



W O M E N ' S
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O N H I V / A I D S

**WOMEN'S RESEARCH
INITIATIVE ON HIV/AIDS**

Santa Fe, New Mexico

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2012 MEETING SUMMARY

WOMEN'S RESEARCH INITIATIVE ON HIV/AIDS 2012 MEETING SUMMARY

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WOMEN'S RESEARCH INITIATIVE ON HIV/AIDS

2012 MEETING SUMMARY

EXECUTIVE SUMMARY

Women and girls represent an estimated 24 percent of the HIV epidemic in the United States, but continue to be marginalized in research, due to a host of factors that are both institutionalized and unrecognized. This must change. Women living with and vulnerable to HIV disease and their advocates must be involved at every level and in every step of research development and implementation, in order to ensure that safe and effective treatments, as well as appropriate prevention strategies are developed for women and girls.

While the quantity of HIV research among women has increased somewhat since the beginning of the epidemic, women continue to experience significant societal, structural and individual barriers that hinder their participation in research overall, and in clinical trials specifically, particularly in the United States. Until we address and mitigate these barriers, we will continue to lack the knowledge necessary to treat and prevent HIV infection among women and girls effectively.

The Women's Research Initiative on HIV/AIDS (WRI) is dedicated to elevating, enhancing and expediting research on women and HIV. The 2012 WRI meeting focused on *contextualizing women's lives: enhancing HIV research and care for women living with and at risk for HIV disease*. Preventing and treating HIV in women and girls – and the research required to do both of these things successfully – require careful consideration of the context in which HIV enters and becomes a part of women's lives. This context includes an array of physical, social, cultural and interpersonal factors that combine to influence HIV transmission, disease progression and health outcomes among women. It also includes the factors that influence whether and what kind of research is undertaken to address the particular situations of women living with or vulnerable to HIV.

As in previous years, WRI 2012 brought together an extraordinary group of leaders in HIV to identify key opportunities to accelerate our understanding of HIV disease in women. WRI members represent a broad range of stakeholders in the fields of clinical care, research, academia, community-based services, advocacy, government, the pharmaceutical industry and women living with HIV. This diverse membership operationalizes the trans-disciplinary approach advocated by the WRI. By addressing issues that affect women through a variety of lenses, the WRI is able to expand understanding of effective treatment and prevention for women and girls living with or at risk for HIV.

In the process of contextualizing women's experiences with HIV at this year's meeting, the WRI made three key observations:

- *We must facilitate women's engagement in the fight against HIV:* the voices of the women we are trying to serve must be heard and considered at every level of HIV program development. As an initiative focused specifically on research, the WRI is tasked with reinforcing the role of women in research programming to ensure that science adequately addresses women's needs.
- *Women's participation in clinical trials needs to be enhanced, at every stage of planning and implementation:* Notwithstanding the existing policies at NIH and FDA related to the inclusion of women (and racial/ethnic minorities) in all clinical trials where appropriate, women remain under-represented as research participants in many HIV/AIDS studies; and most clinical trials, even where women and men are both included, do not address the kind of sex differences and gender analysis that the federal policies encourage.
- *New HIV prevention technologies must be sufficiently explored for safety and efficacy in women as well as men:* The sense of urgency to provide access to pre-exposure prophylaxis (PrEP) must be balanced with a commitment to do the research necessary to fully elucidate how and when to best use PrEP in women as well as understand the potential effects of long-term use of PrEP overall.

Women and the fight against HIV

Epidemiological data on women and HIV in the United States help to contextualize the multitude of factors affecting women's HIV risk and acquisition, as well as treatment and support, and highlight a number of key issues that must be addressed. Region and population-specific HIV prevalence and incidence data, such as those showing the extraordinarily high rates of HIV among women in Washington DC (2.7 percent), the continuing disproportionate impact of HIV among African-American women (66 percent of all cases among women) and epidemic "hot spots" (Washington DC, the South, Puerto Rico and the U.S. Virgin Islands), all point to significant barriers to effective prevention for women and girls.

Risk factors affecting women's acquisition of HIV can be societal, structural, individual or, more likely, some combination of the three. They are extremely diverse and variable, and can include such issues as lack of female-controlled prevention methods, high rates of sexual and gender-based violence, prevalence of heterosexual anal sex, concurrent sex partnerships, other sexually transmitted diseases, lack of access to information and healthcare, poverty, high-risk partnerships with men (history of incarceration, intravenous drug use, etc.), provider bias about HIV risk and social and cultural pressure to bear children, appease partners and demonstrate loyalty through trust. It is important to note that because these factors are not causal, while they may contribute to risk, clearly not every woman living with these societal, structural or individual factors will become infected with HIV.

Women face unique challenges in preventing and managing HIV disease and require relevant and appropriate interventions and outreach. It is all too common for these interventions to be designed *for the women* rather than *with the women* they are intended to serve. As a direct result, the success rates of such interventions are unacceptably low and the epidemic continues to thrive in communities of women in the United States today.

The WRI is committed to ensuring that women are able to significantly participate in all facets of the fight against HIV and AIDS. WRI members will work to ensure that women living with and at risk for HIV have “seats at the table” at the many forums represented by the WRI. WRI members will engage, mentor and cultivate new investigators, clinicians, community leaders and decision-makers in an effort to create more trans-disciplinary venues and opportunities for women’s voices to be heard and upheld. Women’s engagement will facilitate development of and participation in research studies, HIV treatment programs and psycho-social support services that are relevant to and effective for women living with and at risk for HIV disease.

Women’s participation in clinical trials

Successful HIV prevention, care and treatment require the involvement of women across the spectrum of research – from basic laboratory science, to clinical trials, to behavioral and social science investigations. Looking at the clinical trial development process, there are a multitude of entry points, including:

- *Research questions:* women need to be included in the development of the research questions guiding clinical trials and other intervention studies before they are begun, to ensure that the right questions are being asked and that it makes sense to women to participate.
- *Protocol development:* exclusion criteria (including pregnancy intention) and inclusion criteria (including mandatory use of dual-barrier contraceptive methods) often prevent women from participating in clinical trials and researchers from being able to recruit an adequate number of female participants. Involving women in protocol development and proactively designing research that ensures the inclusion and retention of women in studies, even after they become pregnant, when appropriate, increases the chances that useful information on women will be successfully obtained from the research.
- *Site identification:* women may face different logistical challenges than men when participating in research, such as familiarity with research sites and facilities, childcare and transportation challenges and lack of partner/spousal support of research participation. Identifying and addressing these barriers in advance improves the odds of successfully recruiting and retaining women in research. Furthermore, utilizing research sites that can successfully recruit and retain women in studies will increase the chances of obtaining useful information.

- *Gender analyses:* planning sex- and gender-based analyses at the outset of research yields far more substantive data than trying to build them in retrospectively. Involving women in identifying important research questions ensures that relevant studies are developed.
- *Institutionalized biases:* the social and gendered organization of scientific knowledge and the way it is generated itself contributes to the risk environment for women. A close look at the challenges around inclusion of women in clinical trials, the number of women reviewers on basic and clinical science study sections, the documented sex disparity in NIH funding and the limited role of women in regulatory bodies suggest there are structural factors that militate against developing a robust HIV research agenda for women.
- *Women in leadership roles:* it would be naïve to suggest that all women advocate for women; however, the limited number of senior women researchers, thought leaders, clinicians, policy makers and advocates focused on HIV disease in women speaks to a systemic challenge in developing and facilitating women in leadership roles in the HIV/AIDS response.

The WRI is deeply disappointed that women, generally, remain underrepresented in clinical research. The GRACE (Gender Race And Clinical Experience) study, completed in 2009, is an example of a U.S.-based clinical trial that successfully enrolled a diverse population that included women and people of color (nearly 70 percent of study participants were women and 87 percent of participants were people of color). This landmark study proved that women can and will participate in clinical research. It also, importantly, demonstrated that designing a study that prioritizes women's participation and includes outreach to women does not extend the time necessary for enrollment. Since GRACE, the REALMRK study has further demonstrated that proactive efforts to retain women in clinical trials can yield positive results limiting discontinuations and enabling women to successfully participate for the full study duration. There is no longer a valid argument for conducting pivotal research without enough female participants to perform sex- and gender-based analyses on safety and efficacy. Research in women should no longer be an after-thought once a therapeutic agent has been approved for marketing in the United States.

PrEP as a prevention modality for women

Since the last annual WRI meeting, the scientific community has presented and published compelling data on PrEP, an antiretroviral-based intervention to prevent the transmission of HIV. Given the immediacy of this issue (an FDA advisory committee hearing took place on May 10, 2012 to hear testimony and issued their recommendation for approving PrEP to the FDA), the WRI agreed that it was important for the group to address it at this year's meeting.

PrEP has the potential to be an important prevention option for women, and could theoretically be a tool for women to use to protect themselves in a variety of scenarios, including having a sex partner who injects drugs or refuses to use condoms, planned exposures when trying to get pregnant, sex work and having an allergy to latex and/or polyurethane.

Whereas multiple studies have suggested that PrEP is effective in men who have sex with men, there are conflicting results from current data on the efficacy of PrEP in women. One study in serodiscordant couples (Partners PrEP) demonstrated that either daily tenofovir alone or together with epivir (Truvada) was effective in preventing HIV infection in women and another study (TDF-2) showed that Truvada was effective at preventing HIV infection in African men and women. However, one study in women was discontinued because of lack of efficacy of daily Truvada (FEM-PrEP) and the tenofovir-alone arm of the VOICE study was discontinued due to fertility.

The WRI 2012 members and participants have varied perspectives on the potential FDA approval and availability of PrEP as it relates to women. It is incumbent upon the WRI and others who treat and care for women with HIV to take an active role in developing and implementing an ongoing research plan to address the critical unanswered questions about how and when to best use PrEP in women.

Conclusion

The WRI is a unique, trans-disciplinary body of experts focused on HIV research among women. Each year, the group convenes to address the most pressing issues in HIV research and to ensure that the research agenda for women living with or at risk for HIV moves forward. At the 2012 meeting, the WRI concluded that it is essential to involve the women we are trying to serve in every step of the programming process, from conceptualization through implementation. The WRI urges all stakeholders in the fight against HIV to commit to undertaking the necessary steps to ensure this inclusion, across all fields of research (biomedical, behavioral and social sciences) and at all points of contact (clinical, prevention and support services). Furthermore, increased research on women in the United States is essential, as their specific experiences, characteristics, societal norms and pressures and even access to treatment and care across the health spectrum need to be addressed. Doing so will enable the HIV community to achieve the all-important goal of providing women with all of the tools they need to make choices that guide their treatment, support and care.

OVERVIEW OF THE WRI

Critical questions about HIV/AIDS in women remain unanswered, despite the fact that women incur more than half of all new HIV infections globally. Until these questions are addressed, we are limited in our ability to design effective prevention and treatment intervention strategies. This limitation will result in further HIV infections and related deaths among women.

Since 2003, the Women's Research Initiative on HIV/AIDS (WRI) has advocated for "more, better and faster research" into HIV disease in women. The WRI brings together trans-disciplinary experts, including clinicians, research scientists and advocates from academia, community, government, the pharmaceutical industry and HIV-positive women, in an effort to expand, enhance and coordinate efforts to improve research related to HIV disease in women.

The WRI includes 30 current members who serve in staggered three-year terms to maintain the momentum and deliverables from this experience-rich think tank. An executive committee provides oversight and guidance for the annual meeting and related activities. For a full list of WRI attendees and invited speakers for 2012, please see page 14. For a full list of WRI members and past participants, please visit www.womensresearchinitiative.org.

WRI 2012 MEETING APPROACH

The 2012 WRI meeting focused on *contextualizing women's lives: enhancing HIV research and care for women living with and at risk for HIV disease*. This focus was established in collaboration with the WRI executive committee, which helped develop and plan the 2012 meeting.

WRI 2012 sought to address several key questions to help identify opportunities for improving our understanding of HIV treatment and prevention in women through biomedical, behavioral and social research, including:

- What has been the most important research on women through early 2012? How can this research be disseminated and expanded upon?
- How can research practices be modified to take into consideration the interaction of the biological/physiological, behavioral/psychological and social/cultural realities of women's lives in order to improve both study and care outcomes?
- Which critical research gaps are unaddressed by current studies? What specific research needs to be done to fill these gaps?
- What are the most critical opportunities for research in the next few years?
- What are some non-obvious opportunities that might yield critical new insights? How might we develop these "under the radar" ideas or concepts?
- What can you personally do in your work environment to advance the ideas generated through this WRI meeting?

To highlight the most critical research efforts and findings of the past year, invited experts and WRI members presented their work on key topics in biologic, behavioral and social research in women and HIV. Each of these presentations fueled rich discussion and often culminated in unique synthesis and perspective by the group. These talks:

- *Provided detailed epidemiology on HIV among women in the United States (click here):* Dr. Gina Brown, of the Office of AIDS Research at the National Institutes of Health, painted a picture of HIV among U.S. women. She highlighted "hot spots" of infection rates, including Washington DC, the South, Puerto Rico and the U.S. Virgin Islands. She also pointed to the continuing disproportionate impact that HIV has on African-American women, highlighting the fact that African-American women make up one-fifth of the entire domestic epidemic. Dr. Brown described some concerns and challenges around the incomplete nature of existing data, such as the inability to drill down and determine what populations are identifying as mixed race as well the reality that we know very little about HIV on Native American reservations.

- *Described the complex social and environmental factors that influence risk, protection and access to services among women (click here):* Dr. Judith Auerbach of the San Francisco AIDS Foundation described an approach for investigating risk and vulnerability that includes a number of “levels” to be addressed – individual, relationship, group and society. She described some of the social drivers of behavior, both macro and micro, and led a discussion about the appropriate points of intervention. She concluded with a discussion about whether or not randomized clinical trials should remain the gold standard in HIV prevention research.
- *Addressed issues specifically related to adolescent girls and young women (click here):* Dr. Gina Wingood of Emory University, described the social factors that influence risk, protection, care and treatment among adolescent and young women and discussed potential intervention options.

Select WRI members provided short presentations updating the group on their recent research activities.

- Judy Feinberg, MD: *Branching out into prevention - establishing a syringe exchange program with broad public health objectives, including HIV prevention and PrEP for female partners of IDUs*
- Rowena Johnston, PhD: *Women's participation in HIV eradication research*
- Amy Meditz, MD: *Investigations into sex differences in plasma HIV-1 RNA levels (click here)*
- Chuck Wira, PhD: *Steroidal effects on microbicide prevention of HIV infection and scientific research planning meeting – sexual violence and HIV transmission*

As in prior years, WRI 2012 featured several WRI challenges – questions posed to the group, discussed in breakout sessions and then shared with the entire group in an effort to generate tangible action items. These presentations fueled rich discussion about the multifactorial nature of HIV research and the broad needs to ensure appropriate access to care for women. This year's WRI challenges addressed the following timely issues:

- How will changes to Ryan White funding and the Affordable Care Act impact care for women living with HIV and what do we need to do to ensure quality care?
- What are the key questions about PrEP in women? How do we begin to address them?
- What concrete steps can we take to improve HIV-positive women's access to relevant research and researchers' collaboration with community?

For the first time, the meeting also included two panel presentations in which WRI members provided insights from their diverse perspectives:

- *Looking beyond the chart:* Judith Feinberg MD, Sharon Hillier PhD, Dazon Dixon Diallo MPH, – in an effort to illustrate the complexities of women’s lives and the challenges for all stakeholders, including those with extensive experience in the field, this multi-disciplinary panel, representing clinical, prevention and advocacy perspectives, reviewed several women’s case studies. The exercise elucidated some of the biases, assumptions and considerations for providers when caring for women and demonstrated the need to treat the whole woman.
- *Affecting the context of women’s lives through research and advocacy:* Kathleen Squires MD, Fulvia Veronese PhD, Naina Khanna – panelists described ways to enhance research and enact research findings with the potential to change the conditions for women vulnerable to and living with HIV.

MEMBER COMMITMENTS FOR 2012

At the end of the WRI, all participants were asked to briefly highlight their plans to focus on women and HIV in the coming year. Below is a summary of their responses:

Clinical trial protocols

- Review language around exclusion criteria and determine whether it is possible to loosen some of those that restrict access for women
- Ensure that every protocol has been reviewed by an HIV-positive woman
- Identify resources that can help educate individuals about clinical trials
- Educate investigators about the impact of exclusion criteria on enrollment of women and work to address on a case by case basis

Advocacy

- Reinstantiate women's support groups in Kansas City
- Encourage partners and funders to participate in National HIV Awareness Month (NHAM)
- Provide patients with information about seeking support and making connections with other HIV-positive women
- Create and distribute a survey querying women on their perspectives around research
- Make a video with my daughter about my 18 years of diagnosis and about PACTG 076
- Feature research developments in upcoming community newsletters
- Establish a formalized mechanism for funding research in women
- Encourage colleagues to blog for A Girl Like Me

Prevention

- Develop and participate in WRI working group on PrEP
- Work on PrEP for conception
- Develop materials that address the importance of PrEP in women and use them to communicate with key stakeholders
- Conduct community conference call featuring news about PrEP
- Attend the May 10 FDA advisory committee meeting on PrEP

Community involvement in clinical trials

- Invite patients to attend community advisory board meetings
- Ensure that there is at least one woman on my institution's community advisory board

Curriculum development

- Create a lecture on HIV for gynecology residents, work to increase interest in treating HIV-positive women
- Develop and send a letter introducing the WRI and TWP to medical and nursing schools
- Get on the grand rounds schedule (in late June or July to coincide with NHAM) to provide information on women and HIV; encourage inclusion in resident curriculum

Government

- Work to advance research/knowledge on HIV and hormonal contraception, sexual violence among adolescent girls
- Pursue research around sexual violence in women, and the relevant biomedical issues around it
- Ensure that gender and most-at-risk working groups at PEPFAR are communicating with each other

Drug use

- Identify how to attract and treat the female partners of the male IDUs we serve

WRI 2012 MEETING PARTICIPANTS

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