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

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 about half of all people living with HIV in 2013
- But in many HIV studies...

Only 1 in 10 people being studied is a woman





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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



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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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Enter GRACE

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 (**G**ender, **R**ace, **A**nd **C**linical **E**xperience) 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



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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

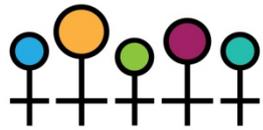


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Successful Recruitment...

- **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



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...But High Dropout

While GRACE successfully enrolled women, nearly $\frac{1}{4}$ of them 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.***



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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



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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](#)