

# Needles and Lubes and Pills Oh My! The Future of HIV Prevention



Jim Maynard

The Fenway  
Institute of  
Fenway  
Community  
Health.

# Greetings from Boston!



Our Annual Winter Speedo  
Home of great cultural events such as  
Run.....

First State to have

Same Sex  
Marriage

So Far!

That's me and  
my hubby.....



# Home of World Class Research



The Fenway Institute

# HIV/AIDS Tool Kit



- Education & Behavior change

- HIV/AIDS Vaccines

- **Pre-exposure prophylaxis (PREP)**

- Male and female condoms

- Anti-retroviral therapy (mother-to-child)

- Post exposure prophylaxis (PEP)

- Microbicides

- Anti-retroviral therapy

- Care

- Education & Behavioral change

- Therapeutic Vaccines

The Fenway Institute at Fenway  
Community Health has a variety of HIV  
Prevention Research Studies going on  
at any one time including.....

Microbicides

Vaccines

And Pre Exposure Prophylaxis

# Our Newest Study is Entitled

Phase II Extended Safety  
Study of Tenofovir  
Disoproxil Fumarate (TDF)  
among HIV-1 Negative Men

Project PrEPare

# Why are we doing this study?

- We know about three major ways men can reduce their risk of getting HIV sexually...
  - not having sex at all (abstinence);
  - only having sex with one HIV negative partner (mutual monogamy); and
  - using condoms correctly every time they have sex.
- HIV infections are increasing worldwide.
- We need new ways to prevent HIV infection.
- Drugs (antiretrovirals) that treat HIV infection may help prevent HIV infection.
- One drug, tenofovir (TDF), is being tested for safety in healthy, HIV negative men.

# Why Tenofovir (TDF)?

- TDF is used in combination with other drugs to treat HIV infected people.
- Among HIV infected people taking TDF in combination with other drugs, side effects have been relatively rare.
- Some animal studies suggest TDF may be useful in preventing HIV infection.

Are there any other studies of TDF planned in HIV negative people?

- Several other larger studies are planned for high risk women and some men in Africa and Asia to see if TDF is safe and if it may prevent HIV infection.

Our study will only see if TDF is safe when used for longer periods of time among HIV negative men in the United States.

But before getting all excited about being in a study, you always need to ask yourself questions such as.....



# Does TDF have any side effects?

- Side effects that some HIV infected people have while taking TDF are:

Stomach problems like nausea,  
gas, or diarrhea

Dizziness

Rash

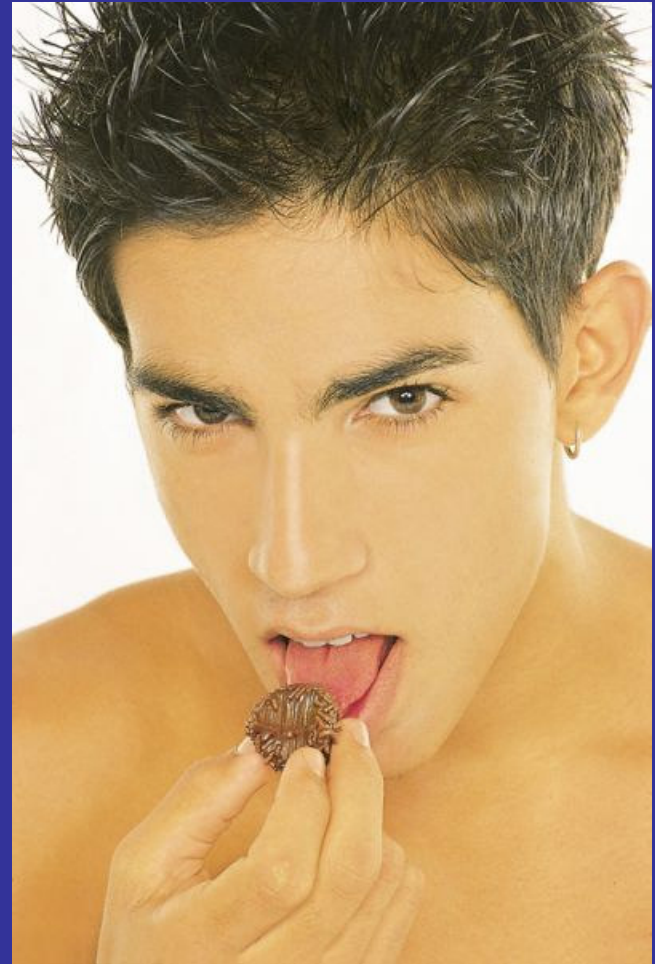
Vomiting

Kidney problems (stopping TDF  
usually reverses this).

TDF *may* cause loss of bone thickness.

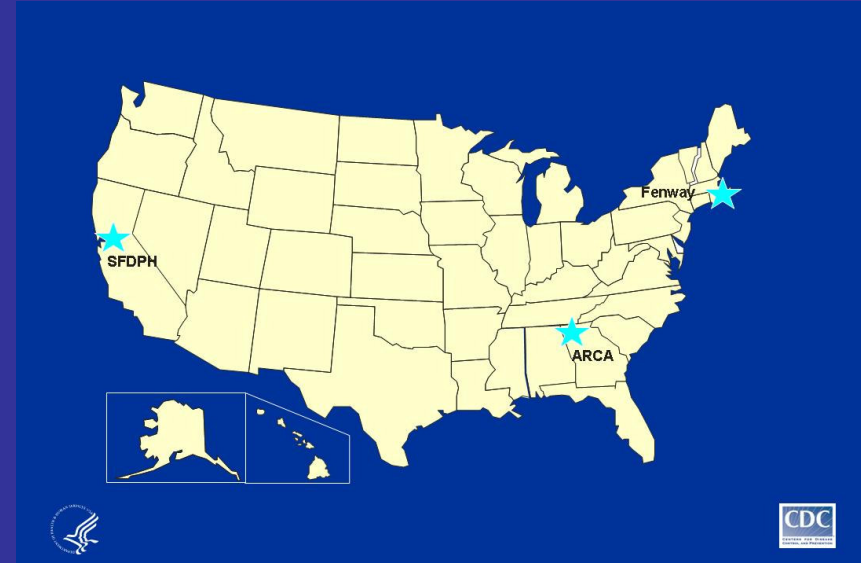
Most symptoms such as nausea will disappear in a couple of weeks.

Editor's Note: totally gratuitous picture of cute guy eating fruit.



# Who is doing this study?

- The Centers for Disease Control and Prevention (CDC) is the study sponsor.
- The study will be done at three sites.
  - AIDS Research Consortium of Atlanta (ARCA)
  - San Francisco Department of Health (SFDPH)
  - The Fenway Institute



# How will we test TDF safety?

- We will ask healthy HIV negative men who have sex with men to join.
- The study will last 2 years.
- All men will receive a daily study pill, either TDF or placebo (a dummy pill).
- Some men will receive the study pills at the start of their study participation, other men start pills after nine months.
- This study will allow us to see if there are any differences in:
  - side effects between men getting TDF and men getting placebo.
  - risk behavior between men getting pills right away and men getting them later.

Question

??????????

If men are taking a pill that they think **might** protect them from infection.....





Will their  
sexual  
choices  
become  
more risky?

What do you  
think?

# Who can enroll?

- HIV-negative men
- Age 18 – 60
- Report anal sex within the last year
- Generally healthy





How do we recruit participants?

# Why will some men in the study wait for nine months to take study pills?

- This will allow us to see if there is any difference in sexual behavior between those taking a pill and those who aren't.
- However...
  - *we will counsel all men in the study to reduce behaviors that put them at risk for HIV.*
- Because...
  - *some men will be getting placebo.*
  - *we don't yet know if TDF works to prevent HIV.*

Can just  
being in a  
research  
study  
increase  
your risk of  
becoming  
infected  
with HIV?



# How will we help protect the safety of study participants?

- Close monitoring of side effects.
- HIV risk reduction counseling.
- During the study, an **independent** committee of scientists will regularly review safety information...
  - About study participants *as a group*. This committee can stop the study if they have major concerns about safety.

# Why is it so important that you continue to practice safer sex?

- You and study staff will not know who is receiving TDF or placebo.
- No one knows...
  - if TDF will prevent HIV infection.
  - how TDF may affect HIV in early infection and how that may affect your future treatment options.

# Our PREP Team at Fenway



## Questions?

What else are we up to?



Our Tops and Bottoms Study to find an  
Glad you asked! HIV Vaccine.

# What is a Vaccine?

- **Vaccine** \vak - 'sen\ a substance that teaches the body's immune system to recognize and protect against a disease caused by an infectious agent or virus

# How does a vaccine work?



Mel Gibson

By teaching the body to recognize and fight invaders through mimicking a natural infection

Guy who looks like Mel





Think of this as making special cells in your body that will act as little soldiers

Soldiers trained to recognize a very specific enemy.

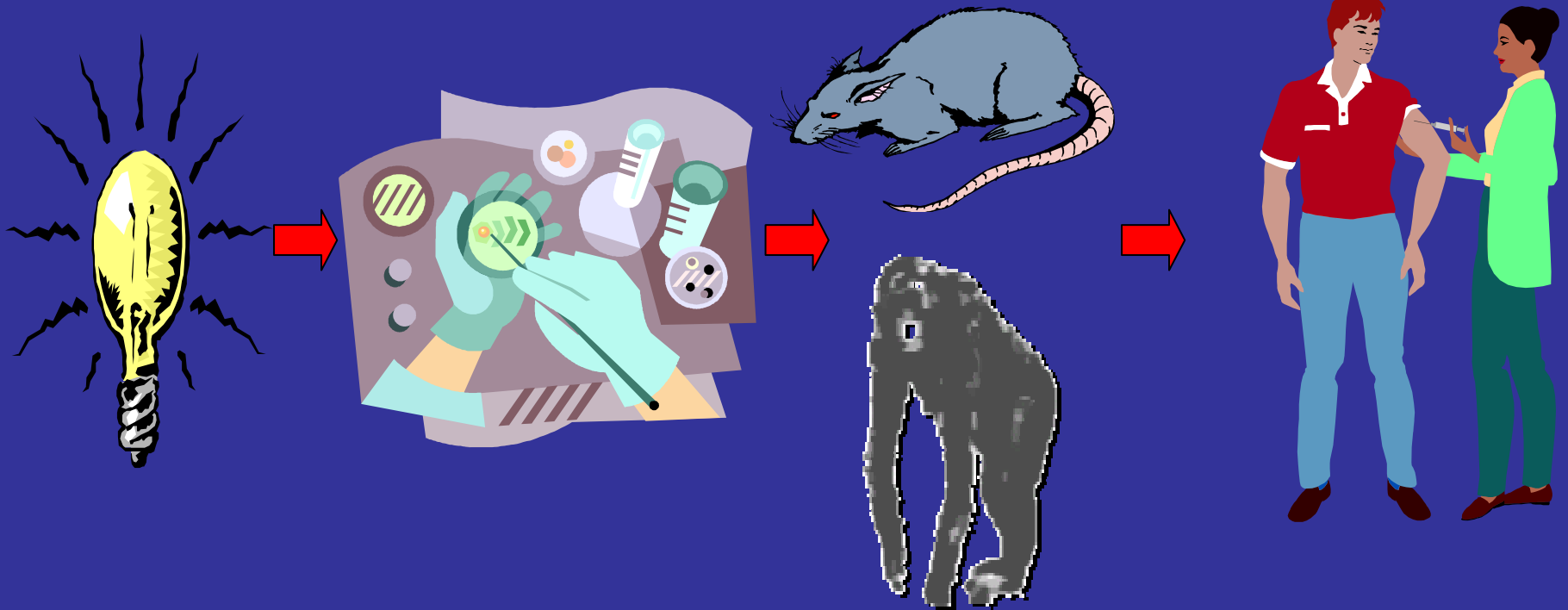
Does an HIV vaccine already exist?

The answer is

**NO**

Research is being conducted today to find a safe and effective vaccine!

# Stages of Vaccine Development



## Phase I

**12 to 18 months**

Small group of healthy, HIV negative participants to test safety



## Phase II

**Up to 2 years**

Hundreds of HIV negative participants to test safety and immune responses



## Phase III

**3 to 4 years**

Thousands of HIV negative participants at risk for HIV to test safety and efficacy





A Phase 3 Study is to see if a vaccine is not just safe, very important as that is.

The goal is to see if it works.

So we need high risk volunteers

For studies like this to work, do we need to encourage volunteers to take risks?



No!

Studies have shown that participants in vaccine trials are at lower risk of contracting HIV

# HIV Vaccine Trials Worldwide

- Phase I: 28
- Phase I/II: 4
- Phase II: 4
- Phase III: 1

TOTAL = 37 *current* trials

Almost 100 worldwide trials have occurred to date in:

- Australia, Belgium, Botswana, Brazil, Canada, China, Cuba, Dominican Republic, Finland, France, Germany, Haiti, Italy, Kenya, Netherlands, Peru, Puerto Rico, South Africa, Switzerland, Thailand, Trinidad and Tobago, Uganda, UK, US (IAVI.org)

# TOPS & BOTTOMS WANTED

FENWAY COMMUNITY HEALTH IS SEEKING HIV-NEGATIVE MEN WHO HAVE SEX WITH MEN TO PARTICIPATE IN THE STEP TRIAL TO DETERMINE THE SAFETY AND EFFECTIVENESS OF AN INVESTIGATIONAL HIV VACCINE.

THE FACT IS, 63% OF ALL HIV/AIDS CASES IN THE U.S. ARE IN GAY AND BISEXUAL MEN AND HIV INFECTION RATES ARE RISING AMONG MEN WHO HAVE SEX WITH MEN.



WE ARE SEEKING VOLUNTEERS: HIV-NEGATIVE MEN, AGES 18-45, WHO HAVE BEEN A TOP OR BOTTOM IN THE PAST 6 MONTHS. VOLUNTEERS RECEIVE COMPENSATION FOR THEIR TIME AND TRAVEL EXPENSES, AS WELL AS CONFIDENTIAL HIV COUNSELING AND TESTING.

YOU CANNOT GET HIV FROM THIS INVESTIGATIONAL HIV VACCINE.

PLEASE CONSIDER VOLUNTEERING

FOR MORE INFORMATION  
OR TO VOLUNTEER  
CALL 617.927.6450  
OR REGISTER AT  
[WWW.FENWAYHEALTH.ORG](http://WWW.FENWAYHEALTH.ORG)

FENWAY COMMUNITY HEALTH  
**Fenway**

4 Year Study

3000 High Risk  
Volunteers

1/2 on a placebo

1/2 on the  
vaccine



Research to  
stop HIV  
infection will  
take us all  
working  
together

Will you help?

Thanks for coming to our  
workshop!

For more information on  
these and other trials, go to

[www.fenwayhealth.org](http://www.fenwayhealth.org)

For more information on HIV  
Vaccine Trials, go to

[www.hvtn.org](http://www.hvtn.org) or

[www.avac.org](http://www.avac.org)