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 Run
Home of great cultural events such as
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

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<td>• Pre-exposure prophylaxis (PREP)</td>
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<td>• Microbicides</td>
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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 Disoprophil 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.
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?

Glad you asked!

Our Tops and Bottoms Study to find an HIV Vaccine.
What is a Vaccine?

- **Vaccine** 
  
  
  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?

By teaching the body to recognize and fight invaders through mimicking a natural infection.
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)
4 Year Study

3000 High Risk Volunteers

½ on a placebo

½ 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

For more information on HIV Vaccine Trials, go to

www.hvtn.org or

www.avac.org