research. During these discussions we heard over and again that the work of peer educators is the heart of success. Participants want to interact with peers, which whom they often develop trust over time and share perspectives and ways of talking. The challenge of retention in PrEP trials is huge. Because carefully monitoring the safety of our participants is so important, we asked them to return every month for an HIV test and every 12 weeks for blood tests. We asked a lot of questions. We know that many people are tired, especially the many who have been with the study for almost 3 years, trying to take a pill every day.

All of this will pay off when we are able to report initial results of the study in early 2011. We are very honored that the vast majority of people who enrolled have stayed with the trial. Their efforts will serve millions of people around the world who want to know whether a pill a day can help protect them from HIV infection. The iPrEx participants are true heroes in their struggle to find new ways to stop the HIV/AIDS epidemic.

It is an honor to work for them.



Robert M Grant, MD, MPH
Protocol chair, iPrEx

But will they come?:

Reaching out to explain PrEP and iPrEx to Sao Paulo's MSM community

Ricardo Gamboa

Community Educator, Universidade de Sao Paulo



Any well-designed and implemented clinical study has to carefully consider whether the people we hope will benefit from the drug or intervention being studied will actually want to participate.

The question is particularly important for something new, like pre-exposure prophylaxis (PrEP) for HIV prevention. We are hopeful that PrEP will help reduce susceptibility to HIV among gay men, male to female transgendered women and other men who have sex with men. But we did not know until we introduced the study whether the community would want to participate in the iPrEx study... or how they would feel about taking a pill a day to prevent HIV infection. The iPrEx study team in Sao Paulo strategized at length about how to best approach gay men and other men who have sex with men in our large and diverse city (the biggest in South America, and one of the biggest in the world). Of particular interest to us was how to work most effectively with the local transvestite and transsexual communities, which we wanted to make sure were well represented in iPrEx. Between June 2008 and January 2009 the recruitment team at Universidade de Sao Paulo dove into the work of mapping the field, identifying community leaders, establishing partnerships with local venues and organizing meetings with the different communities. These activities gave the iPrEx team a broad perspective on the opportunities and challenges we faced, and helped us develop and modify communications and outreach strategies and approaches to reach out to this diverse community to explain PrEP and iPrEx.

In the beginning, we faced a fair amount of skepticism...could a pill a day really help stop HIV infection? Was this a responsible approach to HIV prevention? Responses improved as different audiences, from community organizations to governments, heard our messages... that iPrEx would emphasize the importance of always using proven HIV prevention strategies including consistent use of condoms, and that PrEP, if effective, would be used the same way... as part of a combination approach to HIV prevention. In an effort to reach Sao Paulo's communities of transvestites and transsexual women, the study developed a gender perspective team, and adapted the language and images used in study materials to acknowledge the female gender of some participants. As a result of discussions with the trans movement, we also modified the name of the protocol in Sao Paulo to "Chemoprophylaxis for HIV prevention in men, transvestites and transsexual women". To conduct outreach to sex workers (*michês* in Portuguese), the team established a partnership with the manager of a sauna in downtown Sao Paulo where some sex professionals work. Outreach to men who have sex with men but who do not identify as gay, bisexual, transvestite or transsexual required the team to make a careful

distinction between sexual practice and identity at the time of the approach. Working references to the study into drag shows helped increase recognition and popularity of the study while also building trust among some of our target audiences. For clients from movie theaters, saunas and sex clubs, more eroticized graphic material was developed. Field strategies addressing virtual networks such as chat rooms and other online venues were very useful in reaching MSM who do not patronize the city's "gay scene" venues. Parks and streets that are popular meeting and socializing spaces for MSM provided important outreach opportunities where people were generally open to hearing about iPrEx and to getting information on HIV prevention overall. The positive reception our study team received helped affirm the effectiveness of these outreach approaches. Developing and implementing outreach strategies for the broad diverse community of MSM and transgendered women in Sao Paulo has been essential to our efforts to make iPrEx a truly community based study. It also reinforced our strong respect for the lives, struggles and diversity of the communities we serve.

An Investigator's Perspective

Principal Investigator, the Piman Clinic
Research Institute for Health Sciences (RIHES)
University of Chiang Mai, Thailand



Suwat Chariyalertsak, MD., DrPH

The Piman Clinic experience in HIV Prevention Research in Chiang Mai

The Research Institute for Health Sciences (RIHES) based at Chiang Mai University of Chiang Mai, Thailand, is one of the youngest iPrEx study sites and the only one in Asia.



The site enrolled 114 participants in the study by December 2009, when the Data Safety Monitoring Board (DSMB) recommended that iPrEx cap enrollment. iPrEx's home in Chiang Mai, The Piman Center of the RIHES clinic, is an MSM-friendly service providing voluntary counseling and HIV testing (VCT) and STI management services since April 2008. The term "Piman" in Thai means "the beautiful place or house to stay." For RIHES, opening the Piman Center as a MSM-friendly service located in a popular area for MSM socializing in Chiang Mai has brought us a number of MSM volunteers interested in participating in the iPrEx trial, and has helped with retention as well. More than 600 clients have received free services from the Piman Center since the clinic opened. Individuals who were interested in volunteering for iPrEx and who met the eligibility criteria were carefully evaluated by our staff to make sure that they understood the details of the study, the importance of coming to their visits and the significance of participating as a part of a larger worldwide HIV prevention effort.

To maintain a high retention rate, the sites developed a plan that included reminding our participants of the importance of their collaboration at every visit and giving them the chance to talk about any problems they may have in relation to the study. All participants received a list of mobile phone numbers of our staff that they could reach anytime (24 hours) with any concerns or any problems. Participants who give permission for us to call them also receive reminder calls two weeks, one week and one day before their appointment date. Sometimes, small gestures of appreciation can really help to motivate participants and keep retention rates high. Our participants receive a special little present in thanks for their great co-operation at their 48th week. All participants also receive a birthday card and a birthday present! We have had a lot of good feedback from our participants, who have thanked our staff for the good care they provide, as well as for the understanding and support they receive when they face a challenge or obstacle. For our staff, maintaining high retention among our volunteers is a matter of listening, respect, and sometimes a little extra effort to show our appreciation for all they do.



Retention goes virtual:

The appeal of social networks and electronic media

Rosario Leon, INMENSA

The President of the United States, Barack Obama, introduced his presidential team through MSN (Microsoft Network Messenger, Microsoft Live Messenger). Two of the leading presidential candidates in Peru keep their profiles updated in Facebook. Electronic communication is everywhere, and it is increasingly important in both our personal and institutional lives. As an iPrEx site and as a community center, INMENSA uses social networks and electronic media to inform and retain iPrEx participants, liaise with community leaders and the gay, bisexual and trans community (GBT) on an ongoing basis, and involve the community in the study. INMENSA joined the social networking world back in 2008 when we developed a profile in Hi5, a social network platform from Microsoft. In August 2009 we created our own dynamic social network called Quinto Piso (Fifth Floor) (www.quintopiso.com) to offer study participants and friends a socialization and information space about the activities

of the community center, including occupational training, picnics, community forums and medical, psychological and legal support. At present, Quinto Piso has more than 460 members and has had more than 1,200 visits between February and April.

Quinto Piso Internet Radio was born in February this year and is on the air 24 hours through www.quintopiso.ning.com broadcasting music and shows that are conducted by members of the iPrEx Community Involvement Unit. The radio station not only entertains but also educates on sexual health and the iPrEx study, while also providing regular updates on issues of importance to Peru's GBT community. Quinto Piso's innovative and creative programming includes news on community activities organized by the Community Involvement Unit (Quinto Piso News), a sports show (Noti Voley), a love counselor show (Choque y Fuga), and an iPrEx study show (Espacio i) with interviews, reminders and salutations to study participants. New shows will

include a medical chat show, interviews about the political scene and a show for the trans community.

Quinto Piso's Facebook site does host daily communication with the GBT community, with posts on our activities and opinions on sexual health, clinical trials and community involvement. Also featured on our Facebook page are updates on our publications, the activities bulletin, the Community Guide on HIV Research and, of course, copies of Global iPrEx Update. Retention coordinators also use the Facebook page to help remind participants about the importance of keeping their study appointments.

Together with interpersonal communication by peer educators, electronic media is one of our main communications channels with participants. These electronic media opportunities help enable our participants to express themselves, establish relationships with others and stay informed about the information and services we offer.



News

from the **iPrEx**

Study Sites



Cape Town, South Africa *Networking through Netball*

Cape Town has been implementing a number of creative retention strategies. One of our most successful and entertaining initiatives has been a multi community based sports league that brings together iPrEx study participants and other local MSM community members. Meeting bi-weekly, iPrEx participants and community allies compete in one of South African's oldest sporting events, Netball. Similar to American Basketball, Netball has traditionally been restricted to solely female competitors. Our Netball league is used to inspire healthy behaviors both mentally and physically. Netball fits well within our array of retention activities, designed to keep iPrEx participants engaged and active within our clinic and their communities.



Iquitos, Peru *Iquitos vibrates with the Super Fame and Fashion Show*

As part of iPrEx retention activities, Asociacion Civil Selva Amazonica (ACSA) organized the "Super Fame and Fashion Show" a highly entertaining event featuring Iquitos' renowned local talent. The event offered all iPrEx participants an opportunity to share and interact with friends and family, clinic staff and the community at-large. Hosted at the popular nightclub ASIA, the event included dance shows, fashion performances and prizes. Most importantly, everyone enjoyed an environment of respect and tolerance for and among all of the populations that make up the ACSA study site.





Boston



Boston, USA
Voices of Hope premiere

Fenway Health hosted the Boston premier of “Hope Takes Action” on March 23rd before an enthusiastic crowd. This wonderful film (featured in Global iPrEx Update #3) documents this historic trial at each of the study sites where it is being conducted around the world. A group of 75 study staff, participants and friends gathered in Fenway Health’s new state of the art auditorium to view the film, which features several Fenway staff and community members, as well as views of local landmarks such as Fenway Park (home of the World Champion Boston Red Sox) and Boston’s Victory Gardens. Study Coordinator Jocelyn Trufant also hosted a private reception for study participants and their guests as a way of saying “thank you” to the many men enrolled in this study.



Rio de Janeiro



Rio de Janeiro, Brazil
Building awareness, respect and partnership

In February of 2010 IPEC/FIOCRUZ offered iPrEx volunteers an entrepreneurship course designed to increase their citizen participation, enable new opportunities for income-generation and support study retention. By the end of the course we saw that, beyond reaching these objectives, the course also enabled integration among volunteers and a change of attitudes. One participant who had reservations about the trans community had the opportunity to interact with members of this population and has now partnered with a member of this community to start a business. Speaking about the class, this participant noted, “This experience had a positive effect in my life as a person, accepting the difference and being able to work together”. Alan Leites facilitated the Entrepreneurship course. The IPEC/FIOCRUZ community education and retention team includes Nilo Martinez Fernandes, Lucimar Santos Salgado, Josias de Freitas, Tony Araújo, Ulisses Sousa, Sílvio Rodrigues, Mauro Souza, Wellington Cavalcanti, Cris Bergara e Noé Manoel Filho. All work really hard to keep high retention at the site and make being participants in iPrEx an extraordinary experience.



Lima



Lima, Peru
Quinto Piso makes its mark on the Lima volleyball scene

For the first time, INMENZA/Quinto Piso was represented with a team as one of Lima’s most traditional volleyball tournaments took place during the Easter holidays. Despite their status as first-time competitors, the INMENZA/Quinto Piso team walked away with the third place trophy...providing all with a great sense of pride, as well as with a wonderful opportunity to raise the visibility of iPrEx and talk about the study and HIV prevention for MSM. Congratulations to all who participated!



Lima



Rio de Janeiro

News from the iPrEx Study Sites




Sao Paulo, Brazil A leading cultural center spotlights iPrEx

Sao Paulo's *Museu da Lingua Portuguesa* hosts a week-long program, "iPrEx: Developments and Challenges against AIDS" from the 17th to the 21st of May. The program features daily discussions with experts about the AIDS epidemic in Brazil and the world, sessions dedicated to supporting healthy sexuality, and events promoting the importance of community involvement in clinical trials and in other efforts to control the HIV epidemic. "iPrEx: Developments and Challenges against AIDS" is sponsored by the Municipal Program on STD/AIDS of the city of Sao Paulo, the Coordination of Sexual Diversity Issues of the *Prefeitura de Sao Paulo* and the *Prefeitura de Santo Andre*.



Chiang Mai



Chiang Mai



Chiang Mai, Thailand Retention strategies that work

iPrEx's Chiang Mai site (The PIMAN CENTER) emphasizes retention as key to the safety and well being of our participants. We designed an easy-to-carry calendar for participants, and also distributed a 'Piman Center' T-shirt to participants who came to all visits in first 24 weeks. Participants also receive a nice bag and card for their birthday. When participants miss a visit, the team reaches out to contact them, find out why they missed and work with them to come up with solutions. This individualized approach makes our participants feel cared for and helps keep retention strong.



2nd quarter 2010 · Number 4
Visit the Global iPrEx website:

www.globaliprex.net

Editors: Mark Aurigemma and Pedro Goicochea
Design: Miguel Bernal



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.