



Pregnancy, Breastfeeding and PrEP: Meeting patients where they are

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• No disclosures





- Review attitudes about pregnancy in people at risk for HIV
- Discuss the value of standardizing our risk assessment for HIV in pregnant and breastfeeding people
- Review safety profile of PrEP in pregnancy and breastfeeding
- Discuss available resources and potential avenues for collaboration

Perinatal HIV Transmission is Preventable



In the United States:

About **5,000 women with HIV** give birth annually

In 2018, only 32 babies were born with HIV



But what about preventing maternal HIV acquisition during pregnancy and breastfeeding?

New HIV Diagnoses Among Women in the US, 2018



- 1 in 5 new HIV infections were in women
- 85% of transmissions were via heterosexual contact
- Almost 3/4 among women of childbearing age

Centers for Disease Control and Prevention. HIV Surveillance Report, 2018 (Preliminary); vol. 30. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published November 2019. Accessed June 23, 2020.



National Clinician Consultation Center



- Six hotlines for clinician consultation
 - PrEP line
 - PEP line
 - HIV Warmline
 - Hepatitis C Warmline
 - Substance Use Warmline
 - Perinatal Hotline available 24/7
- Reviewed 52 calls regarding PrEP in pregnancy or breastfeeding from January 2017 to January 2020

What questions do our callers have about PrEP?

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- Is it indicated?
- Is it safe?
- Ongoing monitoring while on PrEP
- Role in conception for serodiscordant couples
- Deciding between PEP to PrEP, how to transition





Pregnant, desiring PrEP



A 25 yo Cis-gender woman presenting for PrEP, partner is a cis-gender male living with HIV. Last sex was yesterday. HIV test is pending.

What the considerations for this patient?

Pregnancy assessment on PrEP



CDC PrEP Guidelines (2017):

"All patients receiving PrEP should be seen as follows:

- At least every 3 months to
 - … Repeat pregnancy testing for women who may become pregnant…"

We would add:

Assess pregnancy desire/intention at initiation of PrEP and periodically thereafter.

Assessing pregnancy intention

VIRTUAL 2020 NATIONAL RYAN WHITE CONFERENCE ON HIV CARE & TREATMENT

- Up to 50% of pregnancies are unplanned
- About **80 percent of pregnancies among young women age 18 to 29** are described by the women themselves as **unplanned**.
- One Key Question provides a framework for health providers, social service providers, and champions to routinely ask, "Would you like to become pregnant in the next year?" possible answers are yes, no, ok either way, and unsure this allows a patient centered approach to the follow up discussion. Allows for room for ambivalence around potential pregnancy





- Desire to Avoid Pregnancy (DAP) scale is validated measure of a person's preferences about a future pregnancy and childbearing
- Assesses thoughts and feelings about becoming pregnant in the next 3 months.
- Accessible at: DAP scale ANSIRH

item	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
I wouldn't mind it if I became pregnant in the next 3 months.	0	1	2	3	4
It would be a good thing for me if I became pregnant in the next 3 months.	0	1	2	3	4
Thinking about becoming pregnant in the next 3 months makes me feel unhappy.	4	3	2	1	0
Thinking about becoming pregnant in the next 3 months makes me feel excited.	0	1	2	3	4
Becoming pregnant in the next 3 months would bring me closer to my main partner. (By main partner, we mean the romantic partner that is the most serious to you. If you don't have a romantic partner, please think about the person with whom you last had sexual relations.)	0	1	2	3	4

Also need to assess men's desires for having children



- Both male partners of women living with HIV but also for men living with HIV.
- <u>https://www.hiveonline.org/mlhiv/thinking_about_baby.pdf</u>
- <u>https://www.hiveonline.org/mlhiv/thinking about baby with woma</u> <u>n.pdf</u>

1st trimester at risk



- 30 yo cis gender female late 1st TM, being seen for suboxone maintanence. Lives with uncle, who has HIV. Partner uses IV drugs and may be sharing needles with that uncle. Nothing known about uncle's ARV or HIV VL history.
- Would offer PrEP, but doesn't know about safety in pregnancy

Safety of PrEP in pregnancy and breast feeding



- •The Partners PrEP study : no significant increase of birth defects or poor birth outcomes with TDF/FTC PrEP vs placebo in the first trimester (PrEP stopped when pregnancy identified)
- •The Antiretroviral Pregnancy Registry : no significant differences in birth defect rates between women who are taking ARV's and those who are not.
- •Review of TDF-containing ART : in women living with HIV, TDF ART appears generally similar to other ART regimens when examining maternal, pregnancy, and growth outcomes
- •Limited drug exposure to TDF or FTC through breastfeeding : safety data from PrEP, TDF/FTCcontaining ART and TDF for treatment of hepatitis B

•No long term safety data in pregnancy or breastfeeding

Mugwanya KK, John-Stewart G, Baeten J. Safety of oral tenofovir disoproxil fumarate-based HIV pre-exposure prophylaxis use in lactating HIV-uninfected women. *Expert Opin Drug Saf*. 2017;16(7):867-871. Mofenson LM, Baggaley RC, Mameletzis I. Tenofovir disoproxil fumarate safety for women and their infants during pregnancy and breastfeeding, AIDS: January 14, 2017 - Volume 31 - Issue 2 - p 213-232. Mugo NR, Hong T, Celum C, et al. Pregnancy incidence and outcomes among women receiving preexposure prophylaxis for HIV prevention: a randomized clinical trial. *JAMA*. 2014;312(4):362-371.

Concentrations of TFV-DP During Pregnancy Among Women Using PrEP *Pyra M et al. CROI 2018 Boston Abs. 809*



Concentrations Between Pregnant & Non-Pregnant Women with 100% MEMS Adherence



www.APRegistry.com





3rd trimester, partner newly diagnosed with HIV



28 yo cis-gender female G2P1 at 34 weeks, HIV negative. Just found out that partner was diagnosed with HIV, is supposed to start ART tomorrow. Last intercourse was one week ago.

How can we counsel her on HIV prevention during pregnancy and breastfeeding?

HIV Acquisition Risk is Higher in Late Pregnancy and Postpartum



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Thomson, et al. Increased Risk of HIV Acquisition Among Women Throughout Pregnancy and During the Postpartum Period: A Prospective Per-Coital-Act Analysis Among Women With HIV-Infected Partners, JID, 218 (1), 1 July 2018.

HIV Prevention Toolkit





Undetectable = Untransmittable



HPTN 052, PARTNER, Opposites attract, Partner2: No HIV transmissions with VL <200 c/mL

U=U considerations



- 2/3 of people in HIV care are virally suppressed for over a year
 - 1/3 are not suppressed
- At least 6 months from diagnosis to U=U
- Adherence is key
- Prevention relies on the partner with HIV

Evidence of HIV treatment and viral suppression in preventing the sexual transmission of HIV. Dec 2018

PrEP + U=U = Reassurance



- People seeking pregnancy often want more than one prevention method
- Gives control to the partner without HIV
- Provides additional reassurance
- Can allow for increased intimacy

How to monitor patients on PrEP?



- 28 yo pregnant female @ 16 wks on PrEP because her male partner has HIV. Her partner is on ART and has an undetectable HIV viral load.
 - How often should the pregnant patient be tested for HIV?

Depends on the scenario:

- Minimum is HIV testing in 1st and 3rd trimester; pregnant people at known heightened risk for HIV should be tested at least every trimester and every 1-3 months during breastfeeding
- Counsel on signs and symptoms of acute HIV, test with HIV RNA if concern
- If partner known to be living with HIV, collaborate with partner's care provider and recommend HIV RNA monitoring every 1-3 months



How did our callers know so much about their patients' risk for HIV?

We can't rely on self-disclosure

Perinatal Roundtable at CROI



- Annual roundtable sponsored by NCCC's National Perinatal HIV Hotline
- Build community between clinicians, researchers, policy makers, and community members
- Inform recommendations to Hotline callers

Grey Zone Discussions





Grey Zone

Best Practice



Best Practices from 2020 Roundtable



- Maternal HIV risk assessment
 - Do it early and often
- Partner HIV status assessment
 - Make it routine

Make PrEP accessible

Take Aways from Roundtable



Assess HIV status routinely.

• PrEP use can change over time.



HIV Prevention Continuum in Pregnancy and Breastfeeding



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Increasing awareness





Gaps in knowledge



- No studies in people assigned female at birth:
 - TAF/FTC as PrEP
 - Long-acting cabotegravir as PrEP
 - Intermittent PrEP dosing
- Optimal monitoring strategies in pregnancy and breastfeeding



Thank you! To learn more, please visit <u>nccc.ucsf.edu</u>

888-448-8765

Substance Use Warmline 855-300-3595 Substance use evaluation and management

HEPline

844-HEP-INFO

HCV testing, staging, monitoring, treatment

HIV/AIDS Warmline 800-933-3413 HIV testing, ARV decisions, complications, and co-morbidities

PrEPline

855-HIV-PrEP

Pre-exposure prophylaxis for persons at risk for HIV

Perinatal HIV Hotline

Pregnant/postpartum women with HIV (or at-risk for HIV) & their infants

PEPline

888-448-4911

Occupational & non-occupational exposure management