

COMMUNITY CROI CURE RESEARCH WORKSHOP 2020

**Mitigating HIV Transmission During
Analytic Treatment Interruptions (ATIs)**

Lynda Dee

DARE CAB Co-Chair

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- **amfAR Cure Institute/UCSF Studies**
- **ATIs - The Gold Standard**
- **Risk of HIV Partner Transmission during ATIs**
- **Recent ATI Trial HIV Transmission Cases**
- **PrEP to Prevent HIV Transmission: Challenges**
- **PrEP Implementation Recommendations for Partners**
- **Limitations of the Paper**
- **Future Studies**

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- **amfAR Cure Institute/UCSF Cure Related Studies**
- **Combinatorial therapy with a conserved element DNA vaccine, MVA vaccine boost, TLR9 agonist and broadly neutralizing antibodies: A proof-of-concept study aimed at inducing an HIV remission (**JAWS**)**
- **Socio-Behavioral Sciences Sub-Study, Karine Dube, John Saucedo, Lynda Dee, Jeff Taylor, Danielle Campbell**

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- amfAR Cure Institute/UCSF Cure Related Studies
- Peluso MJ, Dee L, Campbell D, Taylor J, Hoh R, Rutishauser RL, Saucedo J, Deeks SG, Dube K. A collaborative, multi-disciplinary approach to HIV transmission risk mitigation during analytic treatment interruption. *J Virus Erad*; 2020;6:34-37
- **Practical starting point** to address HIV transmission risk mitigation during ATI studies that describes strategies we are utilizing in an upcoming clinical trial **that may be applicable to some other centers.**

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- **ATIs - The Gold Standard**
 - **No standardized way to measure latent virus**
 - **No validated or universally accepted assay**
 - **Many assays with different pro and cons**
 - **Immune reconstitution efforts**
 - **Chronically infected patients**
 - **Boosting the immune during studies**

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- **Risk of HIV Transmission during ATIs**
 - **Undetectable status lost during ATIs**
 - **Possible adverse health implications**
 - **Risk of HIV transmission to partners**
 - **Negative impact on future ATI studies**
- **Risk directly related to:**
 - **Duration of ATI**
 - **Peak levels of viremia during rebound**

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- **Recent ATI Trial HIV Transmission Cases**
 - **France 2014: Male to female transmission**
 - **Spain 2016: Male to male transmission**
 - **Urgent need to mitigate study transmission risk**
 - **PrEP was unavailable during both studies**

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- **PrEP Recommendations in **JAWS** Protocol**
 - **Standard Exclusion Criteria Example**
 - **Contraception plan to limit pregnancy is standard**
 - **Unacceptable Exclusion Criteria**
 - **Exclusion based on other sexual behaviors**
 - **Range of behaviors that may change any given time**
 - **Years of excluding patient who use drugs**
 - **Restart ART after repeated instances of STIs**

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- **PrEP to Prevent Transmission: Challenges**
- **Study Participants**
 - **Difficulty Disclosing HIV status**
 - **Disclosure of HIV transmission risk during ATIs**
 - **Counseling is often generic and lacking in engagement**
 - **No consistency or follow-up**
 - **Anonymous partners**

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- **PrEP to Prevent Transmission: Challenges**
 - **Partners of Study Participants**
 - **Outside the scope of research**
 - **Medical, regulatory, legal, financial issues**
 - **No direct uniform risk information to partners**
 - **No direct uniform risk mitigation effort**
 - **Counseling is usually generic, lacking in engagement**
 - **Lack of information on most effective approaches**

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- **ATI Transmission Prevention Recommendations**
 - **Collaborative, multi-disciplinary approach involving close consultation among the biomedical study team, our community advisory board which included men and women with and affected by HIV, study participants, socio-behavioral scientists, and bioethicists.**
 - **PrEP intervention based on CDC HIV prevention recommendations**

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- **PrEP Recommendations**
 - **Direct study team engagement** across the study
 - **To determine a “standard of prevention”**
 - **Testing and disclosure in serodiscordant couples**
 - **Collaboration of study team, participant, partner(s)**
 - **Creation of a study specific risk reduction packet**
 - **Potential model based on HIV prevention studies**
 - **Testing and disclosure in serodiscordant couples**

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- **PrEP Recommendations for Participants**
 - **Hands on study team engagement throughout**
 - Counseling and assistance available throughout
 - **Disclosure Script**
 - To facilitate HIV disclosure
 - To aid in describing scientific ATI transmission facts
 - **Written PrEP facts and access info for partners**
 - **Repeated transmission counseling**

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- **PrEP Recommendations for Partners**
 - **Hands on study team engagement with partners**
 - **Participants encouraged to engage partners**
 - **Invite partners to regular study visits**
 - **Partner participation at least 4 weeks prior to the ATI**
 - **Written PrEP facts and access info to partners**
 - **Study developed information sheets, including specially developed information for women**

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- **PrEP Recommendations for Partners**
 - **Aggressive PrEP navigation assistance**
 - Access to study physician to discuss PrEP issues
 - Initial and repeated transmission counseling
 - **Direct referrals to one of several local PrEP sites**
 - Various PrEP sites are available at UCSF
 - **Warm hand-off to PrEP site at least 4 wks before ATI**
 - **Study site team accompanies partner to UCSF sites or directly connects partner to an off-site PrEP clinic**

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- **PEP Recommendations for Partners**
 - **Aggressive PEP navigation assistance**
 - **Known possible HIV exposure**
 - **Study team will promptly facilitate PEP via established pathways as UCSF**

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- **Limitations on Recommendations**
 - **Our study is based on widespread understanding of HIV transmission risks, universal testing, access to treatment and PrEP for prevention in men in SF.**
 - **Strong stakeholder support across the board and the political will to address these issues in SF.**

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- **Limitations on Recommendations**
 - **Unknown PrEP use considerations in women**
 - **Unknown HIV status**
 - **Unaware of benefits of PrEP**
 - **Multiple or anonymous partners**
 - **Unwillingness of participants to disclose HIV status**
 - **Unwillingness to involve partners**

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- **Limitations on Recommendations**
 - **No access to local research or PrEP access centers**
 - **Communities of color, especially in the Southern US**
 - **US rural settings**
 - **Resource limited settings where cure related research is likely to be conducted**
 - **It may be feasible for studies to include the cost of PrEP and PEP (Thailand is a great model.)**

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- **Future Directions**

- **Universal HIV testing, PrEP education and access are essential.**
- **The unique risks faced by women and people of color regarding PrEP referral, use and access are of particular importance.**
- **More behavioral research is needed to understand participants' values, motives and prevention practices, especially in women.**
- **More research is also needed to identify the experiences and preferences of participants' partners.**

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- **Future Directions**

- **Researchers must collaborate with their local communities to create plans that are consistent with local needs and cultures, including gender and sex dynamics, stigma and intimate partner violence.**

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THANK YOU!

Michael J, Peluso, MD

Steven G. Deeks, MD

Karine Dube, DrPH, Mphil

John Saucedo, MD

Danielle Campbell, MS

Jeff Taylor

Richard Jefferys

Michael Louella

ATI Participants

Workshop Attendees

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THANK YOU!

amfAR
MAKING AIDS HISTORY

UCSF

University of California
San Francisco

Delaney AIDS Research Enterprise
DARE
to find a cure