Getting to Zero from the Other Side of the HIV Epidemic – PrEP* in Women, MSM of Color, PWID, and Rural Areas

{ STFM 2019- Toronto, Ontario

* and more

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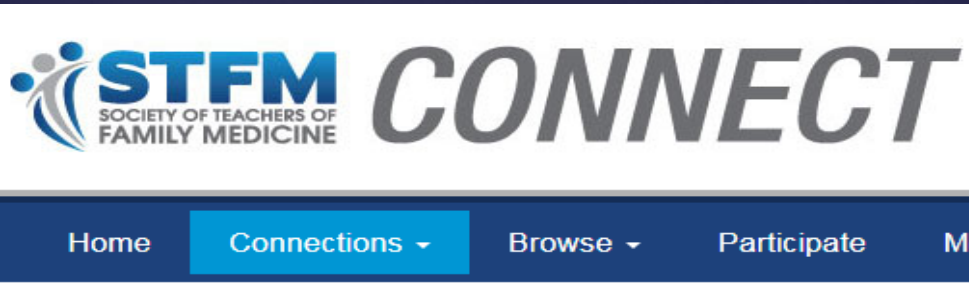
Family Health Centers- San Diego
San Diego, California

Housekeeping…

- Join our STFM HIV/Viral Hepatitis Collaborative
- Don't forget to grab resources, etc.
- We want to hear from everyone! Please ask any and all questions during this session!



Why this? Why now?

- PrEP approved for adults in 2012; adolescents 2018
- PrEP remains vastly underutilized in some areas/ populations: women, younger people of color, rural communities, PWID

Our goal: to share ideas & lessons learned from various approaches/initiatives that have been developed to ↑ visibility of key HIV prevention interventions for some of the above populations…

Looking behind the numbers…

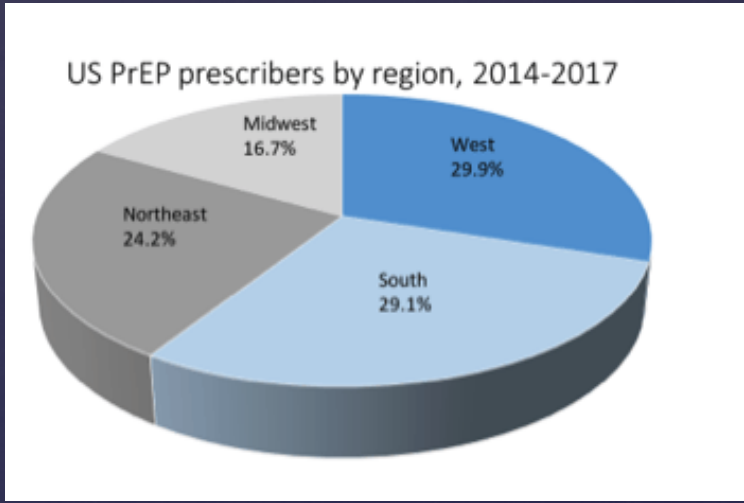
ESTIMATED NUMBER OF ADULTS WHO COULD POTENTIALLY BENEFIT FROM PREP, UNITED STATES, 2015

	Gay, bisexual, or other men who have sex with men	Heterosexually active adults	Persons who inject drugs	Total by race/ethnicity
Black/African American, non-Hispanic	309,190	164,660	26,490	500,340
Hispanic/Latino	220,760	46,580	14,920	282,260
White, non-Hispanic	238,670	36,540	28,020	303,230
Total who could potentially benefit from PrEP	**813,970**	**258,080**	**72,510**	**1,144,550**

Notes: PrEP=pre-exposure prophylaxis; data for "other race/ethnicity" are not shown

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

PrEP prescribing: updates



- From 2014 to 2017, the number of U.S. PrEP prescribers ↑ from 6,368 to 34,337
- In 2017, ~75% of prescribers practiced in urban areas, ~20% in partially urban areas, and ~5% in rural areas (proportion of rural prescribers ↑ from 3.3% to 4.9% from 2014- 2017)

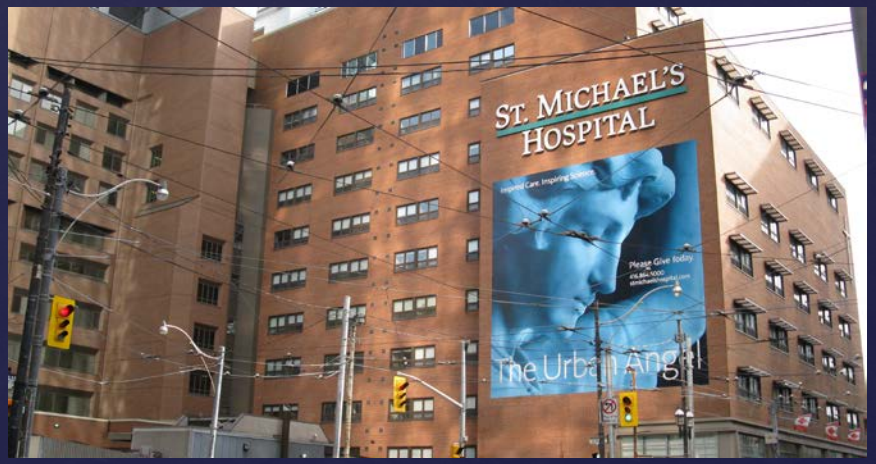
Zhu, Huang, Hoover; abstract 6193
National HIV Prevention Conference, 2019

HIV prevention is still not a common area of focus for many FM training programs

- Lack of experienced faculty
- "Not a problem in our area"
- Seen as a specialist issue
- What's happening in your programs??

Barriers to PrEP access in women: experiences from Canada

Caroline Jeon, MD, CCFP, AAHIVS
St. Michael's Hospital



PrEP prescribing in Ontario

- Provided by:
  - Infectious disease specialists
  - Primary care providers
  - Sexual health clinics

- High variability among primary care providers in perceptions, attitudes, and comfort with PrEP prescribing

It Happens in Canada, Too!

PrEP Guidelines in Canada

- Canadian Medical Association Journal – Canadian Guidelines on HIV pre-exposure prophylaxis and non-occupational post-exposure prophylaxis – www.cmaj.ca/content/190/25/E782

- Limitations to guidelines:

  "Our recommendations focus on heterosexuals in known serodiscordant relationships, because HIV prevalence in the general Canadian heterosexual population is low…"

Barriers to PrEP access – some thoughts…

- Provider awareness, comfort levels
  - Lack of data in interest, uptake in cis/trans-women
  - Lack of guidelines emphasizing barriers that may be particular to these groups
- Patient awareness, comfort levels
  - Cis/trans women – tend to have less knowledge of availability and efficacy within the community
- Drug costs
  - Available on most private insurances and public drug formulary (Ontario Drug Benefit)
  - ODB is accessible to those who are:
    - Under 24 (OHIP+)
    - On social assistance; either a disability program or social welfare program
    - Over age 65
    - Paying for Trillium Benefits

Next steps – PrEP for women in Canada

- Identify high risk groups among cis *and* trans women:
  - PWID
  - Risk of high risk sexual behaviours, including those who participate in sex work, are unable to negotiate condoms consistently
  - Those at risk or have a history of intimate partner violence, trauma
  - Those of indigenous heritage
  - Those within cultural/ethnic groups with high incidence of endemic HIV

Additional next steps – PrEP for women in Canada

- Consider and understand socio-cultural norms within groups of women to look at scalability of future PrEP interventions (e.g. perception of HIV acquisition risk)
- Consider implementations in breastfeeding/pregnant women in high risk groups
- Consider barriers to not only *access*, but *adherence* and *retention in care* that may be specific to cis/trans women

PrEP access for MSM of color: experiences from San Diego

Sarah Rojas, MD, MAS, AAHIVS
Family Health Centers of San Diego

FAMILY HEALTH CENTERS OF SAN DIEGO

¡Prevenga el VIH uniéndose a nuestro estudio de adherencia a PrEP!

PrEP es una pastilla que se toma diariamente y que puede prevenir el VIH.

Los participantes recibirán PrEP, pruebas de laboratorio, de VIH y de otras enfermedades de transmisión sexual gratis en seis visitas en el curso de un año.

Los participantes deben ser mayores de 18 años, ser VIH negativo y ser transgénero o género no conforme.

El seguro médico no es requerido para participar.

Rev. 09/2018

Para más información, llame al (619) 876-4462 o mande un correo electrónico a jessicame@fhcsd.org.

FAMILY HEALTH CENTERS OF SAN DIEGO

UC San Diego School of Medicine
AntiViral Research Center

¡PrEParate!

San Diego State University

PURPOSE

To help Latino Men in the community access HIV prevention care like PrEP

WHAT IS INVOLVED?

One 45 minute interview and one short survey

WHO CAN PARTICIPATE?

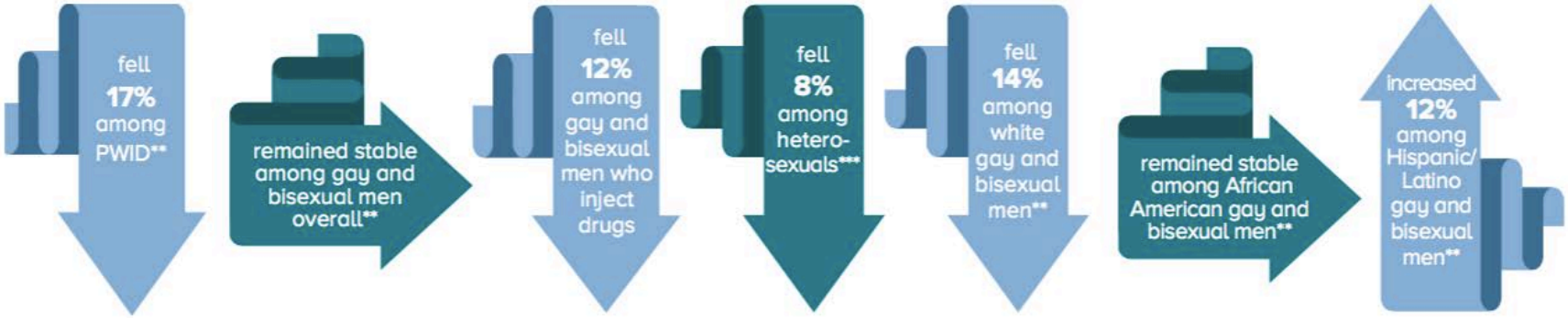
Latino gay and bisexual Men 18-29 years old

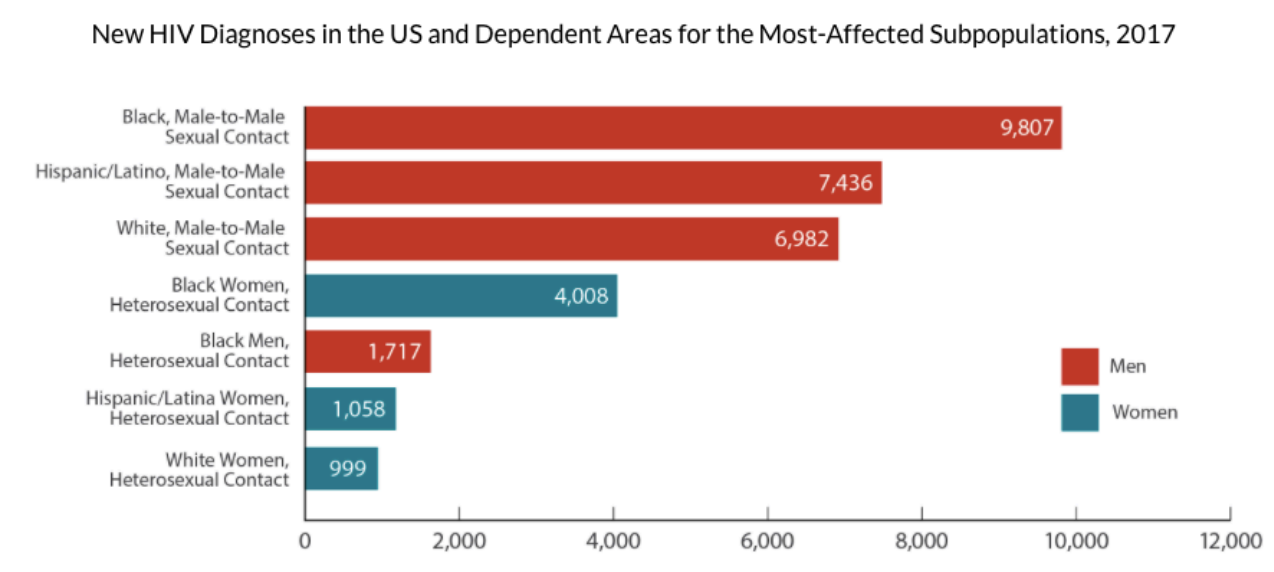
$50 gift cards will be provided to participants of the study

For more information, please email us at **prep.psyc@sdsu.edu**

You can help make a difference in your community!

From 2012 to 2016, HIV diagnoses in the US and dependent areas:





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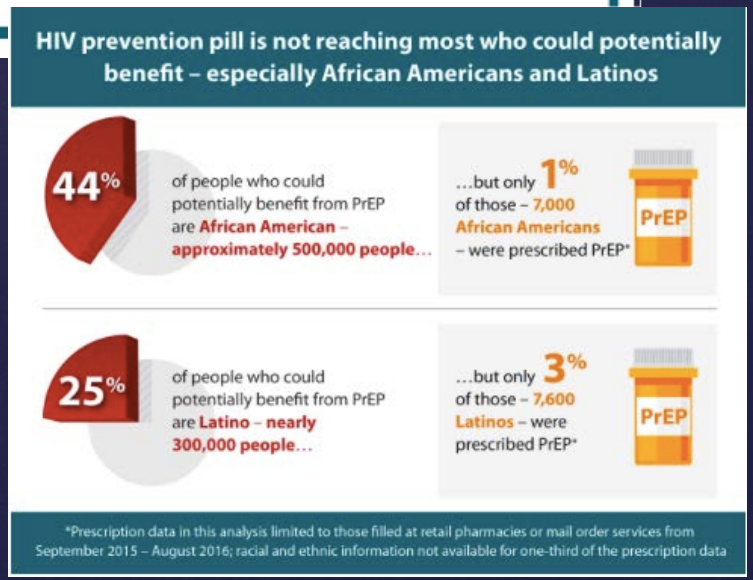
CDC U.S. Department of Health and Human Servi Centers for Disease Control and Prevention



-Smith, CROI 2018
https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018.html

Individual facilitators/barriers

- Having **resources** to pay for PrEP and its care
- Having **correct information** about PrEP and care required
- Having a regular **health care provider**
- Believed **not at risk for HIV**
- Shame, embarrassment
- Not clear **how to get PrEP**
- Gaps in knowledge about PrEP
- Concerns regarding **side effects**
- **Mistrust of efficacy** of PrEP

Interpersonal facilitators/barriers

- **Friends and peers** who provide correct PrEP information and encouragement
- Others in the **LGBTQ community** who use PrEP
  - *"I went there with the express intent of getting PrEP, because my friend told me you could get it for free there."*
- **Trusted** health care providers
- Health care providers who **understand** the health needs of MSM
  - *"So being able to have health care professionals that understand the life of a gay man makes it very easy to talk to about your issues and what things you may need as a gay man that otherwise that doctors don't know."*
- **Discomfort** discussing their sexual orientation with their doctor
- **Stigma** regarding sexual orientation from health care providers
- Health care providers who **lacked knowledge** regarding PrEP
  - *"I had a doctor, who, she was a primary care doctor, who didn't even know….whether she could even prescribe it."*
- Health care provider **negative judgment** regarding or **non-support** of PrEP
  - *"When I asked about it, he actually said that he didn't want to prescribe it, because he felt that it, it was against his morals or philosophy to provide that sort of treatment […] because he believed that the best way to prevent STI or HIV was just to be in a monogamous relationship."*

Community facilitators/barriers

- **Social media and/or online dating applications** tailored for the gay community (Facebook, YouTube, Grindr)
- **Outreach** conducted in gay-friendly neighborhoods, outside gay bars and at Pride events
  - *"It was at a gay bar outside of a gay bar…there was a booth and then we got tested near a corner and then that's when they told us … you know we also offer services like couples counseling and also like just services to get PrEP and PEP, and all these other things"*
- When PrEP use is perceived as **normative** in the LGBT community
  - *"There's a lot of LGBT groups that are very much… connected with the whole PrEP movement, and those do a very good job of informing again and just letting people have access to PrEP"*
- Latino/a community **stigma towards gay, bisexual, and MSM**
- Latino/a community stigma prevents Latino MSM from **discussing their sexuality and sexual health needs**
  - Peers
  - Healthcare professionals
- Taking PrEP could **reveal sexual orientation** to family or community
  - *"As a young Latino gay man, it's just kind of intimidating to look for those things just because you know, in the Latino community being gay is not seen as …something to brag about"*
- **Masculinity and machismo** in Latino culture can prevent men from talking about sexual health with their partners or seeking health care services
  - *"In the Latino community everything has to be masculine and masculine has power…looking for those kind of things [PrEP]….It's something embarrassing…"*

Institutional facilitators/barriers

- Healthcare system **has a PrEP program**
- Clinic or practice is considered **safe for LGBTQ community**
- **Appointment scheduling** is convenient
- **Reminder system** for appointments
- **Difficult to navigate healthcare system** when trying to get a prescription for PrEP
- **Went from clinic to clinic** to find one that prescribed PrEP
- Clinics which offered PrEP are **far or not convenient**

PrEP stigma

- Some in LGBTQ community stigmatize individuals who use PrEP
  - Promiscuous
  - Practice unsafe sex
  - *"When you see on a Grindr profile that someone's on PrEP, it's like clear that they're a slut"*
- Misbeliefs about side effects, especially that it could affect their liver
  - *"Can't party and take it"*

PrEP for women in serodifferent relationships and PWID in prenatal and family-oriented primary care settings

Monica Hahn, MD, MPH, MS, AAHIVS
University of California San Francisco

Janet & Joe*

- Janet: 23yo cisgender woman with no significant PMH and no primary care home
- Hopes to start a family with Joe, her male partner LWH, who has been suppressed on ARVs over the past year
  - Joe has had some past difficulty with adherence in the setting of alcohol and substance use, now in recovery
- Janet has been told by previous providers that she would be "irresponsible" to consider having a child with this partner due to HIV risk to herself and her potential child, and should never have sex without condoms

*Based on real patients, names changed

They want to get pregnant! What do you recommend for safer conception?

A. Counsel that she should always use condoms, and if the condom breaks, to use PEP afterwards. Help her look into option of adoption.

B. Counsel that the only safe way to conceive with Joe is to do sperm washing with insemination at a fertility clinic.

C. Counsel that it is perfectly safe to just have plain old-fashioned condom-less sex – no need for anything else! #U=Uforthewin!

D. She can add taking PrEP to lower her risk of acquiring HIV sexually.

E. I'm not sure, would like more information…

Safety of PrEP in preconception/pregnancy

- Thought to be safe in preconception, pregnancy and breast/chestfeeding
- Antiretroviral Pregnancy Registry: No evidence of adverse effects or birth defects among fetuses exposed to PrEP
- Studies of women who took PrEP around preconception period: No adverse events and no transmissions to negative partners
- 1 study showed possible association with decreased infant head circumference – unlikely to be clinically significant
- US Perinatal Guidelines and British HIV Association statements defend safety of tenofovir in pregnancy

daCosta, Machado et al. 2011, Watts, Huang et al. 2011, Knapp, Brogly et al. 2012;
Floridia, Mastroiacovo et al. 2013; Siberry, 2012; Mugo, 2012; Vernazza et al, 2011; Seidman et al, 2016; Siberry et al, 2012; Fowler et al 2016.

Some points to consider

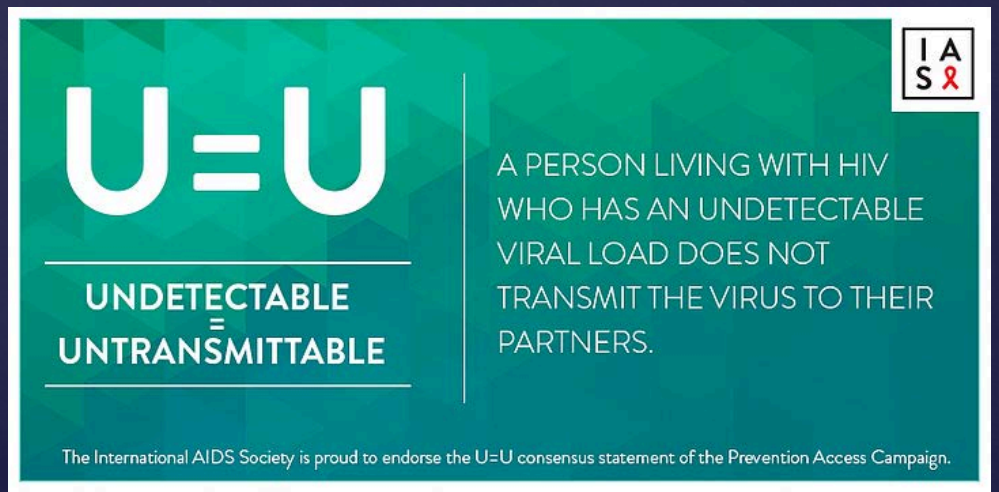
- Each couple's situation is different
  - Our job is help them choose the tools that are right for them
- Stakes are high: if acute HIV transmission to Janet during pregnancy or breastfeeding, risk of transmission to infant increases
- Counseling about U=U (Undetectable = Untransmittable)

  "People who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner." (CDC, Sept 2017)

Suppressed VL in Joe throughout pregnancy and breastfeeding ensures HIV not transmitted to Janet, which eliminates risk of perinatal and postnatal transmission to infant.

Any added benefit of PrEP in setting of TasP and U=U?

- PrEP provides **little added benefit** when:
  - Partner living with HIV is on ART and consistently undetectable
  - There are no outside partners contributing risk for HIV



Heffron 2016

Janet chooses to take PrEP

- Each couple's situation is different
- Janet's reasons for choosing PrEP:
  - Reduce pressure on Joe, uncertainty of his level of adherence
  - Shared responsibility/teamwork approach, reduced anxiety
  - Sense of control and agency for Janet in complex power dynamics of relationship

Molly

- 18yo cisgender woman engaged in sex work, injects heroin with clients when they offer it. Aware of harm reduction strategies, needle exchanges, etc., but doesn't always feel she has the power to negotiate use; "couch surfs" with friends when not spending the night with a client, otherwise unhoused.
  - Last injected and had sex with client of unknown HIV status 2 nights ago
- She recently heard about PrEP from a friend, and wants to start it before she plans to see the same client in 4 days.

What should you offer?

A) Take time to discuss and counsel that she would be a good PrEP candidate, and ensure she is making a fully informed decision. Have her leave with a brochure and follow-up in 2 weeks if still interested.

B) Give Rx to start PrEP today! It's what she wants: let her have it!

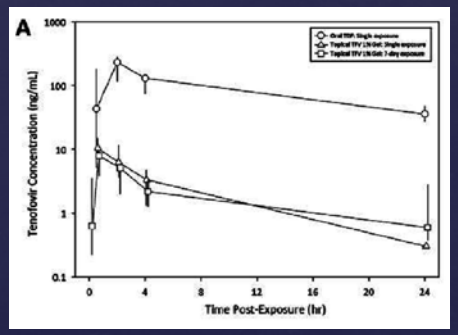
C) Offer HIV testing and STI screen today. Wait until the HIV test comes back negative before starting PrEP.

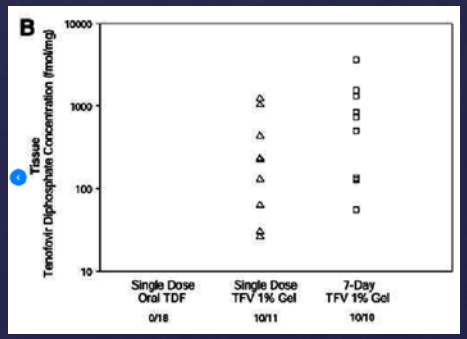
D) Advise against PrEP and counsel about PEP instead.

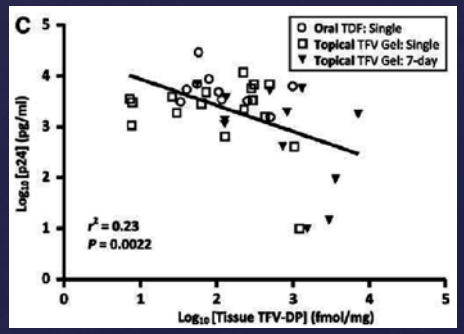
E) Something else (or not sure!)

PrEP for women and PWID

- How long do you need to be on PrEP before it is effective?
  - Rectal exposure: ?
  - Cervicovaginal exposure: ?
  - Blood exposure (for PWID): ?

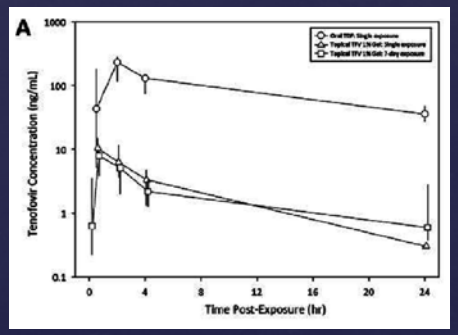


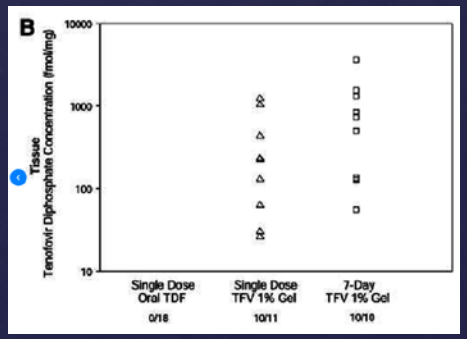


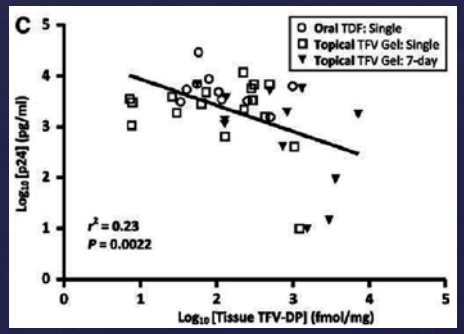


PrEP for women and PWID

- How long do you need to be on PrEP before it is effective?
  - Rectal exposure: 7 days
  - Cervicovaginal exposure: ~20 days
  - Blood exposure (for PWID): ~20 days







Molly chooses PrEP (after PEP)

- Today:
  - Check HIV test, STI screen, PrEP labs
  - Start PEP x 28 days, with plan to transition straight to PrEP afterwards
  - Give Rx for naloxone

- Follow-up:
  - Serial HIV testing negative after starting PEP, all baseline labs came back normal, hep B and hep C negative, STI screen negative
  - Connected to methadone clinic and PrEP dispensed daily with methadone to help facilitate adherence per patient's preference (she does not have a stable place to store meds)

Partner testing, informing guidelines and training students

Lealah Pollock, MD, MS, AAHIVS
University of California San Francisco

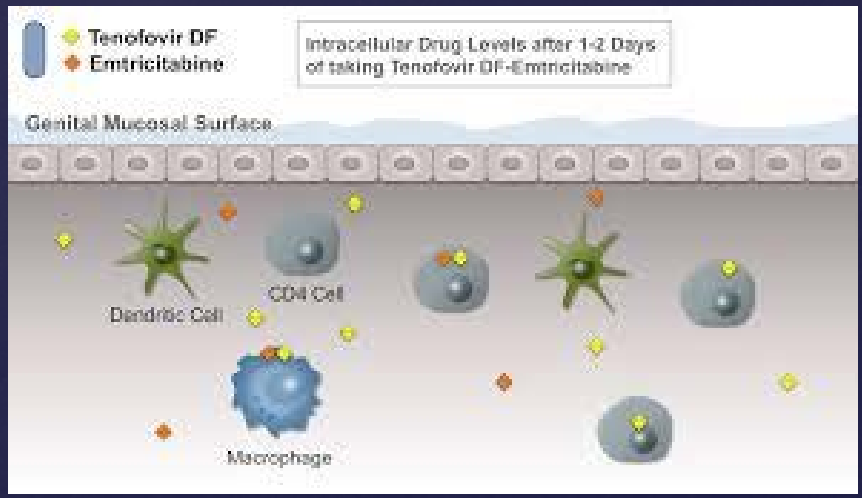
Partner HIV testing in pregnancy

- Do you know the HIV status of all of your sexual partners?
- Are you interested in in learning more about a pill that can prevent HIV transmission?

Increasing comfort with U=U and PrEP, including in pregnancy and pre-conception

Student elective in Women and HIV

National HIV Curriculum



Increasing PrEP access and testing: new frontiers?

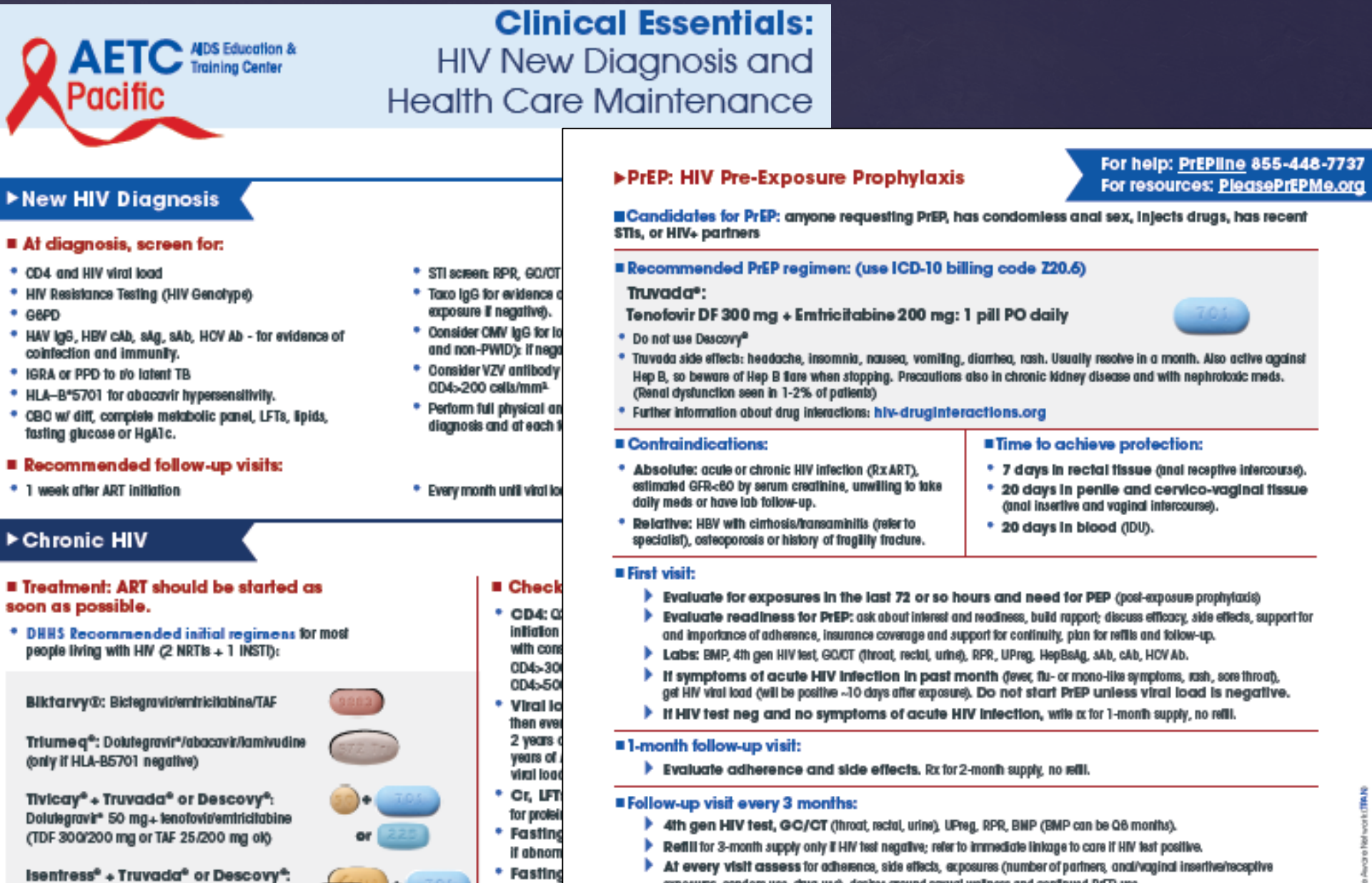
Carolyn Chu, MD, MSc, FAAFP, AAHIVS
University of California San Francisco

CA SB 159: PrEP (and PEP) initiation in pharmacies, no prior authorization

Resources

- For providers:
  - CMAJ – Canadian Guidelines on HIV Pre-exposure prophylaxis and nonoccupational postexposure prophylaxis – www.cmaj.ca/content/190/25/E782
  - British Columbia Guidance for the use of Pre-Exposure Prophylaxis (PrEP) for the prevention of HIV acquisition in British Columbia - http://www.cfenet.ubc.ca/publications/centre-documents/guidance-for-the-use-pre-exposure-prophylaxis-prep-prevention-hiv-acquisition
  - CATIE – PrEP Fact Sheet - https://www.catie.ca/en/fact-sheets/prevention/pre-exposure-prophylaxis-prep

Provider resources: AETC & CCC



AETC AIDS Education & Training Center Pacific

Clinical Essentials: HIV New Diagnosis and Health Care Maintenance

▸New HIV Diagnosis

■ At diagnosis, screen for:

- CD4 and HIV viral load
- HIV Resistance Testing (HIV Genotype)
- G6PD
- HAV IgG, HBV cAb, sAg, sAb, HCV Ab - for evidence of coinfection and immunity.
- IGRA or PPD to r/o latent TB
- HLA–B*5701 for abacavir hypersensitivity.
- CBC w/ diff, complete metabolic panel, LFTs, lipids, fasting glucose or HgA1c.
- STI screen: RPR, GC/CT
- Toxo IgG for evidence o… exposure if negative).
- Consider CMV IgG for lo… and non-PWID); if nega…
- Consider VZV antibody … CD4>200 cells/mm³
- Perform full physical an… diagnosis and at each f…

■ Recommended follow-up visits:

- 1 week after ART initiation
- Every month until viral lo…

▸Chronic HIV

■ Treatment: ART should be started as soon as possible.

- **DHHS Recommended initial regimens** for most people living with HIV (2 NRTIs + 1 INSTI):

Biktarvy®: Bictegravir/emtricitabine/TAF

Triumeq®: Dolutegravir*/abacavir/lamivudine (only if HLA-B5701 negative)

Tivicay® + Truvada® or Descovy®: Dolutegravir* 50 mg + tenofovir/emtricitabine (TDF 300/200 mg or TAF 25/200 mg oral)

Isentress® + Truvada® or Descovy®:

■ Check…

- **CD4:** C… initiation … with cons… CD4>30… CD4>50…
- **Viral lo…** then ever… 2 years … years of … viral load…
- **Cr, LFT…** for protei…
- **Fasting** if abnorm…
- **Fasting**

▸PrEP: HIV Pre-Exposure Prophylaxis

For help: PrEPline 855-448-7737
For resources: PleasePrEPMe.org

■ Candidates for PrEP: anyone requesting PrEP, has condomless anal sex, injects drugs, has recent STIs, or HIV+ partners

■ Recommended PrEP regimen: (use ICD-10 billing code Z20.6)

Truvada®:
Tenofovir DF 300 mg + Emtricitabine 200 mg: 1 pill PO daily

- Do not use Descovy®
- Truvada side effects: headache, insomnia, nausea, vomiting, diarrhea, rash. Usually resolve in a month. Also active against Hep B, so beware of Hep B flare when stopping. Precautions also in chronic kidney disease and with nephrotoxic meds. (Renal dysfunction seen in 1-2% of patients)
- Further information about drug interactions: hiv-druginteractions.org

■ Contraindications:

- **Absolute:** acute or chronic HIV infection (Rx ART), estimated GFR<60 by serum creatinine, unwilling to take daily meds or have lab follow-up.
- **Relative:** HBV with cirrhosis/transaminitis (refer to specialist), osteoporosis or history of fragility fracture.

■ Time to achieve protection:

- **7 days in rectal tissue** (anal receptive intercourse).
- **20 days in penile and cervico-vaginal tissue** (anal insertive and vaginal intercourse).
- **20 days in blood** (IDU).

■ First visit:

- **Evaluate for exposures in the last 72 or so hours and need for PEP** (post-exposure prophylaxis)
- **Evaluate readiness for PrEP:** ask about interest and readiness, build rapport; discuss efficacy, side effects, support for and importance of adherence, insurance coverage and support for continuity, plan for refills and follow-up.
- **Labs:** BMP, 4th gen HIV test, GC/CT (throat, rectal, urine), RPR, UPreg, HepBsAg, sAb, cAb, HCV Ab.
- **If symptoms of acute HIV infection in past month** (fever, flu- or mono-like symptoms, rash, sore throat), get HIV viral load (will be positive ~10 days after exposure). **Do not start PrEP unless viral load is negative.**
- **If HIV test neg and no symptoms of acute HIV infection,** write rx for 1-month supply, no refill.

■ 1-month follow-up visit:

- **Evaluate adherence and side effects.** Rx for 2-month supply, no refill.

■ Follow-up visit every 3 months:

- **4th gen HIV test, GC/CT** (throat, rectal, urine), UPreg, RPR, BMP (BMP can be Q6 months).
- **Refill** for 3-month supply only if HIV test negative; refer to immediate linkage to care if HIV test positive.
- **At every visit assess** for adherence, side effects, exposures (number of partners, anal/vaginal insertive/receptive

Resources

- For patients:
  - CATIE – PrEP Resources and Tools - https://www.catie.ca/prep
  - Women & HIV/AIDS Initiative - http://www.whai.ca/women-and-hiv-in-ontario/prevention

Patient education materials:

HIVEonline.org

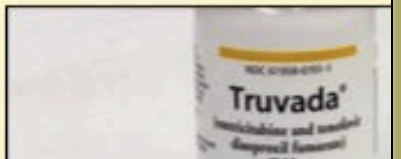
PrEP during Pregnancy and/or While Breastfeeding: A Guide for HIV- Women with Partners who are Living with HIV

hive POWERhealth

"PrEP allows a woman to control her own destiny by not having to rely on her partner's behavior, his ability to take antiretroviral therapy, to have an undetectable viral load, to get tested. These benefits far outweigh the potential risks [of PrEP] for many women." - Erica Aaron, CRNP, Drexel College of Medicine

Preventing HIV During Pregnancy

- Because of changes to the body during pregnancy, there is an increased risk of getting HIV. So preventing HIV during pregnancy is especially important for you and your baby.
- It is important to note that HIV is most easily passed during the weeks following infection, when the viral load is very high. This is why knowing your partners status is very important, particularly when trying to get pregnant, during pregnancy or breas
- Also note that HIV can be passed on ing. Get tested for HIV and STIs often.
- Engaging in ongoing prenatal care is and treated for sexually transmitted infe
- Partners' HIV viral load: If a partner partner(s) in taking their antiretrovirals (An undetectable viral load reduces the r



Is PrEP right for me? A Guide for Women

hive POWERhealth

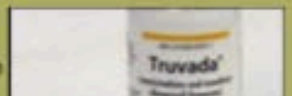
1. **What is PrEP?**
   PrEP stands for "Pre-Exposure Prophylaxis." PrEP is an HIV prevention method where a person at risk of getting HIV takes a pill daily to lower their risk. . The pill currently approved is called "Truvada." Truvada is one pill that is taken one time per day, every day. It combines two drugs (tenofovir and emtricitabine) in a single pill.

2. **How does PrEP work?**
   PrEP works because the drugs in the pill help prevent HIV from multiplying. If you are exposed to HIV, it is less likely it will be able to multiply in your cells, so there is a lower chance that you will get HIV. It is important to take Truvada as prescribed. In research studies, people who took the pill as prescribe decreased their chance of getting HIV by over 90%. Truvada will only work if it is taken correctly. **If you decide to take PrEP, you must take one pill, once a day, every day for it to work.**

3. **What else can I do to decrease my chance of getting HIV?**
   PrEP is one of many ways to decrease your chance of getting HIV. If your partner has HIV or you are unsure, condoms are strongly recommended. Condoms decrease your chance of getting HIV and a lot of other sexually transmitted diseases in addition to preventing pregnancy. No other form of birth control can decrease your chance of getting of HIV. A sexually transmitted infection (STI) increases the chance of both passing on and getting HIV. You and your partner/s should be screened and treated for STIs.

   If you know your partner has HIV, your risk of getting HIV is lower if they are taking HIV medication correctly and have an undetectable viral load. When a person living with HIV takes HIV medication as prescribed it decreases the amount of virus in their body, making HIV harder to pass along through sex. Some women help their partner take their HIV medications correctly and follow up with their medical provider. Also, make sure your medical provider and your partner's HIV provider know that you are HIV negative because this could affect the medications you both are prescribed.

4. **What are the risks of taking Truvada?**
   If you decide to take Truvada, you may experience some side effects. 10-20% of people experience nausea when they start. Other less common side effects include decreased bone mineral density (weaker bones) and liver or kidney damage. People who get HIV even



Thinking about having a baby?

A Resource for HIV– Women with Male Partners who are Living with HIV

hive POWERhealth

Advances in HIV treatment and prevention make starting a family a safe, exciting option for many women who have partners living with HIV. There are a **number of options** available for serodifferent couples (when one partner is HIV+ and the other is HIV-) who want to have a family.

...sions about how to have a family.

...for having a family?

...tegies that have been proven to decrease your ...e allowing you to have a child together.

...nique story and will weigh the pros and cons of ...what is best for their family. **If you remain HIV- ...nancy and while breastfeeding, there is zero ... HIV.**

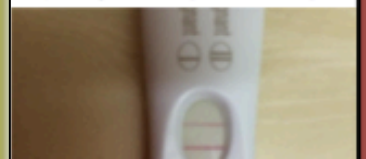
...ape possible. Before trying to get pregnant, talk ...r health.

...**y to pass HIV to you.** Having an undetectable ...t is still present) dramatically reduces the risk of ...**ciated with decreased fertility**, making it more

...)

... **STIs** before trying to get pregnant. Many STIs ...actions can increase the chances of you getting ...ing pregnancy and delivery.

...s overall health, nutrition and exercise. If you ...hma, talk to your medical provider about improv-



Thank you…

- Julie Graves
- Insung Min
- Gordon Arbess
- Our mentors, colleagues, and trainees
- Clinical and research communities advancing this work

- **Our patients and their families**