

SFDPH: MTN-017 Participant Selection

Hailey Gilmore

6 June 2013

The 'right' MTN-017 participant

- Wants to help the community
- Planned sexual outings
- No barriers to being able to store product – i.e. lack of privacy at home, lack of stable housing
- People with partners(** assess support of partner)
- Understands potential for possible side effects
- Established in San Francisco; no plans to move away soon
- Schedule allows for time commitments to study
- Roll-over participants/previously ineligible
- Diverse representation – age, race/ethnicity

Screening Procedures

Pre-Screening

- Face-to-face recruitment/contact sheets
- Telephone pitch
- Pre-screening questionnaire

In-Person Screening

- 1:1 or group “flip-chart” presentations
- Review of pre-screening questionnaire
- Informed consent process & assessment of understanding

Post-Screening

- Multiple screening visits
- Multiple staff assess for eligibility & fit
- Team discussion of ALL participants in screening

Lessons Learned

Outreach strategies

- Highly visible & compelling print campaign
- Community forums & partners
- Online/social media: Craigslist, Reddit, FB, Twitter, dating/hookup sites
- “Refer-a-friend”
- “Roll-over” and “parking lot” participants (participant database)
- STI clinic referrals

Process

- Development and tracking of metrics on methods
- Multiple screening visits
- Team discussion of ALL participants in screening
- Client-centered approach

Outcomes

- Participants motivated by altruism
- High levels of retention and drug detection in previous studies

Where and how efforts will be focused

Site Leadership

- Provide overall vision and motivation
- Oversee weekly team meetings
- Online forums (Reddit, etc.)
- Radio shows
- Community talks

Counseling Staff

- First participant “touch”
- Ensure understanding of study procedures & time commitment
- Utilize community ties
- Counseling supervision

Clinical Staff

- Second participant “touch”
- Assess participant’s motivations to participate in study
- Conduct provider and community education

CP Team

- Create excitement about new HIV prevention products
- Educate potential participants at outreach events
- Social media
- Provide overview during telephone pre-screening

All: Team approach to participant selection





Questions?

MTN-017

RIHES, CHIANG MAI, THAILAND

PARTICIPANT SELECTION

What does the 'right' MTN-017 participant look like to us?

1. Willing to use study product which is required in the study.
2. Not seriously concern or feel very much nervous about side effect of study products using in the study
3. Not seriously concern about stigma issue from using product by their family, sexual partner, friends ?
4. Have a good personality, not an anxiety type person
5. Provide a clear locator and agree to be visited by the staff if necessary (in case we can not contact by phone)

How pre-screening be performed for a potential participants?

RIHES has studies that involved MSM population and process at PIMAN Clinic are

1. Pre Screening study 685 persons
(Since 2007 – current)
2. iPrEx study 114 persons
(Since 2008 – current)
3. HPV study 200 persons
(Since October 2011-Jan 2012)

How are we pre-screening participants?

We plan to select participants for MTN017 by ..

- Pre Screening protocol at Piman clinic => We will know HIV status, willingness, receptive anal intercourse.
- iPrEx protocol => We will know attitude, willingness, cooperation to protocol.
- HPV protocol => We will know attitude, willingness, cooperative to protocol.

Recruitment Lessons Learned from Previous Studies

iPrEx study

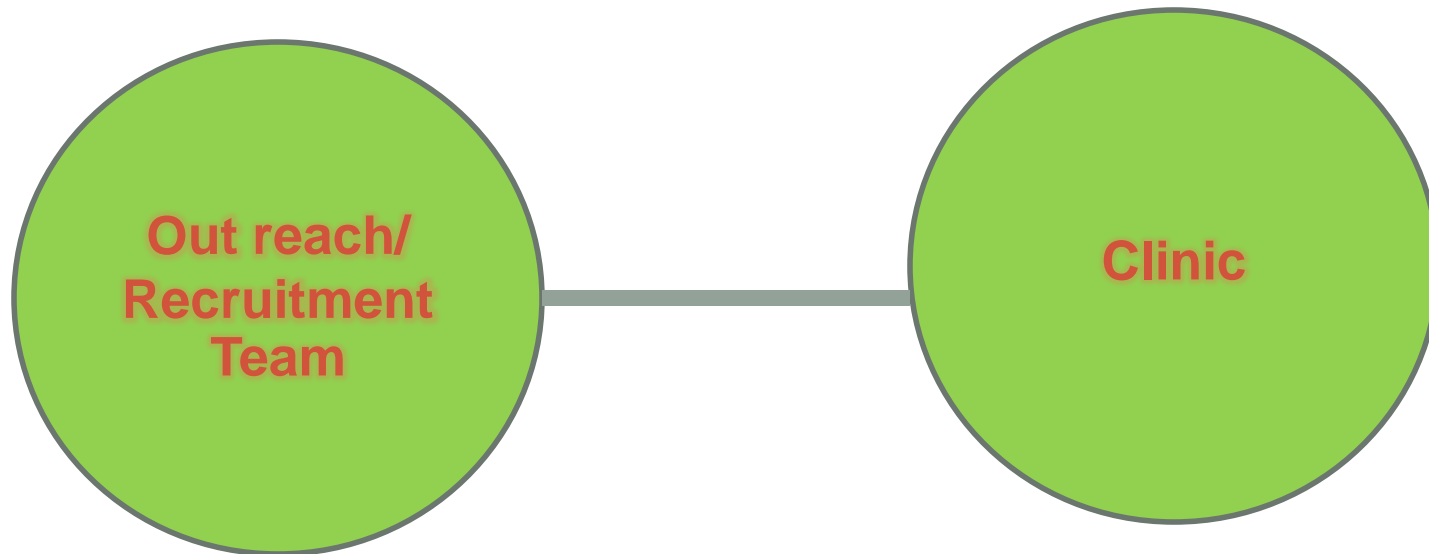
Pre Screen : Screen 3 : 1

Screen : Enroll 1.3 : 1

Recruitment Lessons Learned from Previous Studies

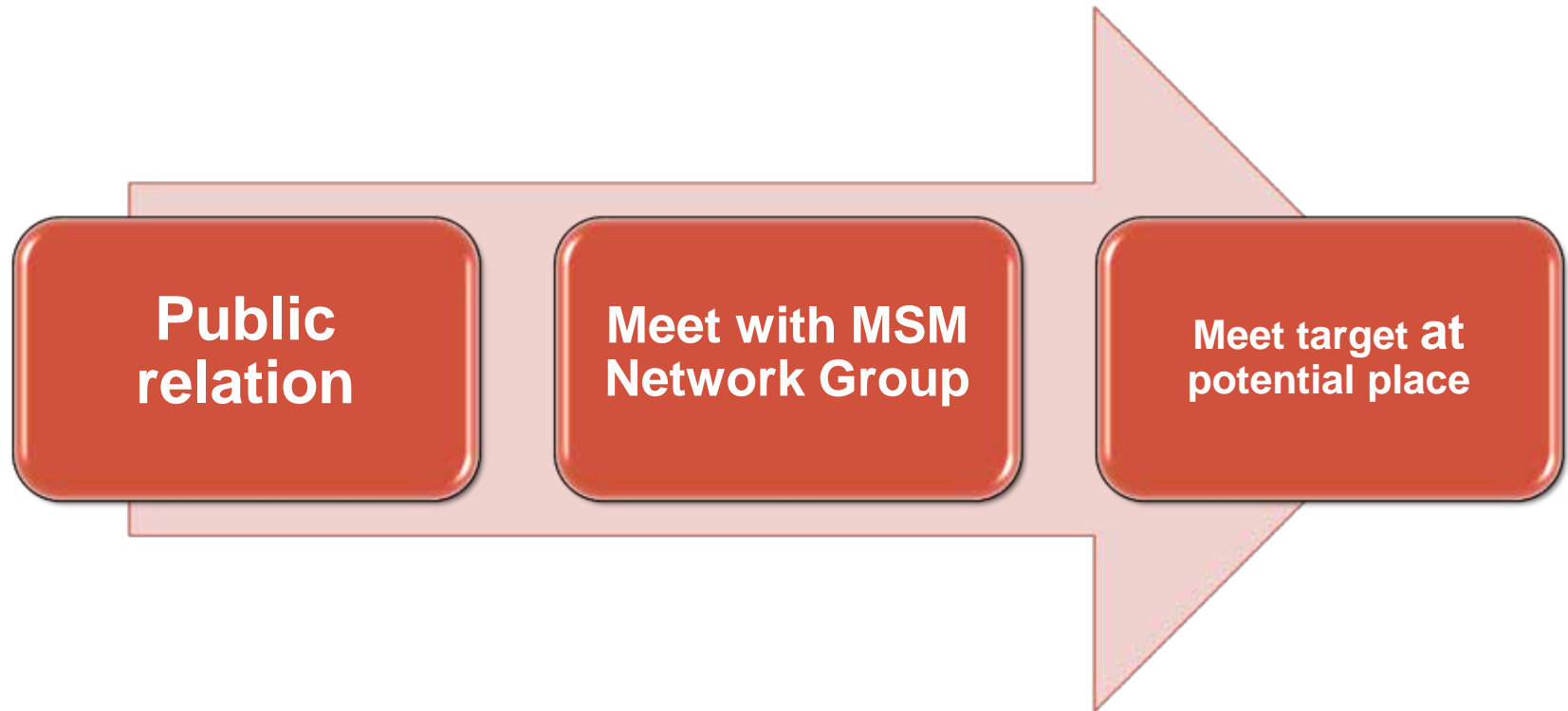
For iPrEx study

- Participants will be recruited from



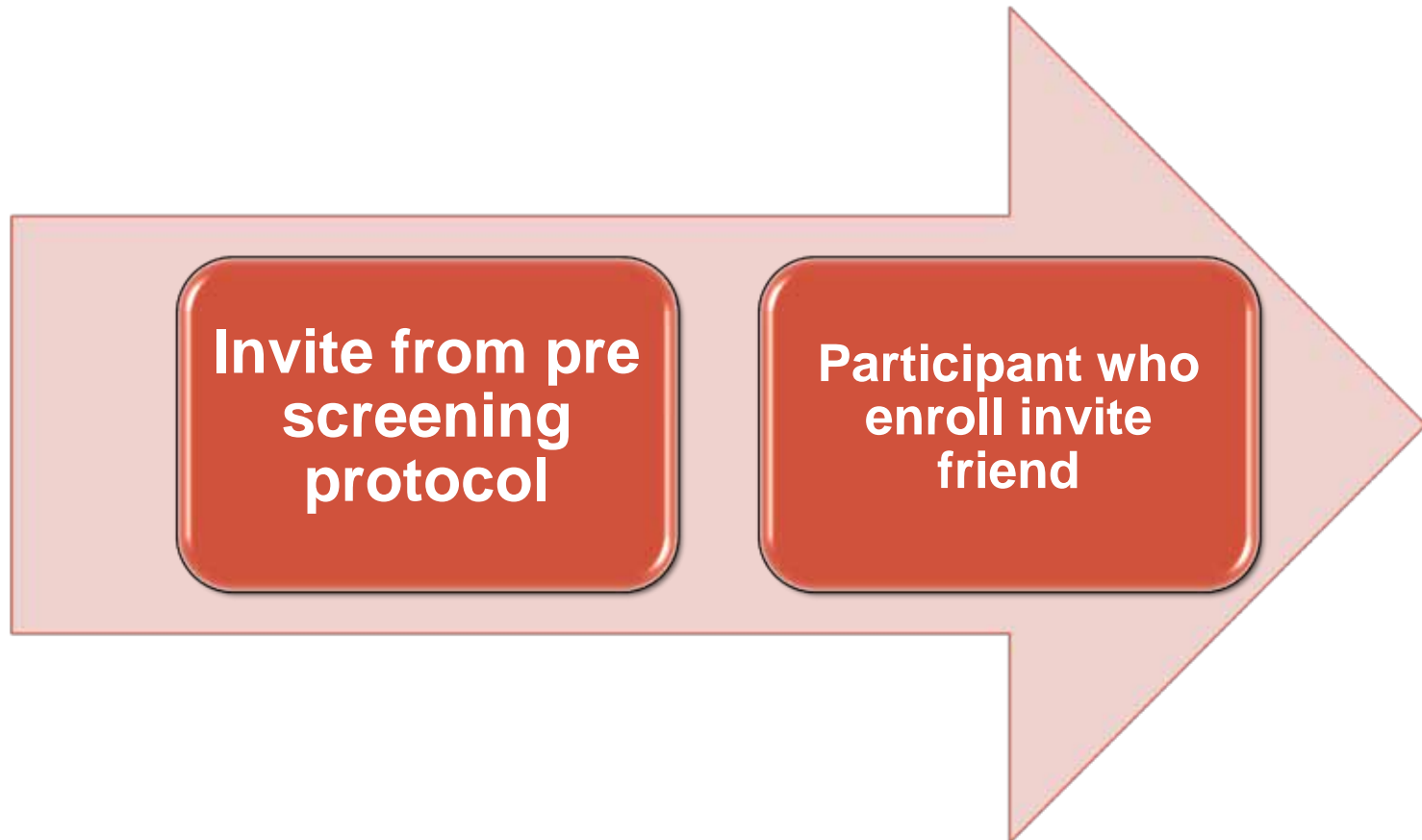
Recruitment Lessons Learned from Previous Studies

Out reach team => using the following methods



Recruitment Lessons Learned from Previous Studies

Clinic team use methods



Recruitment Lessons Learned from Previous Studies

Potential participants will be considered by.....

- Willing and understand to comply with the protocol
- Willing to come to the clinic throughout the study
- No plan to move out of the area in the next 1-2 yrs.
- Have stable residence and agree to be contacted by staff
- Not seriously concern about side effect of the product
- Not seriously concern about stigma that using product
- Not anxiety personality
- Interactive communication with staff

Where and how will our efforts be focused?

- Site Leadership
 - Regular meeting with staff and out reach team
 - Meeting with organize and CAB for explain protocol
- Clinical Staff
 - Regular meeting with out reach team
 - Recommend participant to talk with friend who interest to join the study.
 - Invite participant from previous study to receive information of study
 - Proper equipment for help to explain procedure of protocol
- Community/Recruitment/Outreach Team
 - Regular meeting with clinic team for assess participant who enrolled.
 - Public relation and has connection with MSM's network



MTN-017
Study Recruitment
& Participant Selection

Fenway Site | Boston, MA, USA

Ian R Lemieux, RN, MPH, MLS(ASCP) - Clinical Project Manager
Amber Rucker, BS - Senior Research Associate

RECRUITMENT MATERIAL DESIGN CONCEPT





**Is there a place for
a medicated lube in
HIV prevention?**

Could a medicated lube help prevent HIV?

Help us find out. Fenway Health is looking for males and transgender women to participate in a research study of a medicated gel to prevent HIV. Participants will receive up to \$1,000 for their time.

You may be eligible if you are:

- A male or trans woman who has sex with males
- 18 or older
- HIV-negative
- Sexually active



COM.12.133

For more information, call 617.927.6450
or email MTN17@fenwayhealth.org

THE *RIGHT* PARTICIPANT

Clinic staff will routinely assess participant:

- Punctuality and reliability
- Behaviors – respectful and appropriate
- Honest nature
- Literacy and communication skills
- Understanding of the purpose of this study
- Willingness and ability to follow instructions
- Recognition of potential impact to self and/or study if unable to comply with procedures

Ideal characteristics:

- Willing, able, interested; Available, flexible, organized; Motivated to participate; Past research participation; etc.

PRE-SCREENING

Prior to Enrollment prospective participants and clinic staff will interact, at a minimum, via:



** Not inclusive of initial contacts via field recruitment or intra-clinic referral.*

PRE-SCREENING

•Telephone Pre-screen

- Led by Recruitment Team; Participant visit Hx reviewed; Provide study background; Assess initial eligibility

•Pre-screen Consultation

(Telephone PS Eligible & Interested in Proceeding)

- IRB approved 30 minute sessions; Face-to-face meeting and review of key details of study including *MTN-017 Information Sheet*; Q & A; Provide *MTN-017 Informed Consent Booklet*, if appropriate, for review prior to first part of Screening Visit

•Two-part Screening Visit

- Each part (Visit 1.0a and 1.0b) approximately 2 hours; Requires the participant to visit the clinic an additional time prior to enrollment (staff can assess ability to keep appointments, arrive on time, willingness/readiness to complete study visits)

LESSONS LEARNED

•MTN-007

- Detailed explanation of study during recruitment and screening highlighted its clinical complexities up front
- Leveraged referrals from participants, as well as Fenway staff who were able to connect team with prospective/past participants within study population

•MTN-013

- The need to select appropriate forums for recruitment
- Plan to engage/recruit a large enough cohort to account for missed visits, pre-screen/screen fails, external factors that may preclude participation, etc.
- Institution of required 30 minute, in-clinic, pre-screen consultation to answer/ask questions and meet staff

ENHANCING INVOLVEMENT

- **Site Leadership**

- Daily communications via email or in-person; weekly reports of recruitment and study activities

- **Clinical Staff**

- Weekly Operations Team Meeting for staff to review study status, clinical process, and participant retention

- **Counseling Staff**

- BRWG supervision and assessment of counselors

- **Community Engagement**

- Integration of rectal microbicides in biomedical prevention updates to appropriate community stakeholders

- **Recruitment**

- Weekly meetings with clinical and recruitment staff to review the ongoing success of recruitment strategies, and any enrollment or retention issues



THANK YOU!

Questions for the Fenway site:

ilemieux@fenwayhealth.org

617.927.6027

Questions for Fenway MTN-017 Recruitment:

jly@fenwayhealth.org

617.927.6227

MTN-017

Participant Selection

HIV/STD Research Program
Thailand MOPH – US CDC Collaboration
Bangkok, Thailand

6 June 2013

Silom Community Clinic Research Team

- High retention in Bangkok MSM Cohort Study over 3-5 years
- High retention in Bangkok Tenofovir Study Trial over 8 years
- Perfect (100%) retention in HPTN-067 after 1 year
- Our CRS considers finding the optimal participants to maximize retention very important



What does the 'optimal' MTN-017 participant look like to us?

- Desire to want to help others/ Buddhist “merit making”
- Motivated and interested to participate in research
- History of visiting SCC for cohort study or VCT (monthly and sometimes weekly) frequently
- Self aware about perineal area, has history of having anal exam or at least not squeamish, comfortable with their own anal health
- Comfortable about applicators, and/or has familiarity with rectal douching
- Minimal frequency of receptive sex (planned to have ~1-3 times a month)
- Almost always uses (receptive) condom/lube
- Comfortable with medical procedures/sigmoidoscope

How are we pre-screening participants?

- **Educational tools**

- Timetable tool – one page of visit frequency, potential time requirements, number of visits, length of visits, randomization and crossover
- Pictures of equipment (sigmoidoscope, applicator, pills)

- **Checklists**

- ACASI screening questions (condom use, frequency of visit, previous STI, rectal douching)
- Identification of potential barriers to availability and participation with visits and schedule (working hours, distance to living location, transport restrictions)

- **Nurse interview**

- Silom Clinic nurses get to know participants quite well, understand their personality, motivation, “what makes them tick”

Recruitment lessons learned from previous studies

Describe lessons learned from recruiting for other PrEP or microbicide studies

- Frequency of study visits – HPTN-067
- Participants have been concerned about how often they must come, but so far every enrolled participant has attended 100% of the time (100% retention)
- Participants have done their best despite rigorous schedule
- Side effects
 - We instruct participants that they can come back anytime, that AE's are minimal if at all, we always dispense with caution
 - Truvada® is among the most safe HIV/AIDS drugs in use
 - Close supervision and monitoring of AE's in the population, “we are ready to assist you about any concerns ”
- Resistance risk
 - So far seen only in those who do not take as prescribed

Where and how will our efforts be focused?

For each item below, describe how your site will focus its efforts on enhancing the involvement of each of the groups below.

- Site Leadership

- Engaged in all aspects of the trial

- Clinical Staff

- Be truthful and forthright with potential participants
- Experience, low turnover rate, commitment

- Counseling staff

- Refresher training course three times/year

- Community Outreach team

- Engage with CAB and HPTN CWG
- Using chat application [Line, Twitter, or Facebook] to educate or prep them about the study
- Use participants as word-of-mouth recruiters (this has worked quite well for cohort study recruitment)

Summary

- High interest in finding motivated, self aware, enthusiastic study participants
- Nurses have 7 years of experience working with the study population, are very “tuned in” to what needs and interests are, will enhance with educational tools and checklists
- Lessons learned from HPTN-067 about study visit frequency and concerns about side effects will be applied
- Finding the optimal participants is a team effort

MTN-017

Recruitment & Retention

Renee Weinman | Research Recruiter/Outreach Coordinator

Jonathan Baker | Rita Labbett | Mythili Ramakrishna

University of Pittsburgh



The 'Right' MTN-017 Participant

- The “right” participant does not have a certain look; they vary by race, age, socioeconomic status, education, background, etc.
- However, the “right” participants have common characteristics:
 - They ask thought-out questions
 - They understand the purpose of the study, and can explain it back to you (and their friends)
 - They understand what is required of them and why
 - They are genuinely interested and motivated by altruism (even if they are motivated by compensation as well)
 - *Flyers/ads state “compensation will be provided” but no actual amount is listed

Pre-Screening Participants

- Participants are pre-screened by study staff (recruiter) who is culturally competent and familiar with study protocol
- Phone screens include an explanation of the study focusing on time commitments and participant expectations
- Eligibility criteria are reviewed
- Increased detail in phone screen helps identify most appropriate participants

Informed Consent

MTN-017: A Study of Truvada Pills and Tenofovir Gel

Contact the Study staff with any concerns:

Stacey xxx-xxx-xxxx

Carol xxx-xxx-xxxx

Carly xxx-xxx-xxxx

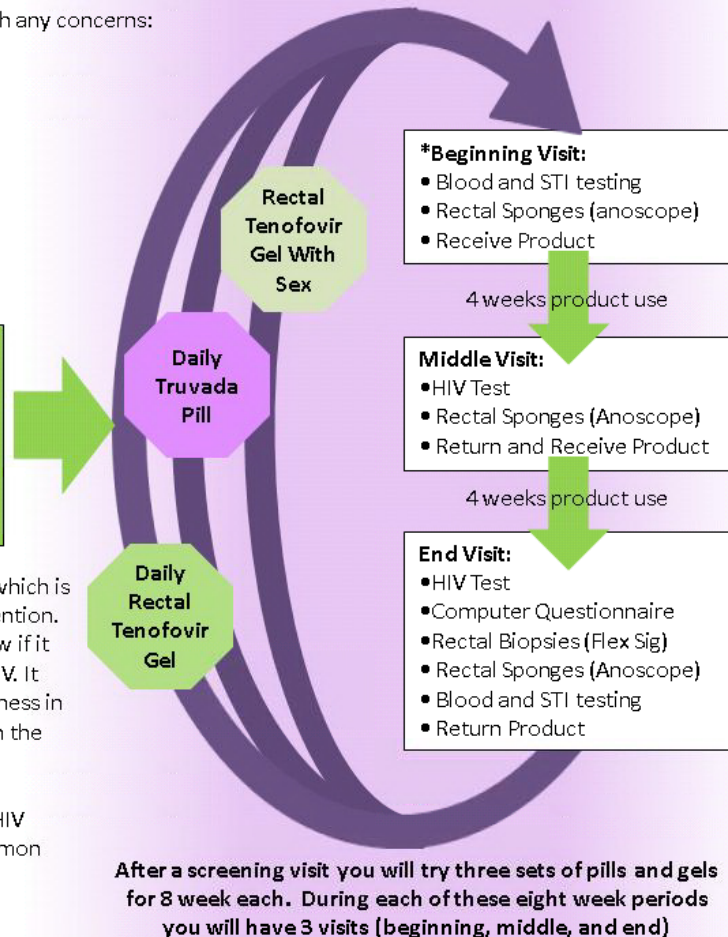
Purpose: To look at the safety of tenofovir gel and Truvada pills, and find out how men feel about using them

Screening Visit: (about xxx hour)

- Review a consent form
- Complete paperwork
- Physical exam
- Rectal exam
- STI and HIV tests

Tenofovir is a medication which is experimental for HIV prevention. This means we do not know if it works to protect against HIV. It may cause burning or soreness in the genital area and pain in the pelvic area.

Truvada is a pill taken for HIV prevention. The most common side effect is nausea/upset stomach



*Beginning Visit:

- Blood and STI testing
- Rectal Sponges (anoscope)
- Receive Product

4 weeks product use

Middle Visit:

- HIV Test
- Rectal Sponges (Anoscope)
- Return and Receive Product

4 weeks product use

End Visit:

- HIV Test
- Computer Questionnaire
- Rectal Biopsies (Flex Sig)
- Rectal Sponges (Anoscope)
- Blood and STI testing
- Return Product

After a screening visit you will try three sets of pills and gels for 8 week each. During each of these eight week periods you will have 3 visits (beginning, middle, and end)



Risks: You may experience discomfort or embarrassment with anal swabs, exams, and questions; Fear or worry about test results. Blood draw may cause pain, bruising, or dizziness.

Biopsies: Biopsies are pieces of tissue approximately the size of a pin head. These should not be painful. There is a small risk of damaging the rectum or causing irritation or infection. They may cause slight bleeding with bowel movements for 1-2 days.

Enema: The tip of an enema bottle will be inserted into your anus, and about 4 ounces of fluid will be squeezed into your rectum. Holding and releasing this fluid may be uncomfortable

*The first beginning visit

- Rectal Biopsies
- Blood draw; HIV Test
- Computer Questionnaire

Participant Retention

- Text or call to remind him of appointments. Texting has yielded high retention results.
- Greet participants in the lobby. Introduce them to staff. Offer them a drink/snack. Make them feel welcomed and relaxed.
- The study staff serves as “hand holder” during the process.
 - Especially for first time participants
- Retention Rates:
 - 100% - MTN-006/RMP-02 - 100% (8 flex. Sig w/ biopsies)
 - 100% - MTN-007 (3 flex. Sig w/ biopsies)
 - 100% - Project GEL Stage 2 (3 set of anoscopic biopsies)

We've Learned This Population:

- Uses of current social media and technology (Craigslist, MSM chat/date sites, Facebook, Twitter, Smartphones)
 - Craigslist has been highly effective, whereas facebook has not. Grindr?
 - Popularity of MSM dating sites vary by geographical location
 - Text messaging is preferred method of communication
- Is very active (school + jobs + activities) and needs clinical flexibility
- Have varied definitions of relationship and condom usage
 - Confident/empowered MSM with friends/family support engage in ↓risk behavior
 - Condom use in “monogamous relationships” is low
 - MSM may be non-monogamous but *think* their partners are monogamous



craigslist 



We've Learned This Population:

- May view exams/testing as benefits, but men may
 - Fear of invasive procedures (rectal exams, needles, biopsies)
 - Fear of knowing HIV/STI status (stigma, privacy)
 - Fear being treated at and reporting findings to local health department
 - Most have never had a rectal exam
- May be wary of trusting researchers, especially black and ethnic minority MSM
 - Recruiters must **repeatedly involve themselves** in the population's culture such as ball scene, bars/clubs, events, and activities
- Maintain function (social/school/work) even with high levels of substance abuse



Our Study Staff

- Site Leadership is available to speak to participants before entry and during participation. Leadership updated on bimonthly at staff meetings
- Clinical staff have experience with MSM and are involved in community outreach events such as Pride
- Counseling staff conduct culturally appropriate counseling specific for MSM. Patient-centered risk-reduction counseling provided, rather than one-size-fits-all approach



Recruitment Efforts

- #1- Tap into our well-established participant pool
- Our HIV Prevention Registry has 311 participants
- Participant word of mouth

Have You Thought about Participating in HIV Prevention Research?

You can be part of local research efforts to prevent HIV worldwide. Anyone 18 or older may join our Research Registry to be contacted to participate in HIV prevention research studies.

If you're a man, a woman, or transgender person—if you're straight, gay, or bisexual—if you're HIV-negative, HIV-positive, or don't know your status—you're welcome to join. For basic information about the clinical research process, [click here](#).

Completing this consent form enrolls you into this Research Registry and gives your permission for us to match you with research studies you may be interested in and to use information provided by you. You will be emailed a password-protected link so you can answer some medical and social questions. Our studies mostly look at developing new ways to prevent HIV such as using [microbicides](#), [vaccines](#) and [PrEP \(pre-exposure prophylaxis\)](#).

There is no compensation for joining this Registry. But, if you are enrolled in a study you will be compensated for your time and travel. Every study compensates differently based on what is involved in participation.

Only members of the HIV Prevention Research Registry staff will have access to your identifiable, self-reported medical information and use this information in a confidential, HIPAA-directed manner. However, just as with the use of your medical information for health care purposes, we cannot guarantee its privacy. Thank you.

1. Please use your full legal name:

First Name:	<input type="text"/>	Middle Initial:	<input type="text"/>	Last Name:	<input type="text"/>
-------------	----------------------	-----------------	----------------------	------------	----------------------

2. Email address I don't have email, please call instead

3. Phone (000-000-0000)

4. I was born: Male Female

5. Date of Birth? (MM/DD/YYYY)


[Press to Confirm your Permission to Enroll in this Research Registry](#)

www.hivregis.pitt.edu

For additional information, email HIVRegis@pitt.edu, call 412-956-9686, or write to HIV Prevention Research Registry, 3520 Fifth Ave., Ste. 510, Pittsburgh, PA 15213.

The Registry is supported by funding from the [National Institutes of Health \(NIH\)](#) and the Registry's Director is [Jan McGowan, MD, PhD](#).

You may withdraw from the Registry by email at HIVRegis@pitt.edu or writing to the address above. Questions you have about research participant rights are answered by the Human Subject Protection Advocate at the [University of Pittsburgh IRB Office](#) at 866-212-2668.



University of Pittsburgh

IRB Number: PRO11110371
Approval Date: 1/2/2013
Renewal Date: 1/1/2014

Recruitment Efforts

- New designed ads that will be:
 - In local publications focused on GLBT- Equal Magazine and broader audiences - City Paper
 - Updated weekly on Craigslist
 - Sent to and posted at local LGBT organizations, bars, bath house, etc. and universities/colleges, non-profits, clinics

HIV Prevention RESEARCH STUDY

The University of Pittsburgh is looking for HIV-negative men 18 years of age and older who have sex with men for a research study that is looking at anti-HIV pills and lubricants for future use to prevent HIV transmission.

BE A HERO. TAKE PART.

COMPENSATION WILL BE PROVIDED.

For more information, please call **412-956-9686**

University of Pittsburgh
www.hivregis.pitt.edu

BE A HERO. TAKE PART.

BE A HERO. HIV Prevention RESEARCH STUDY

The University of Pittsburgh is looking for HIV-negative men 18 years of age and older who have sex with men for a research study that is looking at anti-HIV pills and lubricants for future use to prevent HIV transmission.

COMPENSATION WILL BE PROVIDED.

For more information, please call **412-956-9686**

University of Pittsburgh
www.hivregis.pitt.edu

HIV Prevention RESEARCH STUDY



The University of Pittsburgh is looking for HIV-negative men 18 years of age and older who have sex with men for a research study that is looking at anti-HIV pills and lubricants for future use to prevent HIV transmission.



University of Pittsburgh

www.hivregis.pitt.edu

COMPENSATION WILL BE PROVIDED.

For more information, please call
412-956-9686

BE A HERO. TAKE PART.

Recruitment Efforts

- Pittsburgh Gay Pride (June) and the Black Gay Pride (July)



Be A Hero!
by taking part in an
HIV Prevention Research Study
www.hivregis.pitt.edu
University of Pittsburgh



Recruitment Efforts

- Utilize the Pitt Mens Study (Pittsburgh site of the Multi Center AIDS Cohort Study) for HIV-negative controls and serodiscordant couples
- Attend health fairs and community events such as Black HIV Awareness Day events at University of Pittsburgh



Recruitment Efforts

- Backup Plan: may include hosting events, using Grindr, accessing the ball community





Get a Heart-On for HIV Prevention Research

Thursday, February 9th from 6-9 p.m.
at The Warhol Museum

Good Food Music Prizes Free Parking

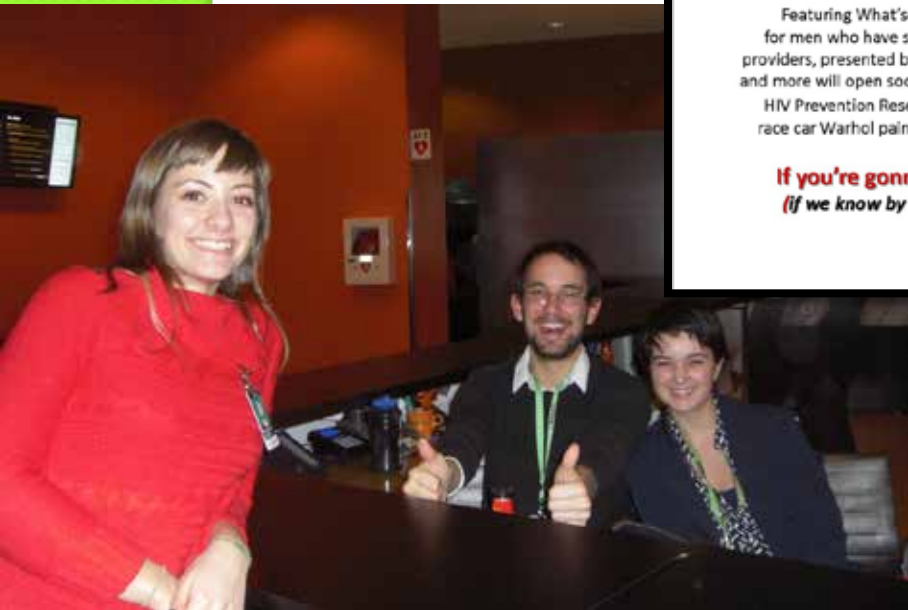
Featuring What's-Going-On in HIV Prevention Research for men who have sex with men, and their LGBT healthcare providers, presented by local researchers. Many studies are open and more will open soon! Your host is the University of Pittsburgh HIV Prevention Research team. **Bonus:** The wild BMW M1 race car Warhol painted in 1977 will be on display that night!

If you're gonna come... call 412-383-1313
(if we know by the 6th it helps us plan the food)

EDUCATION SESSIONS

6:30
7:10
7:50
8:30

PICK UP A PRIZE
AFTER IT'S OVER
(YOU'LL LIKE IT!)





Questions?

MTN-017

Asociación Civil Impacta Salud y
Educación

Participant Selection

What does the 'right' MTN-017 participant look like to us?

- Participants who live in their own apartment
- Participants with their parents living in Lima
- Participants who works or study, but not both
- Participants who does not have plans to travel
- Participants who have "valid" motivations to participate in the study

How are we pre-screening participants?

- To have more than three effective ways to contact the participant, including:
 - Home phone, mobile phone, work phone
 - Facebook profile
 - Friend or close family member
- To visit participant's home prior to enrolment to confirm the address
- To have available participant's schedule for work or study and plan with the participant the best time for study visits.
- To establish empathy with the participant

Where and how will our efforts be focused?

- Sharing information and material about annual MTN meetings with the staff
- Having bi-weekly meetings to discuss protocol operation
- Sharing new findings about microbicides with the staff
- Weekly MTN meeting between counselors to discuss challenges during counseling sessions and obtain feedback from the group

Community Engagement

- ü Annual Plan for MTN approved
- ü GELLUX, poster and brochure
- ü Rectal Microbicides Video
- ü Presentation of the study
 - CAB
 - CBOs
 - Newsletter
 - Radio Shows
 - Facebook
 - Gellux tours

héro[♂]es
Ser Gellux



UPER HEROE
GELLUX -017



* Presenting Gellux to the community



POSTER

herpés

¿ESTÁS INTERESADO EN SABER MÁS DE GELLAX? CONTACTA MÁS EN EL CELULAR

Línea Gratuita 0-800-4431
Email: herpes@capacitacion.org
Web: www.capacitacion.org

herpes.org

SEGÚN LAS ESTADÍSTICAS...

El 90% de los hombres y el 70% de las mujeres usan algún método que los ayuda a evitar el VIH, los **herpes** y otras enfermedades.

EL SEXO ANAL ES UNA DE LAS FORMAS MÁS RIESGOSAS DE TRANSMISIÓN DEL VIH

Considerarlo solo en caso está reduciendo la **seguridad** del intercambio sexual que en el futuro **puede** reducir el riesgo que una persona contraiga el VIH.

¿POR QUÉ LA INTERVENCIÓN DEL GELLAX ES MÁS EFECTIVA Y COMODA QUE OTROS MÉTODOS DE CONTROL DEL VIH?

El microbicida recubierto es un gel que esperamos que en el futuro **pueda** reducir el riesgo de contraer el VIH.

¿CÓMO CONTIENE EL GELLAX?

Contiene el lamivudina, un antirretroviral que se usa en el tratamiento para personas que tienen el VIH.

EL ESTUDIO GELLAX - 071

Con este estudio demostramos que fue **aceptable y seguro** usar el gel de lamivudina por el resto de la vida para compararlo con la toma de una pastilla al día.

El estudio está compuesto por 1 antirretroviral que también se usa para el tratamiento del VIH.

¡PARTICIPA!

TU AYUDA ES ESENCIAL PARA QUE TENAMOS UNA NUEVA ESTRATEGIA DE PREVENCIÓN

...Y NO OLVIDES QUE EL GELLAX ES UNA DE LAS Opciones MÁS EFECTIVAS DE PREVENCIÓN

BROCHURE

facebook Gellux Impa

Gellux Impacta Actualizar información Registro de actividad

- Trebeja en Asocion Civil Impacta Salud y Educacion
- Vive en Lima
- De Lima
- Agregar tu escuela

Información Amigos 313 Fotos 15 Mapa 15 Me gusta 5

Estado Foto Acontecimiento importante

Gellux, ¿cómo te va?

Gellux Impacta compartió un enlace a través de IRMA ALC 3 de enero

Los Microbicidas Vaginales como una estrategia prometedora...

Actividad Reciente

- Gellux agregó a Lima como su ciudad de origen.
- Gellux es soltero(a).
- Gellux cambió la siguiente información: Me interesan.
- Gellux agregó un trabajo en Asocion Civil Impacta Salud y Educacion a su biog...

* FACEBOOK PAGE

465 friends

¿Que pasaría si una sustancia parecida a un gel,
supositorio o lubricante pudiera
protegernos del **VIH**?



Tailandia, Estados Unidos, Sud Africa... y ahora en Perú!

Muy pronto, llevaremos a cabo el estudio de **MICROBICIDAS RECTALES**



FOTO de HEROE
en FB

Gellux-017

Porque nos merecemos
más alternativas para la prevención

¿Interesado
en formar parte
del futuro?
envianos un mensaje
al Inbox para más info

* INTRIGUE CAMPAING ON
FACEBOOK



BOLETÍN

Número 21 - Junio 2012

Pedro Gonzales, MD, MAS

Jefe de la Unidad de Investigación Clínica
Coordinador Clínico
Investigador Principal MTN, HVTN



UNA NUEVA OPCIÓN : MICROBICIDAS

Ante la necesidad de nuevos métodos de prevención, surge una nueva opción: las microbicidas. La finalidad de las microbicidas es de prevenir o reducir significativamente el riesgo de infección por el VIH y otras ITS. Se aplican vía vaginal o rectal, y se presentan en forma de gel, enemas, anillos, etc.

El riesgo de infectarse del VIH por sexo anal no protegido es hasta 20 veces mayor que por sexo vaginal no protegido. Alrededor del 5 al 10 % de la población general practica el sexo anal; tendencia que va en aumento.

En Julio del 2010, por primera vez un microbicida vaginal conteniendo el antiretroviral Tenofovir probó ser seguro y efectivo. Luego de este éxito, se propone probar el microbicida a nivel rectal, y es así como nace el estudio **Gellux 17**. Este estudio responderá a la pregunta que tan seguro y aceptable es el gel de Tenofovir 17 y que incluirá 186 HSH y

mujeres transgénero de Sudáfrica, Tailandia, Estados Unidos y Perú. Cabe mencionar que Impacta es ahora sede oficial del Instituto de Salud de los Estados Unidos para llevar a cabo este estudio.

GELLUX® te invita a probar los microbicidas en gel como un método de protección contra el VIH. El te informará sobre el estudio y los microbicidas en general.

Como parte de la preparación de este estudio, se realizó una consulta comunitaria en Lima, con la participación de las principales Organizaciones de Base Comunitaria del país, quienes brindaron sus opiniones con respecto al estudio.

Soy optimista con respecto al futuro de los microbicidas rectales, y confío que los resultados serán beneficiosos para la población. Desde Impacta continuamos con nuestro compromiso de encontrar un microbicida rectal que sea eficaz de prevenir el VIH y disminuir la epidemia



*Gellux es un super héroe que nace de la campaña Heroes Ser Voluntario

* NEWSLETTER

FEATURING THE MTN 017 STUDY

- * Presentation of the MTN – 017 study to Casa Abierta



- * Presenting the MTN 017 to the Epicentro Community Group



MTN-017
Site Presentation
Participant Selection

**Maternal-Infant Studies Center
University of Puerto Rico
Medical Sciences Campus
CRS-30350**

What does the 'right' MTN-017 participant look like to us?

1. Responsible:
It will determine the success of the study.
2. Wants to learn more:
Will help us engage into conversation about the study.
3. Curious!:
Self-motivated to ask and take a step forward.
4. Accessible:
We need participants that will stay connected all the step of the way.

How are we pre-screening participants?

Face-to-face pre-screening activities:

1. Maintaining a community presence during key events: Getting out there, letting us know...
Letting know our clinic support the LGBTTT community!
2. Scheduling pre-screening visits to the clinic:
Will help to know the participant in person and establish a rapport. Will help to determine better the commitment the participant has and start an education process.

Recruitment Lessons Learned from Previous Studies: Project Gel, Puerto Rico

1. Online recruitment works well for MSM and face-to-face works better for trans women in Puerto Rico.
2. There's still a necessity to educate about the existence of microbicides.

Where and how will our efforts be focused?

For each item below, describe how your site will focus its efforts on enhancing the involvement of each of the groups below.

- Site Leadership: being involved in the community and recruitment plan development, attending recruitment activities.
- Clinical Staff: being involved in the recruit process and in the planning of activities. Getting trained during staff meetings.
- Counseling/Staff/Community/Recruitment/Outreach Team: we are one! Working together every step of the way.



DESMOND TUTU
HIV FOUNDATION

MTN 017 Participant Selection

6 June 2013

Mr. Right...meet 'Simphiwe'

- Simphiwe is **25** and has lived in Delft, a township just outside of Cape Town, his entire life. Simphiwe came out as gay to his parents 10 years ago and **they have always been supportive**. In fact, he still lives with his parents so that he can save money for school.
- Simphiwe is **studying** at the Cape Peninsula University of Technology (CPUT), just down the road from our site. He wants to become a software programmer and work for Google someday. Simphiwe **isn't employed full time** since he is studying, but he does work part time for Incredible Connection, a local computer business.
- Simphiwe has never been a participant in a clinical trial, but he is **actively involved** in his community and has participated in a number of DTHF community activities. He can't get enough of the netball tournaments
- Simphiwe first heard about MTN 017 from watching a microbicides video at one of the DTHF meetings in Delft. He has a lot questions but he's **motivated to take part** in the study because he sees how other gay men in his community are affected by HIV.



"Simphiwe", an ideal participant for MTN 017

Mr. Right...meet 'Simphiwe'

- He understands that by participating in MTN 017, he is **doing his part** to protect his community. Simphiwe is very involved in his community and **he's in touch regularly** with DTHF outreach staff.
- Also, Simphiwe's best friend was an iPrEX participant, so **he's heard about our research** and learned a lot about what clinical trials are from his friend.
- Simphiwe isn't real but he embodies the characteristics that we've found are the most important in a study participant.
- For 017, the "right" participant is someone who is motivated to take part in the study in order to contribute to the fight against HIV.
- They are someone who is actively involved in their community and who has engaged with the DTHF previously. Our right participant would also be someone who is easily reach and who doesn't drop communication with the site.



"Simphiwe", an ideal participant for MTN 017

Important Characteristics

- **Age.** The right participant for us is in his mid- to late-twenties. From previous studies, younger participants (18-22) have proven more challenging to retain and to sustain regular communication with. They also have the highest frequency of missed or late study visits.
- **Previous Experience.** Has considerable involvement with the DTHF through prior research experience or community activities.
- **Social Support.** Is out of the closet, has the support of family or friend support, or has a partner.
- **Employment.** There is no clear distinction between which type of employment is most beneficial for study participation. Full-time employment often creates stability over longer periods of time but can often restrict participants availability. Furthermore, it can lead to stress which is conducive to participants terminating their participation. Unemployment provides flexibility in scheduling appointment and offers participants time to fulfill study requirements but overall creates instability for retention. Participants may easily move to find employment elsewhere in the country.
- **Location.** Mobility is common so some connection to Cape Town is important. No plans to move, if studying, he is not graduating within the year, and ideally has stable accommodation within reach of the site

Pre-Screening

- Pre-screening activities are established at all levels of the site.
- Beginning with community-based work, all potential participants will or have already interacted with study staff, including outreach workers, recruiters, and counselors.
- Through these interactions, staff are able to gain a deeper understanding of participant lifestyles and personalities outside of a study setting.
- This allows us to rule out potentially complicated retention challenges in the future. This also offers ability to judge participants commitment and creates additional points of contact.
- On a site-level, participants will be required to attend an informational pre-screen visit during which they can meet study staff, and receive further in-depth information about the study.
- During this time the requirements for the study are clearly explained and discussions are held with participants to identify any potential barriers to their participation and retention. A formal pre-screen protocol is in development.



Outreach staff get to know MSM at a DTHF Netball Game



Counselors take part in outreach activities to discuss study participation 5

Lessons Learned

- From previous studies, we have learned a great deal about both recruitment and retention.
- It is critical to have multiple points of contact with a participant prior to enrollment. If not, it's easy to enroll a participant who is not committed or otherwise challenging to retain.
- Points of contact include community meetings, social events, and clinic information sessions. It also includes points of contact with multiple types of staff including outreach and clinic staff.
- In terms of recruitment, in-person strategies have proven the most effective; however, multiple strategies must be implemented simultaneously, rigorously monitored, and adjusted as needed.
- A large team of outreach workers who are able to rotate their involvement with the study is essential. This also promotes a wider reach in terms of diversity in community and social networks. A commission-based system has been developed in order to invest resources into most successful recruiters.



The counseling team engage in multiple points of contacts with potential participants.



The recruitment team attends a monthly training meeting.

Lessons Learned

- Establishing a true relationship of partnership with the MSM community is absolutely necessary.
- Community activities are always focused on capacity building, education, and growth *not* on recruitment.
- Creating relationships and understanding between community members and the site is always the primary goal, recruitment is a byproduct.
- Staff Flexibility and scheduling is critical. In order to create strong relationships with community members and participants, staff must be willing to accommodate evening clinics, weekend events, and after-hour community activities.
- In doing so, participants who are unable to come during traditional hours are accommodated and staff are able to demonstrate to participants their commitment and motivation.



An outreach workers prepares warm Pap and Veg during a winter community meeting.

Recruitment: A Team Effort

- **Overall, its a team effort.** Recruiting the right participant is a team responsibility. Each study staff member will play an active role in the recruitment and retention of study participants for MTN 017. This is facilitated by clear roles and responsibilities as well as regular communication between all staff. All staff will: Promote comfort and openness environment to encourage trusted relationship. Ensure that the study site is a friendly, safe, and welcoming environment.
-

Site Leadership.

- Will be responsible for designing, monitoring, and evaluating the recruitment and retention strategies in order to shift directions or change resources as needed.
 - Engages in daily check-ins among staff and facilitates weekly meetings with full clinic and community team to discuss updates, challenges and evaluations of pre-screening and screening attempts.
 - Works with site to develop solutions to challenges and barriers that are experienced.
-

Counseling staff.

- Keep in touch with participants during pre-screen and after enrollment.
- Includes social networking, email, phone, and house visits at multiple intervals during pre-screen and after enrollment
- Orientation of potential participants to site and staff.
- Ensure participants needs are met during site visits.

Clinic Staff.

- Provide all relevant information to potential participants and answer questions to their satisfaction during pre-screening, screening, and throughout the study.
 - Study Coordinators are responsible for ensuring the smooth functioning of administrative aspects of the project and to facilitate regular trainings with all staff.
 - Over see the implementation of dry runs with team to ensure that visit flows provide the best experience for participants and maximum recruitment efforts.
-

Outreach and Community Teams.

- Facilitate all community-based activities and responsible for disseminating information to potential study participants, with support of counseling staff.
- Conduct multiple activities to build rapport and trusting relationship which will aid regular visit attendance.

If all else fails...

We turn to “Three tons of Fun”, Cape Town’s infamous drag super stars...

