

# Women in HIV Cure-Related Research Speakers Notes



**Slide 1:**



**Slide 2:**

Who is the WHRC? We are! As of July 2019, there are 23 WHRC members, most of whom are pictured here.

The WHRC is a cross-network working group of the Legacy Project comprised of women who are leaders in women's health and HIV from around the United States. With community and staff representatives from all five NIH-funded HIV/AIDS clinical trials networks, this group provides culturally appropriate guidance and leadership in development, implementation, and dissemination of information about HIV research focused on and responsive to the needs of cisgender and transgender women and girls in the United States. The WHRC works to raise the visibility of issues related to HIV in women in the US and promote awareness of scientific research for women in disproportionately impacted communities.



**Slide 3:**

Here's where current WHRC members are located.

The WHRC focuses on advocating for HIV research with women living in the United States but operates with a comprehensive awareness of the potential for American women to benefit from HIV research that is being conducted internationally. To that end, WHRC's focus is domestic, but its interests are both global and optimistic.



**Slide 4:**



**Slide 5:**

Play video:

<https://www.youtube.com/watch?v=JdgN1nd4Dvc>

The WHRC is proud of all the women who contribute to HIV cure research as well as HIV research overall:

- All 5 NIH-funded research networks are led / co- led by women as Network Principal Investigators / Chairs
- Network Directors
- Laboratory Center Principal Investigators
- Statistical and Data Management Center Principal Investigators
- Women’s Health Inter-Network Scientific Committee
- Advocates
- Front desk
- Managers
- Recruiters



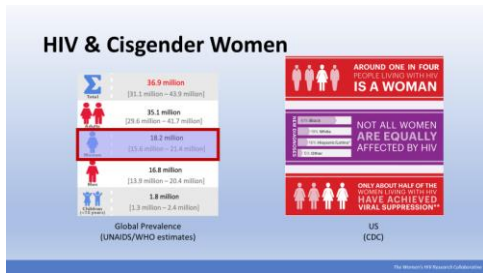
**Slide 6:**

No notes.

**Slide 7:**

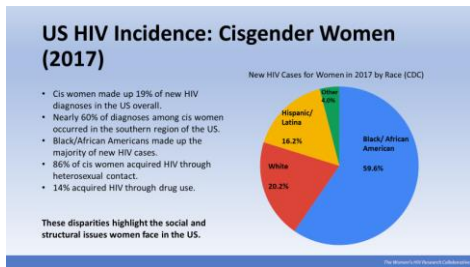
19.2 million women estimated to be living with HIV globally.

About one in four PLHIV in the US is a woman.



Racial disparities in the US where women of color—especially Black and Indigenous women--are the most affected group among all women. Only about half of cis women with HIV in the US have reached viral suppression (the same compared to all PLHIV in the US)

The data are clear: if researchers develop a cure for HIV, it needs to work for women.

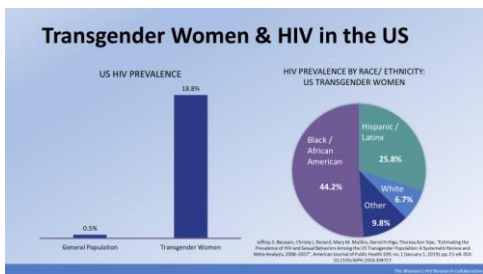


**Slide 8:**

Zeroing in further on the US...

While HIV incidence among cis women has been steadily declining for the past decade or so, there are still about 7,000 cis women diagnosed with HIV in the US annually. Source: Centers for Disease Control and Prevention. HIV and Women, 2018.

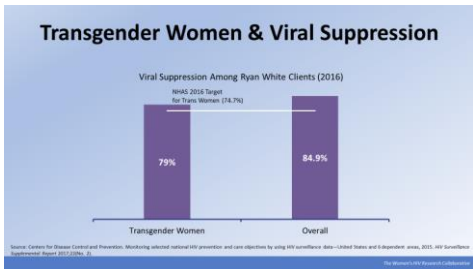
<https://www.cdc.gov/hiv/group/gender/women/index.html>



**Slide 9:**

HIV prevalence among trans women in the US is much higher than among the general population. Transgender women of color are disproportionately affected. Again, social and structural issues abound for transgender women—especially trans women of color. Jeffrey S. Becasen, Christa L. Denard, Mary M. Mullins, Darrel H.Higa, Theresa Ann Sipe, “Estimating the Prevalence of HIV and Sexual Behaviors Among the US Transgender Population: A Systematic Review and Meta-Analysis, 2006–2017”, American Journal of Public Health 109, no. 1 (January 1, 2019): pp. E1-e8. DOI: 10.2105/AJPH.2018.304727. Accessed from <https://ajph.aphapublications.org/doi/10.2105/AJPH.2018.304727> 21 Feb. 2019.

(Charts created by Brian Minalga using data from above publication)



**Slide 10:**

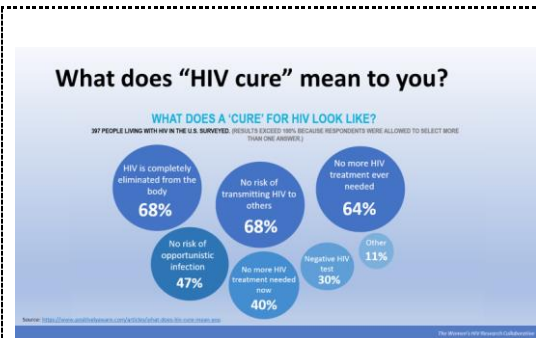
Take-home message: Women need a cure for HIV. While all clients under Ryan White Care exceeded the 2016 viral suppression targets set by the US National HIV/AIDS Strategy, transgender women in Ryan White Care lag behind due to a variety of factors—largely social and structural factors involving stigma and discrimination that create barriers to viral suppression for transgender women. Considering the disproportionate impact of HIV on transgender women, HIV cure research must include and respond to the needs of transgender women.

It should be noted that clients receiving Ryan White Care have much better outcomes than the general population of PLWH in the US. In 2014, viral suppression among the general population of people living with HIV in the US was 57.9%. There are no viral suppression data available for transgender women with HIV outside of Ryan White, but we can infer based on these trends that fewer transgender women achieve viral suppression, inside or outside of Ryan White care.

(Bar chart created by Brian Minalga using data from: Source: Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2015. *HIV Surveillance Supplemental Report* 2017;22(No. 2). <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published July 2017. Accessed 30 May 2018.)

**Overview:  
HIV Cure Research**

**Slide 11:**



**Slide 12:**  
 Before advancing slide to the bubble images, ask the audience what they think of when they hear "HIV cure." How would they define/describe it?  
 Then advance: This is what other folks think when they hear "HIV cure."  
 Source:  
<https://www.pozitivelyaware.com/articles/what-does-hiv-cure-mean-you>

### Cure: A Loaded Word

The NIH makes an important distinction:

- **Classic cure:** eliminating all cells with HIV from the body
- **Sustained ART-free remission:** HIV remains present, but at undetectable levels without ART

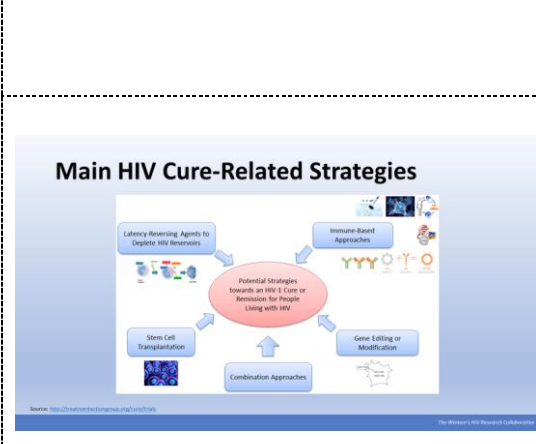
**Cure:** "the strategies that eliminate HIV from a person's body, or permanently control the virus and render it unable to cause disease" (AVAC).

The concept of "cure" has multiple social/cultural connotations.

- In the context of clinical trials, "cure" may be defined by different endpoints or clinical measures (size of reservoirs, extent of immune response, etc).
- In other words, "cure" doesn't always mean the same thing to everyone!

Source: <http://www.pozitivelyaware.com/articles/what-does-hiv-cure-mean-you>

**Slide 13:**  
 NIH: <https://www.niaid.nih.gov/diseases-conditions/sustained-art-free-hiv-remission>  
 The FDA defines HIV cure *research* as: "any investigation that evaluates: 1) a therapeutic intervention or approach that controls or eliminates HIV infection to the point that no further medical interventions are needed to maintain health; and 2) preliminary scientific concepts that might ultimately lead to such a therapeutic intervention."



**Slide 14:**  
 This slide shows examples of the main strategies being pursued in HIV cure-related research.  
<http://treatmentactiongroup.org/cure/trials>

### A Broad Spectrum of Strategies

- Treatment Action Group (TAG), with support from the Bill and Melinda Gates Foundation, conducted a landscape analysis of current HIV cure trials.
- There are presently 128 HIV cure-related trials grouped into 24 different categories, reflecting the breadth of strategies under consideration.
- Combined, the 128 studies plan to enroll a total of over 7,000 participants.
  - Individual studies' recruitment targets are between 5 and 905 participants.
- Most of these studies are early development trials (Phase I or Phase II).

LATENCY-REVERSING AGENTS				
Chikvasha	LA-301 (GSK-2857983)	King's College London	Phase III	December 2014
Adaptive and 1 <sup>st</sup> generation	LA-302 (GSK-2857983)	University of California, San Diego	Phase III	April 2015
Adaptive (second generation) (second generation)	LA-303 (GSK-2857983)	NIH	Phase III	December 2015
IMMUNE-BASED APPROACHES				
Immune-based	LA-304 (GSK-2857983)	NIH	Phase III	December 2015
GENE EDITING				
CRISPR/Cas9	LA-305 (GSK-2857983)	NIH	Phase I	May 2016

Source: <http://www.pozitivelyaware.com/articles/what-does-hiv-cure-mean-you>

**Slide 15:**  
 This is a snippet of a table prepared by Treatment Action Group (TAG) that categories HIV cure-related clinical trials based on their approach. These are all trials listed on [clinicaltrials.gov](http://clinicaltrials.gov).  
 One noteworthy approach is called "treatment intensification / early treatment." There are two large trials included in this category that, combined, will be enrolling over 1,500 pregnant women with HIV and treating their newborns who are diagnosed with HIV. The purpose is early treatment with ART to observe the effects of early ART on the HIV reservoir.

## A Major Investment by Participants

Many of the studies in TAG's analysis require multiple study visits and at least one invasive procedure.

- At least 32 require an analytic treatment interruption (ATI).
- At least 67 require invasive procedures like rectal biopsies, lengthy imaging procedures, lymph node biopsies, lumbar puncture, leukapheresis, and/or stem cell transplants.

Currently, most cure studies offer no direct benefit to participants (e.g. they are not expected to actually cure participants of HIV).

- Sites and study teams will need to think carefully about how to engage communities that have been historically underrepresented in research.

\*Information on study procedures was collected from the clinicaltrials.gov listing. It is possible that there are additional invasive procedures that were not submitted to the registry record.

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Link to table:

<https://www.treatmentactiongroup.org/cure/tri>

Current as of Q3/4 2018. A survey was sent to the contacts listed in the studies clinicaltrials.gov entries. These contacts were PIs, core study team members.

### Slide 16:

For more on equipoise in HIV cure research, see Dubé et al:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5768449/>

Define terms

- **ATI:** Stopping regular HIV treatment to analyze the effect of the HIV cure strategy in question. Typically, therapy is interrupted until study participants reach a pre-determined viral load and/or CD4 count (at which point regular HIV treatment is re-initiated).
- **Leukaphereses** and **aphereses** defined as 'laboratory procedures where selected immune cells are separated out from the blood and the rest of the blood is returned to the veins.'
- **Autologous transplants** of stem cells defined as 'studies involving transplantation of your own ("autologous") stem cells.'
- **Allogeneic transplants** of stem cells defined as 'studies that involve a transplantation of someone else's ("allogeneic") stem cells.'
- **Lymph Node Biopsy:** tissue lymph nodes will be collected, probably from lymph nodes in groin
- **Lumbar puncture aka Spinal Tap:** cerebrospinal fluid (also known as CSF) will be collected from spinal cord by a spinal tap
- **Genital Secretions:** semen will be collected from cisgender men and vaginal cells and fluid will be collected from cisgender women
- **Gut biopsies :** pieces of tissue will be taken from the gut



## Women in HIV Cure Research

### Slide 17:

### NIH Revitalization Act of 1993

- NIH policy: women and minority groups must be included in all NIH-funded clinical research, unless a clear and compelling rationale establishes that inclusion is inappropriate.
- The inclusion of women must be addressed in research proposals, including the composition of the study population in terms of sex/gender and racial/ethnic group.
- Sex differences are strongly encouraged in results for all publications.
- Women of childbearing potential should not be routinely excluded.
- The NIH Director...
  - shall ensure that the trial is carried out in a manner sufficient to provide for valid analysis of whether the variables being studied affect women differently than other subjects.
  - shall conduct or support outreach programs for the recruitment of women and minority groups.
- Applicable to Phase III and pivotal Phase II and IV studies.

### Slide 18:

By congressional act, the NIH requires that women and minority groups are included in all NIH-funded clinical research. It's not only important to include women in HIV cure research from an epidemiological standpoint or because it's "the right thing to do"; it's also the law. But are women being included in HIV cure research? Spoiler alert: by and large, they are not. The reasons for women's exclusion from HIV cure research are varied and often unclear, but we will look at some of the reasons in this presentation.

Bullet 2: the policy language is written as it appears ("sex/gender and racial/ethnic group"). The WHRC advocates for the use of sex AND gender as well as racial AND ethnic group, since sex and gender are not the same and race and ethnicity are not the same. It's important to capture all four demographic categories, and we will get to important reasons why later on.

Bullet 3: A recent publication came out called "Low-rate of sex-specific analyses in presentations at the Conference on Retroviruses and Opportunistic Infections (CROI) meeting, 2018: Room to improve." The study, which was conducted and authored almost exclusively by women (including WHRC members and affiliates), showed that only about half of the oral abstracts in their analysis included the distribution of the study sample by sex, and another 10% mislabeled sex as "gender." Only about a quarter of these abstracts presented sex-stratified analyses or sex-delineated outcomes. Only 8 of the remaining presentations (12%) provided an explanation for why sex stratification was not presented.

Last bullet: Importantly, most current HIV cure trials are Phase 1 or Phase 2. Of the 128 trials in TAG’s online listing of cure-related trials, 75 (59%) are Phase I and 38 (30%) are Phase II. So it’s significant that the Act’s scope is limited to Phase III and pivotal Phase II and IV studies.

Source:

[https://grants.nih.gov/grants/funding/women\\_min/guidelines.htm](https://grants.nih.gov/grants/funding/women_min/guidelines.htm)

Additional resources:

History of women’s inclusion in clinical research:  
<https://orwh.od.nih.gov/toolkit/recruitment/history>

ORWH website: <https://orwh.od.nih.gov/about>

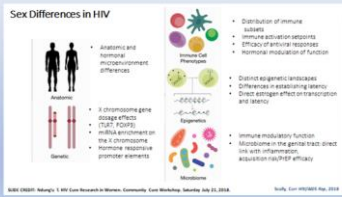
NIH Diversity statement (investigators, etc):

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-210.html>

Women in the biomedical workforce:

<https://extramural-diversity.nih.gov/diversity-matters/women-workforce>

### Sex Matters



### Slide 19:

Why is it important to study HIV across sexes? Because HIV is different across sexes, so our prevention, treatment, and cure responses have to differ across sexes.

This slide shows main factors that can cause sex-based differences in HIV. These have been reviewed by Eileen Scully in Current HIV/AIDS Reports (2018). These factors may include:

- Anatomical compartment
- Hormonal differences
- Genetic differences, mainly related to the X chromosome
- Immune-based differences
- Epigenetic landscape
- Differences in establishing latency (cisgender women appear to have smaller HIV reservoir sizes than cisgender men)
- Microbiome factors

There is a strong rationale for studying sex/gender differences in HIV cure-related research.



### Hormones & HIV Cure Research

Estrogen is a key mediator of the immune system.

"Estradiol at peak menstrual cycle levels is a potent inhibitor of viral reactivation suggesting important differences between [cis] men and women for viral replication and reservoir sizes."

"The design of regimens for proviral reactivation needs to account for estrogen, and perhaps other hormones, as confounding factors affecting potency" (Karn, 2015).

Nearly a decade after demonstrating oral PrEP's safety and efficacy overall, we are just now beginning to understand the role of hormones in PrEP effectiveness for cisgender and transgender women. We should start with hormones and other sex differences in mind as we explore HIV cure strategies for all women.

Source: Barr, J. (2015) Estrogen blocks HIV re-emergence from latency and points to gender-specific differences in HIV reservoirs. Project Inform webinar, September 4, 2015.

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### Slide 20:

The Karn quote specifically describes how sex hormones affect HIV cure approaches (in this case, the “shock and kill” approach is implicated).

Karn, J.(2015) Estrogen blocks HIV re-emergence from latency and points to gender-specific differences in HIV reservoirs. Project Inform webinar, September 4, 2015.

For more on sex differences, see Gianella, Tsibris, Barr, and Godfrey, “Barriers to a cure for HIV in women” (2016) in JIAS

<https://www.ncbi.nlm.nih.gov/pubmed/26900031>

Also Eileen P. Scully, “Sex Differences in HIV Infection” (2018)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5882769/>

PrEP: some studies are now suggesting that cis and trans women’s adherence to oral PrEP must be higher than cis men’s adherence in order to be fully protective. Hormonal differences are thought to be one factor affecting this, with one study even suggesting that further research is needed to see if transgender women on hormone therapy may benefit from a higher dose of one of the drugs in oral PrEP than is currently prescribed to all (Cottrell ML et al. Clin Infect Dis 2019 Apr9, “Transgender Women on Tenofovir Have Lower Tenofovir Diphosphate Levels in Rectal Tissue”).

### So, are women included?



### Slide 21:

Back to the TAG analysis of the 128 cure-related studies. Clearly we are failing to include women as outlined in the NIH Revitalization Act.

TAG’s analysis found information about participants’ sex for only 44 of the 128 studies.

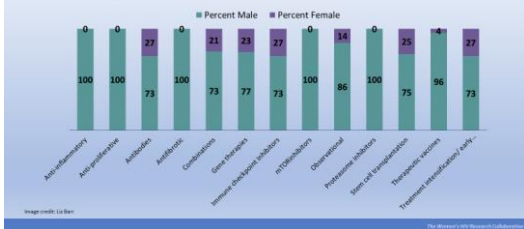
- 1 study enrolled women exclusively, which should be applauded
- The mean female enrollment in the 25 studies that enrolled male and female participants is 28% (median 11%). When look only at studies that enrolled adults (removing studies that enrolled infants/children who acquired HIV

perinatally), that percentage drops to 16% (range 3%-37%).

- For 18 of the 44 studies, enrollment (or enrollment-to-date) was 100% male.
  - Two studies were limited to male participants but did not say why.
  - The other 16 were not limited to male participants but only enrolled men.
- Given what we know about sex differences in HIV reservoirs, persistence, and disease progression, the field will need to increase female enrollment dramatically in future studies.

We would never allow this if the numbers were reversed and women made up the vast majority of HIV cure participants. This is what we call systemic and institutionalized misogyny.

Participants' sex from TAG's Analysis



**Slide 22:**

Here's another way to think about this. On the bottom of the screen are various HIV cure approaches being studied. The bars show how many women are included in studies of each category. It's wonderful that there are so many approaches to HIV cure under study, but we're missing out on how these approaches may or may not benefit women.

So female enrollment is far too low. But there's another problem here. Who sees the problem? >>

The problem: we're only seeing "male" and "female." Where do transgender people fit into HIV cure research? Based on the data provided on these 128 studies, "male" refers to assigned male at birth. Survey respondents did not indicate that gender identity was collected in addition to sex. The two studies that were limited to male participants (as an inclusion criteria) did not provide a rationale for the sex-based exclusion criteria.

### So, what about transgender women?

There is only **one** transgender woman documented as having participated in an HIV cure clinical trial.

HIV cure research **must** become trans-inclusive in all aspects, including study design, data collection, recruitment and retention, analysis, reporting, and staffing.



1. What is your current gender identity?
  - Genderqueer
  - Gender Variant, Gender Non-conforming
  - Man
  - Transgender Man/Trans Man
  - Transgender Woman/Trans Woman
  - Woman
  - Additional category, please specify \_\_\_\_\_
  - Decline to answer
2. What was your sex assigned at birth?
  - Female
  - Male
  - Intersex
  - Decline to answer

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### Slide 23:

- Protocols referring only to “male” and “female” participants are unclear; does this refer to participants who identify their gender as male/female, or does it refer to participants assigned male/female sex at birth? Protocols should use the terms cisgender and transgender as well as “assigned female/male at birth” to clearly define the study population.
- The two-step method for data collection is crucial for capturing accurate data. The NIH-funded HIV/AIDS clinical trials networks use the two-step method in all studies where they could reasonably expect that asking about gender identity would not put participants in harm’s way. We miss important differences for transgender women if we miscategorize them as cisgender men or women (which are both likely miscategorizations if researchers don’t use the two-step method).

Theoretically, the 43 studies in TAG’s analysis that enrolled participants assigned male at birth could have enrolled transgender women, but we can’t know because gender identity was not also collected. The failure to collect gender identity demonstrates the structural discrimination that makes transgender people invisible in this research.

### The MOXIE Trial (ACTG A5366)

tamoxifen to increase the Effects of vorinostat



First HIV cure-related study designed specifically for cisgender women with HIV.

- Testing two drugs to see if they can reactivate the “latent” HIV that can’t be detected by the immune system
- 30 participants: 20 women with tamoxifen plus vorinostat, 10 women with vorinostat alone
- All 30 women stay on their regular HIV treatment throughout the study
- Includes a socio-behavioral sciences component at study entry and exit

**Lessons learned about recruitment:**

- It is possible to recruit women in HIV cure-related research!
- Women greatly appreciated having a study dedicated to them.

**BUT we shouldn’t have to create an HIV cure study specific to women!**

- Sex/gender-based analyses should be built into *all* studies
- Need to set minimum enrollment for women
- Studies with female-relevant strategies should have a plan for inclusion of women

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### Slide 24:

It IS possible to include women in HIV cure research! This is the one study in TAG’s analysis with 100% enrollment of women (as an inclusion criterion). This study fits into the “latency-reversing agents” category of HIV cure-related research described earlier. First we need to know if we can reverse latency (or “wake up” the HIV that is “hiding” from the immune system), and this study will help us to know more about reversing latency in cisgender women living with HIV.

Recruitment: The study team devised a number of plans in the event that women weren’t enrolling, but women did enroll with enthusiasm. We applaud the ACTG and this study team and hope to continue seeing more trials focused on the unique biology of women.

There are other trials in early stages of development seeking to specifically address the role of estrogen in the HIV reservoir in transgender women. We hope to see those studies move forward!

**More study-specific info:**

This is a randomized, open-label, exploratory study assessing the effects of tamoxifen exposure in combination with vorinostat compared to vorinostat alone on viral reactivation among post-menopausal women living with HIV with virologic suppression on ART.

There is no analytical treatment interruption in this study.



**Slide 25:**

Adapted from Rowena Johnston (amfAR)

First theme: meaning that the old-school way of thinking is we're not going to learn anything from including women in research that we can't learn from research with men.

Second theme: The underlying old-school way of thinking here is that the male body is "normal" and the female body is "other." Meaning, women complicate the research because their bodies are different from men's, leading to complicated answers to research questions. Also, many women can become pregnant, which is another historical reason women have been excluded from research, which has resulted in providers being left clueless on how to treat women and their fetuses/babies in the real world during pregnancy and breastfeeding because research has excluded pregnant and breastfeeding women from clinical trials.

Considering the biological differences we are aware of, there is clear scientific justification and necessity for cis and trans women's inclusion in cure research.

**Slide 26:**

There are many barriers between women and HIV cure research participation. We know little about barriers to women's participation in the context of an ongoing cure



study, but here are some examples from HIV research generally.

Adapted from Sullivan PS et al. J Natl Med Assoc. 2007;99(3);24250.

Gianella S et al. Journal of the International AIDS Society 2016, 19:20706

**Facilitators to Women's Participation**

- Flexible schedules**
  - Open early/stay open late
- Provide transportation assistance**
  - Bus pass, parking fees, cab vouchers, Uber/Lyft
  - Better (closer, safer) parking
- Resources for children and family on site**
  - Coloring books, DVD players
  - Wi-Fi
  - Food, snacks, drinks
- Appreciation and recognition of women's efforts to participate**

Adapted from Kate Starr on behalf of the WHRC. The Wharton HIV Research Collaborative

**Slide 27:**

Slide credit: Kate Starr on behalf of the WHRC

**Facilitators to Women's Participation**

Compared to men, **cis and trans women are more likely** to be motivated by:

- Feeling good helping others like themselves
- Receiving money for transportation
- Getting special knowledge about their own health
- Having someone to speak to about their HIV status
- Engaging with research teams
- Being treated as a special patient
- Having regular access to study nurses
- Receiving support from family and friends
- Being compensated
- Being offered a meal

Adapted from Dubé, K and Evans, D. 2018 NIH-sponsored Workshop on HIV Cure. The Wharton HIV Research Collaborative

**Slide 28:**

Dubé, K and Evans D. 2018 NIH-sponsored Workshop on HIV Cure

When the authors looked at factors that would motivate people living with HIV to participate in HIV in the U.S.: Women seem to be more motivated by having regular access to study nurses, or by financial compensation and receiving support for transportation.

Although there were diversity in responses, we should pay attention to how motivators and 'possible benefits' are portrayed.

The possible motivators appear more relevant for women.

**Recommendations for HIV Cure Research**

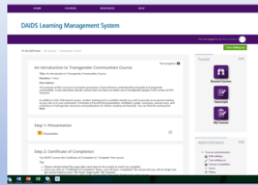
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**Slide 29:**

## Transgender Training Curriculum for HIV Research

### At the very least...

- Use the 2-step method for data collection
  - Gender identity
  - Sex assigned at birth
- Always describe study populations accurately in protocols, publications, and other study documents
  - Cisgender and transgender
  - Assigned Male/Female/Intersex at birth



<https://daidslearningportal.niaid.nih.gov>

### Slide 30:

Recommendation 1: Take this training through the DAIDS Learning Management System.

<https://daidslearningportal.niaid.nih.gov/>

Five training modules were developed by a group of transgender and cisgender subject matter experts. The modules are intended for use by research staff and stakeholders across the NIH-funded HIV/AIDS clinical trials networks, but they can be used by anyone interested in HIV research and transgender communities. As of March 2019, the first two modules are available online; use the link above to create an account with the DAIDS Learning Management System and start the trainings. You can also access the additional resources listed on the slide to conduct in-person trainings and seek additional learning.

In addition to the training, you can access additional resources:

- PowerPoint presentation (for in-person training or just to have the slides for reference)
- Facilitator's guide (for in-person trainings)
- Exercises and answer keys (for in-person trainings)
- Handout of resources and publications

Train your entire staff!

At the very least, researchers should be collecting data correctly and describing study populations accurately.

Reasons for not using the 2-step method should be explained in protocols since failure to collect both gender ID and sex assigned at birth compromises the accuracy of the data. Do not assume that the term "women" or "MSM" is enough information; include whether you're talking about cisgender or transgender women/MSM or both.



**Research Recommendations (continued)**

- Reprioritize the vision of the NIH Revitalization Act
- Design studies with strategies relevant to cis and trans women
- Build sex- and gender-based analyses into protocols and statistical analysis plans
- Require minimum enrollment for cis and trans women
- Report results by sex and gender (even with 0 women enrolled)
- Include social scientists to address issues related to women's enrollment and retention
- Pay attention to what women need and want
- Engage women and community members at all stages of HIV cure research
- Actually enroll and retain women

Source: Regulation of Clinical Research Related to HIV Cure meeting in Bethesda, MD (January 2018)

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**Slide 31:**

These recommendations come from a meeting held in Bethesda, MD in January 2018: Regulation of Clinical Research Related to HIV Cure.

NIH Revitalization Act: enlarge its vision to include all phases of research, including animal research. Relevant strategies: Cure must fit into women's lives, literally (in terms of biology) and metaphorically (in terms of social/structural factors that make women unique).

Building sex/gender analyses makes it so you have to think about women.

Minimum enrollment: this has been done in other studies. HPTN 083 is a good example where the protocol required that a minimum of 10% transgender women be enrolled. As of May 2019, that study has enrolled 12% transgender women! That's nearly 500 transgender women in this large HIV prevention study. We can do it in cure research too.

Report results even when 0 women: we need to know when results are and are not generalizable to cis and trans women.

Social science can help with all of this.

Listen to women.

**Get Involved!**

The Women's HIV Research Collaborative

**Slide 32:**

**Join the WHRC!**

Contact Brian Minalga:  
[bminalga@fredhutch.org](mailto:bminalga@fredhutch.org)  
[www.facebook.com/HANCLegacyProject](https://www.facebook.com/HANCLegacyProject)

Recent Topics:

- Women and HIV cure research
- HIV prevention research for cis and trans women
- Pregnancy and lactation in HIV clinical trials
- Mental health, HIV, and gender
- Screening for intimate partner violence in HIV research
- Women of color in research
- Building partnerships with other women-centered organizations



The Women's HIV Research Collaborative

**Slide 33:**

If you want to get involved, please consider joining us! Membership on the WHRC involves participating on bi-monthly conference calls and/or working on the topic/area of your interest with other members (e.g. planning a webinar, authoring an abstract, collaborating as a community partner, assisting with developing the annual work plan). You decide your level of involvement!

For more information, contact Brian Minalga:  
[bminalga@fredhutch.org](mailto:bminalga@fredhutch.org)

**WHRC's Webinars**

See the WHRC's three-part webinar series on women & HIV cure research:  
<https://www.hanc.info/cp/resources/Pages/Legacy-Project-Webinars.aspx>



The Women's HIV Research Collaborative

**Slide 34:**

**ACTG & IMPAACT**



**ACTG: AIDS Clinical Trials Group**  
<https://actgnetwork.org/>

**IMPAACT: International, Maternal, Pediatric, Adolescent AIDS Clinical Trials Network**  
<https://impaactnetwork.org/index.htm>

Consider engaging with:

- Community Advisory Boards
- Community Scientific Subcommittee (CSS)
- Women's HIV Inter-network Scientific Committee (WHISC)

The Women's HIV Research Collaborative

**Slide 35:**

These are the two research networks primarily funded by the National Institute of Allergy and Infectious Diseases, National Institute of Child Health and Human Development, and National Institute of Mental Health that are leading the HIV cure research agenda.

ACTG: <https://actgnetwork.org/>

Has a Global Community Advisory Board or GCAB (<https://actgnetwork.org/node/223>) which helps to integrate community involvement in the research conducted by the network.

Also has a Community Scientific Subcommittee (<https://www.actgnetwork.org/node/760>), which is part of the GCAB. The CSS strives to ensure that the ACTG scientific priorities reflect the pressing needs of PLHIV and to protect the interests of research participants in ACTG studies.

**Martin Delaney Collaboratory Programs & CABs (2016-2021)**



**Slide 36:**

These 6 centers have also been funded by the NIH to focus on different HIV cure research questions. They each have a CAB.


NIH funded Martin Delaney Collaboratory programs for 2016-2021 (the 6 research teams)

- defeatHIV, Cell & Gene Therapy for HIV Cure
  - Fred Hutchinson Cancer Research Center, Seattle, WA
  - CAB: <http://defeathiv.org/2014/05/16/defeathiv-cab-meetings/>
- DARE, Delaney AIDS Research Enterprise
  - UCSF, San Francisco, CA
  - CAB: <https://www.daretofindacure.org/bios>
- CARE, Collaboratory of AIDS Researchers for Eradication
  - UNC, Chapel Hill, NC
  - <https://delaneycare.org/>
- BELIEVE, Bench to Bed Enhanced Lymphocyte Infusions to Engineer Viral Eradication
  - George Washington University, Washington, DC
  - CAB: <https://believe.weill.cornell.edu/community/about-cab>
- I4C, Combined Immunologic Approaches to Cure HIV-1
  - Beth Israel Deaconess, Boston, MA
  - CAB: <https://www.i4cacure.org/cab/>
- BEAT-HIV, Delaney Collaboratory to Cure HIV-1 Infection by Combination Immunotherapy
  - Wistar Institute, Philadelphia, PA
  - CAB: <http://beat-hiv.org/community-advisory-board/>

**International Workshop on HIV & Women**

**Recent Topics:**

- HIV cure research: considerations for women
- Current controversies for ART use in women of childbearing potential and in pregnancy
- ART in women overall
- New drug delivery systems: are they right for women?




<https://www.virology-education.com/event/upcoming/9th-hiv-women-workshop/>

**Slide 37:**

The International Workshop on HIV and Women is an opportunity for health care providers, researchers, government, industry, and community to discuss, debate, and further their knowledge on the issues related to HIV and women. The meeting also provides a forum for new investigators to present their work, and to meet personally with experts they view as mentors and inspiration for their work. The meeting considers both local and global issues, and information learned in one setting is often translated to another. The timing now enables participants to combine this meeting with CROI.

**Participate In A Trial!**



<https://www.youtube.com/watch?v=jmaaMv1PaIA>


**Slide 38:**

Video is 8:36 long. Recommend showing just a portion of it and referring people to the entire video if they'd like to see the whole thing. The most relevant parts are:

0:00 – 0:55  
2:20 – 4:27

<https://www.youtube.com/watch?v=jmaaMv1PaIA>

**Get Informed**



amfAR (Foundation for AIDS Research) - Consortium on HIV Eradication: <https://www.amfar.org/cure/>  
Institute for HIV Cure Research: <https://www.amfar.org/Cure-Research-Institute/>

Treatment Action Group - <http://www.treatmentactiongroup.org/cure>

POZ.com - <https://www.poz.com/tag/cure>

TheBody.com - <https://www.thebody.com/category/curing-hiv>

International AIDS Society - <https://iasociety.org/hivcure>

Positively Aware - <https://www.positivelyaware.com/>

**Slide 39:**

amfAR: <https://www.amfar.org/cure/>  
<https://www.amfar.org/Cure-Research-Institute/>

AmfAR has set a strategy to develop the scientific basis for an HIV cure by the end of 2020. The amfAR consortium and institute support HIV cure research and include news and resources on the topic. They also offer a CAB.

More news resources:

TAG: <http://www.treatmentactiongroup.org/cure>  
POZ: <https://www.poz.com/tag/cure>  
TheBody: <https://www.thebody.com/category/curing-hiv>  
IAS: <https://iasociety.org/hivcure>

IAS also has a Stakeholders Advisory Group, Industry Collaboration Group, and International Scientific Working Group

PA: <https://www.positivelyaware.com/>

**Slide 40:**

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