INTEGRATING PrEP for HIV PREVENTION INTO WOMEN'S HEALTH CARE IN THE UNITED STATES

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Preexposure Prophylaxis for HIV Prevention in U.S. Women. Obstet Gynecol 2016

One in five new HIV diagnoses in the U.S. are among women

64% **OF WOMEN** living with HIV in the U.S. are Black, though Black women are 13% of the female population

The CDC estimates 468,000 **U.S. WOMEN** are eligible for PrEP

Women's health care providers are uniquely positioned to screen, counsel about, and offer PrEP

PREP: WOMAN-CONTROLLED HIV PREVENTION

- Before approval of PrEP, HIV prevention strategies included condoms, PEP, limiting sexual partners, screening for and treating sexually transmitted infections, and partner testing. **None of these options provides a discreet, reliable, and woman-controlled method** for HIV prevention.
- PrEP offers an **effective, safe, and private option** for individuals to reduce their HIV risk.

REACHING WOMEN

- Strikingly similar determinants underlie women's HIV acquisition and unintended pregnancies.
- Women's health providers have extensive experience counseling women and are well equipped to champion HIV prevention services that incorporate reproductive choice.
- Reaching women who may consider using PrEP requires clinicians to take careful sexual histories, exploring individual vulnerabilities to HIV and personal risk assessments.
- Ultimately we must trust women as experts in their own vulnerability to HIV.

SHARED DECISION-MAKING: A WOMAN-CENTERED, ETHICAL APPROACH TO OFFERING PREVENTION

- Shared decision-making is a collaborative process allowing patients and clinicians to make healthcare decisions together when there are multiple options and no clear recommendation.
- The clinician and woman each bring unique expertise: the clinician provides evidence-based information, while the woman offers her experience, values and preferences.
- Shared decision-making is an on-going conversation, offering support to women as sexual practices or reproductive goals change.

a hub of positive reproductive & sexual health

INTEGRATING REPRODUCTIVE GOALS AND HIV PREVENTION

- More than 250,000 male–female serodifferent couples live in the U.S., and approximately half want children.
- Safer conception is a critical component of shared decision-making, allowing clinicians to support women to achieve sexual and reproductive health goals while mitigating risks.
- HIV prevention discussions before and during pregnancy prompt conversations about the data behind increased HIV susceptibility during pregnancy.
- Pregnancy intentions must be discussed and unwanted pregnancies avoided as part of HIV prevention.

INTEGRATING SEXUAL AND REPRODUCTIVE HEALTH CARE FOR WOMEN

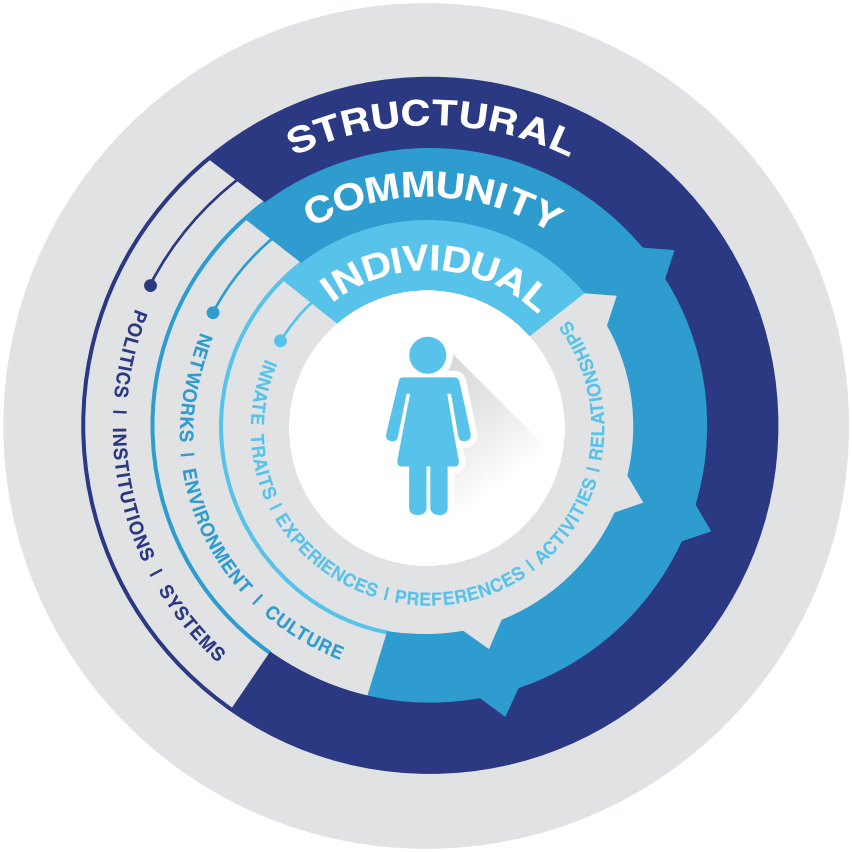
- Shared decision-making requires cross-trained clinicians to:
    - Fluently elicit women's values and preferences,
    - Offer the spectrum of HIV prevention services,
    - Review risks and benefits of each method in the context of a woman's sexual and reproductive goals.
- Providers may require additional training on multidisciplinary content to offer integrated sexual and reproductive healthcare. Nevertheless, women's health providers remain uniquely poised to offer PrEP to women.

BEST PRACTICES FOR PREP PROVISION

- Foster a trusting clinical relationship between provider and patient. Be mindful of historical context and patients' experiences with the health care system, taking care to reflect on personal biases.
- Provide anticipatory guidance about medication side effects and management.
- Link pill-taking to daily routines, using reminder systems, creating a network of adherence support.
- Identify barriers to adherence and provide referrals for mental health needs, substance use, intimate partner violence, and experiences with trauma.
- Prevent over-medicalization of PrEP with excessive laboratory tests and appointments.
- Navigate financial barriers through utilization of drug assistance programs.

A CALL TO ACTION FOR WOMEN'S HEALTH PROVIDERS AND HIV PREVENTION EXPERTS

- Discuss HIV vulnerability with every sexually active woman.
- Discuss pregnancy intentions with every reproductive-aged woman.
- Learn about all HIV prevention methods & counsel women about a range of options.
- Advocate for PrEP accessibility.
- Prescribe PrEP or develop a streamlined referral system for care.



A conceptual model of intersecting factors influencing a woman's susceptibility to HIV

Italicized characteristics are also associated with unintended pregnancy.

Innate traits include *age, sex, biology, and resilience*. **Experiences** include *coping mechanisms; sexual agency; trauma; violence; coercion; mental and physical health; substance use; health literacy; food, housing, and immigration insecurity; education and knowledge; poverty; gender identity; gender transition status and history; and pregnancy status*. **Preferences** include *type of sex (anal or vaginal); number and type of partners; sexual orientation; method(s) of protection against HIV, pregnancy, or both; and reproductive goals*. **Activities** include *sexually transmitted infection (STI) screening and treatment*, postexposure prophylaxis, pre- exposure prophylaxis, *barrier protection, substance use, exchange sex, contraception, and employment*. **Relationships** include partners' HIV status, partners' HIV treatment and adherence, partners' HIV and STI testing, partners' infectious risk factors, partners' circumcision status, *partner violence, partner power dynamics, and child and elder care responsibilities*. **Networks** include HIV prevalence, community viral load, STI prevalence, and *incarceration rates*. **Environment** include *violence; transportation, education, housing, and health care access; and poverty*. **Culture** includes *stigma (racism, sexism, homophobia,), medical distrust, sexual or reproductive norms and beliefs, and religion*. **Politics, Institutions, Systems** include *poverty, immigration, criminalization, and stigma*.

APPENDIX 1

An Expanded Human Immunodeficiency Virus Prevention Toolkit for Vaginal and Rectal Exposures: Biomedical and Barrier Prevention Methods Currently Available in the United States

	Efficiacy per sex act* (95%CI)	Benefits	Drawbacks	Dosing	Access
Male/female condoms	RR 0.2 (0.08–0.47)	No systemic therapy. Inexpensive and accessible. Simultaneously prevent STIs and pregnancy (if pregnancy prevention is desired).	Partner-dependent. Requires correct application. Prevents pregnancy (if pregnancy is desired).	Event-driven	Over-the-counter
Early treatment of partner living with HIV (vs. delayed treatment)	RR 0.04 (0.01–0.27)	Highly efficacious method. Improves long-term health of partner.	Partner-dependent. May require another prevention method while partner's viral load responds to therapy.	Chronic daily medication(s) of partner	Partner must know status, engage in care with HIV provider and adhere to life-long therapy.
Post-exposure prophylaxis (PEP)‡	OR 0.19 (0.06-0.52)†	Individual-controlled, short-term therapy. Do not need to wait for HIV testing before starting.	Efficacy dependent on adherence and initiation of drugs within 72 hours of exposure. Side effects occur in 10% of users (gastrointestinal, headache). Toxicities are rare (1/200 risk renal toxicity). Lab monitoring recommended.	Event-driven: must start within 72 hours of exposure. Oral dosing: 200 mg emtricitibine/300mg tenofovir (1 tab fixed combination) daily AND raltegravir 400 mg twice daily OR dolutegravir 50 mg once daily x 28 days after exposure.	Accessible in most emergency rooms. Patient assistance program available through Gilead & Merck.
Pre-exposure prophylaxis (PrEP)§	RR 0.29 (0.17–0.47)	Individual-controlled, longer-term therapy allowing prevention in advance of exposure.	Efficacy dependent on adherence. Side effects occur in 10% of users, usually self-limited to first month of use (gastrointestinal, headache). Toxicities are rare (1/200 risk renal toxicity; 1% average loss of bone mineral density recovers after stopping PrEP). Must confirm HIV-negative status prior to initiation. Regular toxicity labs, HIV and STI testing recommended.	Daily oral dosing: 200 mg emtricitib-ine/300 mg tenofo-vir (1 tab fixed combination). Medication taken before and after exposure during seasons of substan-tial risk of HIV infection in an individual's life; no predetermined duration of therapy.	Requires engagement with long-term provider. Covered by most insurance. Medication assistance available through Gilead, private foundations, and some local governments.

*All values except post-exposure prophylaxis were reported by Patel P, Borkowf CB, Brooks JT, Lasry A, Lansky A, Mermin J. Estimating per-act HIV transmission risk: a systematic review. AIDS 2014;28:1509-19.

†Extrapolated from data on post-exposure prophylaxis for needle-stick injuries: Smith DK, Grohskopf LA, Black RJ, Auerbach JD, Veronese F, Struble K et al. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. MMWR Recomm Rep. 2005;54:1-20.

‡For further information on prescribing PEP including recommended lab monitoring, please see the CDC guidelines, updated in 2016: *http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf.*

§For further information on prescribing PrEP including recommended lab monitoring and scheduled visits, please see the CDC guidelines, updated in 2014: *http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf.*

CI: confidence interval. RR: risk ratio. OR: odds ratio. STI: sexually transmitted infection.

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