WOMEN'S RESEARCH INITIATIVE ON HIV/AIDS

Behavioral and Social Sciences Overview

Loreen Willenberg, Bridgette Picou, Karine Dubé

Story telling and lived experiences

Social and behavioral sciences

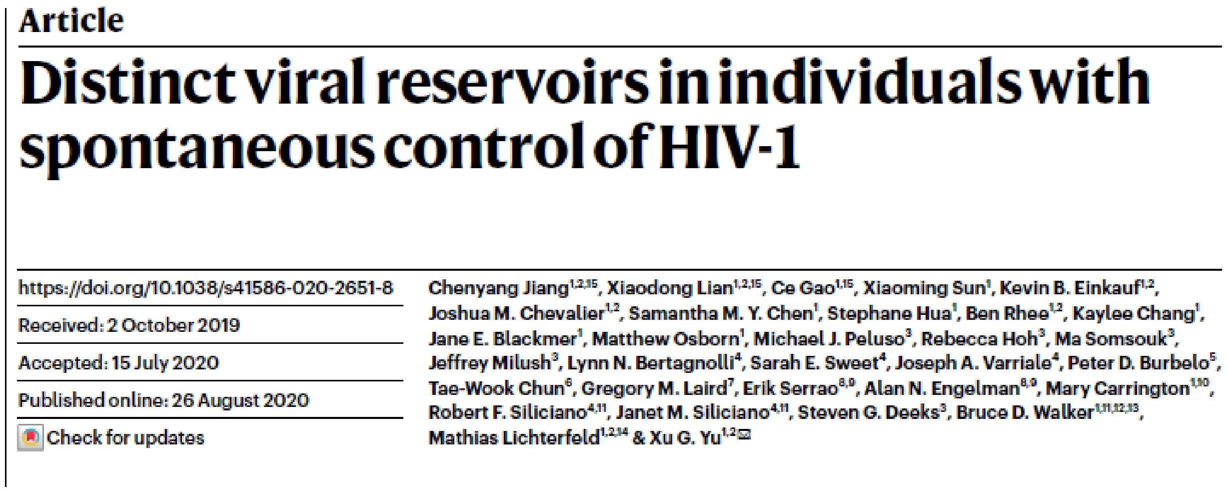
Ethical aspects; trustworthiness

Terminology/ Linguistics/ Humanities

Policy aspects
- Identity
- Access

Our positionality to HIV cure research

LOREEN WILLENBERG



Article

Distinct viral reservoirs in individuals with spontaneous control of HIV-1

https://doi.org/10.1038/s41586-020-2651-8

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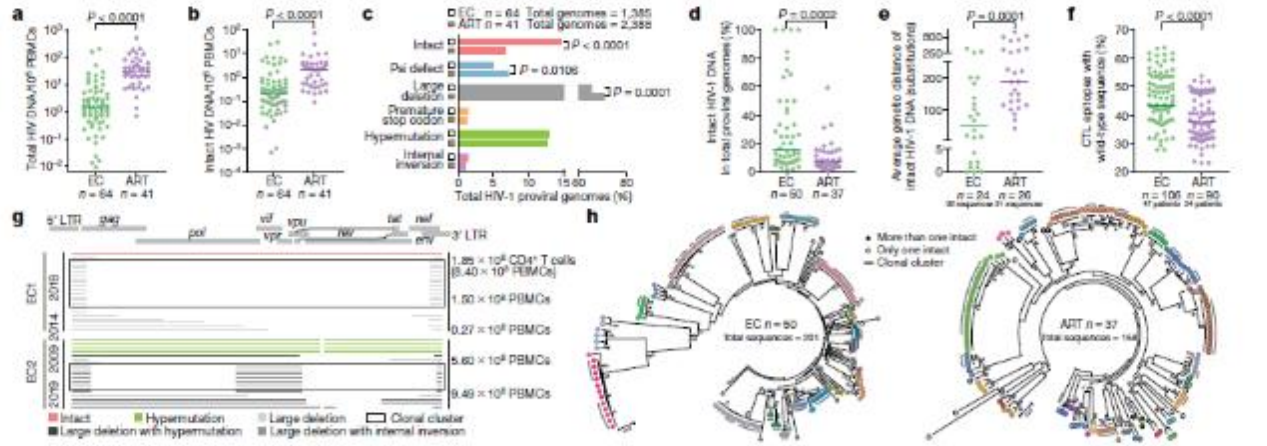
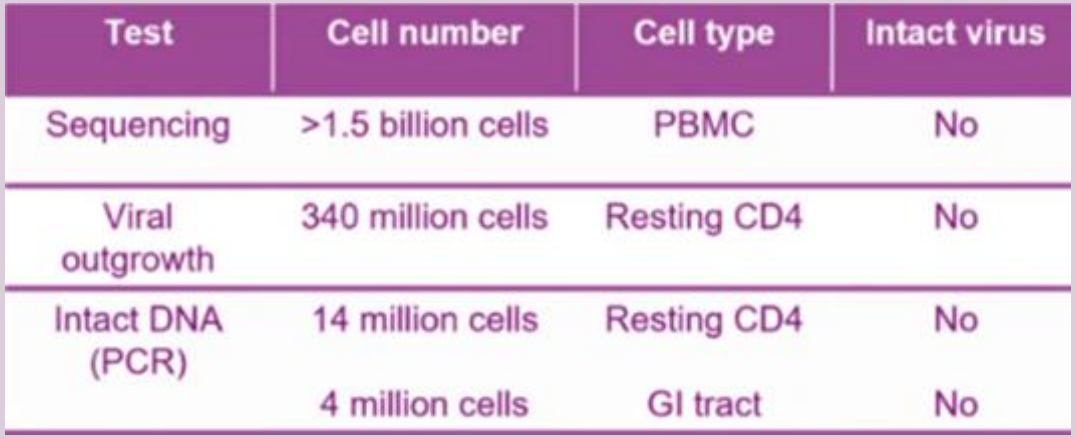


Xu Yu, MD
Ragon Institute

Loreen WIllenberg



Test	Cell number	Cell type	Intact virus
Sequencing	>1.5 billion cells	PBMC	No
Viral outgrowth	340 million cells	Resting CD4	No
Intact DNA (PCR)	14 million cells	Resting CD4	No
	4 million cells	GI tract	No

General Definitions for HIV Controllers

Long-Term Non-progressor (LTNP)

People living with HIV who do not take antiretroviral (ART) and still maintain CD4 counts in the normal range indefinitely. In general, LTNPs do not develop AIDS or may do so very slowly.

Source: HIV/AIDS Glossary clinicalinfo.hiv.gov

Viremic Controllers (VCs)

People living with HIV who register a viral load at or below 2,000 copies/mL yet remain healthy with minimal rates of CD4 decline over time. These individuals may have a history of antiretroviral (ART) treatment yet suppress the virus despite lack of current treatment.

Source: Zephyr Foundation archived brochure

Elite Controllers (ECs)

People living with HIV who maintain undetectable viral loads for at least 12 months yet remain healthy with minimal rates of CD4 decline over time without antiretroviral (ART) treatment.

Source: Zephyr Foundation archived brochure

Exceptional Elite Controllers (EECs) *2 confirmed cases to date (women)

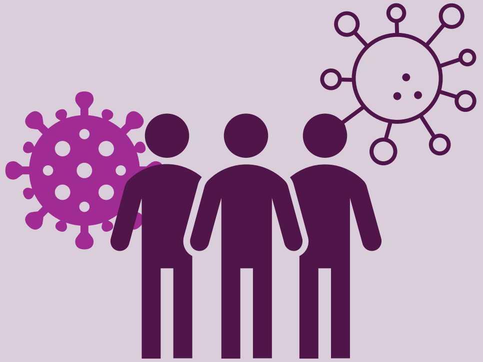
"Exceptional elite controllers represent an extremely rare group of people with HIV-1 (PWH) who exhibit spontaneous, high-level control of viral replication below the limits of detection in sensitive clinical monitoring assays and without disease progression in the absence of antiretroviral therapy for prolonged periods, frequently exceeding 25 years."

Source: Salgado et al. 2024 Cell Press |Author: L. Willenberg 13 March 2025

BRIDGETTE PICOU

RESEARCH QUESTIONS

How to better engage populations that carry the greatest burden of HIV



How to enhance trust and diminish mistrust in healthcare settings

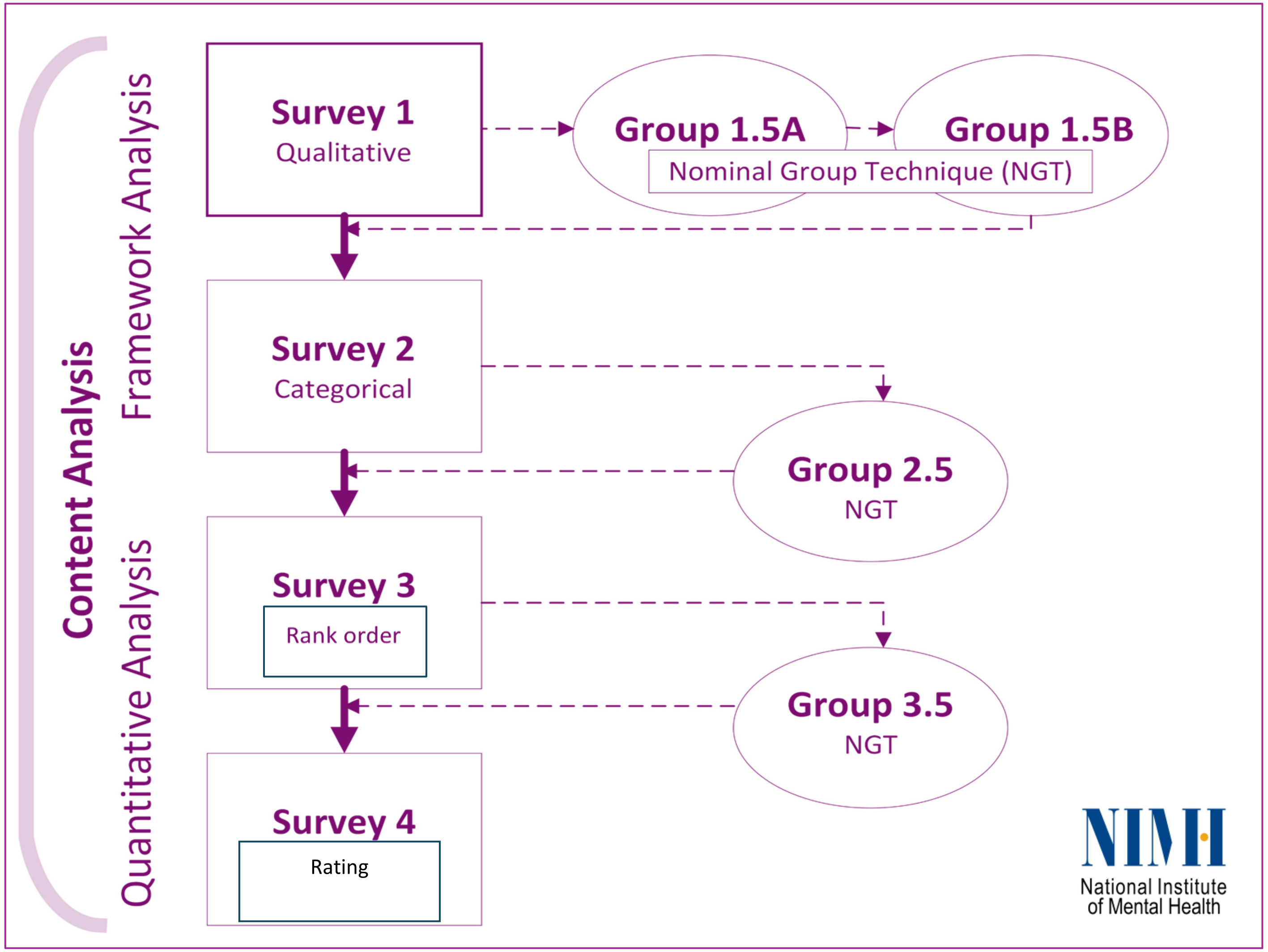
How to design protocols that do not limit working adult participation

Delphi Consensus Building: United States

2023 – 2025

PERSIST

- Hybrid Delphi consensus-building process
- Four iterative rounds of Qualtrics^{XM} surveys
- Six expert groups (A – F, n=56)
- Between round hybrid group discussions (The Well Project)



Content Analysis

Framework Analysis

Quantitative Analysis

Survey 1
Qualitative

Group 1.5A

Group 1.5B

Nominal Group Technique (NGT)

Survey 2
Categorical

Group 2.5
NGT

Survey 3
Rank order

Group 3.5
NGT

Survey 4
Rating

NIMH
National Institute of Mental Health

thewellproject

NMAC leads with race

TRUEVOLUTION
ORGANIZE · EDUCATE · MOBILIZE

PANEL CHARACTERISTICS

63% Cisgender women

59% White/Caucasian

98% College degree or above

~20 years of expertise

Group		Invited	Completed	
		n	n	%
A	Community experts and members	17	**15**	88.2
B	Biomedical researchers	9	**5**	55.6
C	HIV care providers	9	**9**	100.0
D	Funders and private industry members	5	**4**	80.0
E	Bioethicists, regulators, IRB members	8	**8**	100.0
F	Individuals studying medical mistrust, medical racism, and community engagement	8	**7**	87.5
Total	Round 4	56	**48**	85.7

CONSENSUS DEFINITION

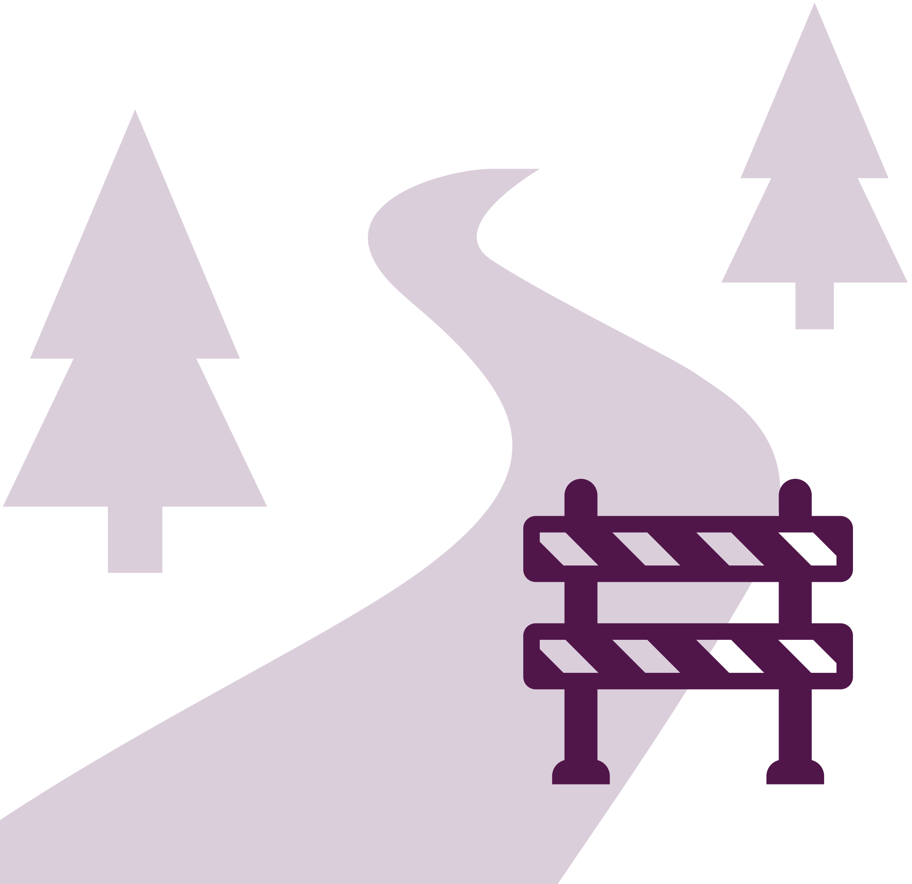
Mean rating on 1-9 scale

1 = equal relative importance/urgency (lowest priority)

9 = extreme importance/urgency (highest priority)

Ratings ≥7 considered strongly to very strongly important/urgent

BARRIERS & STRATEGIES



- Overall Engagement
- Black and Latinx PWH
- Ciswomen
- Transwomen

BLACK & LATINX PEOPLE WITH HIV

Results from the pooled sample – all groups combined

TOP 3 BARRIERS

1. **Inadequate outreach, and educational information on HIV cure-related research**
2. Medical mistrust, racism, and discrimination
3. Participation and logistical hurdles, limited access, competing priorities

TOP 3 SOLUTIONS

1. **Focus on Inclusion**
2. Increase group representation among researchers and medical professional
3. Assist with logistical challenges, prioritizing access to research sites

CISGENDER WOMEN

Results from the pooled sample – all groups combined

TOP 3 BARRIERS

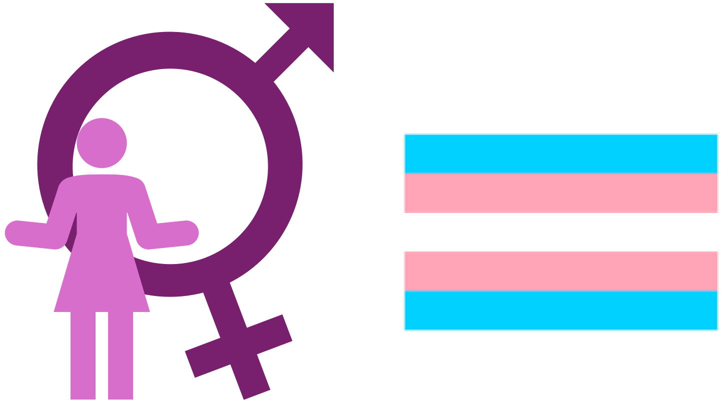
1. **Participation and logistical hurdles**
2. Limited awareness of HIV cure-related research opportunities
3. Researchers’ sex-bias concerns, exclusion criteria

TOP 3 SOLUTIONS

1. **Offer equitable compensation**
2. Minimize study participation burdens
3. Center the study design on cisgender women’s unique needs

TRANSGENDER WOMEN

Results from the pooled sample – all groups combined



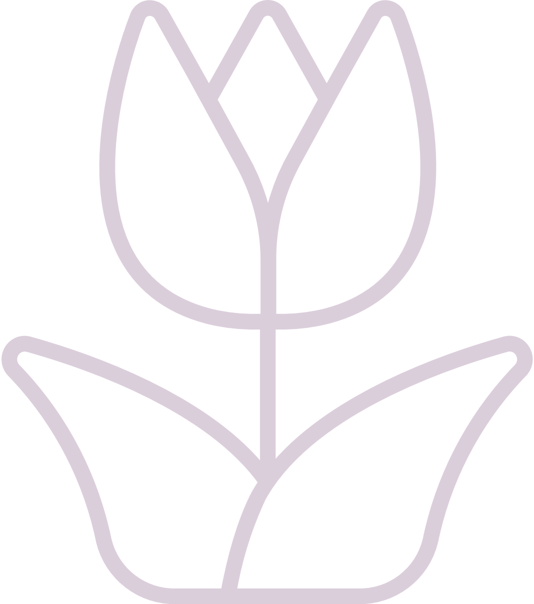
TOP 3 BARRIERS

1. **Lack of transgender focus in research design**
2. Poor participant engagement, outreach, and relationship building
3. Anti-trans sentiment: ***transmissia*** and transphobia

TOP 3 SOLUTIONS

1. **Center research on transgender women's unique needs**
2. Focus on Inclusion
3. Create gender-affirming research learning opportunities

THEMATIC ANALYSIS



- Increase awareness and education around HIV and ATIs
- Meaningfully involve participants in all aspects of ATI study design
- Reduce clinical visits and overall study requirements
- Offer support to participants
- Provide participants' partners with supportive services
- Engage primary care physicians
- Adapt holistic approach to increase engagement in ATI studies
- Adapt the listed consensus strategies, as they are accurate

MEDICAL MISTRUST

Ranked Strategies to Reduce Medical Mistrust

Address Medical Mistrust to Better Engage Priority Populations in HIV Cure-Related Research

1

Connect people living with HIV with previous ATI participants

2

Engage in active listening

3

Explore the basis of medical mistrust

CONCLUSION

The Delphi expert panel recommends restructuring and preplanning HIV cure-related trials to address the unique needs of Black and Latinx individuals, cisgender women, and transgender women.

Many believe that thresholds are a crucial strategy for increasing engagement among underrepresented populations in research trials, despite the scientific and structural limitations they present.

Connecting potential participants with individuals who have previously participated in an ATI may help reduce medical mistrust.

OVERALL ENGAGEMENT OF PEOPLE WITH HIV

Results from the pooled sample – all groups combined

TOP 3 BARRIERS

1. **Concerns about treatment interruptions and side effects**
2. Risk of viral transmission to sex partners
3. Study procedures and requirements may burden participants

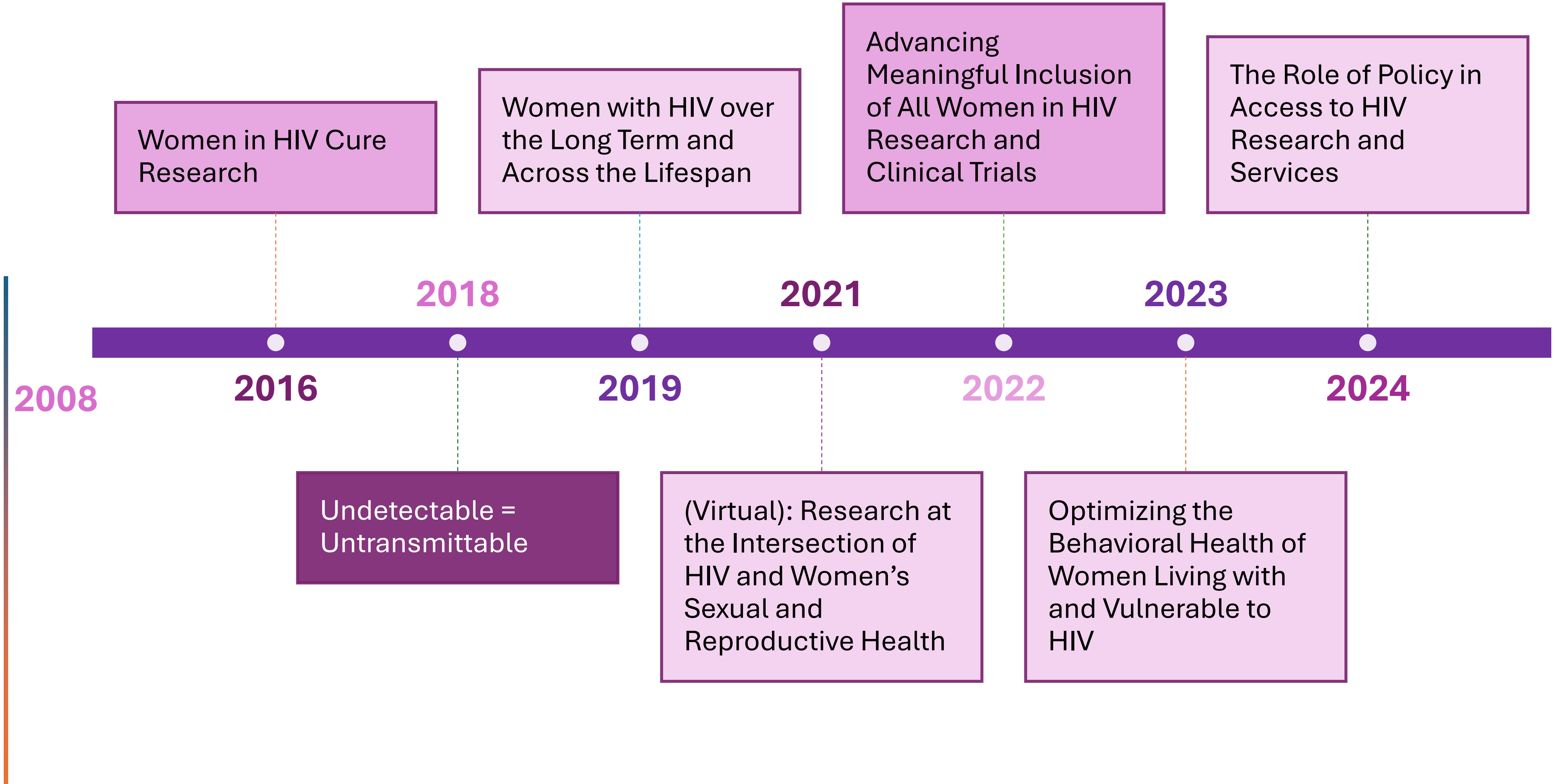
TOP 3 SOLUTIONS

1. **Center clinical trials around participant needs throughout the research process**
2. Offer equitable compensation
3. Ease logistical hurdles

KARINE DUBÉ
WRI COLLABORATIONS

WRIs that have shaped my socio-behavioral research

WOMEN'S RESEARCH INITIATIVE ON HIV/AIDS
a program of The Well Project



2008

2016
Women in HIV Cure Research

2018
Undetectable = Untransmittable

2019
Women with HIV over the Long Term and Across the Lifespan

2021
(Virtual): Research at the Intersection of HIV and Women's Sexual and Reproductive Health

2022
Advancing Meaningful Inclusion of All Women in HIV Research and Clinical Trials

2023
Optimizing the Behavioral Health of Women Living with and Vulnerable to HIV

2024
The Role of Policy in Access to HIV Research and Services

ISSUE BRIEF

WOMEN IN HIV CURE RESEARCH:

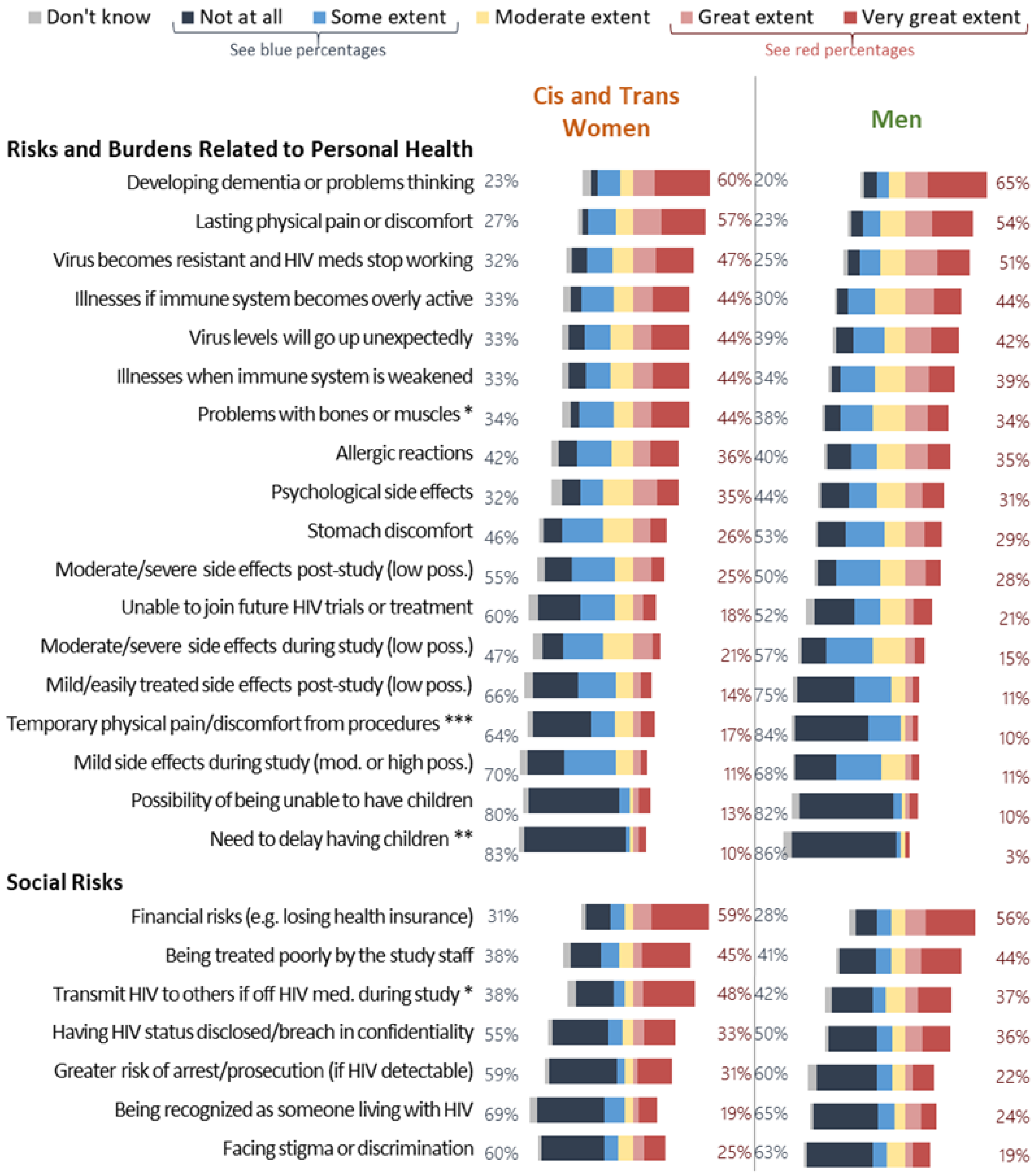
Advocating for, Discovering and Delivering a Cure

WOMEN'S RESEARCH INITIATIVE ON HIV/AIDS (WRI)

2016

QUESTIONS ABOUT HIV CURE RESEARCH FROM WOMEN LIVING WITH HIV

1. What does being cured mean?
2. Where will the research be done? Will it be accessible? Will women/people of color feel welcomed?
3. What are the potential benefits and harms and to whom?
    - What protections will exist for people who enroll in the research?
4. What are some of the long-term consequences of being cured?
    - Will the cure require adherence over time?
    - How will the cure interact with other medications?
    - Will it be permanent? Would my immune system be restored?
5. What are the social justice implications of a cure?
    - Who will have access?
    - Will it work the same for everyone?
    - How would a cure impact testing policy?
    - How will we adjust to it being "over"?



Extent to Which Risk Factors are "Likely to Stop" Respondent from Participating in an HIV Cure-Oriented Study, by Gender

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**]

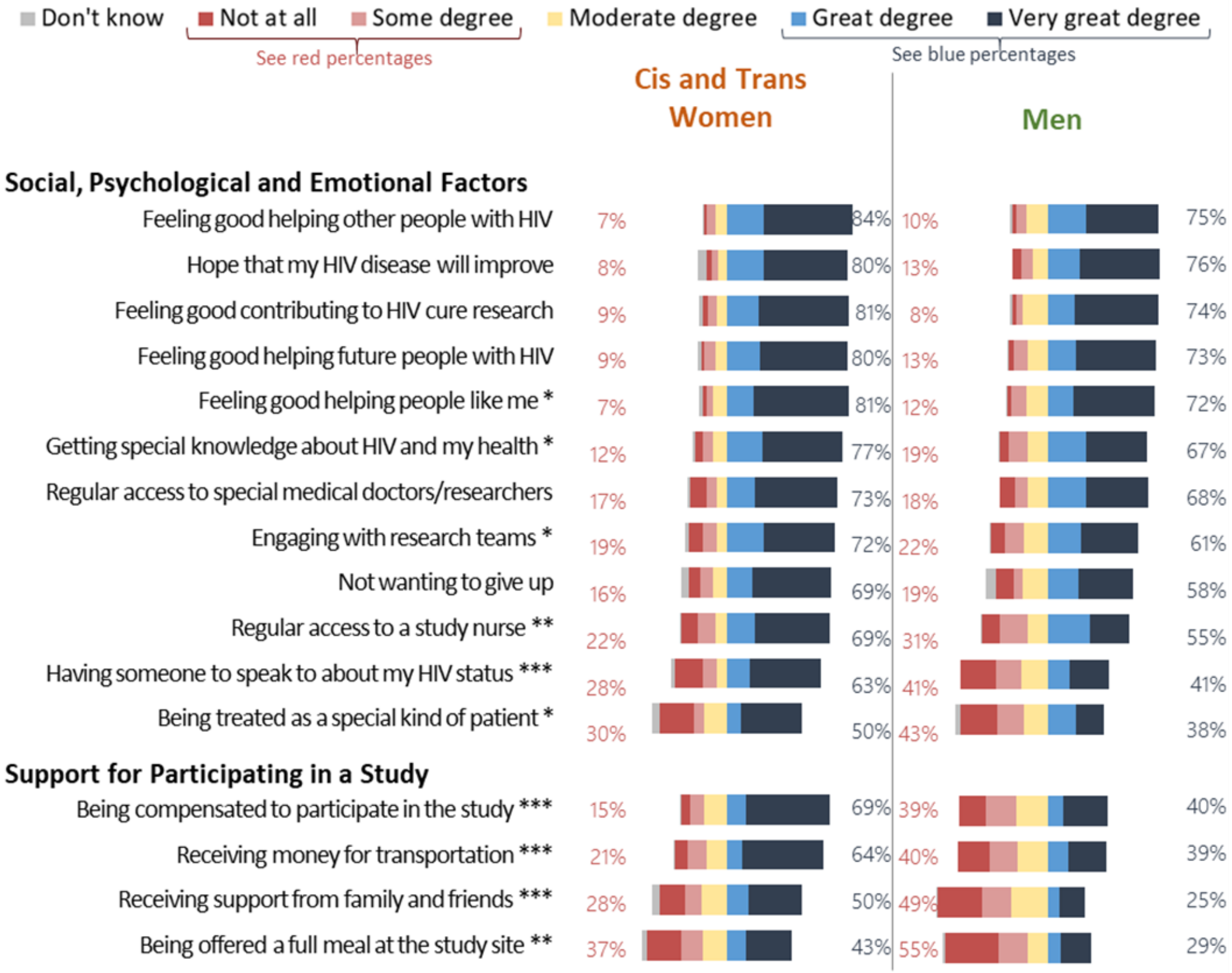
Compared to cis and trans women, **men are less likely** to be concerned by these risks:

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

PERCEIVED MOTIVATORS

By Gender

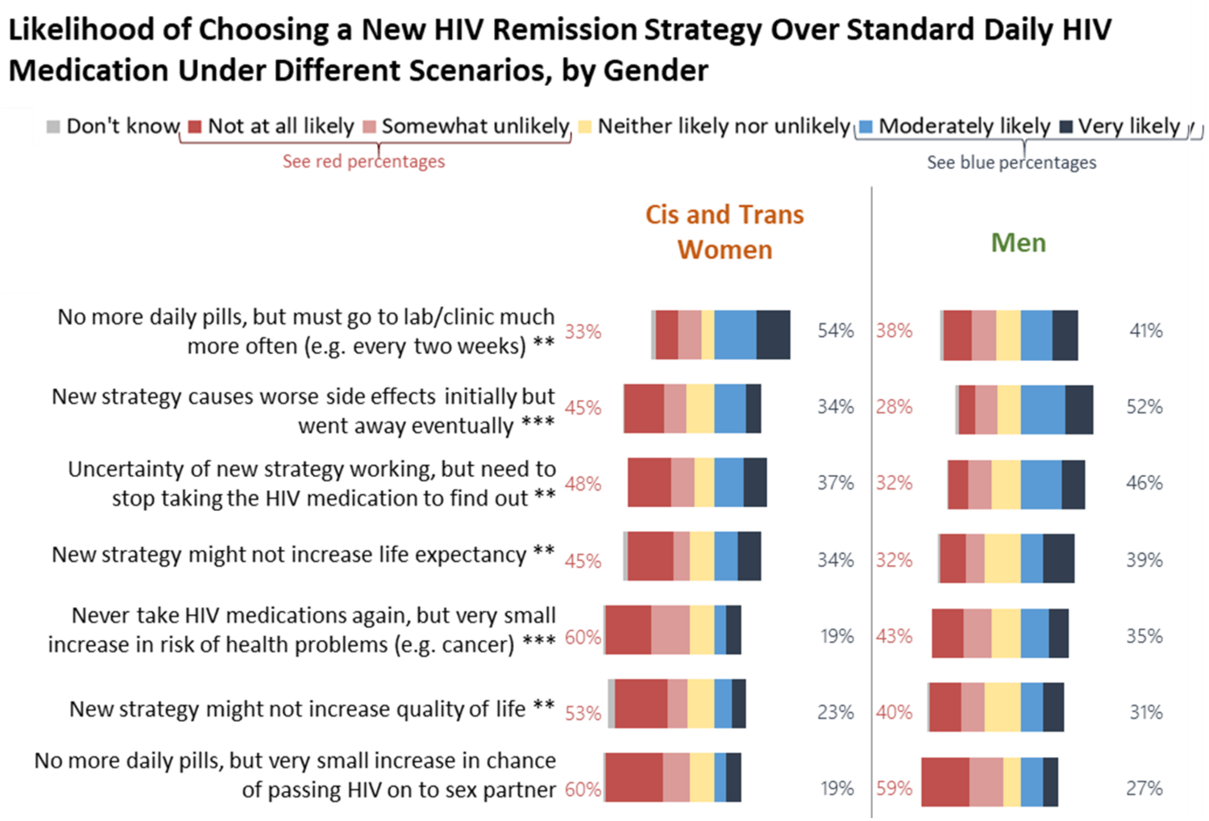
Degree by Which Factors Would Increase Respondent's Willingness to Participate in an HIV Cure-Oriented Study, by Gender



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**]
- Being treated as a special patient [**OR 1.70**]
- Receiving support from family and friends [**OR 3.28**]
- Having someone to speak to about HIV status [**OR 2.55**]
- Being offered a meal [**OR 1.89**]

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


Likelihood of Choosing a New HIV Remission Strategy Over Standard Daily HIV Medication Under Different Scenarios, 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:

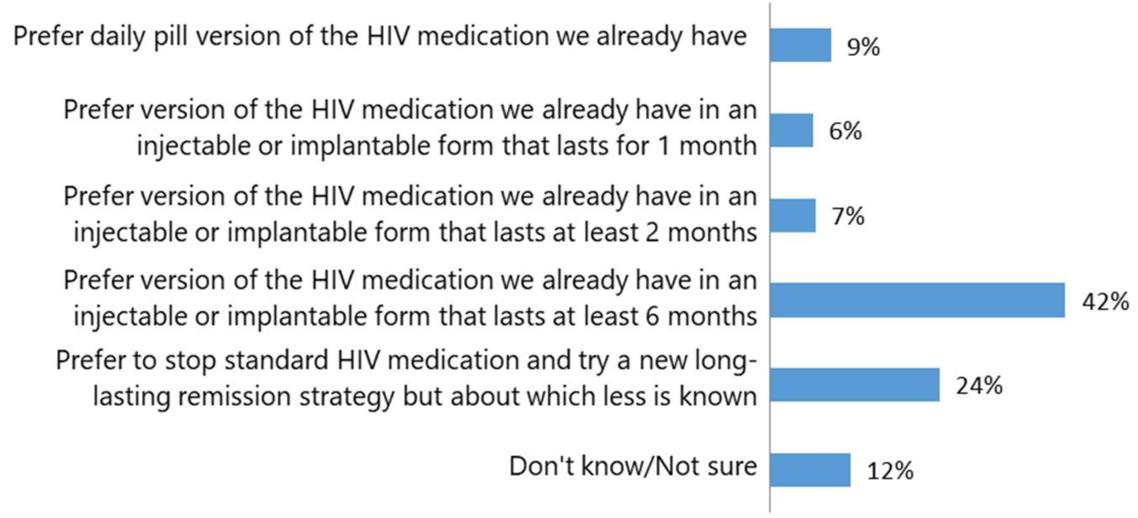
- temporarily worse side effects [**OR 0.46**]
- small increase to risk of developing health problems later in life like cancer [**OR 0.46**]

more likely to stay with ART if the new strategy:

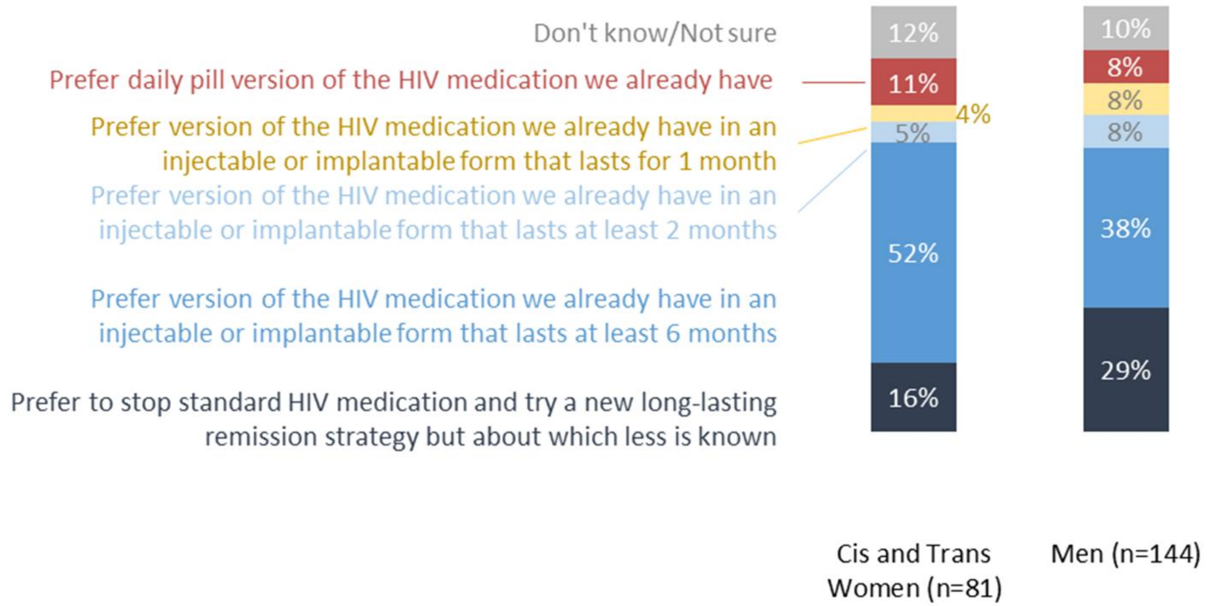
- won't increase life expectancy **[OR 1.79]**
- won't improve quality of life **[OR 1.84**
- requires going off ART to find out if will be effective **[OR 1.96]**

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

(n=226)



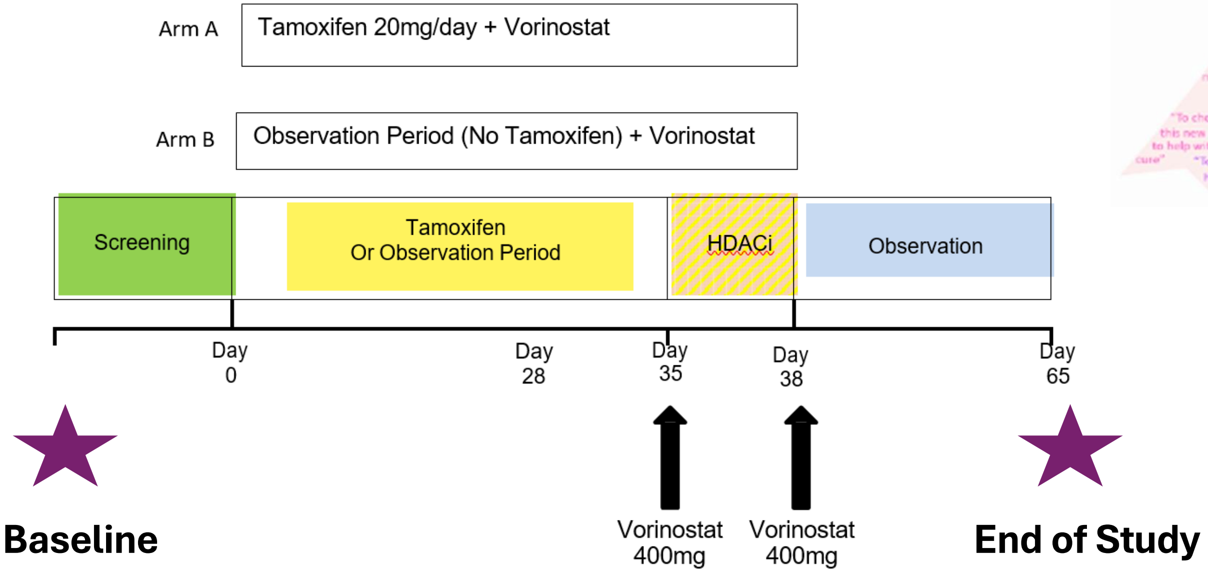
Choice Between Current Standard Daily HIV Medications versus Long-Acting Antiretrovirals versus New Experimental HIV Remission Strategy, by Gender



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.

A5366: Moxie Trial

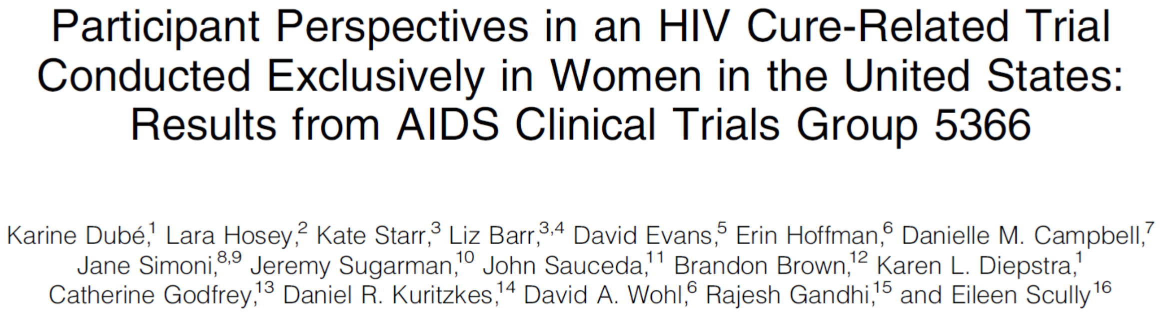
September 2017 – July 2020



N = 30 participants (20 in Arm A and 10 in Arm B)

Eileen Scully, MD, PhD
Johns Hopkins SOM

Rajesh Gandhi, MD
MGH



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

Karine Dubé,[1] Lara Hosey,[2] Kate Starr,[3] Liz Barr,[3,4] David Evans,[5] Erin Hoffman,[6] Danielle M. Campbell,[7] Jane Simoni,[8,9] Jeremy Sugarman,[10] John Sauceda,[11] Brandon Brown,[12] Karen L. Diepstra,[1] Catherine Godfrey,[13] Daniel R. Kuritzkes,[14] David A. Wohl,[6] Rajesh Gandhi,[15] and Eileen Scully[16]

Community representative: Kate Starr

INTERVIEWS WITH TRANSGENDER WOMEN LIVING WITH HIV IN THE US

Tonia Poteat, PhD

RESEARCH ARTICLE

“I would really want to know that they had my back”: Transgender women’s perceptions of HIV cure-related research in the United States

Tonia Poteat[1]*, **Anushka Aqil**[2], **Dana Corbett**[3], **David Evans**[4], **Karine Dubé**[3]

1 Department of Social Medicine, University of North Carolina School of Medicine, Chapel Hill, North Carolina, United States of America, **2** Department of Health, Behavior, and Society, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, United States of America, **3** Public Health Leadership Program, University of North Carolina Gillings School of Global Public Health, Chapel Hill, North Carolina, United States of America, **4** Delaney AIDS Research Enterprise (DARE) Community Advisory Board, New York City, New York, United States of America

* tonia_poteat@med.unc.edu

Table 3. Recommendations for engaging black transgender women in HIV cure-related research.

Recommendation 1	Complete the five modules of the Transgender Training Curriculum for HIV Research developed by the NIH DAIDS Cross-Network Transgender Working Group. All trainings are available as e-learning modules and in-person training tools. Modules can be accessed via the DAIDS Learning Portal: https://daidslearningportal.niaid.nih.gov.
Recommendation 2	Build HIV cure-related research protocols with gender-affirming and racial equity framework using a trauma-informed research lens using knowledge and skills.
Recommendation 3	Train and/or mentor researchers from the Black transgender community and hire Black transgender women onto the research staff.
Recommendation 4	Ensure transgender participants feel welcome at research sites and are referred for research opportunities; research teams should provide information on how HIV cure-related research protocols affect the transgender community; establish academic-community partnerships with organizations that have experience engaging with the transgender community, include Black transgender-led organizations.
Recommendation 5	Initiate and maintain dialogue about HIV cure-related research with the Black transgender community, for example, informational community forums.

https://doi.org/10.1371/journal.pone.0244490.t003

What are some of the barriers to women’s participation in HIV cure research?

Insufficient emphasis from funders

Lack of women-centered information

Complex trial designs

Competing priorities

Inadequate compensation

Recruitment strategies do not emphasize women inclusion

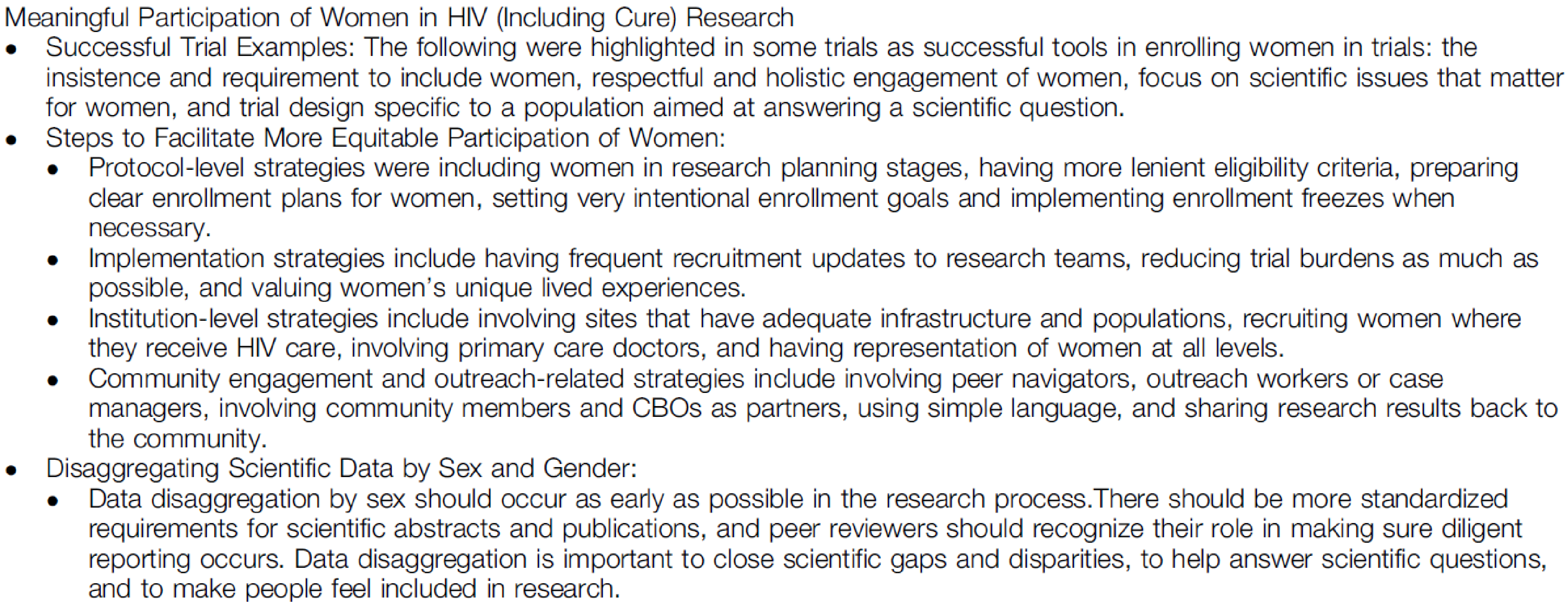
Stigma

Inclusion and exclusion criteria

Increasing the meaningful involvement of women in HIV cure-related research: a qualitative interview study in the United States

Karine Dubé, Elizabeth Barr, Morgan Philbin, Amaya Perez-Brumer, Brian Minalga, Beth Peterson, Dawn Averitt, Bridgette Picou, Krista Martel, Cecilia Chung, María Mejía, Martha Cameron, Gail Graham, Lynda Dee, Dázon Dixon Diallo, Ebony Gordon, Anastasia Korolkova, Typhanye Dyer, Judith D. Auerbach, Eileen Scully, Krista L. Dong & Sara Gianella

- → Attention to trauma and healing
- → Adequate support (logistical, psychosocial, mental, emotional and physical)
- → Adequate counseling and disclosure support



Meaningful Participation of Women in HIV (Including Cure) Research

- Successful Trial Examples: The following were highlighted in some trials as successful tools in enrolling women in trials: the insistence and requirement to include women, respectful and holistic engagement of women, focus on scientific issues that matter for women, and trial design specific to a population aimed at answering a scientific question.
- Steps to Facilitate More Equitable Participation of Women:
    - Protocol-level strategies were including women in research planning stages, having more lenient eligibility criteria, preparing clear enrollment plans for women, setting very intentional enrollment goals and implementing enrollment freezes when necessary.
    - Implementation strategies include having frequent recruitment updates to research teams, reducing trial burdens as much as possible, and valuing women's unique lived experiences.
    - Institution-level strategies include involving sites that have adequate infrastructure and populations, recruiting women where they receive HIV care, involving primary care doctors, and having representation of women at all levels.
    - Community engagement and outreach-related strategies include involving peer navigators, outreach workers or case managers, involving community members and CBOs as partners, using simple language, and sharing research results back to the community.
- Disaggregating Scientific Data by Sex and Gender:
    - Data disaggregation by sex should occur as early as possible in the research process.There should be more standardized requirements for scientific abstracts and publications, and peer reviewers should recognize their role in making sure diligent reporting occurs. Data disaggregation is important to close scientific gaps and disparities, to help answer scientific questions, and to make people feel included in research.

INCREASING DIVERSITY

- GENDER AND SEX
- AGE AND POWER DIFFERENTIALS
- RACE AND ETHNICITY
- HIV STATUS OF PARTNER(S)
- PARTNERSHIP STATUS (INCLUDING IPV)

AIDS RESEARCH AND HUMAN RETROVIRUSES
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DOI: 10.1089/aid.2021.0023

SOCIO-BEHAVIORAL

Considerations for Increasing Racial, Ethnic, Gender, and Sexual Diversity in HIV Cure-Related Research with Analytical Treatment Interruptions: A Qualitative Inquiry

[W]e need trauma informed research… That the whole history, whether it's based on gender or whether it's based on race, or even in some instances, whether it's based in geography, we don't know where people have come from and we don't know what they all walk with… But there are so many different kinds of traumas and it's not just about women and it's not just about Black and Brown people… That the diversity is what we want, the intersectionality is what we have to understand. —Community member (#07)

A partner protection package for HIV cure-related trials involving analytical treatment interruptions

Karine Dubé, Tia Morton, Lawrence Fox, Lynda Dee, David Palm, Thomas J Villa, William Freshwater, Jeff Taylor, Gail Graham, William B Carter, John A Sauceda, Michael J Peluso, Annette Rid

Enable and encourage participants to protect their partners

- Provide information or counselling on HIV testing,[21] HIV prevention (eg, barrier protection, PrEP,[7,9,13,17,18,21,31,85] and PEP[7,21]) with use of evidence-based materials and approaches in a range of formats (eg, fact sheets, presentations, videos, and text messaging) that are tailored to diverse individuals (eg, with respect to gender, sex, age, sexual orientation, education level, etc) and specific locations[9]
- Provide or refer to HIV prevention options (eg, no cost barrier protection, PrEP referral for partners)
- Encourage participants to inform their partners and provide counselling[7,9,21] on HIV and ATI trial participation disclosure,[7,9,21] provide sample disclosure scripts,[9] offer disclosure role playing sessions as needed
- Encourage participants to include their partners in trial visits (eg, optional site visits and discussions with the trial team)[9,21]
- Provide mental health support or counselling referrals as needed[18,21]
- Offer peer support[17] (eg, former ATI trial participants)
- Encourage partners to communicate with the trial team[9,17] (eg, provide written information tailored to partners, invite partners to accompany participants during trial visits in person or via telehealth)[21]
- Offer information or counselling on HIV prevention (eg, barrier protection, PrEP,[7,9,13,17,18,21,31,85] and PEP[7,21]) with use of evidence-based and partner-specific materials and approaches in a range of formats, including fact sheets, presentations, videos, and text messaging[25]
- Provide HIV testing, PrEP,[7,13,18,31,85] and PEP[7,21] referrals and navigation assistance[9] (eg, refer partners to full range of PrEP options)
- Facilitate access to mental health support[18,21,,53] or counselling as needed
- Engage the local community in discussions about trial involving ATIs[9]
- Promote broader community engagement about ATI trials and consider health promotion and social marketing campaigns to raise awareness about HIV prevention needs for partners of ATI trial participants

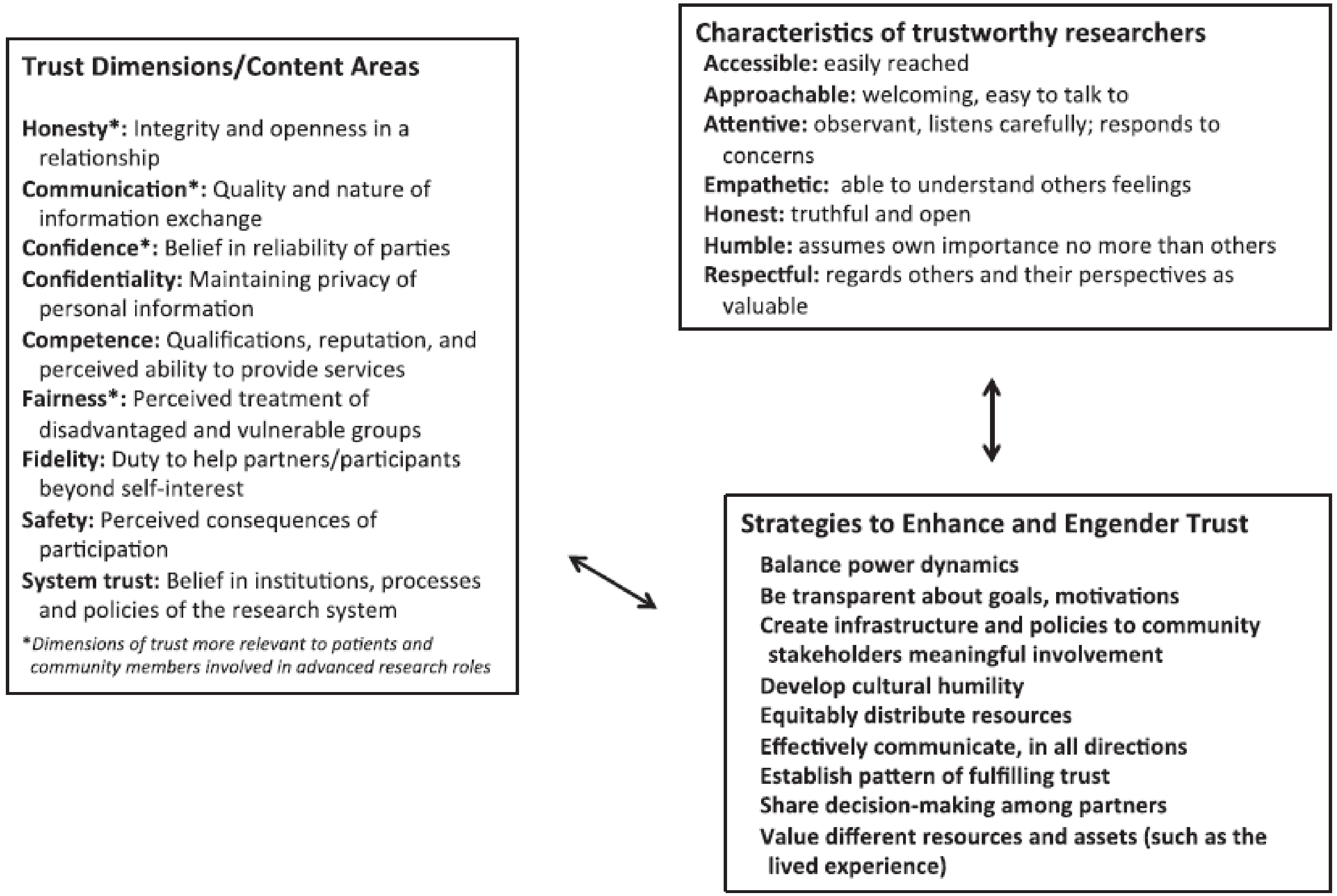
Key messages

- Analytical treatment interruptions (ATIs) are used to evaluate the effects of experimental HIV cure-related interventions. During ATIs, sex partners of trial participants might be at risk of acquiring HIV.
- This Review proposes a partner protection package (P3) to address concerns around onward HIV transmission during trials involving ATIs.
- Our P3 proposal is informed by a series of community-driven conversations and two focused literature reviews.
- The prototype P3 delineates three basic considerations for protecting participants' sex partners during ATI trials: (1) ensuring the scientific and social value of the ATI and the trial, (2) reducing the likelihood of unintended HIV transmission, and (3) ensuring prompt management of any acquired HIV infection.
- The prototype P3 also outlines possible ways of implementing the three basic considerations and highlights ethical limitations or tradeoffs with specific approaches.
- A comprehensive P3 framework could help make a crucial contribution to the successful and ethical conduct of HIV cure-related trials involving ATIs, and ultimately, the development of effective HIV cure strategies.

Effective Engagement Requires Trust and Being Trustworthy

Consuelo H. Wilkins, MD, MSCI

Enhancing trust and building effective partnerships with patients and community stakeholders must consider the variability in dimensions of trust and characteristics of researchers who are trustworthy



Trust Dimensions/Content Areas

Honesty*: Integrity and openness in a relationship
Communication*: Quality and nature of information exchange
Confidence*: Belief in reliability of parties
Confidentiality: Maintaining privacy of personal information
Competence: Qualifications, reputation, and perceived ability to provide services
Fairness*: Perceived treatment of disadvantaged and vulnerable groups
Fidelity: Duty to help partners/participants beyond self-interest
Safety: Perceived consequences of participation
System trust: Belief in institutions, processes and policies of the research system

**Dimensions of trust more relevant to patients and community members involved in advanced research roles*

Characteristics of trustworthy researchers

Accessible: easily reached
Approachable: welcoming, easy to talk to
Attentive: observant, listens carefully; responds to concerns
Empathetic: able to understand others feelings
Honest: truthful and open
Humble: assumes own importance no more than others
Respectful: regards others and their perspectives as valuable

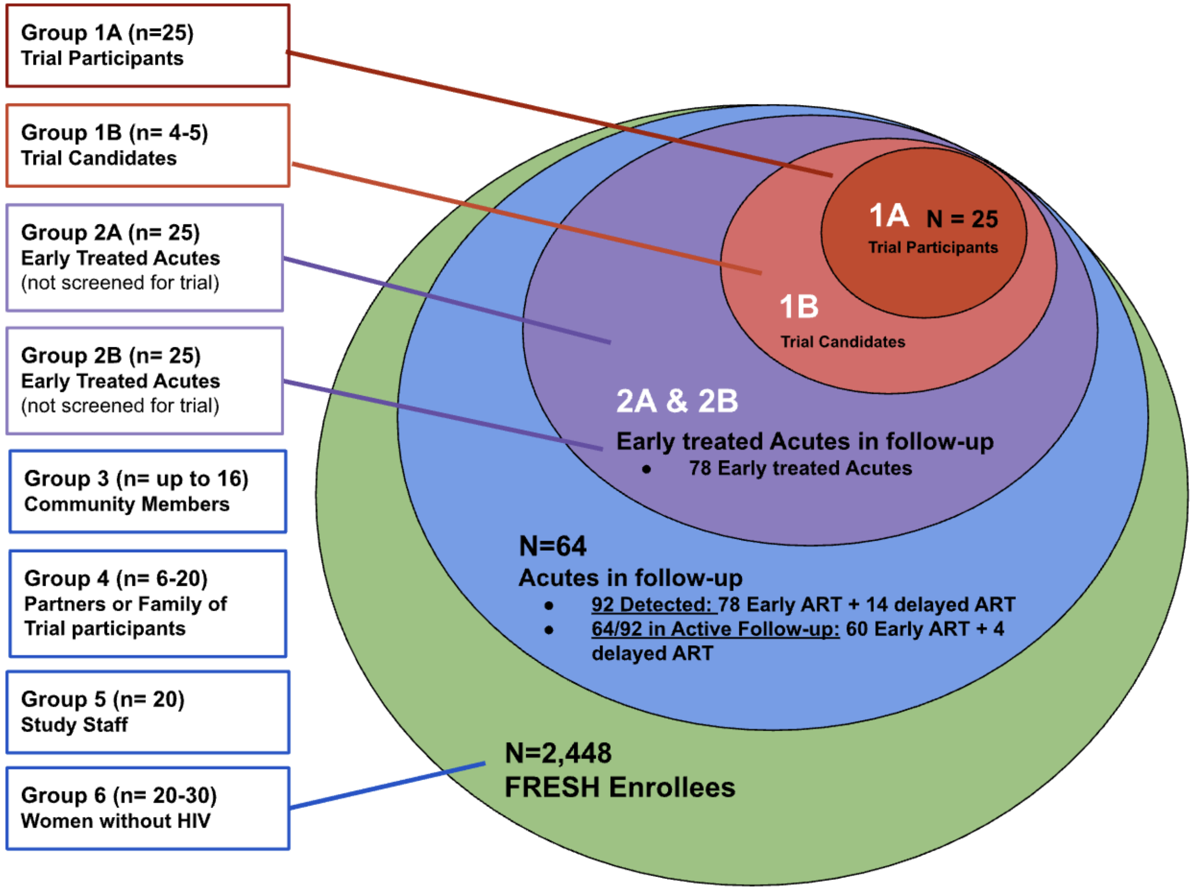
Strategies to Enhance and Engender Trust

- Balance power dynamics
- Be transparent about goals, motivations
- Create infrastructure and policies to community stakeholders meaningful involvement
- Develop cultural humility
- Equitably distribute resources
- Effectively communicate, in all directions
- Establish pattern of fulfilling trust
- Share decision-making among partners
- Value different resources and assets (such as the lived experience)

FRESH

Females Rising through Education, Support and Health

1. FRESH-Gilead trial participants at 4 timepoints (N = 20)
2. Women diagnosed during acute HIV
3. Community members
4. Partners or third-parties
5. FRESH clinical research staff
6. FRESH women living without HIV



Group 1A (n=25)
Trial Participants

Group 1B (n= 4-5)
Trial Candidates

Group 2A (n= 25)
Early Treated Acutes
(not screened for trial)

Group 2B (n= 25)
Early Treated Acutes
(not screened for trial)

Group 3 (n= up to 16)
Community Members

Group 4 (n= 6-20)
Partners or Family of Trial participants

Group 5 (n= 20)
Study Staff

Group 6 (n= 20-30)
Women without HIV

1A N = 25
Trial Participants

1B
Trial Candidates

2A & 2B
Early treated Acutes in follow-up
- **78 Early treated Acutes**

N=64
Acutes in follow-up
- **92 Detected: 78 Early ART + 14 delayed ART**
- **64/92 in Active Follow-up: 60 Early ART + 4 delayed ART**

N=2,448
FRESH Enrollees

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ITEACH
INTEGRATION of TB in EDUCATION and CARE for HIV AIDS

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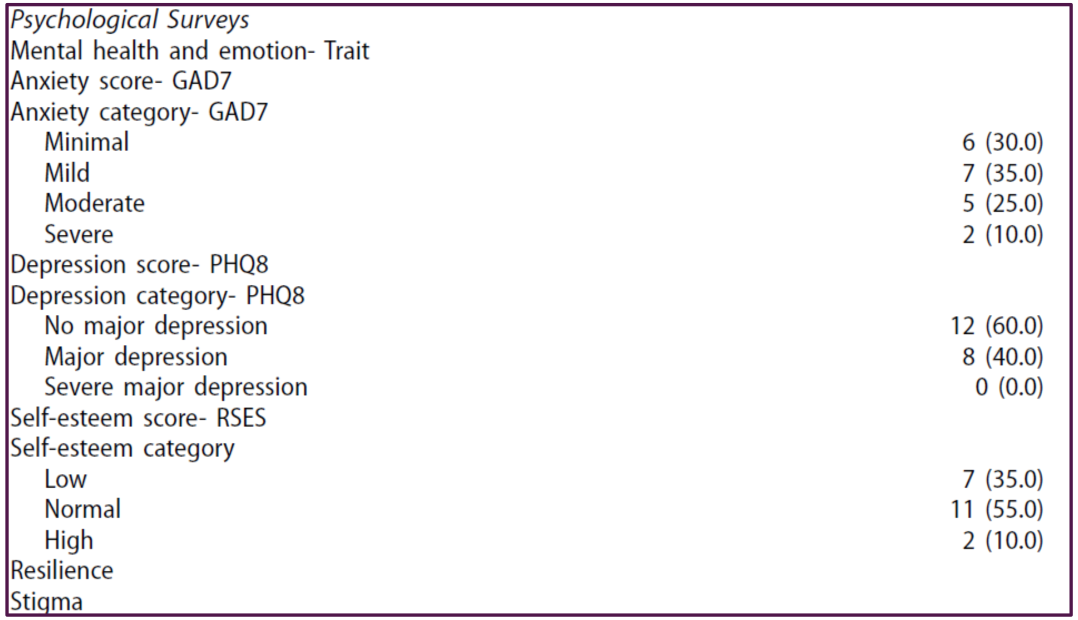
NIMH
National Institute of Mental Health

'It is scary to pause treatment': perspectives on HIV cure-related research and analytical treatment interruptions from women diagnosed during acute HIV in Durban, South Africa

Socio-Behavioral research

Deli Mthimkhulu, Krista L. Dong, Mzwakhe Wiseman Ngcobo, Deborah Mindry, Ayanda Zulu, Ntombifuthi Langa, Luyanda Maphalala, Vanessa Pillay, Maud Mthembu, Annie Miall, Whitney Tran, Ana Dillen, Fang Wan, Ali Ahmed, Jamila K. Stockman, Maryam Hussain, Thumbi Ndung'u & Karine Dubé



Psychological Surveys	
Mental health and emotion- Trait	
Anxiety score- GAD7	
Anxiety category- GAD7	
Minimal	6 (30.0)
Mild	7 (35.0)
Moderate	5 (25.0)
Severe	2 (10.0)
Depression score- PHQ8	
Depression category- PHQ8	
No major depression	12 (60.0)
Major depression	8 (40.0)
Severe major depression	0 (0.0)
Self-esteem score- RSES	
Self-esteem category	
Low	7 (35.0)
Normal	11 (55.0)
High	2 (10.0)
Resilience	
Stigma	

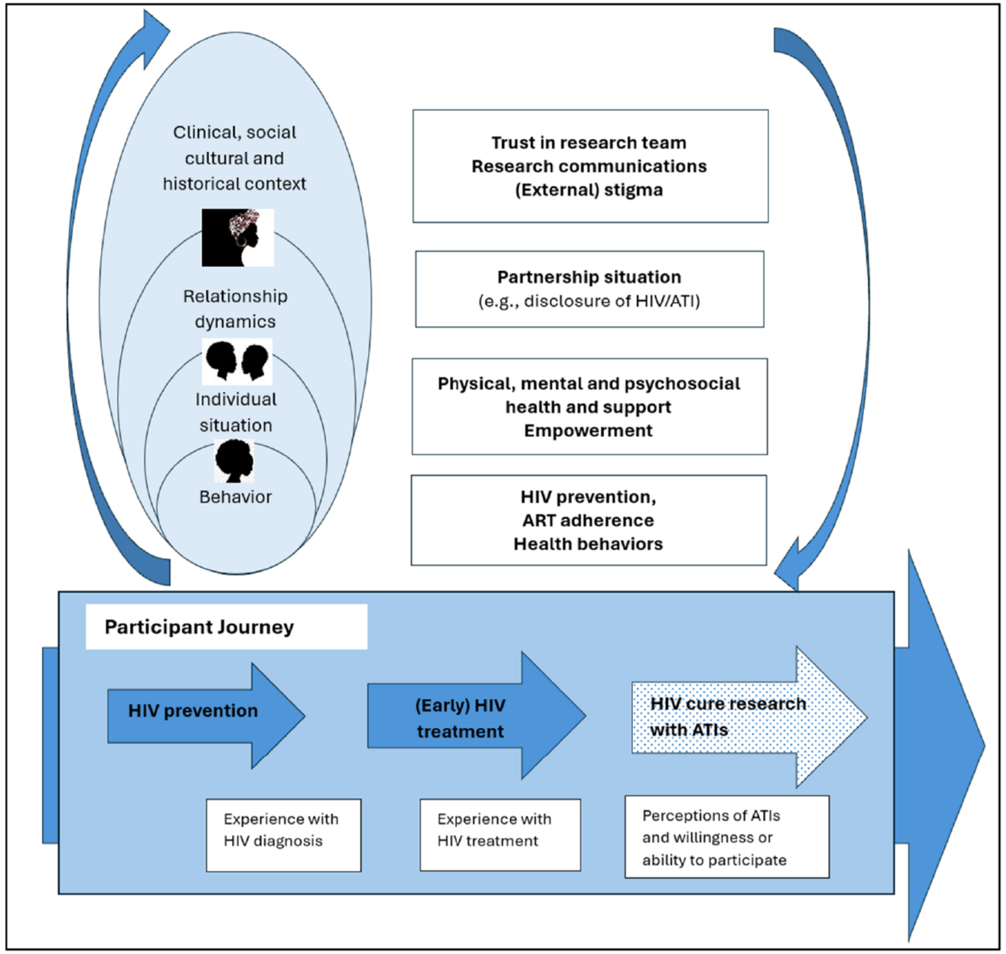


Figure 1. FRESH participant journey and emerging conceptual framework.

Figure 1 summarizes the FRESH participant journey from HIV prevention, HIV diagnosis, early HIV treatment and perceptions of HIV cure-related research and analytical treatment interruptions (ATIs), alongside a continuum. Further, the figure shows the interplay between behavioral factors, individual situations, relationship (or partnership) dynamics, and the broader clinical, social, and cultural context, as described throughout this paper.

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Table 4. Summary of emerging considerations for designing and conducting HIV cure research with women diagnosed during acute HIV.

Topics	Considerations
Informed consent and decision-making	• Ensure robust informed consent and provide decision-making support to avoid curative misconception. • Ensure safeguards against therapeutic misconception when programs involve both care and research. • Provide comprehensive and clear information about HIV cure research and ATI trial processes and expected outcomes, including the nature of experimental interventions and potential risks of both interventions and ATIs.
Continuity of care	• Conduct thorough pre-ATI health evaluations and continuous clinical monitoring combined with communication during the trial. • Emphasize the importance of the continuity of care, particularly after ATI trials (during the period of HIV re-suppression and beyond), and ensure participants have back-up regimens in place in case of viral resistance.
Mental health and psychosocial support	• Integrate mental health and psychosocial support systems as part of HIV trials to mitigate potential undue consequences (e.g. HIV-related stigma). • For ATI-inclusive HIV cure trials, offer psychological counseling and self-care resources to address emotional challenges associated with ATIs. • To the extent possible, create comprehensive support systems surrounding HIV research participants to address evolving emotional and logistical needs. • Adopt trauma-informed and healing-centered approaches to minimize the risk of re-traumatization and promote psychological safety as much as physical safety. • Conduct more research to develop evidence-based mental health interventions in the context of HIV cure research programs.
Participant autonomy and empowerment	• Respect personal autonomy and choice regarding sharing HIV and/or ATI status. • Foster communication and negotiation skills related to partner protections.
Addressing fears and anxieties	• Acknowledge and address fears associated with HIV and ATIs, including concerns about health deterioration and the risk of passing HIV to sex partner(s). • Provide reassurance and constant updates during clinical trials.
Trust and communication	• Build trust with participants through regular communication and transparency about the HIV cure research trial aims and processes. • Ensure participants have a clear understanding of the implications of participating in research on their long-term health and relationships.
Partner protections and psychosocial support	• Implement active partner protections such as PrEP and condoms to minimize HIV transmission risks and HIV superinfection during and after ATIs. • Develop and provide evidence-based support around sharing HIV/ATI status during ATI trials while considering sex, gender and partnership dynamics and cultural contexts. • Find ways to engage more directly with partners of ATI trial participants although they are not part of research.
HIV trial designs	• Integrate both research with social good to increase direct benefits and increase meaning of participation and encourage retention. • Incorporate syndemic and intersectionality-informed approaches into research protocols alongside the continuum of HIV prevention, treatment, care and cure/ATI research. • Ensure biomedical trials integrate behavioral and social sciences research and take social, cultural, socio-economic and historical contexts into consideration.

2024 – 2025 ATI Consensus Recommendations

2024 Analytical Treatment Interruption (ATI) Consensus Workshop

8-10 May 2024 ·Trademark Hotel, Nairobi, Kenya

Participant Considerations - *Recommendations (in review)*

	2019	2024	Comments
PARTICIPANT CONSIDERATIONS	• **PrEP for partners.** Refer for HIV testing and PrEP • **Psychosocial monitoring** recommended	• **PrEP for partners:** Refer to established reliable providers (or provide PrEP on site) • **Psychosocial monitoring.** Assess all visits during trial, especially during ATI. Provide on site counseling or refer depending on need and capacity • **Disclosure of HIV status and ATI participation.** Assess disclosure and provide onsite disclosure support at all visits to enable implementation of partner protection measures. • **ART adherence support.** After VL rebound and prior to ART restart , provide adherence support until VL undetectable. • **Socio-behavioral research.** Incorporate within ATI trials when there are important research questions to be answered related to participant experience, and for ATI trials at new sites/regions.	Expanded participant protection measures, including mental health & strategies to reduce transmission risk during ATI Onsite PrEP provision is complicated by responsibility for partners who are not enrolled in the trial. Many sites either do not have the capacity or funds to provide PrEP

	2019	2024
Engage community/CABs early	N/A	Recommended
Set enrolment equity targets	N/A	Recommended
Screen for mental health	N/A	Recommended
Support for HIV disclosure	N/A	Recommended
Counseling pre-, during, post-ATI	N/A	Recommended
Socio-behavioral research	Recommended	Specific topics listed

Acknowledgements

SANTHE
WRAIR

PLANNING COMMITEE

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2024 ATI Consensus Workshop **Subcommittees**

2024 ATI Consensus Workshop **Participants**

2024 ATI Interactive Webinars **Participants**

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Call for justice-informed HIV cure trials with ATIs

Participants

- **How are the physical, psychosocial, and emotional harms of participation assessed? How are harms discussed with potential participants?**
- **What are the contextual sociostructural processes that shape harms?**

Partners of participants

- What are the physical, psychosocial, and emotional harms for partners? How are these potential harms acknowledged and mitigated?
- Should partners be counselled on risk of HIV acquisition (partners without HIV) or risk HIV superinfection (partners with HIV)?

Affected communities

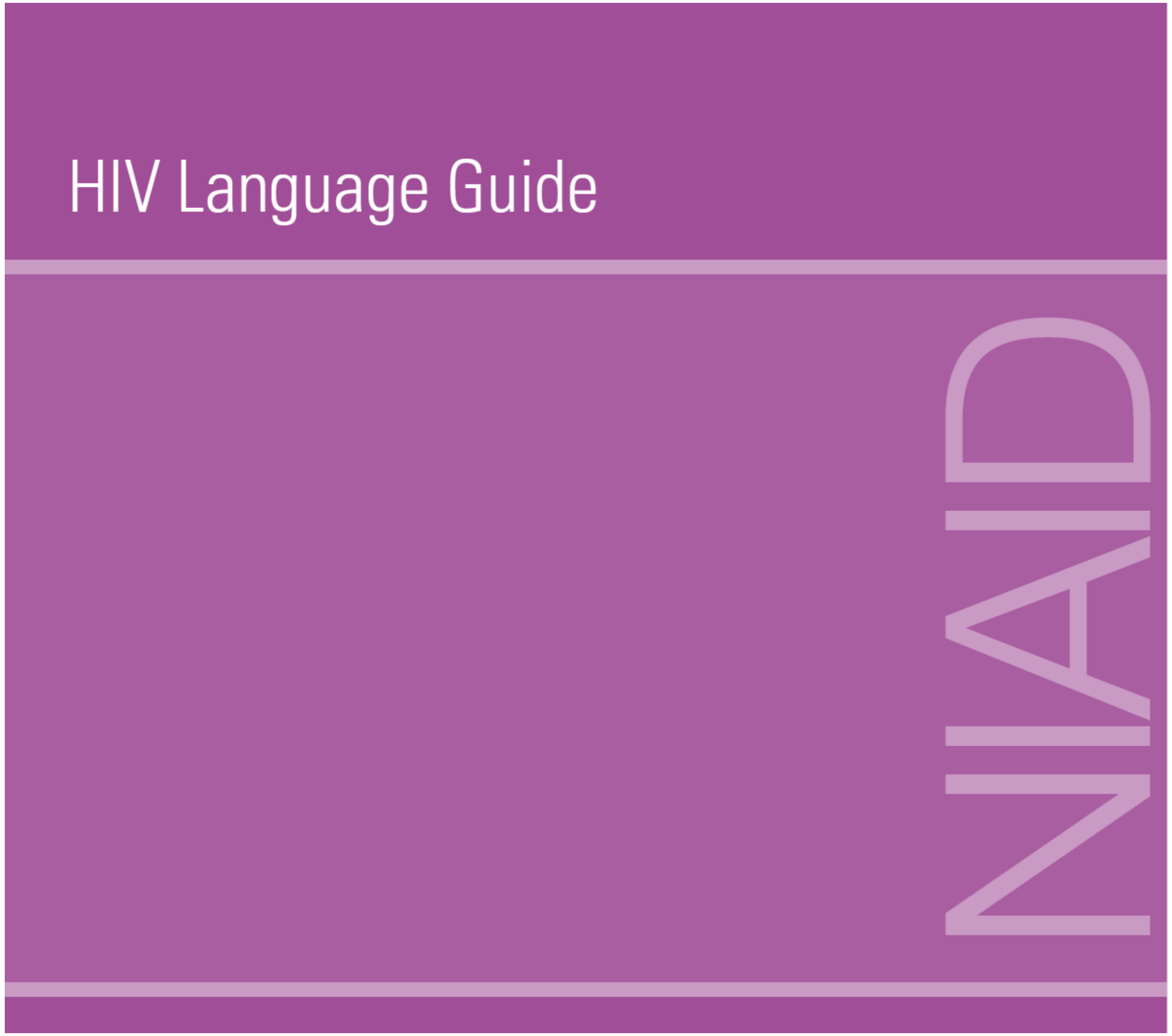
- How are affected communities included in designing strategies to mitigate potential analytical treatment interruptions-related harms?
- How is local knowledge assessed and integrated in research design and implementation?
- How do institutional systems and sociopolitical environments shape potential harms?

Global HIV science

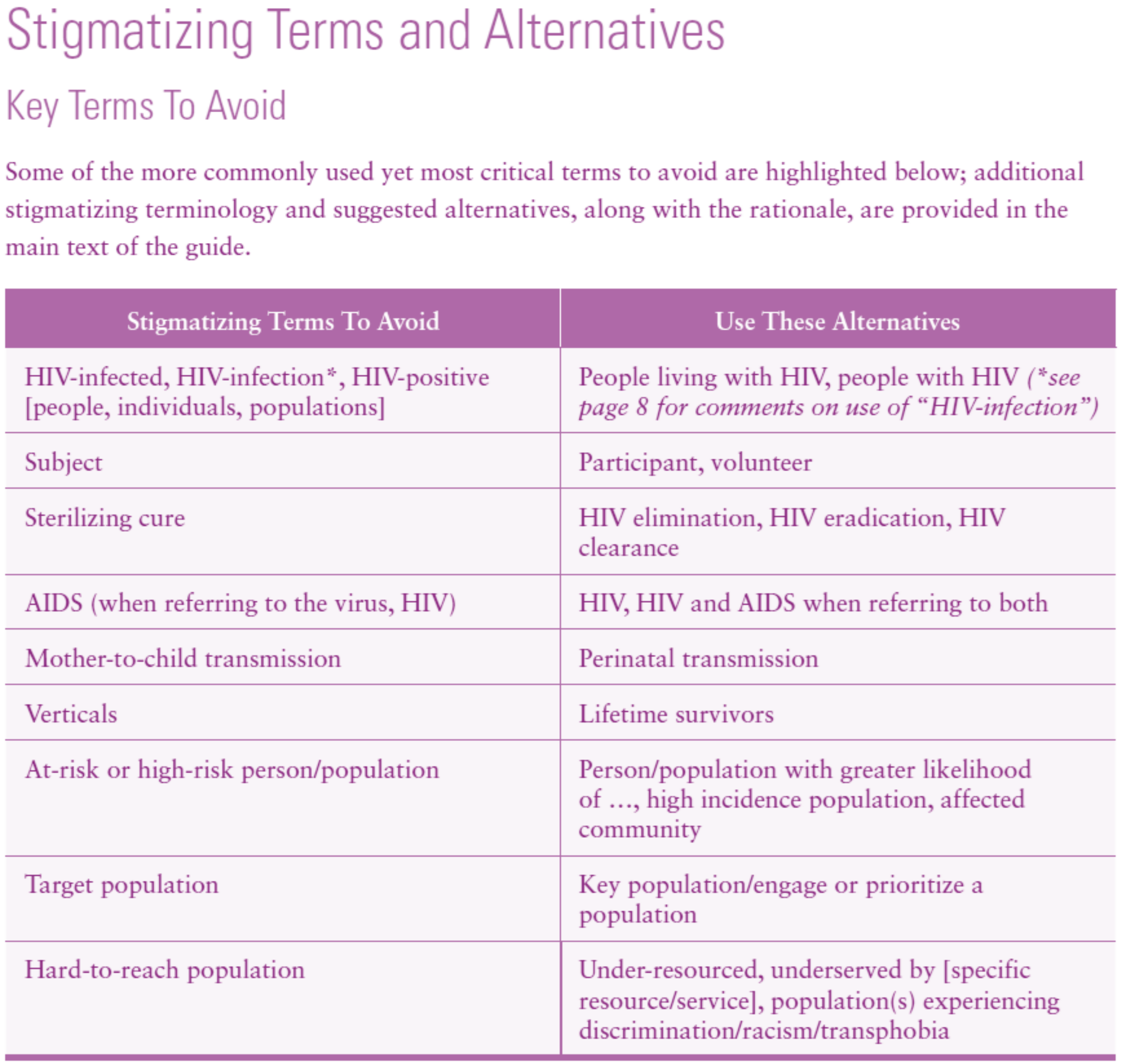
- What are the processes of accountability to ensure the harms are mitigated for participants and affected communities immediately and in the long-term?
- How do multiple intersecting systems of oppressions influence potential for undue harms?

Figure: Key questions to mitigate potential harms related to HIV cure-related research with analytical treatment interruptions

Linguistics



HIV Language Guide



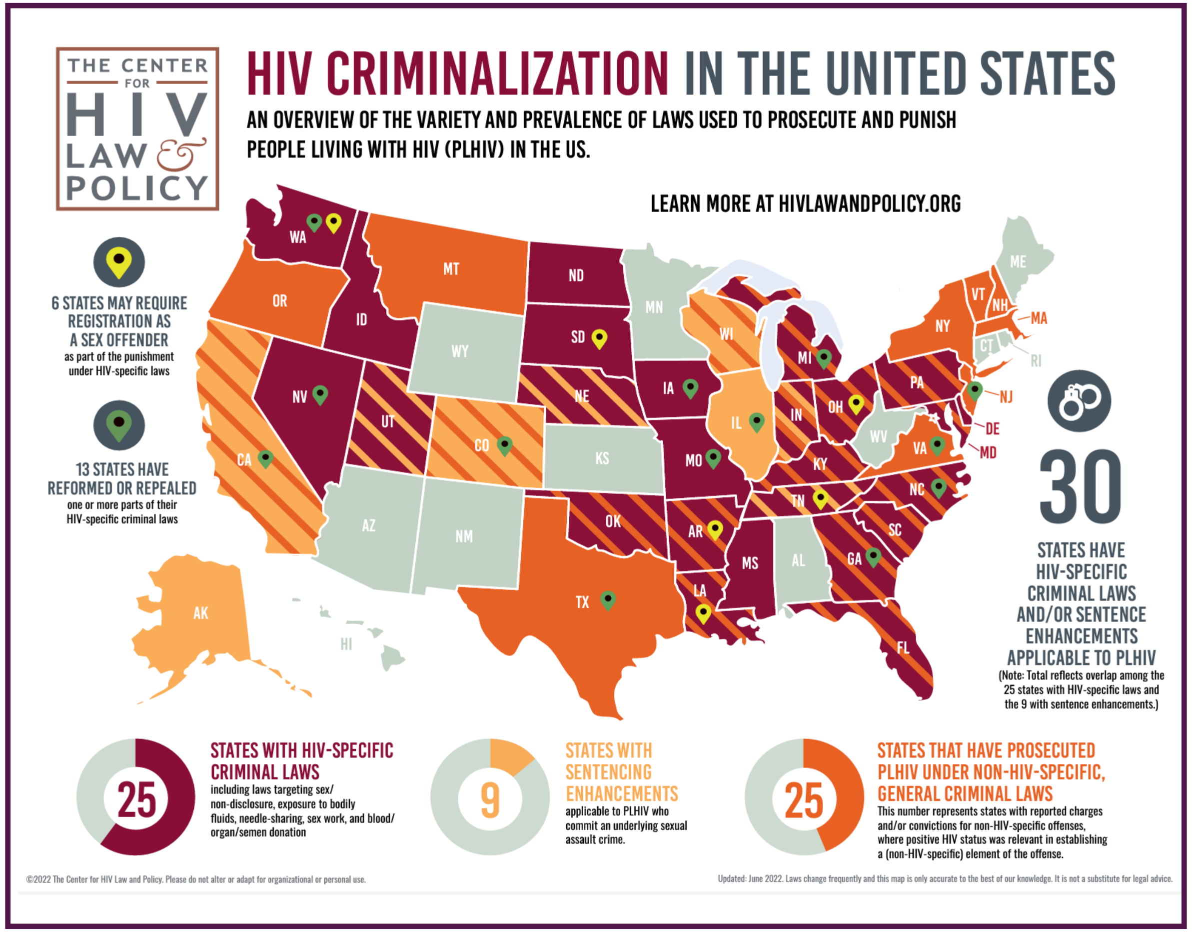
Stigmatizing Terms and Alternatives

Key Terms To Avoid

Some of the more commonly used yet most critical terms to avoid are highlighted below; additional stigmatizing terminology and suggested alternatives, along with the rationale, are provided in the main text of the guide.

Stigmatizing Terms To Avoid	Use These Alternatives
HIV-infected, HIV-infection*, HIV-positive [people, individuals, populations]	People living with HIV, people with HIV *(*see page 8 for comments on use of "HIV-infection")*
Subject	Participant, volunteer
Sterilizing cure	HIV elimination, HIV eradication, HIV clearance
AIDS (when referring to the virus, HIV)	HIV, HIV and AIDS when referring to both
Mother-to-child transmission	Perinatal transmission
Verticals	Lifetime survivors
At-risk or high-risk person/population	Person/population with greater likelihood of …, high incidence population, affected community
Target population	Key population/engage or prioritize a population
Hard-to-reach population	Under-resourced, underserved by [specific resource/service], population(s) experiencing discrimination/racism/transphobia

WRI 2024
HIV Criminalization and Anti-LGBTQ+ Climate



THE CENTER FOR HIV LAW & POLICY

HIV CRIMINALIZATION IN THE UNITED STATES

AN OVERVIEW OF THE VARIETY AND PREVALENCE OF LAWS USED TO PROSECUTE AND PUNISH PEOPLE LIVING WITH HIV (PLHIV) IN THE US.

LEARN MORE AT HIVLAWANDPOLICY.ORG

6 STATES MAY REQUIRE REGISTRATION AS A SEX OFFENDER as part of the punishment under HIV-specific laws

13 STATES HAVE REFORMED OR REPEALED one or more parts of their HIV-specific criminal laws

30 STATES HAVE HIV-SPECIFIC CRIMINAL LAWS AND/OR SENTENCE ENHANCEMENTS APPLICABLE TO PLHIV

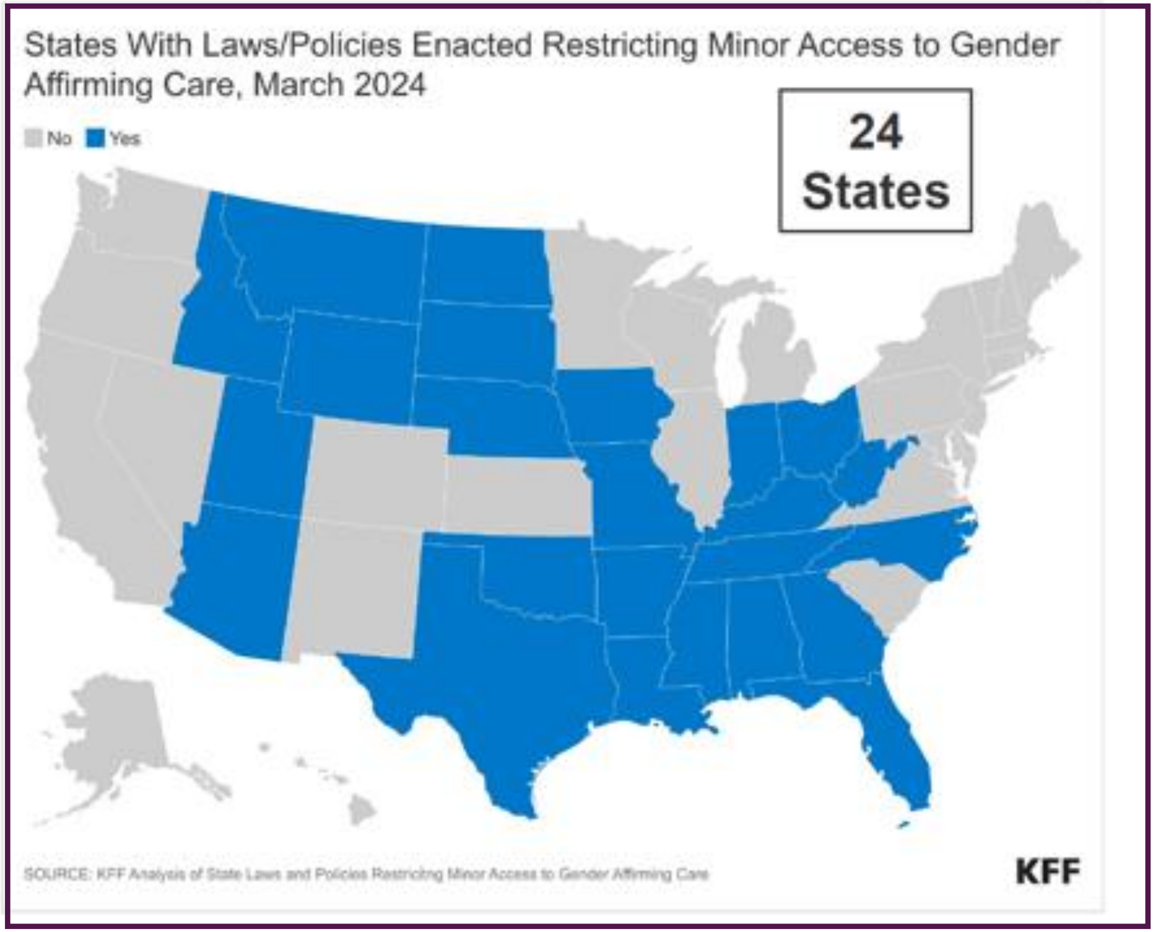
(Note: Total reflects overlap among the 25 states with HIV-specific laws and the 9 with sentence enhancements.)

25 STATES WITH HIV-SPECIFIC CRIMINAL LAWS including laws targeting sex/non-disclosure, exposure to bodily fluids, needle-sharing, sex work, and blood/organ/semen donation

9 STATES WITH SENTENCING ENHANCEMENTS applicable to PLHIV who commit an underlying sexual assault crime.

25 STATES THAT HAVE PROSECUTED PLHIV UNDER NON-HIV-SPECIFIC, GENERAL CRIMINAL LAWS This number represents states with reported charges and/or convictions for non-HIV-specific offenses, where positive HIV status was relevant in establishing a (non-HIV-specific) element of the offense.

Updated: June 2022. Laws change frequently and this map is only accurate to the best of our knowledge. It is not a substitute for legal advice.



States With Laws/Policies Enacted Restricting Minor Access to Gender Affirming Care, March 2024

No ■ Yes

24 States

SOURCE: KFF Analysis of State Laws and Policies Restricting Minor Access to Gender Affirming Care

KFF

https://www.hivlawandpolicy.org/sites/default/files/HIV%20Criminalization%20in%20the%20US%2C%20CHLP%20062822.pdf

Long-Term Survivors Series

JIAS
JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

“A Cure Might Help, but It Won’t Erase It All”: Policy Challenges and Priorities for Long-Term Survivors of HIV in the United States

Submission Status Under Review

HEALTH POLICY CHALLENGES (PRE-CURE)

HEALTHCARE TAILORED TO LTS

Policies must address unique health challenges of LTS, including aging, prolonged ART use, and comorbidities.

> *"Healthcare for LTS is not the same as for someone newly diagnosed... Our needs are different, and policies should reflect that." —74 years, White, Male*

Holistic care approaches are critical to meet the interconnected health needs of LTS.

FRAGMENTED MEDICARE & MEDICAID SYSTEMS

Systemic gaps in essential services create barriers.

High copays and inadequate coverage strain LTS financially.

> *"$650 worth of copays in a month... Without ADAP, I'm really screwed." — 67 years, Female, Black*

Telehealth programs suggested to improve access for LTS in rural/underserved areas.

HOUSING INSECURITY

Aging, financial instability, and medical needs compound housing challenges.

> *"HIV is not just a health issue; it's a housing issue too." — 69 years, Male, White*

Programs like HOPWA need stronger guarantees for stability as LTS age.

ECONOMIC MARGINALIZATION

Lost earning years and disability leave many LTS in precarious economic situations.

> *"HIV robbed me of my earning years... We need programs that help us financially, not just medically." — 70 years, Transgender female, Black*

MENTAL HEALTH & COMMUNITY SUPPORT

Mental health policies must address trauma, loss, and stigma.

Peer support programs seen as vital for reducing isolation and fostering resilience.

> *"Support groups are lifelines for older survivors." — 65 years, Female, Black*

Future Path is Uncertain

HOW DO WE MOVE FORWARD?

- POLITICAL LANDSCAPE
- CENSORSHIP
- TERMINATED SCIENCE
- RESILIENCE AS COMMUNITY MEMBERS AND SCIENTISTS

Thank You
Questions
Discussion