Women's Involvement in HIV Cure-Related Research: Empirical Data, Unresolved Challenges and Opportunities for the Future

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Boston, MA

UNC GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH

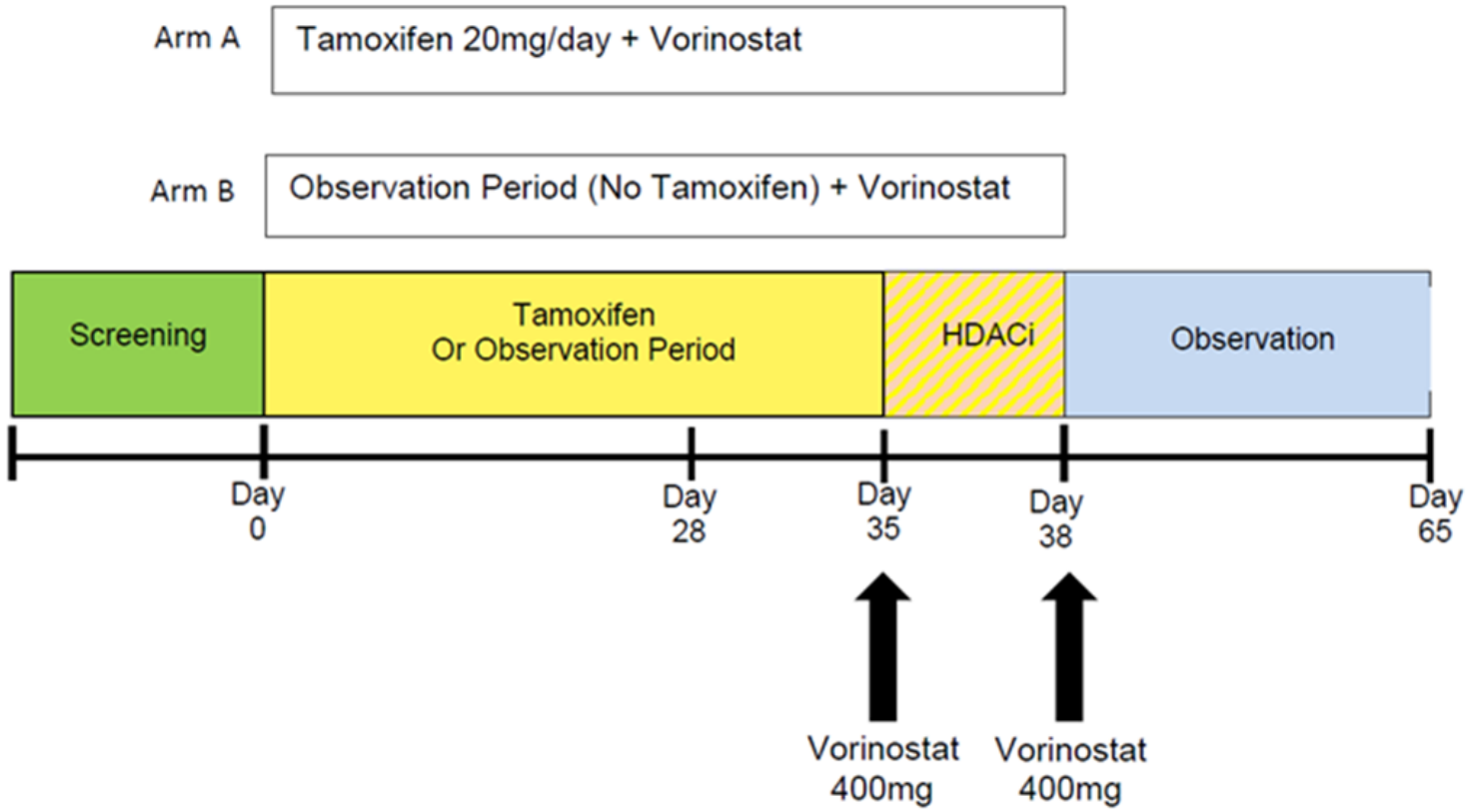
Proposed Outline

- A5366 social sciences results
- Survey on preferences for virologic control strategies ('dose response' paper)
- FRESH cohort preparation
- Questions for discussion

A5366: HIV Cure Study in Women

Randomized, Open-Label, Exploratory Study of HIV-1 Infected Post-Menopausal Women with Virological Suppression on ART Assessing Effect of Tamoxifen Exposure in Combination with Vorinostat (Arm A) Compared to Vorinostat alone (Arm B) on Viral Reactivation

Figure 1: Study Design



A5366: Social Sciences Time Points and Domains

Entry Questionnaire (Enrollment Visit)	Exit Questionnaire (End of Study Visit – Day 69 or Before)
N = 29; excludes 6 null or duplicative records	N = 27
• Module 1: Demographic characteristics • Module 2: Attitudes towards HIV cure research • Module 3: Decision to participate in study • Module 4: Understanding of the study • Module 5: Perceptions of risks and benefits • Module 6: Perceptions of health • Module 7: Meaning/purpose and altruism • Module 8: Stigma • Module 9: Role of incentives	• Module 1: End of study questions

A5366: Meaning of HIV Cure

"My life with no meds"

"Not having to take anymore meds"

"Never taking medicine"

Not having to take HIV medications (n = 8)

"It means liberation from HIV stigma and a revolution of medical proportion"

"Living without fear"

"A miracle – freedom"

"Hope for HIV patients"

Freedom, Hope, Empowerment, Life Without Fear (n = 6)

"Making the HIV virus go away forever"

"It means live, getting better and clearing the virus from my body completely"

"That I do not have it anymore"

No longer having HIV or HIV completely eliminated (n = 5)

"That I would be healthier"

"So I don't have to go to the doctor all the time"

"Better immune system"

Other (n = 3)

A5366: Primary Reasons to Participate

"The primary reason I decided to participate in this study is to help see if certain medicines will help researchers with a cure for the disease"

"I am very interested in finding a cure for HIV. I interested in learning about the medications that can help bring the virus out of wherever it is hiding in my body and kill it"

"To help provide data to further cure"

"To serve as a participant and to enable the process towards finding a cure that will help others be liberated from this deadly virus"

"To help my community"

"I dedicated because I want to be an example for other people that are living with the virus that there is research and medicine out there that can help them get better. I want to help with the answer to HIV cure"

"To give forward"

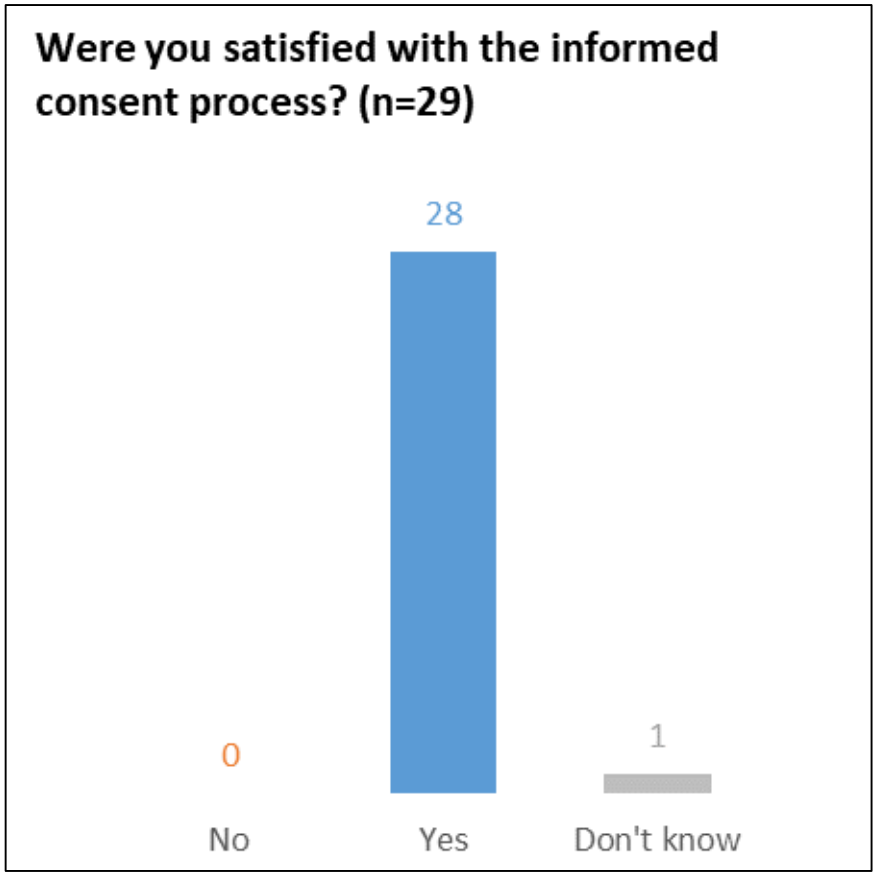
"Because the study help them to find out how to cure HIV"

"Ayudar a la ciencia y contribucion a los estudios"

"To move along the possibility of a cure"

Altruism
To Help Find a Cure (n = 21)

A5366: Informed Consent



"The study and consent were explained so that I understood"

"Because it was clear and simple and it helped me understand what medication I will be taking and the side effects and everything"

"The study nurse reviewed everything very nicely"

"Because the consent is very thorough so I can understand the study"

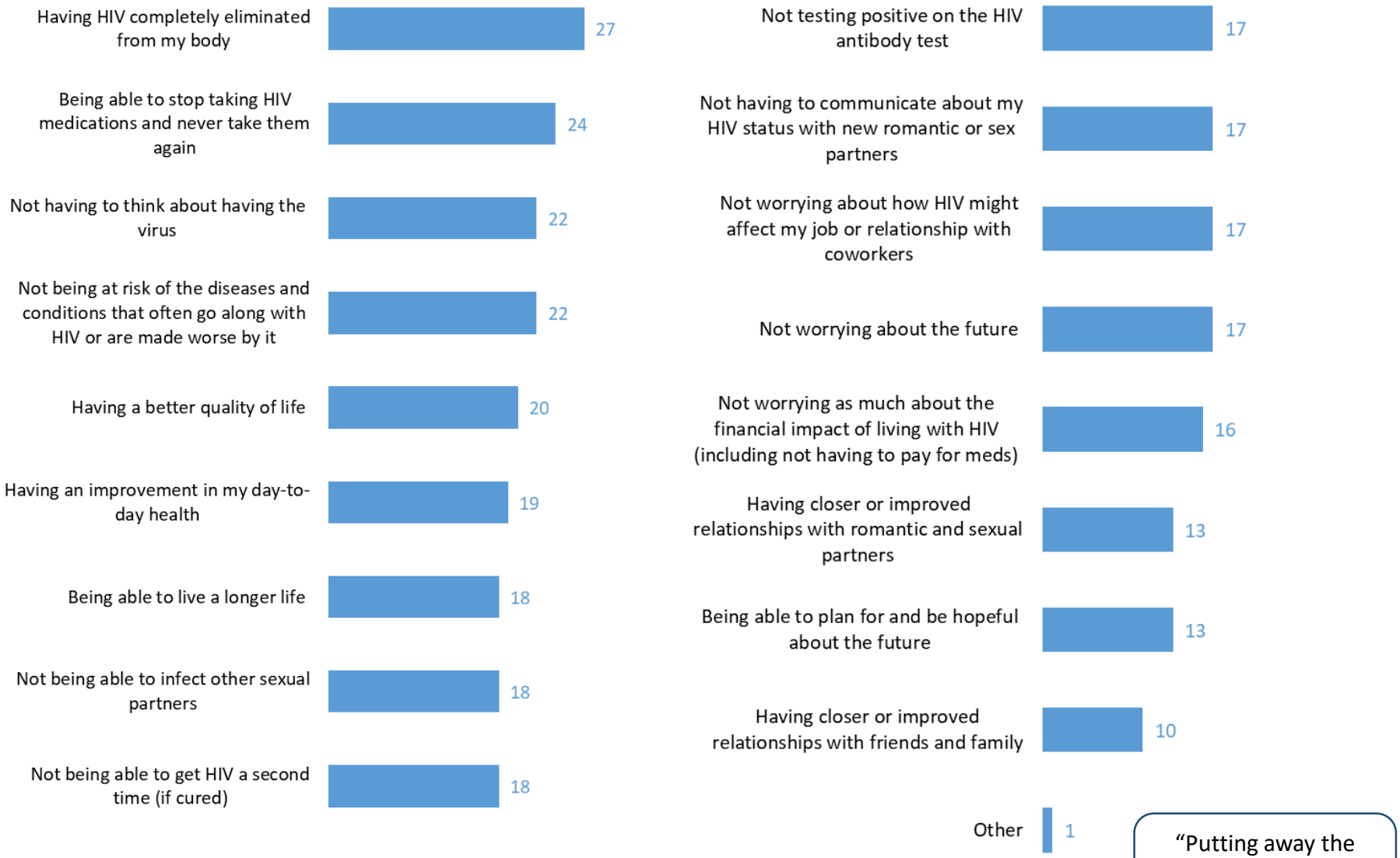
"The nurse was very specific"

"Discussion made me understand the process"

"Doctor explained the study thoroughly and that made me feel that I was not in danger"

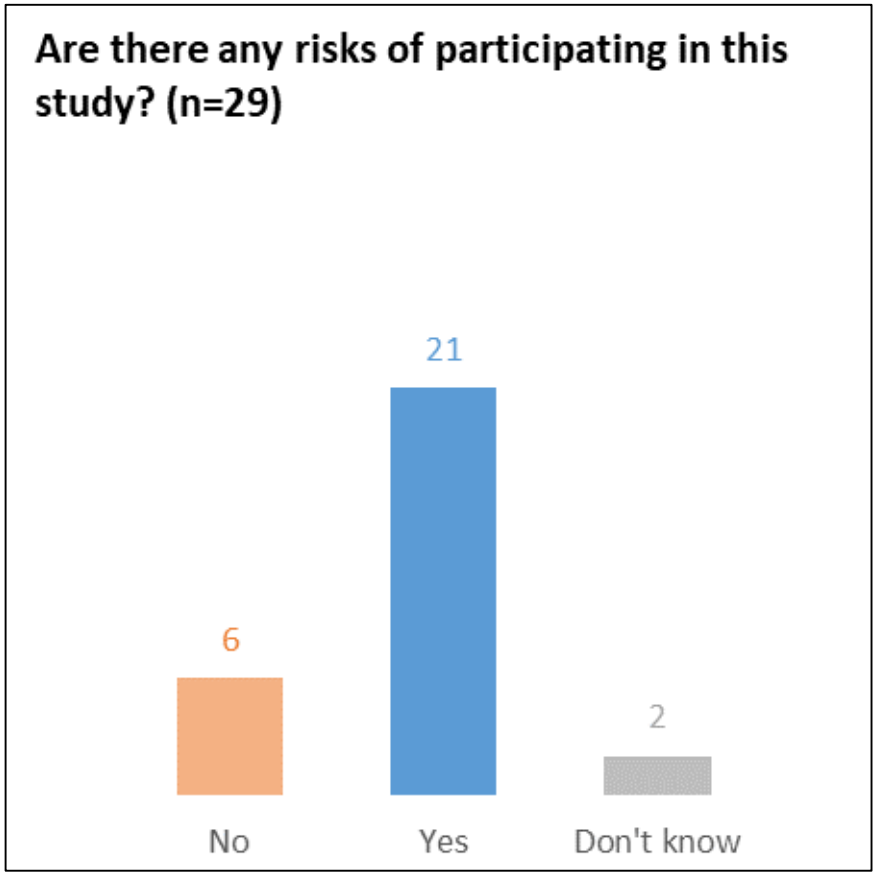
"The process was very clear and all my questions were answered"

A5366: Perceived Benefits – Most Positively Affect Life



"Putting away the stigma that comes with the status"

A5366: Perceived Risks



"Drugs can make me nauseous and I can get bruises from punctures"

"Symptoms from the meds"

"There is a risk for everything"

"There are minimal risks to all studies"

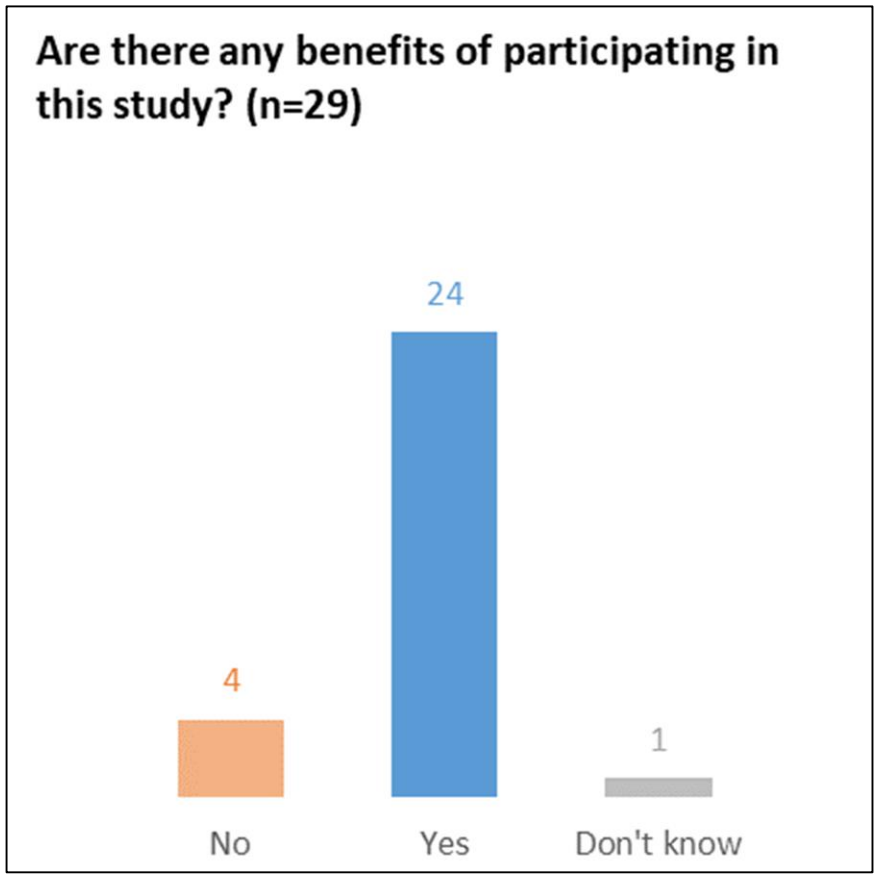
"Posibles efectos sedundarios"

"Possible side effects of the medication"

"A reaction to the drugs"

"I don't know what they are"

A5366: Perceived Benefits



"Helping finding a cure"

"Yes your time is not wasted besides getting 500.000 you are being part of something that can insure life"

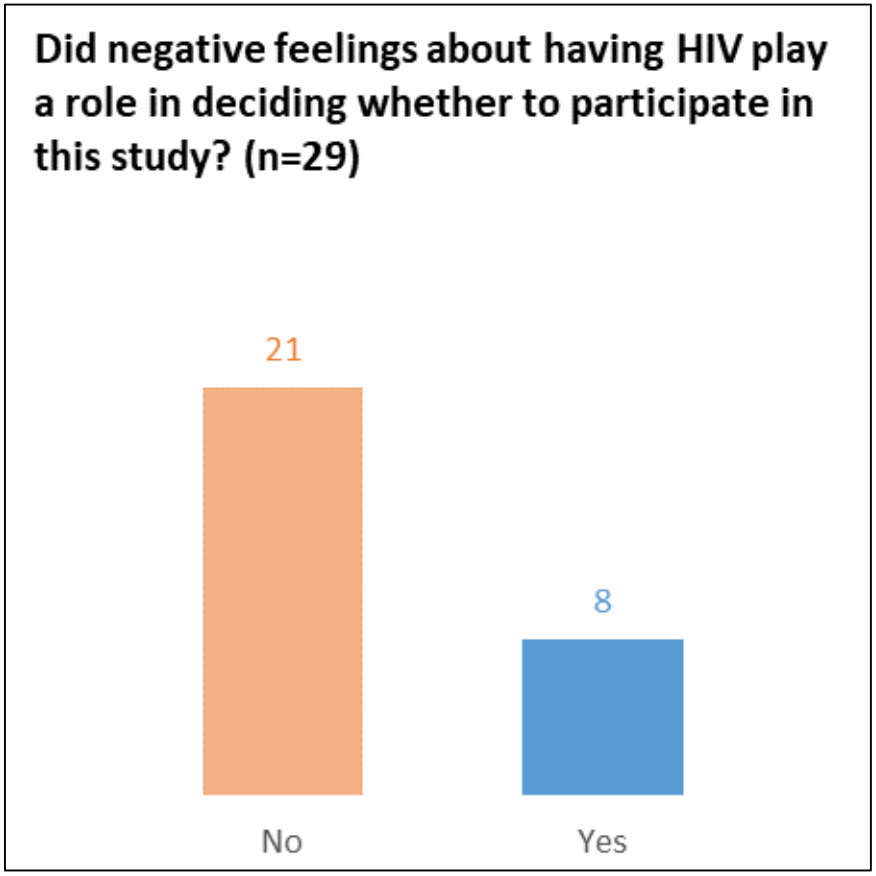
"Psychological"

"Adding to science and the $25 compensation"

"It enables me to look anxiously to a cure"

"It can help researchers find answers and compensation cards"

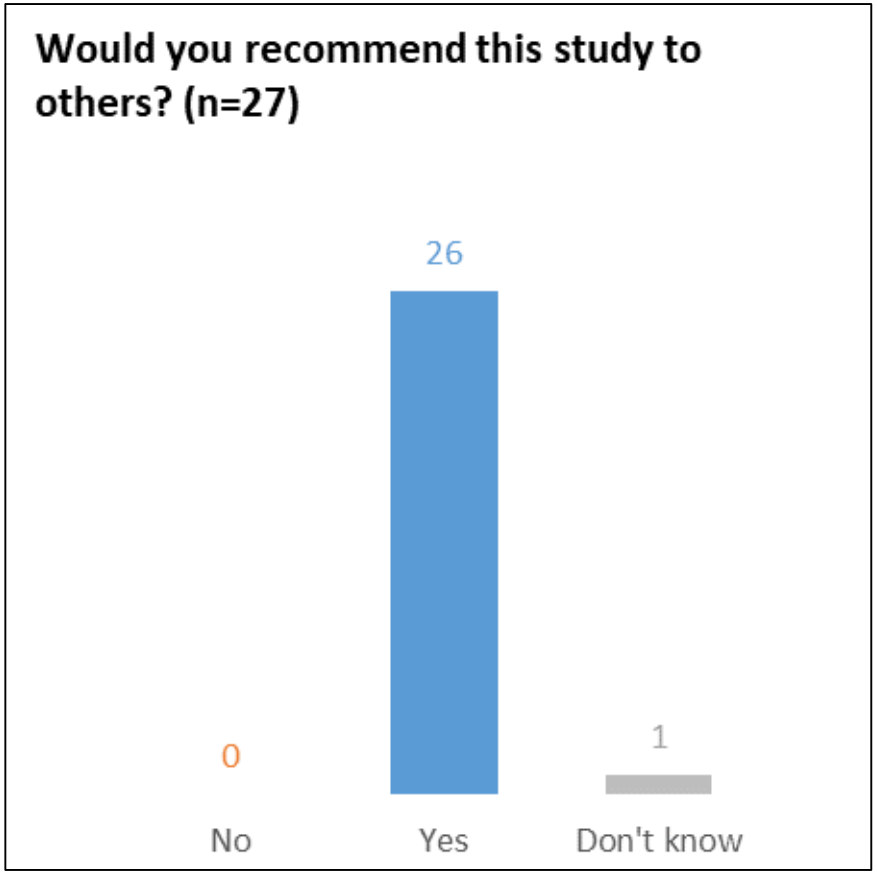
A5366: Perceived Stigma



Responses included:

- "Tired of feeling alone"
- "Not easy to explain"
- "I hate this disease"
- "The stigma has been toxic to me and it stifles conversation"
- "I hate living with the virus and it played a role in me participating in the study"
- "Scared of having it, HIV"
- "The care giving to me"
- "Stigmatizing"

A5366 Exit Surveys



"Because when you join you learn so many things that can help with having HIV"

"Because they are investigating how they can help people with the HIV virus"

"I think the cure study is a great study. Its one step closer to finding a cure"

"Be part of something greater than self"

"It was easy, didn't require a lot of time"

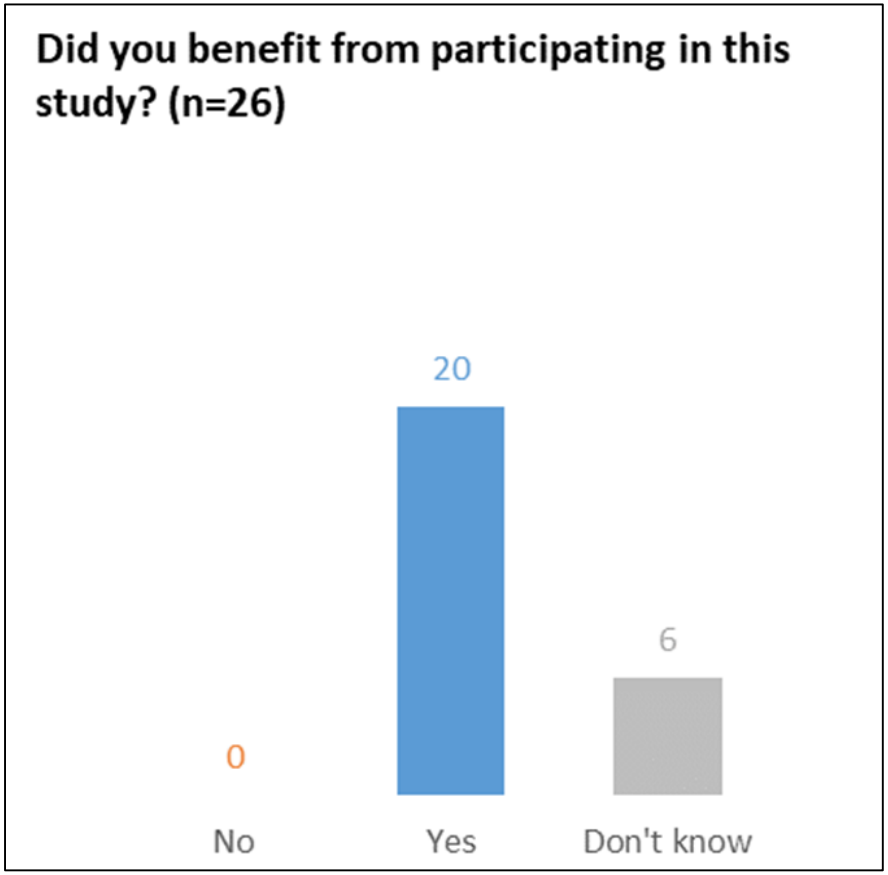
"The only way we can find a cure is for us to participate in studies and this was very easy. No side effects to this point"

"Because we don't have enough women going research w/ HIV"

"Beneficios y sequimientos de laboratorio"

"Pretty easy to tolerate, did not require anything invasive"

A5366 Exit Surveys



"My benefit is not just the money it is helping to find a cure, giving my blood to help (…)"

"Hopefully help science move along"

"For me to know what's going on in my body"

"It gave me an immense satisfaction that I was given an opportunity to be part of this study"

"Taught me discipline about taking my HIV meds"

"I was monitored closely"

"Gained knowledge"

"I benefited from the gift cards"

"I learned more about reservoirs than I knew before"

Did you experience any of the following problems? Choose all that apply. (n=27)

What did we learn from A5366 participant surveys?

- We identified societal and personal motivators of participation, understanding of risks, and misconceptions in some trial participants. Results point to the need to continue engagement and clarify expectations in cure studies.
- Stigma still plays an important role in women's lives and in decisions to join HIV cure studies
- Compensation clearly played a role in motivations to participate
- **Almost all women had a very positive experience participating and would recommend the study to others**
- We need to appreciate the psychosocial and affective aspects of HIV cure research participation
- We were able to successfully integrate socio-behavioral science as part of an ACTG biomedical HIV cure-related study

A5366 Some Implications of Findings

- Avoid word ‘cure’ in informed consent forms; use precise terms
- Increase readability of informed consent forms
- Simplify risk information
- Appreciate psychosocial aspects of HIV cure-related research participation
- Ascribe value to lived experiences of study participants
- More research is needed to understand the role of stigma and self-image in decisions to participate
- Need to work on reducing barriers and enhancing facilitators
- Still need to understand factors related to ATIs

AIDS Research and Human Retroviruses

AIDS Research and Human Retroviruses: http://mc.manuscriptcentral.com/aidsresearch

Perspectives in an HIV Cure-Related Trial Conducted Exclusively in Women in the United States: Results from AIDS Clinical Trials Group (ACTG) 5366

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Manuscript Keywords (Search	women living with HIV, HIV cure-related research, vorinostat, tamoxifen,

Ragon Institute of MGH, MIT and Harvard

Review

Recommendations for analytical antiretroviral treatment interruptions in HIV research trials—report of a consensus meeting

Boris Julg, Lynda Dee, Jintanat Ananworanich, Dan H Barouch, Katharine Bar, Marina Caskey, Donn J Colby, Liza Dawson, Krista L Dong, Karine Dubé, Joseph Eron, John Frater, Rajesh T Gandhi, Romas Geleziunas, Philip Goulder, George J Hanna, Richard Jefferys, Rowena Johnston, Daniel Kuritzkes, Jonathan Z Li, Udom Likhitwonnawut, Jan van Lunzen, Javier Martinez-Picado, Veronica Miller, Luis J Montaner, Douglas F Nixon, David Palm, Giuseppe Pantaleo, Holly Peay, Deborah Persaud, Jessica Salzwedel, Karl Salzwedel, Timothy Schacker, Virginia Sheikh, Ole S. Søgaard, Serena Spudich, Kathryn Stephenson, Jeremy Sugarman, Jeff Taylor, Pablo Tebas, Caroline T Tiemessen, Randall Tressler, Carol D Weiss, Lu Zheng, Merlin L Robb, Nelson L Michael, John W Mellors, Steven G Deeks, Bruce D Walker

Monitoring

- HIV RNA monitoring weekly for 12 weeks, then every other week
- CD4 count monitoring every two weeks
- Monitoring of clinical symptoms, in particular in people who started ART during the hyperacute HIV phase
- Monitoring of participants' psychosocial experiences

COMMUNITY RECOMMENDATIONS FOR CLINICAL RESEARCH INVOLVING ANTIRETROVIRAL TREATMENT INTERRUPTIONS IN ADULTS

NOVEMBER 2018

TAG Treatment Action Grou

*"**Monitoring of participants' psychosocial experiences** during ATIs is crucial. There was consensus that the **psychosocial and lived experiences of study participants** should be **strategically assessed** during analytical treatment interruptions.*

The large majority of meeting participants agreed with integrating socio-behavioral assessments and monitoring of study participants in HIV ART-free remission protocols during ATIs."

Women and HIV Cure-Related Research

2018 Forum Meeting

- Reprioritize the vision of the NIH Revitalization Act
  - Issues not unique to women (e.g., minority populations)
- Design studies with female-relevant strategies (Ananworanich, Scully)
- Account for sex/gender in HIV cure clinical studies
  - Sex-based analyses built into protocols and statistical analysis plans
  - Minimum enrollment for women
- Ensure better reporting of results (even if n = 0) (Gianella)
  - Reporting of sex/gender in HIV cure studies is incomplete (Johnston)
  - Sex/gender is a neglected variable – also in animal research
- Think beyond risks (and benefits)
- As a field, need more standardization of assessments to make meaningful comparisons across studies
- Include social scientists to understand and address barriers to women's enrollment and retention
  - Pay attention to what women need and want (Ramirez)
- Forge a pathway towards patient-centered HIV cure research agenda
  - FDA vision for patient-focused drug development
- Engage women and community members at all stages of research

Expanding Social and Behavioral Sciences in HIV Cure-Related Research (2018 Survey)

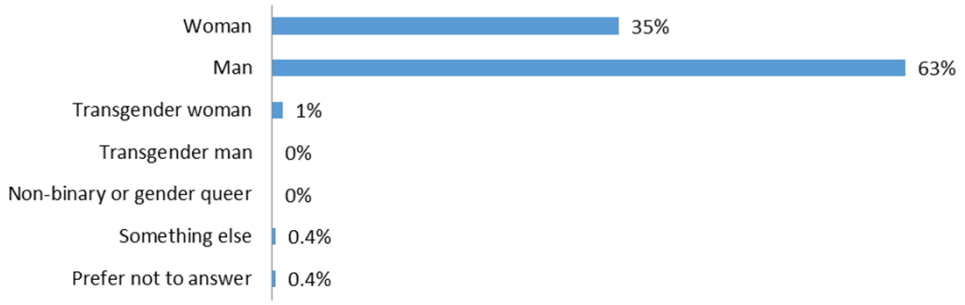
HIV Cure Survey

The opinions of people living with HIV are critical to focus time, money and attention on HIV cure studies that are acceptable, safe and ethical. We want to know what you think.

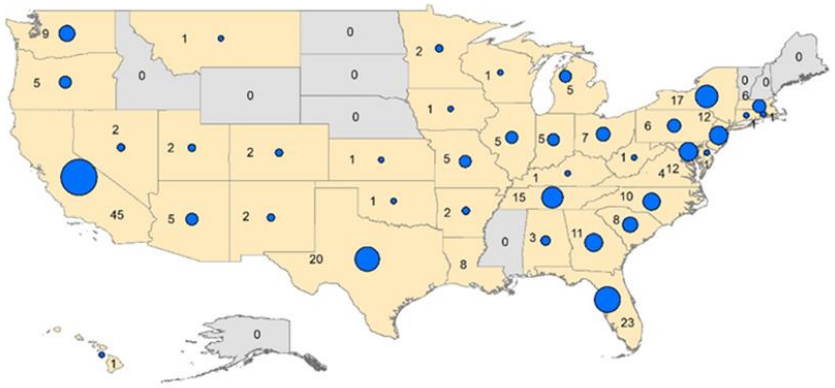
If you're a U.S. or U.S. territories resident, at least 18 years of age, and want to share your opinion with us about HIV cure strategies, we invite you to take a survey.

If you're interested, click here by July 31, 2018
http://bit.ly/2DoCx8e

Gender of Respondents
(n=282)



Residence of Survey Respondents
(n=272)



Additionally, 10 respondents did not specify their place of residence.

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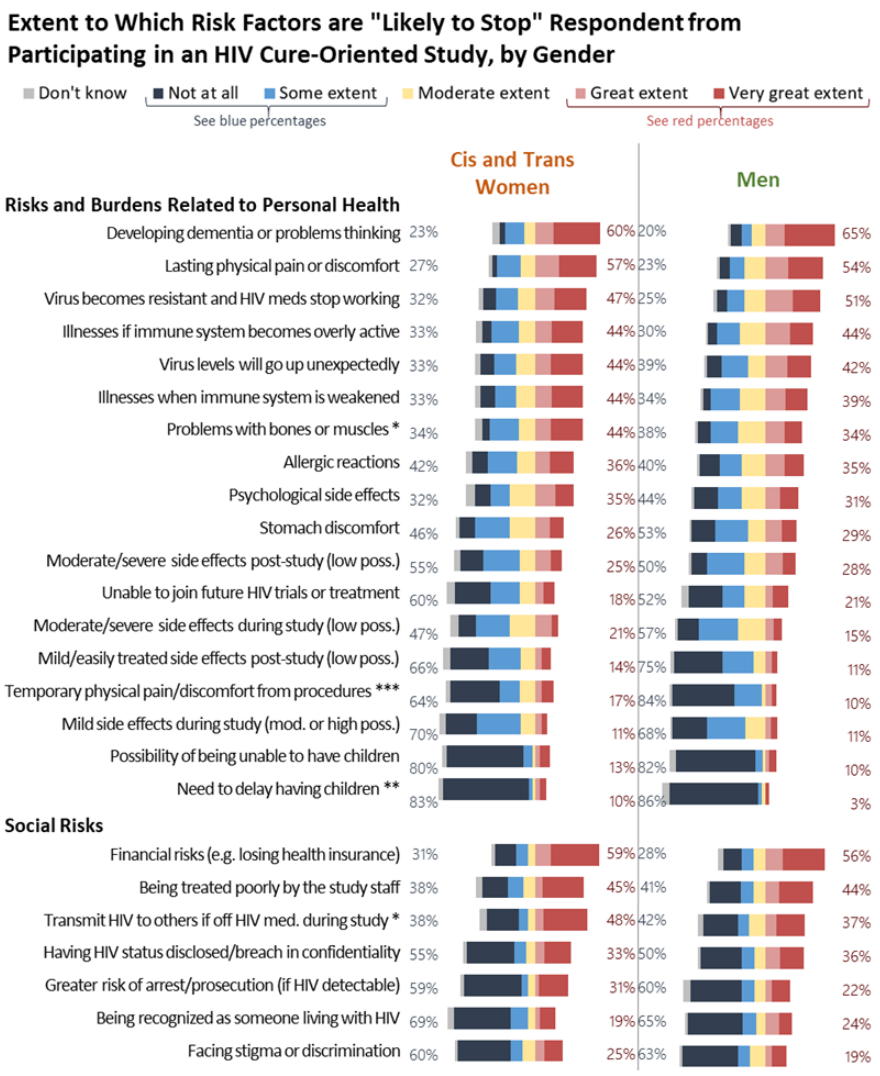


2018 Survey
Perceived Risks, by Gender

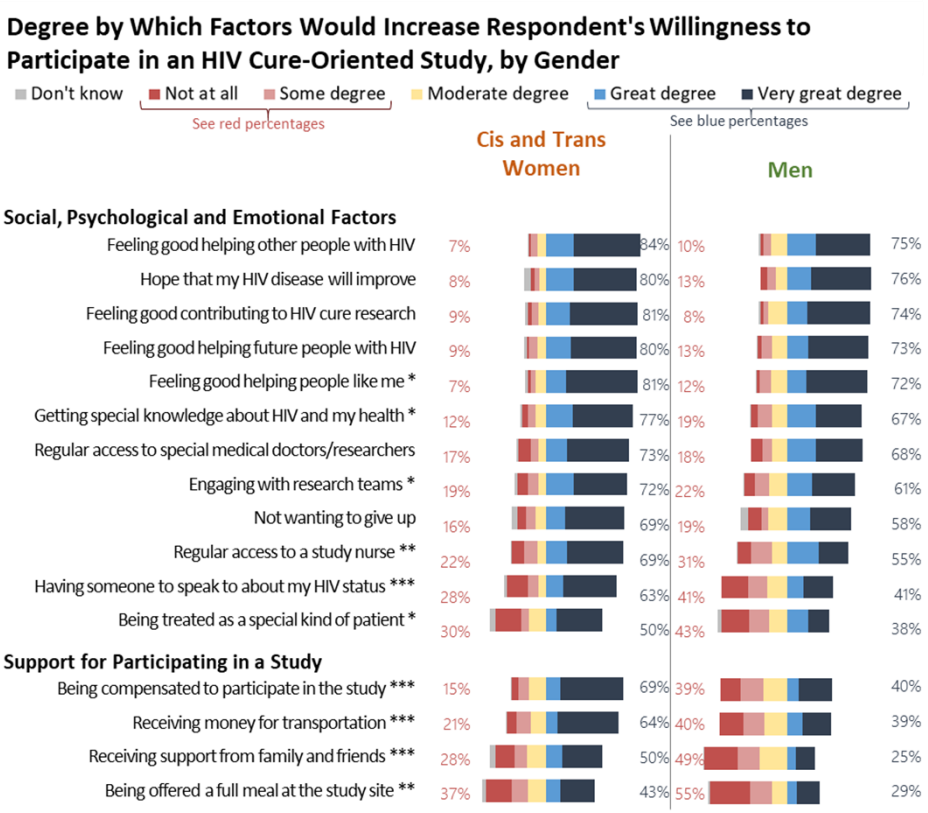
Compared to men, **cis and/or trans women are more likely** to be concerned about these risks:

- Increased likelihood of transmitting HIV to others during the medical study [OR 1.71]
- Problems with bones or muscles [OR 1.68]
- Need to delay having children [OR 4.03]

Compared to cis and trans women, **men are less likely** to be concerned by these risks:

- Temporary physical pain or discomfort from study procedures [OR 2.94]

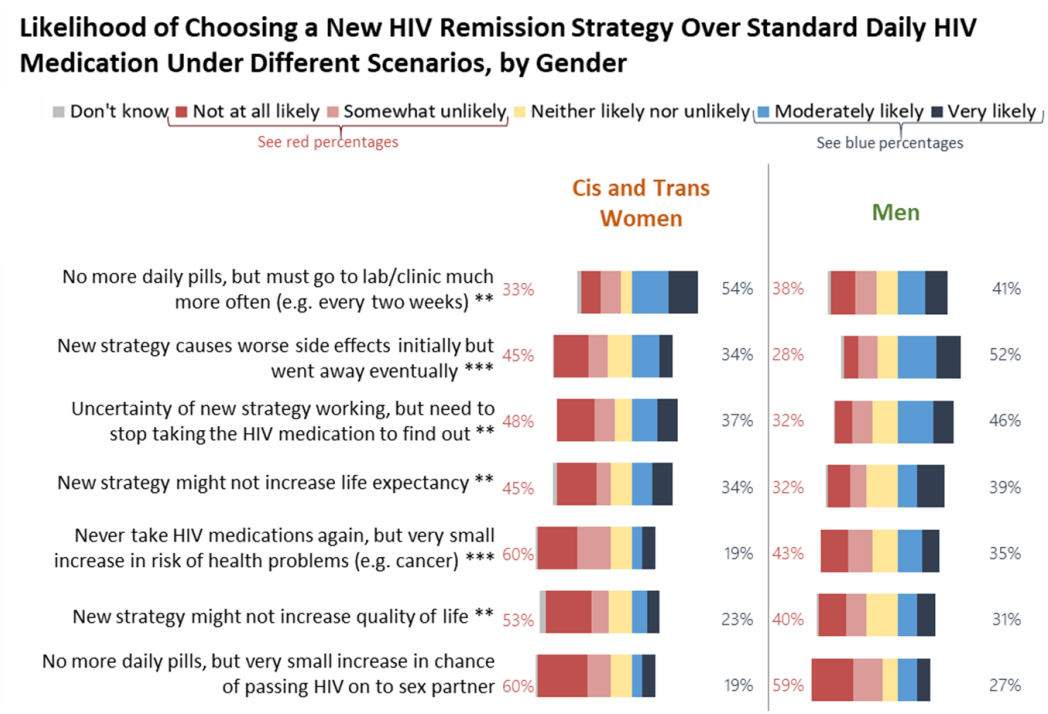
2018 Survey
Perceived Motivators, by Gender



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

- Feeling good about helping others like themselves [OR 1.88]
- Obtaining special knowledge about own health [OR 1.78]
- Engaging with research teams [OR 1.73]
- Having regular access to study nurse [OR 1.82]
- Being compensated [OR 3.40]
- Receiving money for transportation [OR 2.83]
- Having someone to speak to about HIV status [OR 2.55]
- Being treated as a special patient [OR 1.70]
- Receiving support from family and friends [OR 3.28]
- Being offered a meal [OR 1.89]

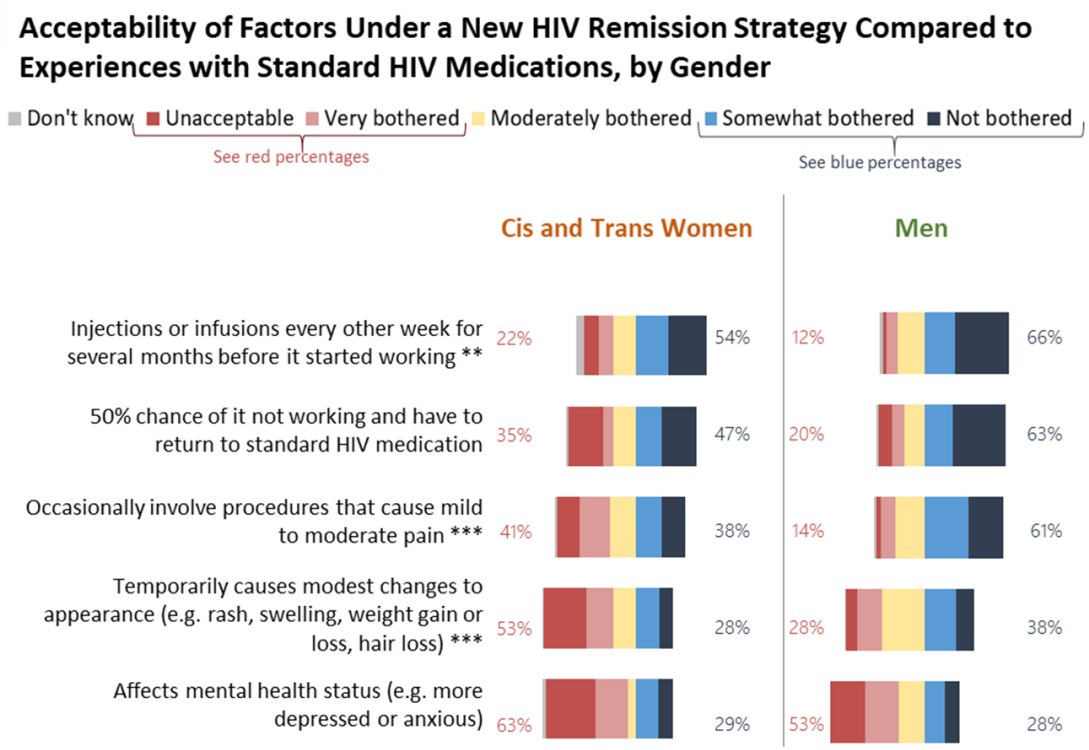
Likelihood of Switching to New Scenarios of HIV Remission Strategies, by Gender



Compared to men, **cis and trans women are:**

- **more likely to switch** to the new scenario despite having to go to clinic/lab appointments much more frequently [OR 1.77]
- **less likely to switch** to the new scenario because of:
  - temporarily worse side effects [OR 0.46]
  - small increase to risk of developing health problems later in life like cancer [OR 0.46]
- **more likely to stay with ART** if the new strategy:
  - won't increase life expectancy [OR 1.79]
  - won't improve quality of life [OR 1.84
  - requires going off ART to find out if will be effective [OR 1.96]

Acceptability of Trade-Offs Under New HIV Remission Strategies, by Gender

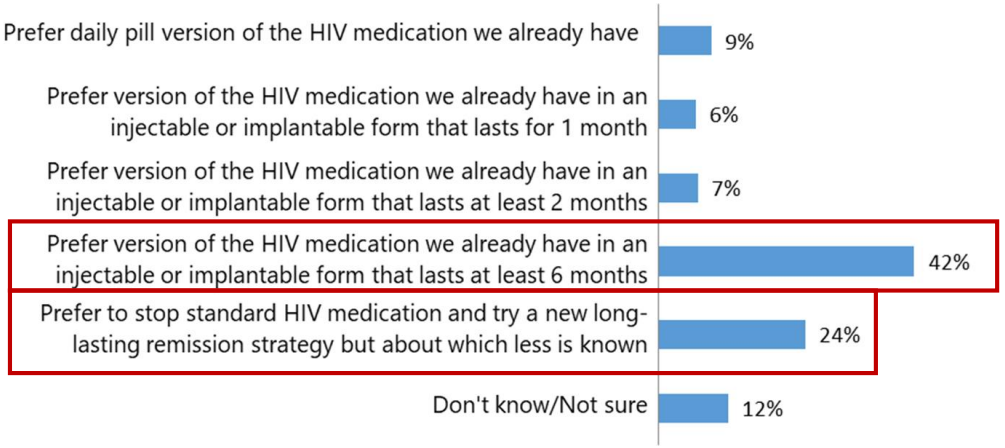


Compared to men, **cis and trans women are more likely** to be very bothered or find the following factors unacceptable:

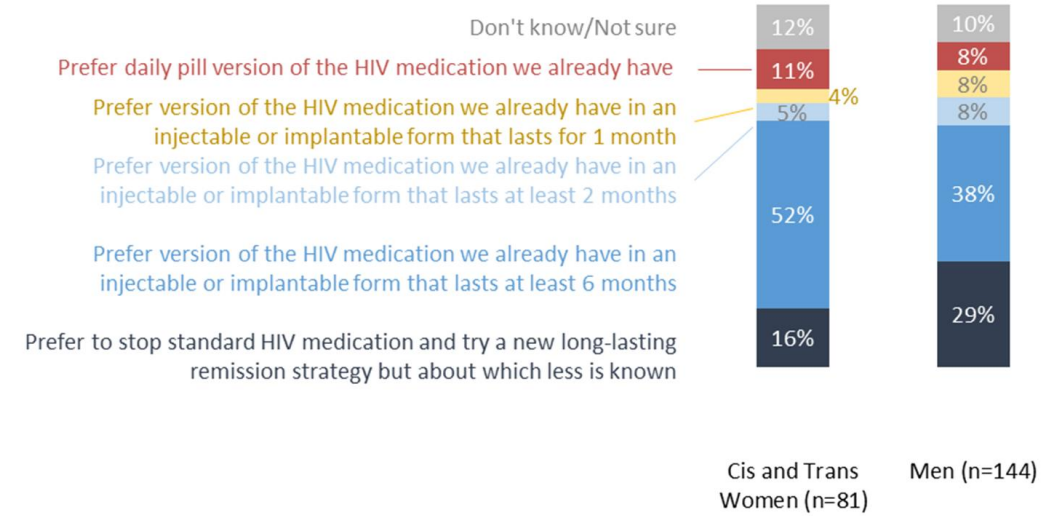
- New remission strategy might temporarily and modestly makes change to appearance [OR 3.00]
- Procedures that occasionally cause mild to moderate pain [OR 4.04]
- New remission strategy involves bi-weekly injections or infusions every for several months before the new medications started working [OR 2.31]

Choice Between Current Standard Daily HIV Medications versus Long-Acting Antiretrovirals versus New Experimental HIV Remission Strategy

(n=226)



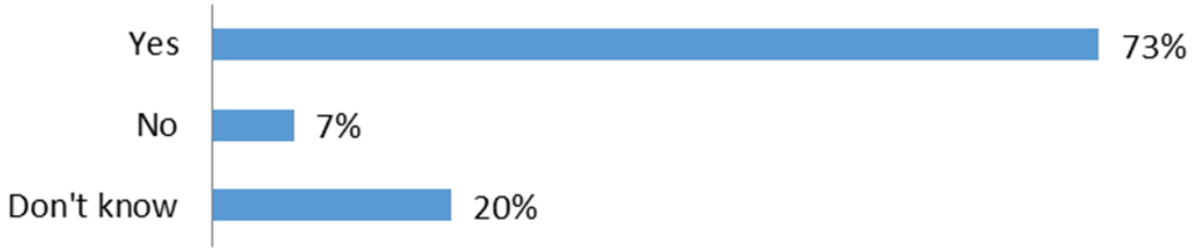
Choice Between Current Standard Daily HIV Medications versus Long-Acting Antiretrovirals versus New Experimental HIV Remission Strategy, by Gender



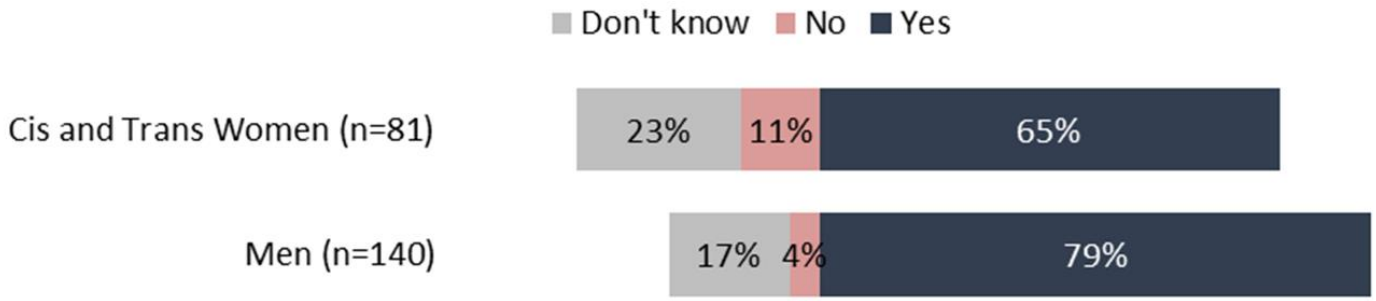
Excludes two respondents who did not specify their gender. No transgender men participated in the survey. Differences in choices between cis and trans women versus men are not statistically significant at the 10% level.

Willingness to Try an HIV Remission Strategy to Avoid the Long-Term Consequences of Long-Term HIV Treatment

(n=222)



Willingness to Try an HIV Remission Strategy to Avoid the Long-Term Consequences of Long-Term HIV Treatment, by Gender



Excludes two respondents who did not specify their gender. No transgender men participated in the survey. Differences in percentages of choosing "Yes" is statistically significantly different for cis and trans women than for men (p=0.040**).

Multivariate results: Statistically-Significant Odds Ratios of Higher Likelihood to Choose a New HIV Remission Strategy Over Standard Daily ART Based on Perceptions of Potential Risks, *ceteris paribus*

	Increased likelihood of choosing new HIV remission strategy over standard daily ART if…						
Potential risk that would "to a great or very great extent" (vs. lower extents) likely stop participation in an HIV-cure study	No more daily pills, but must go to lab/clinic much more often (e.g. every two weeks)	No more daily pills, but very small increase in chance of passing HIV on to sex partner	New strategy causes worse side effects initially but went away eventually	Never take HIV medications again, but very small increase in risk of health problems (e.g. cancer)	Uncertainty of new strategy working, but need to stop taking the HIV medication to find out	New strategy might not increase life expectancy	New strategy might not increase quality of life
Virus levels will go up unexpectedly	0.27	0.50	0.48	0.46	0.19	0.34	0.43
Possibility that the virus will become resistant to current HIV medication	0.27	0.45	0.36	0.33	0.31	0.33	0.39
Temporary physical pain or discomfort from procedures	0.11		0.10	0.24	0.30	0.34	0.23
Lasting physical pain or discomfort	0.39	0.52	0.44	0.37	0.42	0.36	0.40
Developing dementia or problems thinking or remembering		0.40	0.30	0.33			
Stomach discomfort	0.25	0.46	0.24	0.25	0.32	0.47	0.45
Psychological side effects	0.21	0.46	0.26	0.36	0.37		0.31
Illness that can occur when my immune system is weakened	0.52		0.33	0.30	0.27	0.38	0.30
Illnesses that can occur if my immune system becomes overly active	0.43	0.49	0.40	0.32	0.48	0.43	0.44
Problems with my bones or muscles	0.26	0.39	0.28	0.25	0.36	0.30	0.33
Allergic reactions	0.28	0.42	0.25	0.22	0.35	0.35	0.31
A moderate/high chance of mild side effects during the study			0.18	0.16	0.30		
A low chance of moderate/severe side effects during the study	0.37		0.24	0.29			0.23
A very low chance of mild side effects that might occur post-study				0.20			
A very low chance of moderate/severe side effects that might occur post-study	0.41	0.45	0.29	0.37	0.45	0.44	0.19
Need to delay having children							
Possibility of being unable to have children in the future			0.25	0.13			
Becoming ineligible for future HIV trials or treatment							
Transmitting HIV to others if off HIV medication during the study		0.28			0.45		
Being at greater risk of arrest or prosecution if virus becomes detectable		0.42			0.41		
Being recognized as someone living with HIV		0.40		0.42			
Being treated poorly by the study staff							0.51
Financial risks		0.44					0.51
Having HIV status disclosed or breach in confidentiality				0.47			
Facing stigma or discrimination	0.35	0.39		0.43	0.34		

Each risk perception variable was included in a separate model with the control variables: gender, age, race, ethnicity, education, relationship status, income, region, longevity of HIV status, number of ART pills per day, frequency of ART pill-taking per day, timing of ART pill-taking, side effects of ART, past participation in HIV treatment trials, and attitudes towards current ART (except when omitted for perfect collinearity). Odd ratios on the control variables are not displayed.

2018 Survey Preliminary Results – Dubé K and Evans D. 'What Would People Living with HIV Perceive as Improvements above Standard ART'

AIDS RESEARCH AND HUMAN RETROVIRUSES
Volume 00, Number 00, 2019

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The Dose Response: Perceptions of People Living with HIV in the United States on Alternatives to Oral Daily Antiretroviral Therapy

Karine Dubé,[1,2] Shadi Eskaf,[3] David Evans,[4] John Sauceda,[5] Parya Saberi,[5] Brandon Brown,[6] Dawn Averitt,[2,7] Krista Martel,[2,7] Maria Meija,[8] Danielle Campbell,[4] Liz Barr,[9] John Kanazawa,[1] Kelly Perry,[1] Hursch Patel,[1] Stuart Luter,[1] Tonia Poteat,[2,10] Judith D. Auerbach,[2,7,11] and David A. Wohl[12]

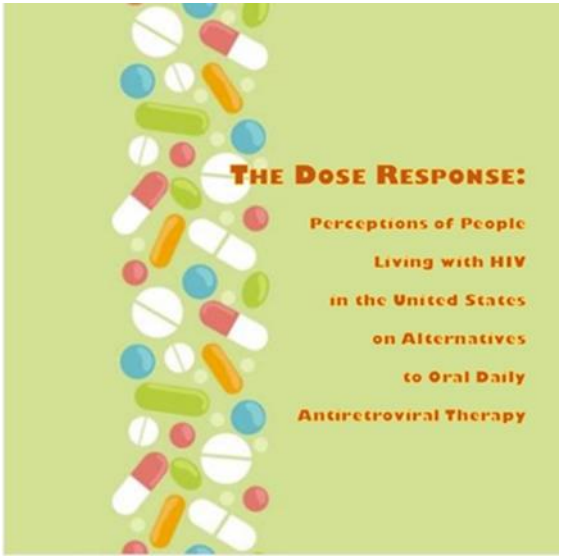
Abstract

There are two concurrent and novel major research pathways toward strategies for HIV control: (1) long-acting antiretroviral therapy (ART) formulations and (2) research aimed at conferring sustained ART-free HIV remission, considered a step toward an HIV cure. The importance of perspectives from people living with HIV on the development of new modalities is high, but data are lacking. We administered an online survey in which respondents selected their likelihood of participation or nonparticipation in HIV cure/remission research based on potential risks and perceived benefits of these new modalities. We also tested the correlation between perceptions of potential risks and benefits with preferences of virologic control strategies and/or responses to scenario choices, while controlling for respondent characteristics. Of the 282 eligible respondents, 42% would be willing to switch from oral daily ART to long-acting ART injectables or implantables taken at 6-month intervals, and 24% to a hypothetical ART-free remission strategy. We found statistically significant gender differences in perceptions of risk and preferences of HIV control strategies, and possible psychosocial factors that could mediate willingness to switch to novel HIV treatment or remission options. Our study yielded data on possible desirable product characteristics for future HIV treatment and remission options. Findings also revealed differences in motivations and preferences across gender and other sociodemographic characteristics that may be actionable as part of research recruitment efforts. The diversity of participant perspectives reveals the need to provide a variety of therapeutic options to people living with HIV and to acknowledge their diverse experiential expertise when developing novel HIV therapies.

Keywords: antiretroviral therapy (ART), oral daily ART, long-acting ART, HIV cure research, HIV remission, people living with HIV, United States

Key Findings

- We will need to provide a variety of therapeutic options to people living with HIV in the future
- Decision tools and educational materials will be necessary to help patients and HIV care providers
- There are important sex/gender differences in perceptions of risks and preferences of HIV control strategies
- More research is needed to understand patient preferences in diverse populations
- Long-acting ART formulations will be associated with implementation challenges
- Need to further investigate perceptions of analytical treatment interruptions required for some HIV cure/remission research protocols



Interviews with Trans Women Living with HIV (2018)

- Positive views about HIV research in general
- Positive views of health care system
  - Assistance with achieving health goals and gender-affirming care
- Mix of HIV cure research optimism and skepticism
- Desire for ‘complete’ cure; some believed cure already exists
- Questions about HIV treatment interruptions
- Special protections should be in place for transgender participants
  - Need for basic respect
- Transwomen identified many community priorities besides HIV research
  - Appearance, ART adherence, navigating relationships, avoiding HIV transmission, safety, dealing with addiction, finding jobs, psychological challenges, living a good/normal life

Interviews with Trans Women Living with HIV (Cont.)

- Excellent experiences with current HIV medications
  - Providing stability
- Anxiety with switching HIV regimens
- Participants identified possible risks/burdens and benefits of participating in HIV cure research
  - Wondered if body could withstand so many changes
- Receptivity and gut/gist reactions about HIV cure-related research strategies
- Strong desire to receive more information
- Opportunities to connect with other transwomen

FRESH Cohort Proposed Deliverables

- Glossary of important terms (i.e. bnAbs, LRAs, ATIs, durable suppression, etc.)
- Patient ‘engagement’ tools: FAQs, etc.
- Simplified vignettes for study participants (i.e. story telling, gist statements, FAQs)
- Test of understanding
- Simplified study calendar
- Simple one-pagers:
  - Injectable contraception
  - Risks of STIs
  - Partner protection scenarios/scripts/algorithm
  - Possible study risks
  - Scientific and clinical aims
- Social harm case report forms, risk mitigation strategies
- Contact logs; intense study monitoring
- TBD: Preparedness protocol
- Role play scenarios for training

English	Zulu
• Suppression of HIV without ARVs • Drug free long-term control • Undetectable off treatment • Undetectable off treatment • Viral suppression off treatment • ART free viral remission	***Cindezeleka Kwegawane*** ***Ngaphandle Kwemishanguzo***
• Remission	
• BNAbs (bee'-nabs) = broadly neutralizing antibodies	
• Antibodies	***Amasosha Omzimba***
• ATI = Analytic Treatment Interruption	***Ukuphazamiswa Kokwelashwa***
• Viral rebound	
• Latency (Latency Reversals Agent)	

Key Questions for Your Input

- How do we help women participate in HIV cure-related studies involving analytical treatment interruptions?

- How should we best adapt the proposed ‘standard of prevention’ package for diverse populations? (Lynda’s presentation)
  - Special considerations for women
  - Special considerations for low- and middle-income countries

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INTEGRATIVE SOCIO-BEHAVIORAL AND ETHICS RESEARCH TOWARDS HIV CURE OR REMISSION

UNITED STATES

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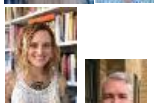




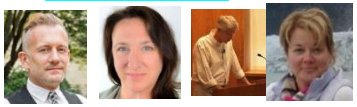

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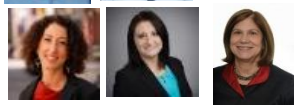


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