Why Is It Important for Women to Participate in Clinical Trials?
Lessons from GRACE

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Together, we can change the course of the HIV epidemic…one woman at a time.

#onewomanatatime
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The Need for Studies of Women Living with HIV

• In the U.S., about 1 in 4 people living with HIV is a woman
• Almost 8 in 10 U.S. women living with HIV are African American or Latina
• Globally, women made up just over half of all people living with HIV in 2014
• But in many HIV studies...

*Less than 1 in 5 people being studied is a woman*
Need for Studies of Women Living with HIV

• Despite the number of women living with HIV, studies of HIV clinical trials traditionally include very small numbers of women
  – Most information on effectiveness and safety of HIV drugs is based on research done in men
• Because some HIV drugs may act differently in women’s bodies, studies need to be designed to answer questions for women:
  – Specific drug doses for women
  – Possible differences in lab tests (CD4 cells, viral load)
  – How infections and gynecological conditions affect women living with HIV
  – What side effects are likely to affect women
• Only way to get this information is for more women living with HIV to participate in clinical trials

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Why Have So Few Women Participated?

- For many years, The Well Project founder Dawn Averitt, and other community advocates have *called for trials to include more women and people of color*

- Historically, women were kept out of many types of clinical trials (not just HIV studies)
  - Concern that women might become pregnant while on a trial of an experimental drug that could harm a baby
  - In 1993, U.S. regulations were changed and women were encouraged to participate in clinical trials, but progress has been very slow
Why Have So Few Women Participated?

- Distrust of medical establishment/clinical researchers in some African-American and Latino communities
  - Based on past unethical trials conducted among communities of color, before U.S. government established strong guidelines to protect participants
- Some women concerned trial may be unsafe or they won’t be allowed to drop out
- Stigma
- Lack of support
- Lack of child care
- Lack of information about the studies
- Lack of transportation

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An HIV clinical trial needed to be designed to overcome barriers for women and people of color

- Providers, advocates worked with Tibotec (now Janssen)
- Result was the GRACE (Gender, Race, And Clinical Experience) study
  - Began in 2006
  - Designed to identify differences in Prezista’s effectiveness, safety, side effects between men and women over 48 weeks
  - Largest U.S. treatment trial to focus on women living with HIV
  - First to focus on women who had experience taking HIV drugs
  - Specifically designed to enroll women and people of color
Successful Recruitment...

• GRACE was *successful in overcoming barriers to having women participate*
  – Reached goals for recruiting participants on schedule
  – Enrolled 67% women, 84% people of color
  – Showed it was possible to recruit large numbers of women, African Americans, Latinos into clinical trials

• Some of the new strategies were:
  – Selecting study sites (clinics, medical centers) that were accessible to women and people of color
  – Raising awareness among people they hoped to enroll
  – Providing support for participants and study sites

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Successful Recruitment...

- **Site Selection**
  - Finding sites where women living with HIV received care, including sites that had not participated in clinical trials before
  - Selecting sites in areas where there were high numbers of HIV cases among women and people of color
  - Requiring sites to enroll 3 women before enrolling 1st man

- **Outreach**
  - Awareness campaigns in minority media
  - Community advisors, advocates getting word out
  - Materials/logo that study sites and participants both liked
  - Community events, articles in HIV community newsletters

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Successful Recruitment...

• **Participant and site support**
  – Providing other HIV drugs free of charge to study participants (in addition to Prezista)
  – Increased flexibility and availability of health care providers at study sites
  – Funds for child care and travel for participants
  – Study kits for both sites and participants with materials to support study participation
  – Continuous involvement, including regular site visits and support meetings, through all phases of the study
...But High Dropout

While GRACE successfully enrolled women, nearly one in four dropped out by week 24; only 9% of male participants dropped out.

- Most common reason for women to drop out: “Lost to follow up”
- Refers to participants whom study can no longer reach or track:
  - They move away
  - They decide not to participate in study, don’t tell study managers
  - They become ill or die

- High dropout rate among women may be sign of:
  - Difficulties in treating underserved populations
  - Working with sites unaccustomed to conducting research studies
  - Obstacles U.S. women of color living with HIV face in remaining in care

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GRACE Study Results

At 48 weeks:

• No major differences in response to treatment between women and men taking Prezista

• No major differences in safety or side effects

This should give women peace of mind that a drug they take has been *studied in bodies similar to their own.*
The Bottom Line

- It is important for more women to get involved in HIV clinical trials – and for more trials to be designed with women, people of color in mind.
- There are many women's health issues that still need to be studied in women living with HIV.
- You can help by getting involved and participating and helping others understand clinical trial participation!

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“A whole lot of what worked in GRACE was just about the sense of being a part of something bigger than yourself, being really valued, appreciated, and respected in an environment where, frankly, a lot of people are dealing with shame and stigma.”

-- Dawn Averitt, founder of The Well Project
Learn More!

- To learn more, please read the full fact sheet on this topic:
  - Lessons from GRACE: A US Study Focused on Women Living with HIV

- For more fact sheets and to connect to our community of women living with HIV, visit:
  - www.thewellproject.org
  - www.facebook.com/thewellproject
  - www.twitter.com/thewellproject