


## Samples of Newsletters for Clinical Trials



# Trial Update

## FEM-PrEP Pre-Exposure Prophylaxis for HIV

### Putting HIV in its Place in Pretoria

#### FEM-PrEP scientists use an innovative strategy to recruit participants

A few years ago, the massive metropolis that includes Pretoria, South Africa, was renamed *Tshwane*—a word that means, “we are the same,” according to city officials. The name change, and even the meaning of the word *Tshwane*, are controversial subjects in South Africa. What remains uncontroversial is that the HIV epidemic has not affected the two million residents of Tshwane in the same way.

For various reasons, the virus has affected some communities more than others. The FEM-PrEP researchers need to identify these communities because an HIV-prevention trial can only be effective in places where there is a high incidence of HIV. In other words, the women who volunteer for the trial must be at “higher risk” of acquiring the virus.

Finding and recruiting these women is often a significant challenge for HIV-prevention trials. However, FEM-PrEP’s socio-behavioral and community (SBC) team is taking a novel approach to recruiting participants for the clinical trial. “The approach combines a method called *Priorities for Local AIDS Control Efforts* (PLACE) with computer-based mapping strategies to identify promising recruitment areas to focus recruitment efforts,” says Amy Corneli, the SBC principal investigator.



The PLACE method was originally developed to improve the reach of AIDS-prevention programs. The SBC researchers are using modified PLACE questionnaires to interview members of the community, asking them about the places where people go to meet potential sex partners. The researchers visit these places—*shebeens* (informal taverns), guesthouses, and even bushes by the side of the road—where they talk to the people who go there to socialize.

Business owners are asked about the clientele and about the busiest times at the establishment. The interviewers also collect information from the patrons about their alcohol consumption, sexual practices, and risky behaviors.


Local research staff based at the Setshaba Research Centre conduct these interviews. Among them is Dimakatso Molete, who has extensive knowledge of the social networks in the area. Molete, who is known as *Aus Maki*, has conducted hundreds of interviews with establishment owners and patrons. It’s a task that has its challenges.

“Establishment owners are difficult to get in touch with,” says Aus Maki. “This takes much of our time as we may visit the place several times before we can find them. At first, their staff are suspicious of people they do not know,” she says.

(continued on page 4)

Issue No. 2 July 2009



Sello Mkwandishi/FHI

**Interviewers, Dimakatso Molete and Ross Malamatscho, use a global positioning system device to map the coordinates of a recruitment area.**

Number **01**

GLOBAL  
**iPrEx Update**

- What is PrEP? •
- iPrEx Medication Receives Generic "OK" •
- Letter from iPrEx Protocol Chair •
- iPrEx Goes Global •
- MSM Taking the Lead in HIV Prevention Research •
- Protecting iPrEx Volunteers •
- News from the iPrEx Study Sites •
- "A PI's Perspective," Javier Lama, MD, MPH •

Welcome to  
iPrEx Update,

Number **02**

GLOBAL  
**iPrEx Update**

- Letter from iPrEx Protocol Chair •
- The Andes Study on Adherence •
- A short guide to adherence aids •
- Seeing the volunteer as a whole person •
- How is adherence measured in iPrEx •
- iPrEx volunteers speak out on adherence •
- News from the iPrEx Study Sites •
- "Somewhere over the rainbow...there is hope" •



a ne  
lates  
prop  
Chair  
in M  
of G  
inter  
part  
invo  
a loc  
and  
  
iPrE  
mak  
your  
and  
add  
com  
the

iPrEx U



**Adherence, compliance or just taking your pills**

**Whatever** you call it, the challenge of taking a medication every day is one of the greatest obstacles to medical treatment. Anyone who has ever had to take medication daily knows how hard it can be to take it without fail. This can be especially true when it comes to medication for a chronic condition...something you have to take every day. People are prone to forgetting -- especially if they are feeling well and healthy.

Pre-exposure prophylaxis, or PrEP is an approach to preventing HIV infection in individuals at high risk for HIV acquisition that requires taking an anti-HIV medication, or antiretroviral, every day. PrEP is being studied in clinical trials around the world. iPrEx is the largest of these studies that focuses exclusively on men who have sex with men (MSM).

Since PrEP is designed to prevent HIV infection in healthy individuals, the challenges associated with "adherence" can be even greater. How can you remember to take a pill every day if you are not even sick? iPrEx researchers are consulting with study volunteers and examining different ways to help promote adherence to PrEP as an important part of our research efforts. This edition of iPrEx Update looks at the adherence challenge from many angles. What we learn from iPrEx volunteers today may help us develop better ways to support our participants and to prevent and treat HIV and other diseases for many years to come.

Source: Pre-Exposure Prophylaxis Initiative (i-PrEx). Global i-PrEx Update. 2009. Reprinted with permission.

# Unidad de Educación Comunitaria e Involucramiento

## En este número

- 1 **Notas Breves**
- 2 **Reclutamiento**
- 3 **Retención**
- 4 **Educación Comunitaria**
- 5 **Comité Asesor Comunitario**
- 6 **Próximos Acontecimientos**



Difusión del servicio de diagnóstico de VIH de Impacta a través de la guía Gay Epicentro.



Diálogo entre investigadores y comunidad respecto los estudios

"Para el mejor papi del mundo! Te amaré por siempre, con cariño: Muñequita"... mensaje exhibido en una de las mantas de amor

## 1. Notas Breves

El 09 de Diciembre **participamos** en el II Encuentro de Lucha contra el VIH-SIDA organizado por el Congreso de la República y la Asociación Hogar de Vida. En dicho evento se hizo una revisión sobre los últimos hallazgos en prevención, así como se brindó un reconocimiento al doctor Alberto La Rosa Domínguez entre otros, por su dedicación y aporte al tema del VIH-SIDA. ¡Felicitaciones al Dr. La Rosa!

El 12 de Diciembre se presentó el **Plan Anual de Educación Comunitaria e Involucramiento** de la unidad de ensayos clínicos peruana para los estudios de la red de vacunas. Dicho plan ha sido elaborado por los miembros del equipo y describe las estrategias de reclutamiento y retención a ser implementadas durante el año 2010 con el objeto de alcanzar la cuota de reclutamiento programada en el tiempo establecido.

El servicio de diagnóstico de VIH que nuestra clínica Impacta ofrece, se sigue difundiendo a través de la Guía Turística Gay de Lima de Epicentro, quien quincenalmente actualiza y extiende los puntos de distribución.



El **centro de llamadas** ha atendido a través de la línea SIDA, 181 contactos telefónicos de los cuales 139 (76.8%) corresponden a participantes de TARGA principalmente.

## 2. Reclutamiento

El 1 de Diciembre se realizó en el Centro de Salud Cuartel General (Pentagonito) un encuentro con la finalidad de informar y sensibilizar a la población militar acerca del estudio de investigación en vacunas contra VIH e identificar potenciales voluntarios. La convocatoria estuvo a cargo del personal de salud del Pentagonito, Lic. Patricia Vilchez y Lic. Paola Coahila, alcanzando la asistencia de 80 personas aproximadamente entre personal militar de tropa y administrativo.

De igual forma, el 10 de diciembre se presentaron los estudios de la red de tratamientos en reclutamiento activo a las profesionales enfermeras de la Región de Salud del Callao. 42 profesionales de los establecimientos participaron del mismo.

La red de salud revisó y aprobó la implementación del sistema de referencia Plus de los establecimientos de sus respectivas jurisdicciones los estudios presentados: a) Lima Sur: A5259, A5253 Y A5255; b) Lima Este: A5253 y c) Callao: A5259.

## 3. Retención

59 visitas domiciliarias han sido efectuadas, de las cuales 30 corresponde al estudio EBV, 15 corresponden a estudios de vacunas y 14 a estudios de tratamiento. Los participantes que no fueron recuperados (8) corresponden en su mayoría a participantes del HVTN 504, quienes se han mudado (6) o han viajado fuera del país (2).