

W O M E N ' S R E S E A R C H INITIATIVE ON HIV/AIDS

WOMEN'S RESEARCH INITIATIVE ON HIV/AIDS Adairsville, Georgia March 17-20, 2011

2011 MEETING SUMMARY

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Table of Contents

Executive Summary	3
WRI 2011 Meeting Theme	6
Key Constraints	9
WRI 2011 Recommendations	11
Conclusion	12
Appendix A: Overview of the WRI	13
Appendix B: WRI 2011 Meeting Participants	14
Appendix C: Meeting Approach	15
Appendix D: Member Commitments	17



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Executive Summary

Women and girls at risk for and living with HIV continue to be marginalized and underrepresented in domestic research, prevention and treatment agendas. Yet, according to the Centers for Disease Control and Prevention (CDC), African-American women have a higher rate of HIV infection than any other group except for African-American men. And AIDS is still the leading cause of death for African American women aged 25-44. Research in women is essential now more than ever to stem the tide and the toll of the AIDS pandemic, both domestically and globally.

It is within this context that the Women's Research Initiative on HIV/AIDS (WRI) was established in 2003 to elevate, enhance and expedite research on women with HIV. Each year, the WRI brings together an extraordinary group of leaders in this field to identify key opportunities to accelerate our understanding of HIV disease in women. WRI members represent a broad range of stakeholders in the field, including clinical care, HIV research, academia, community-based organizations, government, the pharmaceutical industry and HIV-positive women.

The 2011 meeting of the WRI focused on the issues surrounding *antiretroviral (ARV) use in women for the prevention and treatment of HIV disease.* This theme was selected in order to encompass the broad range of interdisciplinary work that is both ongoing and necessary to effectively prevent and manage HIV disease in women. Although the development of an impressive range of effective ARV drugs has created the possibility of a chronic disease state, the realities of access, uptake, manageability, acceptability and long-term effectiveness prevent us from achieving this desired outcome. This makes it incumbent upon all stakeholders to take a more comprehensive approach to HIV research, including among women.

The need to understand the range of issues affecting the use of ARVs in women throughout the lifespan continues to grow in magnitude and complexity, as HIV prevention science advances and more people begin long-term use of ARVs. While WRI 2011 could only scratch the surface of this discussion at the meeting, this group draws on a broad range of expertise, uniquely positioning it to identify gaps and opportunities in research and, following the meeting, drive the research agenda in women forward.

To highlight the most critical research efforts and findings of the past year, invited experts and WRI members presented biologic, behavioral and social research on key topics related to ARV use among women. These invited talks highlighted the most recent advances in PrEP and microbicides, provided data on biologic correlates of risk and aging, contextualized the work of the WRI in current key science and policy issues and provided an overview of recent and ongoing research in HIV-positive women. In addition, several WRI members shared ongoing work or recent learnings directly related to the discussions at WRI, including advocacy efforts on microbicide



W O M E N 'S R E S E A R C H INITIATIVE ON HIV/AIDS development, topic highlights in cure research, identifying next steps in research in women and the impact of the doctor-patient relationship on healthy outcomes and good care delivery. (For details of these presentations and discussions, please see the full meeting report.)

Beyond these formal presentations and in an effort to holistically address ARV use among women for the prevention and treatment of HIV disease, the WRI focused on four key areas to enhance and expand research in women:

- Biomedical HIV prevention strategies: The WRI shares both optimism and concerns about the future practical implementation and availability of PrEP and microbicides in the United States. The 2011 meeting generated a preliminary list of questions that will need to be addressed in this process: How will biomedical prevention be paid for and what impact will this structure have on access? How will availability of these prevention options affect perception of risk among women? What potential stigma concerns may emerge if specific populations are prioritized? How will these products be made available (OTC, prescription, etc.)? While preliminary research has indicated acceptability among women of a few preparations, how can this kind of prevention be normalized for general uptake and routine use? [Note: WRI 2011 occurred prior to the announcement of the discontinuation of the FEM-PrEP study.]
- Stigma: Stigma continues to be an enormous barrier to care and is an overwhelming driver of social isolation. The WRI recognizes the complex layers of stigma and social isolation, from the individual experience to factors that contribute on an institutional level. These institutions operate within healthcare systems, the business sector and other social organizations and networks, such as religious and community-based groups. While peer advocacy programs appear to be an effective tool to address stigma and social isolation, the WRI suggests the need for evaluative research that demonstrates the impact of peer advocacy and provides additional insights into mechanisms for systems change.
- Aging for women with HIV: Although there is an expanded focus in the research community on the effects of long-term HIV disease on the aging process and aging population in general, a great deal remains unknown about the unique and specific issues that women living with HIV may face as they age. The WRI maintains that it is critical that we conduct research to further understand the pathogenesis of HIV in women who are living longer, drug interactions and pharmacokinetics in aging populations, as well as the need for good matched age and gender controls for HIV-positive volunteers in research.
- Cure research: The WRI discussed the excitement as well as the potential challenges to cure research for women with HIV. Questions about the conduct of clinical trials, what will constitute success (and how this may be variable based on individual perception) and how to design studies that will engage women, were all raised and discussed. Further dialogue addressed the potential to obtain novel insights from the active engagement of women in cure research (from biologic to behavioral aspects) and highlighted the need for a greater focus on the female immune system and the systematic inclusion of women in this important work by advocates and researchers.



In addition, the WRI members identified several important next steps for advocacy efforts to ensure that ARV use in women for the treatment and prevention of HIV disease is adequately addressed in research and policy activities:

- **Policy:** Highlight women's research at the International AIDS Conference in Washington, DC in 2012; encourage inclusion of information about women and HIV in the agendas of physician organizations; target federal research dollars toward issues affecting women and HIV; develop a strategy to educate federally qualified health centers (FQHCs)
- Academia: Integrate issues of HIV and women into interdisciplinary research course work; work to incorporate efforts

to increase HIV awareness into medical school curriculum; conduct grand rounds on HIV and women

- **Research:** Fund research into linkages to care for women; integrate qualitative questions into WIHS cohort; mine existing data to ensure that the stories about women and HIV are told in a public arena
- Industry: Integrate systematic needs assessment for women across all efforts (research, publications, etc.); increase awareness of women and HIV among pharmaceutical company employees

The WRI 2011 meeting provided a rich and robust discussion about the use of ARVs in women for both prevention and treatment of HIV disease. Although this theme is extraordinarily broad, it provided the group with the unique opportunities to both survey the landscape of research in women and to delve deeper into a few core areas.

This process illuminated a tremendous need to actively engage, cultivate and mentor new leaders – specifically advocates, clinicians and researchers – in the field of HIV treatment and prevention research in women. As more leaders emerge, the WRI will work to expand the representation of women treaters and researchers in positions of leadership and on policy-making bodies. To this end, the WRI commits to explore the development of formal mentor programs to encourage young professionals to enter and stay in the field of HIV research and care as well as identify efforts to work with government and other organizations to ensure that women remain a focus of HIV work and research.

Finally, the WRI commits to redouble our efforts to ensure that the focus on women with HIV is not lost or diminished by current trends targeting prevention and outreach resources on specific sub-populations. Providers, researchers, policymakers and advocates all must recognize that both men and women are infected and affected by HIV and that women's issues in HIV prevention and treatment must remain a research and implementation focus in order to achieve success in the fight against this pandemic.



WRI 2011 Meeting Theme

The 2011 WRI meeting focused on addressing the issues surrounding *ARV use in women for the prevention and treatment of HIV disease*. This focus was established in collaboration with the WRI executive committee, which helped develop and plan the 2011 meeting.

The 2011 meeting sought to address several key questions:

- What is the most important research on women and HIV that has been conducted through early 2011? What developments in ARV treatment and prevention evolved in 2010?
- Much of the 2010 meeting suggested that a greater focus on interdisciplinary research is vital to adequately address issues that impact HIV treatment and prevention for women. Have you found opportunities to address these needs in your work?
- Which critical research gaps are unaddressed by current studies? What specific research needs to be undertaken to fill these gaps?
- What are the most critical opportunities for research in the next few years?
- Where are some not-so-obvious opportunities that might yield critical new insights? How might we develop these "under the radar" ideas?
- 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 biologic, behavioral and social research on key topics related to ARV use among women. These talks:

- *Highlighted the most recent advances in PrEP and microbicides (link here):* Dr. Sharon Hillier, a leader in the field of HIV biomedical prevention, shared a presentation on recent advances in the field. Dr. Hillier began her presentation by pointing out that biomedical prevention needs to offer women real choices not merely options (options not always being practically implementable). Her talk highlighted the key lessons from iPREX and CAPRISA-004, described other PrEP and microbicide trials currently underway, described our understanding of topical ARVs as microbicides during pregnancy and laid out a potential path forward to support their licensure and described how these prevention tools may be implemented if they are proven to work in trials.
- Provided data on biologic correlates of risk and aging (link here): Dr. Amy Meditz, a researcher with the University of Colorado, shared data that was presented at CROI 2011, investigating several aspects of biologic risk of HIV infection for aging women. Dr. Meditz and her colleagues found higher CCR5 expression on CD4+ and activated CD4+ T cells from the peripheral blood and cervix of post-menopausal women. They also found that CCR5 expression on CD4+ and activated CD4+ T cells from peripheral blood and cervix positively correlated with age. However, they saw no difference in the percentage of activated CD4+ T cells in peripheral blood or cervix between pre-menopausal and post-menopausal women.



6

- *Contextualized the WRI in current key science and policy issues (link here):* Dr. Judith Auerbach, vice president of research and evaluation for the San Francisco AIDS Foundation, provided context for the issues being addressed by the WRI, focusing specifically on two areas science (HIV/AIDS and aging and combination HIV prevention) and policy (National HIV/AIDS strategy, health care reform and budget cuts). Her talk outlined a number of current and impending challenges in the United States, including identifying the U.S. healthcare system as a "resource-constrained setting," as well as the potential impact of the current political environment on women's access to reproductive health services.
- *Provided an overview of recent and ongoing research in HIV-positive women (link here):* Dr. Gina Brown of the Office of AIDS Research at the NIH presented data compiled by Dr. Monica Gandhi (also a WRI member), highlighting the breadth of research already conducted and currently underway around the world addressing issues in the management of HIV disease in women. The presentation included NIH-funded intramural and extramural research, CDC studies and studies undertaken by other governments and clinical trials consortiums globally. The presentation reinforced several key findings: globally, HIV is the leading cause of death among women of reproductive age; the largest cohorts of women being studied are in Africa; and most knowledge about how to treat women with HIV in the United States has come from the Women's Interagency HIV Study (WIHS).

Beyond these formal presentations and in an effort to holistically address ARV use among women for the prevention and treatment of HIV disease, the WRI focused on four key areas to enhance and expand research in women:

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Select WRI members provided short presentations updating the group on their recent research activities. All participants briefly highlighted their plans to focus on HIV and women in the coming year. These presentations fueled rich discussion about the multifactorial nature of HIV research and the broad needs to ensure appropriate access to care for women. For a full agenda, please see Appendix B.



Key Constraints of Current Research, Care and Prevention

Intensive discussion around the data and experiences presented at the 2011 WRI led to several important findings.

The role of women in HIV prevention and treatment activities, including research, is vitally important and cannot be overstated

Anecdotal evidence shared at the meeting suggests that despite increasing numbers of women conducting HIV research and treating HIV patients, women remain underrepresented in leadership in the field. Furthermore, the group expressed concern about the numbers of new professionals choosing to enter the field of women and HIV research, across disciplines. The WRI membership was especially concerned that without the cultivation of providers who are knowledgeable about treatment management, we will not achieve the goal of universal access and care established by the National HIV/AIDS Strategy.

The WRI argued for several necessary elements:

- Elevate the role of women across disciplines as decision-makers and policy-makers
- Expand the HIV treatment and research workforce
 - Develop mentoring support for new investigators, researchers, clinicians, scientists
 - $\circ\,$ Cultivate women to enter the fields of HIV research and practice

Women's issues in HIV prevention and treatment must remain a research and implementation focus

The WRI agreed that providers, researchers, policymakers and advocates need to recognize that HIV affects both men and women. The group argued that prioritizing specific populations over others can result in a lack of awareness about risk and decreased funding, both of which make it impossible to provide women with the care they need. The WRI identified several specific needs:

- Ensure inclusion of women in relevant treatment and prevention guidelines and professional association agendas (including AAFP and ACOG)
- Educate the healthcare workforce about how HIV impacts women
- Continue to target interventions for women. Biomedical prevention efforts were discussed as an example of how to use a prevention strategy to advocate for access and better research and technology. Assuming that positive data continue to emerge from PrEP and microbicide studies, there will exist an opportunity to develop novel delivery modalities

(such as a sustained product that delivers a microbicide combined with a contraceptive), allowing for the provision of an array of HIV prevention strategies for women.



W O M E N ' S R E S E A R C H INITIATIVE ON HIV/AIDS

Beyond these specific findings, the WRI identified and discussed several key research questions, including:

- PrEP and Microbicides
 - What do we need to allow microbicide use during pregnancy?
 - How will PrEP be delivered? Will it follow a model of hypertension? Depo-provera? Condoms?
 - \circ How effective will intermittent PrEP be? And what are the particular concerns?
 - \circ What will be the role of disinhibition if/when PrEP and microbicides are approved?
 - How do we influence the roll out of PrEP in an environment in which patients can't always access ARVs for treatment?
- How do we use risk assessment as a tool to help women make decisions?
- What is the cause of premature aging among women with HIV? Is it due to HIV itself, the length of time patient has been infected with HIV, ARV treatment or some combination?
- What is the risk benefit for cure research? What is a trial success? What percentage has to see a real cure?
- What does cure mean for identity?



WRI 2011 Recommendations

Based upon these findings, the WRI has identified several opportunities within two key areas. These recommendations are broad and should be considered by the institutions represented by members of the WRI, as well as any organization involved in servicing women with HIV or conducting research in women and HIV. For each of these recommendations, the WRI has committed to concrete next steps, as described below.

Develop formal mentor programs to encourage young professionals to enter and stay in the field of HIV research and care

- In an effort to address the need to increase the workforce qualified to conduct research in and treat HIVpositive women, the WRI commits to explore the development of a fellowship program in 2011 that will provide mentorship in the field of women and HIV. This program will enable four young professionals to work with members of the WRI to address key research questions and attend the annual meeting.
 - $\circ\,$ WRI members will have the opportunity to nominate fellows from four disciplines
- Social/behavioral sciences
- Basic science
- Clinical care
- HIV community
 - Fellows will be mentored by WRI members throughout the year. Each will execute a research project over the course of the year, which will be conceived by, refined with and mentored by members of the WRI.
 Fellows will have the opportunity to present their research at the 2012 annual WRI meeting.
 - The program will be dependent upon funding (to be secured by WRI staff) and the development of structure that provides the necessary academic leadership for mentees (to be provided by the WRI membership).

Work with government and other organizations to ensure that women remain a focus of HIV work and research

- WRI members will conduct outreach to relevant organizations to ensure that the topic of HIV and women is included in relevant protocols and agendas for scientific conferences as they are developed, including:
 - Inclusion of issues affecting women in the National HIV Prevention Conference
 - Expansion of CDC sexual health initiative to include awareness and education for all audiences
 - $\circ\,$ Broader inclusion of women in the agenda as the NIH networks recompete
 - Understanding among professional organizations (including AAFP, AAP and ACOG) of HIV testing, reatment, referrals, care networks, etc.
- WRI members will conduct outreach to the chairs of relevant committees to ensure appropriate representation of women researchers and clinicians in positions of leadership
 - Identify the committees for guidelines that are making national recommendations for women's health and ensure that women's perspectives are being shared (through representation of women on those committees)



Conclusion

The WRI 2011 provided a rich and robust discussion about the use of ARVs in women for both prevention and treatment of HIV disease. HIV research has made tremendous strides in the three decades since the virus was first identified. This year's meeting highlighted recent exciting research into biomedical prevention approaches that are likely to become commercially available in the next few years and provided an overview of research that has taken place in women around the world. It also contextualized this research into the current policy environment and real-life experience of women living with HIV.

However, these presentations also confirmed that additional research is needed and that women remain underrepresented in research, treatment and prevention agendas. Thus, this year's WRI illustrated the need to continue to focus on women in HIV research.

The group recommended targeted activities to ensure that women are specifically addressed in all efforts, including research. Furthermore the group was concerned by a continuing lack of female leadership in the field and recommends activities to both ensure that women are represented at the highest decision-making levels and to expand the HIV research workforce by encouraging young women investigators, treaters and advocates into the field.

WRI members made a number of personal commitments to women and HIV research over the coming year, across disciplines and efforts, including advocacy, mentoring, conducting outreach to government organizations, placing an additional emphasis on compassionate patient care and more.

The WRI is widely described by its members as a uniquely cross-disciplinary meeting opportunity, unparalleled in the HIV arena. As with past years, WRI 2011 identified key areas of interest that will continue to fuel the research agenda in women and provide ongoing opportunities for the WRI membership to persist in efforts to enhance, expand, and expedite HIV research in women throughout the year.



Appendix A: 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 interdisciplinary experts, representing 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 2011, please see Appendix B. For a full list of WRI members and past participants, please visit www.womensresearchinitiative.org.



Appendix B: WRI 2011 Meeting Participants

Erika Aaron, MSN, CRNP Drexel University College of Medicine

Kathryn Anastos, MD Montefiore Medical Center

Laura Armas-Kolostroubis, MD* Texas/Oklahoma AETC

Judith Auerbach, PhD* San Francisco AIDS Foundation

Julie Barroso, PhD, ANP, APRN, BC, FAAN Duke University School of Nursing

Dawn Averitt Bridge* The Well Project

Gina Brown, MD* Office of AIDS Research, NIH

Susan E. Cohn, MD, MPH Northwestern University

Elizabeth Connick, MD University of Colorado Denver

Rebecca Denison WORLD

Dazon Dixon Diallo, MPH SisterLove, Inc.

*2011 Executive Committee Member

Shari L. Dworkin, PhD, MS University of California, San Francisco

Judith Feinberg, MD* University of Cincinnati

Carrie Elizabeth Foote, PhD Indiana University-Indianapolis

Yasmin Halima Global Campaign for Microbicides

Sharon Hillier, PhD University of Pittsburgh Medical Center

Rowena Johnston, PhD amfAR – The Foundation for AIDS Research

Alan Landay, PhD Rush University Medical Center

Sharon Lee, MD Family Health Care

Sandra N. Lehrman *Merck and Co., Inc.*

Louise Martin-Carpenter ViiV Healthcare

Henry L. Masters III, MD Boehringer Ingelheim Amie Lynne Meditz, MD University of Colorado Denver

Caroline Mitchell, MD, MPH University of Washington, Harborview OB/Gyn

Tonia Poteat, PA-C, MPH Chase Brexton Health Services

Monica S. Ruiz, PhD, MPH George Washington University

Kathleen Squires, MD Thomas Jefferson University

Stephen P. Storfer, MD* WRI Executive Committee

Kimberly Struble, PharmD *FDA*

Jonathan Uy, MD Bristol-Myers Squibb

Fulvia Veronese, PhD NIH, NIAID, DAIDS

Kirsten White, PhD Gilead Sciences, Inc.

Charles Wira, PhD Dartmouth Medical School



Appendix C: Meeting Approach

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

Invited speakers and topics included:

• PrEP and Microbicides

Sharon Hillier, PhD, University of Pittsburgh Department of OB/Gyn/RS and Microbiology and Molecular Genetics Reviewed recent and ongoing research into biomedical prevention with a focus on women; addressed implications for pregnancy; described the difference between options and choice for HIV prevention tools among women

Biologic Correlates of Risk and Aging

Amie L. Meditz, Division of Infectious Diseases, University of Colorado Denver Evaluated the role of CCR5 and CD4 T-cells in HIV acquisition among post-menopausal women

• Contextualizing the WRI: Key Science and Policy Issues

Judith Auerbach, PhD, San Francisco AIDS Foundation

Described key current relevant science and policy factors, including recent biomedical prevention advances, National HIV/AIDS Strategy, Patient Protection and Affordable Care Act of 2010, federal HIV research funding

• Overview of Cohorts of HIV-infected Women and Girls

Monica Gandhi MD, MPH, Divisions of HIV/AIDS and Infectious Diseases; HIV Consult Service, University of California, San Francisco; presented by Gina Brown, MD, Office of AIDS Research, NIH Described data generated by NIH cohorts, NIH-funded clinical trial cohorts and other cohorts from around the world

WRI member updates included:

- Yasmin Halima, PhD: Acceptability and adoption of a vaginal microbicide among women in Africa
- Rowena Johnston, PhD: Three research approaches to curing HIV rendering the immune system resistant, "shock and kill" and ongoing immune activation
- Alan Landay, PhD: Inter-CFAR collaboration on HIV research in women
- Rebecca Denison: Experience and challenges of an HIV-positive woman seeking gynecological care

For the first time, the meeting included WRI challenges, questions that were posed and then discussed by the entire group or through breakout sessions. The challenges include:

- How does cure research relate to women, particularly those on long-term therapy?
- What are the core issues related to aging for women HIV?
- What is the impact of social isolation on the long-term management of HIV disease?
- How will PrEP and microbicide availability impact the lives of women domestically?



The meeting also included the screening of a rough cut of a documentary produced by WRI member Rebecca Denison, highlighting the patient/provider relationship and experience.

In addition, the WRI conducted group roundtables in which each speaker briefly highlighted their personal areas of focus for the past and coming year, outlining areas of need and making requests for information and knowledge. This provided participants with the opportunity to identify synergies in their work and connect with other participants to establish projects moving forward.

The WRI announced the Executive Committee that will be responsible for planning the 2012 WRI meeting: Judith Auerbach, PhD, San Francisco AIDS Foundation; Dawn Averitt Bridge, The Well Project; Elizabeth Connick, MD, University of Colorado Denver; and Tonia Poteat, PA-C, MPH Chase Brexton Health Services.



Appendix D: Member Commitments for 2011

At the end of the WRI members were asked to describe their commitment to women and HIV in the coming year. Below is a summary of their responses:

- Patient care/focused
 - Begin looking at the feasibility of PrEP in advance of commercial availability, especially in women who are trying to get pregnant in discordant couples
 - Highlight the experience of HIV-positive American women of color through photo essay exhibition
 - Commitment to "hug my patients more"
 - Communicate to [my provider] why compassionate care is essential for HIV-positive women
- Policy
 - Highlight women's research issues on the agenda for the International AIDS Conference in Washington DC in 2012
 - Encourage inclusion of information about HIV and women in ACOG, AAFP, AAP agendas
 - Target federal research dollars toward issues affecting women, specifically related to aging
 - Draft letters to federal agencies to ensure inclusion of women in guidelines and relevant protocols
 - Work to develop a plan to educate FQHCs on HIV care
- Academia
 - Offer interdisciplinary research course, addressing issues of HIV and women
 - Work to integrate HIV awareness into medical school resident curriculum
 - $\circ\,$ Do grand rounds on HIV and women
- Research
 - $\circ\,$ Address access among women by funding research into linkages to care
 - Integrate qualitative questions into WIHS cohort
 - \circ Mine existing data and make sure the stories get told in the public arena
- Industry
 - Integrate systematic needs assessment for women across efforts (research, publications, etc.)
 - Reexamine formerly abandoned potential antimicrobials
 - $\circ\,$ Increase awareness of HIV and women at my company
- Materials development
 - Develop patient handout that provides information about website resources and a plan for patients to access the internet
 - Create a one-page handout for female patients that provides women with specific medical guidance (including frequency of screening, etc.)
- WRI
 - Establish a mentoring network
 - Ensure collaboration across other groups committed to women and HIV research

