PrEP me, Please!

Understanding PrEP's role in women's health & safer conception

September 23 2014

Speakers

Shannon Weber, MSW, Director, Perinatal HIV Hotline, Bay Area Perinatal AIDS Center

Caroline Watson, volunteer outreach for BAPAC and PRO Men

Erika Aaron, MSN, CRNP Assistant Professor, Drexel University College of Medicine, Division of Infectious Diseases and HIV Medicine

Moderator: Dázon Dixon Diallo, MPH, Founder and President, SisterLove, Inc.

BAPAC Bay Area Perinatal AIDS CENTER

AVAC Global Advocacy for HIV Prevention

thewellproject

HIV·PJA HIV PREVENTION JUSTICE ALLIANCE

SisterLove, Inc.

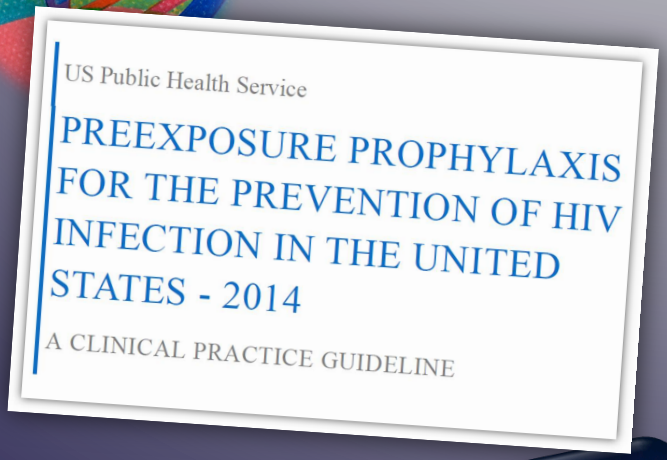
CLINICIAN CONSULTATION CENTER

The Purpose of the Working Group

- National Community representing women's voices
- Inquiry, Advocacy & Accountability
- Ensure women's safety, efficacy and accessibility in PrEP research & rollout
- Educate and engage community in PrEP discourse and information dissemination
- Mobilize a diversity of women's HIV and health advocates, researchers and policy makers in PrEP and other BmPO for women

What's Next?

- Ongoing communication w/ Federal & Industry Partners
- National Webinars on US Women & PrEP & other BmPO
- WG Face2Face Meeting – Seattle, February 2015
- National & Int'l Engagement (USCA, CROI, AIDS2014, NIH Networks, IAPAC, R4P, etc.)
- Articles, Workshops, Satellites, Orals & Posters



Get Involved –

- Next webinar: Risky Women: **Disrupting Simple Notions of Women's HIV Risk**
  - **Early November 2014**

- **Join the US Women & PrEP Working Group**
  - **Email: *annaforbes@earthlink.net***
  - **Website: www.prepwatch.org/uswomen**

CLINICIAN CONSULTATION CENTER

National rapid response for HIV management and bloodborne pathogen exposures.

Prep me, please: Understanding PrEP's role in women's health & safer conception

Shannon Weber
sweber@nccc.ucsf.edu
9.23.2014


You
are
here.
LoveYou2

Disco Survey: HIV- ♀ in a relationship with an HIV+ ♂ & desire children

IRB approval to recruit from other sites; study ongoing launched Jan 2010, 40% before PrEP approval July 2012

- 123 surveys started, 93 completed
  - 90% want children with their HIV+ male partner
  - 25% have tried to get pregnant with their HIV+ male partner
  - 67% had vaginal sex without condom with HIV+ partner
- Condom use: 27% always, 42% half time, 31% never

- 42% have seen a provider to discuss ways to get pregnant

  45% primary care, 80% HIV specialist, 35% OBGYN, 30% fertility specialist

Most women are willing to use various methods to prevent transmission

53% are willing to use PrEP, 51% Timed unprotected sex, 84% ovulation prediction kit, 47% PEP, 62% sperm washing vaginal insemination, 22% IVF, 44% adoption, 9% insemination with donated sperm

Still enrolling: http://hiv.ucsf.edu/care/perinatal/pro_men.html

BAPAC
Bay Area Perinatal AIDS CENTER

Early Experiences Implementing Pre-exposure Prophylaxis (PrEP) for HIV Prevention in San Francisco, PLOS March 2014, Liu et al.

ty medical care to over 185,000 members in San Francisco. More than 2,500 HIV-positive adults receive care through Kaiser's HIV Care and Prevention Program. Health plan members have a broad

PAC) is a program of the University of California San Francisco, providing comprehensive preconception management and prenatal care to HIV-positive women and HIV-negative women with

selves or their babies, and cessation of risk behavior.

While only a few women have initiated PrEP at BAPAC thus far, data suggest HIV-serodifferent couples in the US want

Table 2. PrEP uptake and follow-up in three PrEP delivery programs in San Francisco.

PrEP Uptake Cascade and Follow-up	Date Began Offering PrEP		
	SFCC	Kaiser	BAPAC
	September 2012	April 2012	January 2010
n referred/assessed for eligibility	571	123	15
n ineligible[a]	40	5	4
n potentially eligible	531	118	11
n initiated PrEP	261	70	7
n person-months of follow-up	1,585	370	24
Average duration (months) of follow-up (range)	6.0 (0.3–11.7)	5.3 (0.5–16)	3.4 (1–7)

Data through September 2013.
[a]Includes medical and behavioral eligibility and program eligibility based on health insurance coverage.
doi:10.1371/journal.pmed.1001613.t002

Perinatal HIV Guidelines: March 2014

Reproductive Options for HIV-Concordant and Serodiscordant Couples

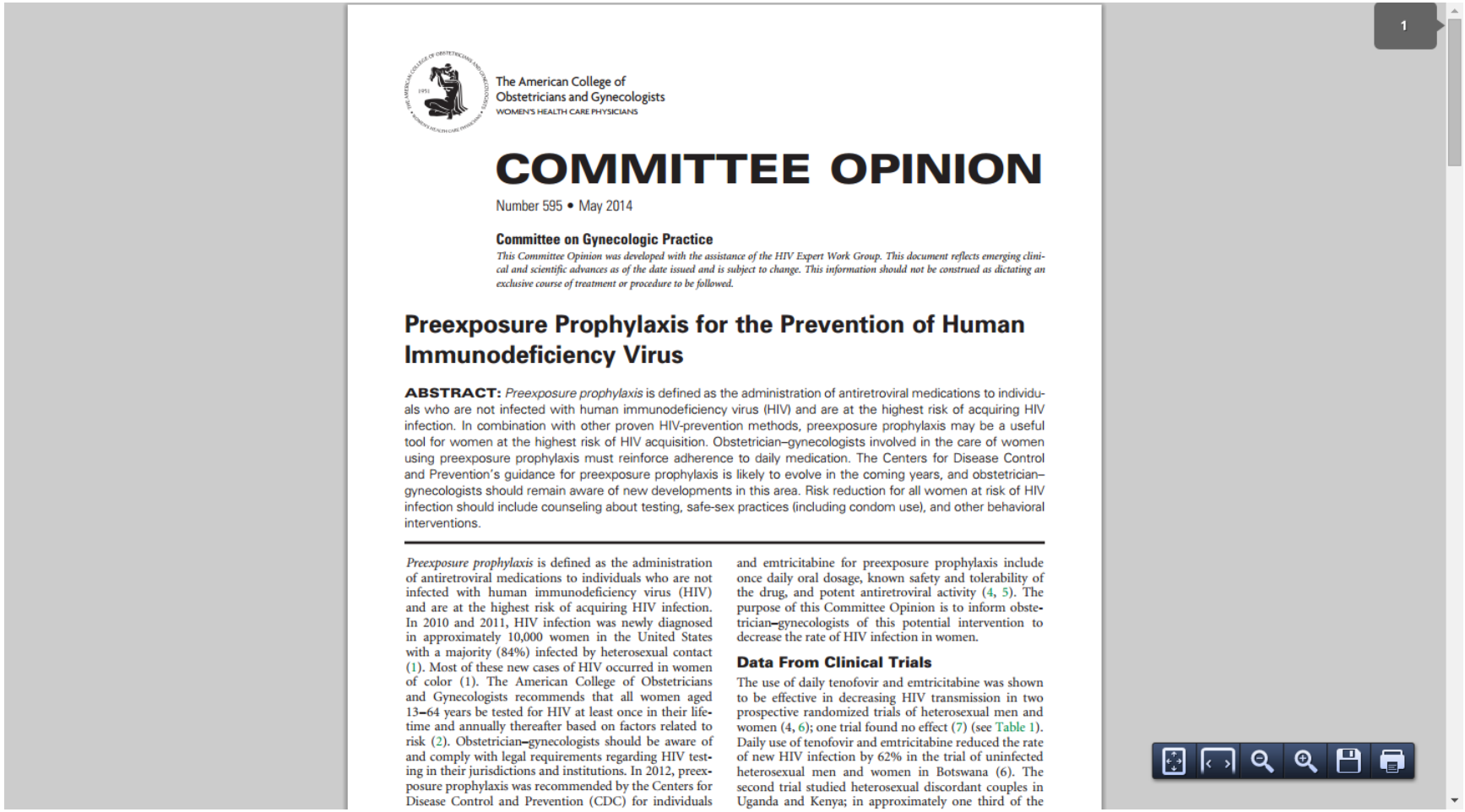
- The Panel recommends that HIV-infected partner(s) in HIV-seroconcordant and HIV-serodiscordant couples planning pregnancy attain maximum viral suppression before attempting conception **(AIII).**
- The Panel notes that periconception administration of ARV pre-exposure prophylaxis (PrEP) for HIV-uninfected partners may offer an additional tool to reduce the risk of sexual transmission **(CIII).** A new table has been added reviewing clinical trials of PrEP (see Table 4: Clinical Trials of Pre-Exposure Prophylaxis).
- The Panel also notes that no studies exist about the utility of PrEP in an uninfected individual whose infected partner is receiving combination antiretroviral therapy (cART) and has a suppressed viral load.
- Pregnancy is not a contraindication to PrEP.

www.aidsinfo.nih.gov

Washington Post: April 2014

Join the conversation on Twitter #HIVLoveWins

ACOG Committee Opinion: April 2014



The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

Number 595 • May 2014

Committee on Gynecologic Practice

This Committee Opinion was developed with the assistance of the HIV Expert Work Group. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Preexposure Prophylaxis for the Prevention of Human Immunodeficiency Virus

ABSTRACT: *Preexposure prophylaxis* is defined as the administration of antiretroviral medications to individuals who are not infected with human immunodeficiency virus (HIV) and are at the highest risk of acquiring HIV infection. In combination with other proven HIV-prevention methods, preexposure prophylaxis may be a useful tool for women at the highest risk of HIV acquisition. Obstetrician–gynecologists involved in the care of women using preexposure prophylaxis must reinforce adherence to daily medication. The Centers for Disease Control and Prevention's guidance for preexposure prophylaxis is likely to evolve in the coming years, and obstetrician–gynecologists should remain aware of new developments in this area. Risk reduction for all women at risk of HIV infection should include counseling about testing, safe-sex practices (including condom use), and other behavioral interventions.

Preexposure prophylaxis is defined as the administration of antiretroviral medications to individuals who are not infected with human immunodeficiency virus (HIV) and are at the highest risk of acquiring HIV infection. In 2010 and 2011, HIV infection was newly diagnosed in approximately 10,000 women in the United States with a majority (84%) infected by heterosexual contact (1). Most of these new cases of HIV occurred in women of color (1). The American College of Obstetricians and Gynecologists recommends that all women aged 13–64 years be tested for HIV at least once in their lifetime and annually thereafter based on factors related to risk (2). Obstetrician–gynecologists should be aware of and comply with legal requirements regarding HIV testing in their jurisdictions and institutions. In 2012, preexposure prophylaxis was recommended by the Centers for Disease Control and Prevention (CDC) for individuals and emtricitabine for preexposure prophylaxis include once daily oral dosage, known safety and tolerability of the drug, and potent antiretroviral activity (4, 5). The purpose of this Committee Opinion is to inform obstetrician–gynecologists of this potential intervention to decrease the rate of HIV infection in women.

Data From Clinical Trials

The use of daily tenofovir and emtricitabine was shown to be effective in decreasing HIV transmission in two prospective randomized trials of heterosexual men and women (4, 6); one trial found no effect (7) (see Table 1). Daily use of tenofovir and emtricitabine reduced the rate of new HIV infection by 62% in the trial of uninfected heterosexual men and women in Botswana (6). The second trial studied heterosexual discordant couples in Uganda and Kenya; in approximately one third of the

http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Preexposure-Prophylaxis-for-the-Prevention-of-Human-Immunodeficiency-Virus

ACOG Committee Opinion: Who?

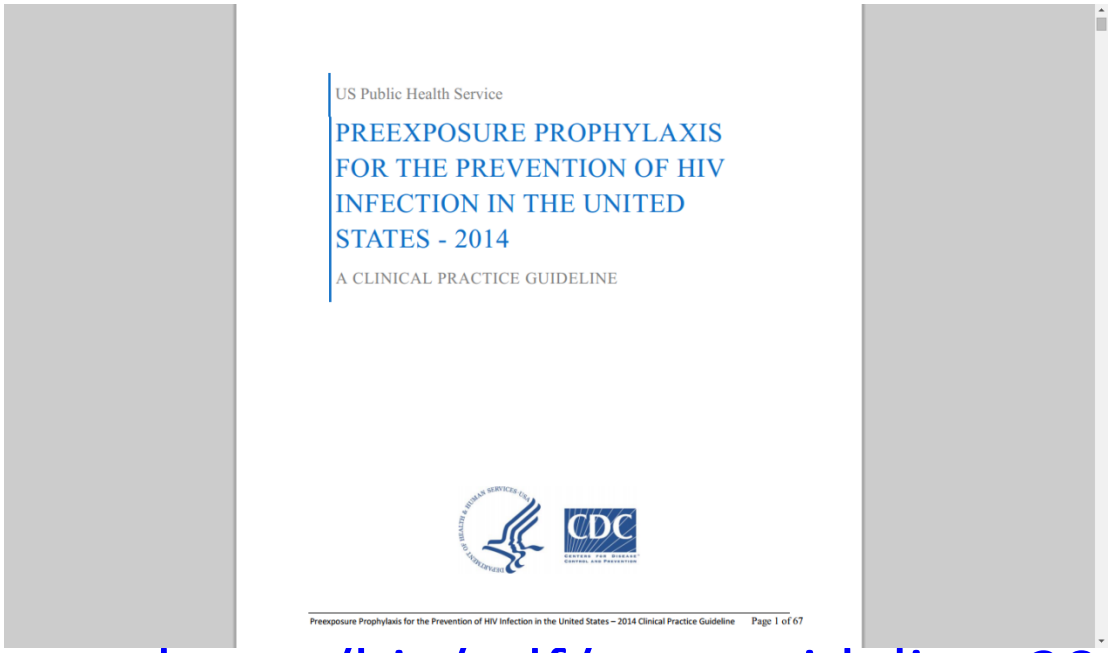
- Women in serodifferent relationships
- Sexually active women within a high HIV-prevalence area or social network and one of the following:
  - inconsistent or no condom use
  - diagnosis of sexually transmitted infections
  - exchange of sex for commodities (such as money, shelter, food, or drugs)
  - use of intravenous drugs or alcohol dependence or both;
  - incarceration
  - partner(s) of unknown HIV status with any of the factors previously listed

ACOG Committee Opinion

- The drug combination of tenofovir and emtricitabine is commonly used during pregnancy and has a reassuring safety profile.

- Human immunodeficiency virus infection is one of the few contraindications to breastfeeding, and clinicians should be vigilant for new HIV seroconversion in lactating women at risk of new HIV infection.

CDC Clinical Practice Guideline & Provider Supplement: May 2014



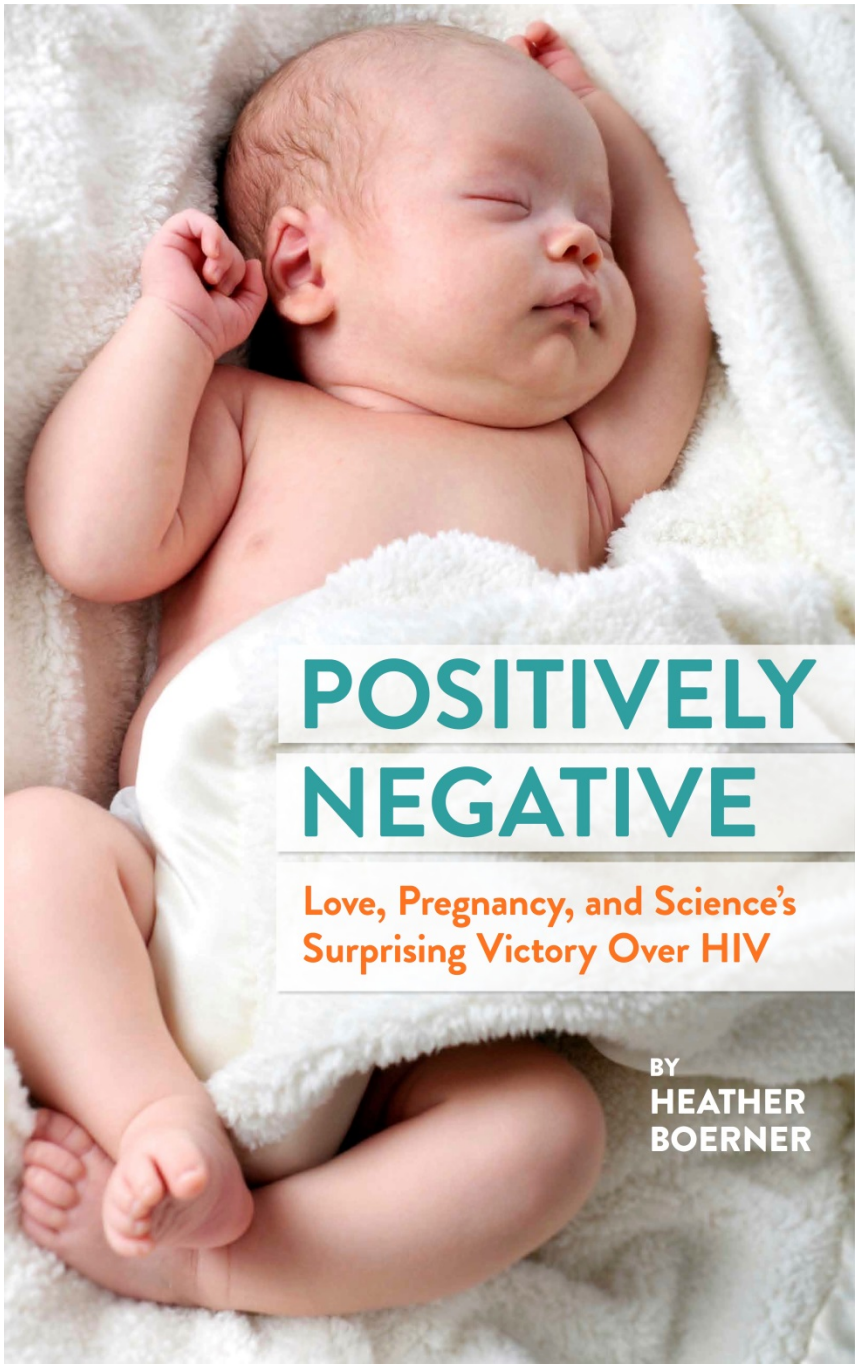
http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf

http://www.cdc.gov/hiv/pdf/prepprovidersupplement2014.pdf

PrEP: Time to reach protection

These data suggest that maximum intracellular concentrations of TFV-DP are reached in blood after approximately 20 days of daily oral dosing, in rectal tissue at approximately 7 days, and in cervicovaginal tissues at 20 days

- http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf



"Follow the Hartmanns and the Morgans from the blush of first love to the squalls of their newborn daughters. Then, join the pre-eminent scientists in the field as they uncover the surprising new science of HIV, one that means that unprotected sex for some HIV-affected couples isn't crazy.

It's natural."

https://positively-negative.squarespace.com

Mugo, et al for Partners PrEP Study Team

Pregnancy Incidence and Outcomes Among Women Receiving Preexposure Prophylaxis for HIV Prevention: A Randomized Clinical Trial

JAMA, July 2014

- "Among HIV-serodiscordant heterosexual African couples, differences in pregnancy incidence, birth outcomes, and infant growth **were not statistically different for women receiving PrEP with TDF alone or combination FTC+TDF compared with placebo at conception**."

NY Dept of Health – July 2014

- PrEP included as part of the 3-pronged approach to ending the AIDS epidemic in NY

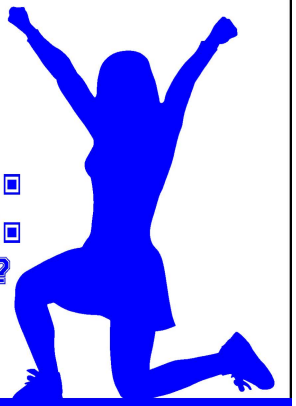
- Dear Colleague letter supporting widespread PrEP implementation included HIV- partners in serodiscordant relationships and “high risk” heterosexual women.

www.health.ny.gov

ACT UP New York, Gay Men's Health Crisis &
Mount Sinai Hospital present

PrEP Rally 4:

WHAT DOES PREP MEAN FOR WOMEN?



A community discussion on HIV, pre-exposure prophylaxis (PrEP) and women*

TUESDAY, OCTOBER 14, 2014 6-7:30 PM

Roosevelt Hospital — 1000 10th Avenue, Conference Room B (2nd floor)
(between 58th and 59th Streets)

Guest panelists:

LYNNETTE FORD, MSW, GMHC
JASMINE, Woman currently using PrEP
JULIE LYNN, Woman currently using PrEP
POPPY, Woman who was on PrEP when trying to get pregnant
KIMBERLEIGH J. SMITH, Harlem United Community AIDS Center
SHOBHA SWAMINATHAN, MD, Division of Infectious Diseases, Department of Medicine
Rutgers, The State University Of New Jersey New Jersey Medical School

Guest moderator:

TERRI L. WILDER, MSW, Mt. Sinai Institute for Advanced Medicine & ACT UP/NY Women's Caucus

The discussion is free and all are welcome. Light refreshments will be provided.
For more information, email krishnas@gmhc.org or call (212) 367-1016.

*We invite women in all our diversity, including gender identity and sexual expression, to attend.

ACT UP AIDS Coalition to Unleash Power

GMHC FIGHT AIDS. LOVE LIFE. gmhc.org

Mount Sinai Institute for Advanced Medicine

Co-endorsers

AVAC Global Advocacy for HIV Prevention · HARLEM UNITED · NYC Health · Planned Parenthood Care. No matter what. Planned Parenthood of New York City · THE BODY The Complete HIV/AIDS Resource · TAG Treatment Action Grou

Thomas Street Clinic, Houston, TX

- Launched a PrEP clinic.
- All individuals tested for HIV are offered a referral to the PrEP clinic.
- All women in the PrEP clinic offered a visit with an ob/gyn for contraception/safer conception counseling.
- All services in one building.
- Half of those prescribed PrEP are women.

PrEPception Study

- Enrolling now
- Acceptability and feasibility, continuous dosing, observational PrEPception study

- Meg Sullivan, Boston University, Lead PI
- Erika Aaron, Drexel University College of Medicine
- Jean Anderson, Johns Hopkins University

PrEPception

Expanding Conception Options for Serodiscordant Couples

- Observational study of the acceptability and feasibility of PrEP for conception in HIV serodiscordant couples
- Asssessment of adherence and behavioral patterns while taking daily PrEP during attempts to conceive
- Evaluation of potential challenges to generalizability of PrEP for conception
- PrEP follow up can be by local health care provider or in BMC ID clinic

Inclusion Criteria

Male Subject

- HIV-positive in relationship with HIV-negative female
- Partner has chosen to use PrEP for conception after completing counseling with health care provider

Female Subject

- Confirmed HIV-negative in relationship with HIV-positive male
- Between the ages of 18 to 40 years
- Has chosen to use PrEP for conception after completing counseling with health care provider

Please contact:
For patient appointments:
Desiree Jones-Eaves RN at 617-414-5923

For questions regarding this study:
Meg Sullivan, MD at mea.sullivan@bmc.org
Ashley Leech at ashleyl@bu.edu

San Francisco PrEP Hearing

Maria

- Referred to BAPAC by SF City Clinic, when she was contacted for partner services for syphilis
- Her male partner was also identified as HIV+.
- Couple had not been using birth control and had talked about getting pregnant.
- At BAPAC, Maria initiated PrEP and was seen frequently for a variety of complaints.
- Maria discloses to her BAPAC provider violence and control in her relationship. Also says she does not want to be pregnant. Maria says PrEP is the one thing she feels like she has control over in her life.
- Maria initiates contraception and continues PrEP. Her partner begins care but continues to be viremic.

Carolina

- 33 year old spanish speaking woman and her an HIV+ husband want to conceive, currently consistent condom users.
- Her community clinic provider says it is impossible to get pregnant without sperm washing +IUI or IVF, cost prohibitive for this couple.
- Couple referred to BAPAC for preconception visit.
- Initial focus on husband's detectable virus. Once he is undetectable, Carolina starts PrEP, they have timed intercourse and have a baby.
- http://myprepexperience.blogspot.com/

Alexa

- 35 year old woman married 8 years to an HIV+ man, wants a baby. He has been undetectable for 5 years.
- Alexa has read relevant journal articles, spoken with fertility clinics. Due to cost and location, sperm washing + IUI/IVF not feasible.
- The local perinatal HIV specialist will not offer PrEP, refers her to REI who does not provide services for affected couples.
- She asks her ob/gyn & family practice doctor for PrEP. Both decline.
- Alexa seeks services from the clinic offering PrEP to MSM. With consultation from the Perinatal HIV Hotline, ID provider prescribes Alexa PrEP.
- For 2 months the couple tries timed intercourse, do not get pregnant.
- With a job change and new insurance his monthly co-pay is now $1600, hers $900. The couple continues condom use and stops PrEP.

Tremendous Momentum

- Clinical guidelines
- Political will
- Patient desire
- Public acceptance

Tremendous Opportunity

- Provider education.
- Medical care and medication access.
- Integrated approach to HIV prevention, contraception, pregnancy planning.
  - Preconception care movement
  - Broader definition of family planning visit
- Support for women to share their stories.

Integrated reproductive & sexual health care:

- Every HIV-exposed pregnancy will be planned and well-timed
- There will be no HIV transmission to infants or to uninfected partners
- The health of all HIV-affected parents and infants will be optimized

Paradigm Shift

PrEP as a woman-controlled HIV prevention method, does not require disclosure to partners.

We are building out infrastructure and systems to support women's access to an expanding prevention portfolio.

Prevention/Wellness Portfolio

- STI and HIV prevention
- Pregnancy testing
- Pregnancy planning or contraception
- Domestic violence, including emotional abuse
- Prior trauma
- Depression
- Alcohol and drug use
- Stable housing
- Adherence
- Disclosure

We have the science to end sexual HIV transmission.

What remains is implementation & scale up of effective interventions.

This means you CAN make a difference.

Caroline: One Woman's Story

San Francisco Chronicle

SFGATE.COM | Thursday, February 7, 2013 | PRINTED ON RECYCLED PAPER | $1.00 ★★★★★

TOP OF THE NEWS

World/Nation

» **South Pacific:** A tsunami smashes into the Solomon Islands, killing six people. A3

» **Tunisia turmoil:** The assassination of a leading opposition figure triggers protests across the nation. A4

» **Secretary of the interior:** President Obama picks REI executive Sally Jewell to head the department. A7

» **Boy Scouts:** The iconic youth organization delays a vote on whether to ease its policy of excluding gays. A8

Lance Iversen / The Chronicle

Sporting Green

» **AT&T Pro-Am:** Scott Ostler follows Wayne Gretzky, above, around Pebble Beach. B1

» **Raiders:** The latest plan to avoid TV blackouts: tarp off 11,000 seats. B1

Business Report

» **Texas hold 'em:** Luring California businesses away isn't proving easy. C1

» **Hard math:** Stanford start-up puts numbers to work. C1

Bay Area

» **Distributing cops:** Oakland politicians say fewer officers are needed at art event where people were shot. D1

» **Cable car accident:** Seven are injured, one seriously, when a cable car on Nob Hill comes to a sudden stop. D1

Lance Iversen / The Chronicle

Datebook

» **Rural restoration:** Port Costa's Burlington Hotel, left, is being revived as a destination for the adventurous. E1

» **Catching Up:** S.F. lawyer Dennis Riordan has an appealing role in a film. E1

96 Hours

» **Expanded coverage:** New section includes Ovation features.

» **'The Fourth Messenger':** Visions of a female — and singing — Buddha at Berkeley's Ashby Stage. **Page 17**

MEDICINE

Photos by Lacy Atkins / The Chronicle

Caroline and Deon stand in a delivery room in the perinatal unit at San Francisco General Hospital. They're getting help from a program that caters to straight men who are HIV-positive and want to have a family.

HIV fatherhood — safely

S.F. clinic's process ends risk for mom and baby

By Erin Allday

Deon was in jail when he tested positive for HIV.

He knew that his long-term girlfriend was HIV-positive, and they hadn't taken many precautions to keep him safe. So he wasn't surprised by the diagnosis, but the news was still crushing.

"I was devastated," said Deon, 32, a San Francisco resident who asked that his last name not be used. "I didn't know if I was going to live. I didn't know if my social life was basically over. I didn't know how I was ever going to have a family."

Nearly five years later, Deon has a new girl-

HIV continues on A14

Dr. Deborah Cohan uses an ultrasound machine so that Caroline and Deon can hear their baby's heartbeat.

BAY BRIDGE

Footsteps to sound opening of east span

By Michael Cabanatuan

The long, arduous and expensive task of building the new east span of the Bay Bridge will end with one final bridge closure that includes plans for a bash featuring a public bridge walk, 10-kilometer and half-marathon runs, a bike ride and fireworks launched from both San Francisco and Oakland.

"As opposed to opening it to cars, we're going to open it to people," said Randy Rentschler, a spokesman for the Metropolitan Transportation Commission, which also serves as the toll authority.

The $6.3 billion new span will open to cars, trucks and motorcycles on Sept. 3, the day after Labor Day, bridge officials said Wednesday. But people will get to walk, run and bike across the bridge, and possibly hear a

Bay Bridge continues on A11

POSTAL SERVICE

Saturday mail cut — a fight expected

Ending 150-year tradition defies Congress' mandate

By John Wildermuth and Ellen Huet

In a desperate effort to shore up its financial future, the U.S. Postal Service plans to end more than 150 years of Saturday mail delivery in August, but it might face a battle in Congress before that happens.

The plan, announced by Postmaster General Patrick Donahoe on Wednesday, will eliminate all mail delivery to homes and businesses on Saturdays, beginning the week of Aug. 5, but continue six-day-a-week package delivery. Post offices would continue to stay open on Saturdays, though there would be no pickups at mailboxes.

The cutbacks, which the Postal Service has wanted for years, are expected to save about $2 billion annually and allow the elimination of up to 25,000 postal worker jobs through attrition.

"Our financial condition is urgent," Donahoe said at the news conference. "This is too big of a cost savings for us to ignore."

Mail continues on A14

PUBLIC EDUCATION

Schools illegally spent cash meant to feed poor kids

By Wyatt Buchanan

SACRAMENTO — School districts across California have illegally misused nearly $170 million in funding meant for free or reduced-price student lunches, but the documented problems span only a few years and no one knows how widespread the practice may be, according to a legislative oversight report released Wednesday.

One state official cited in the report described the situation as "literally taking food out of the mouths of kids," and the report found that the misspent money contributed to eligible students not getting meals to which they were entitled.

While the intentional misuse or misappropriation of the money is a criminal act, no one has been charged with a crime, and the funds were spent on other school needs and didn't go to

Lunches continues on A11

Only in The Chronicle

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Index

Weather

Showers, maybe thunderstorms. Highs: 50-58 Lows: 31-45 **B10**

CLINICIAN CONSULTATION CENTER
National rapid response for HIV management and bloodborne pathogen exposures.

sweber@nccc.ucsf.edu

Thank you!

Clinical implementation of PrEP for Women

Erika Aaron, MSN, CRNP

Drexel University College of Medicine

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eaaron@drexelmed.edu

Sept 23, 2014

PrEP prescription practices in US

- Between Jan 2011 – March 2013 pharmacy data from aprox 55% US pharmacies assessed for PrEP prescriptions.
- Prescribers; general practitioners and internal medicine practitioners, NP s prescribed 1/10 scripts
- Total of 1,774 subjects were identified as starting TVD for PrEP.
  - **47.7% were women (OR 1.8 times)**
  - **Median age 37, 14% <25 yrs old (OR 1.4 times)**
  - **Majority in Southern States (OR 1.4 times)**

Mera RM et al.ICAAC 2013

Heterosexual risk of HIV transmission per sexual act Supervie AIDS 2014

- The study combined data from studies to investigate the per act risk of HIV transmission through unprotected sex with:
  - An HIV infected individual
  - On cART for > 6 months (whether or not virally suppressed)
  - In comprehensive HIV care
- The per act risk of transmission is <13:100,000

A modeling approach of the benefits of PrEP during attempted conception — Hefron et al CROI 2013

- Primary outcome of interest was an HIV-uninfected woman remaining negative and successfully conceiving and delivering while on PrEP
- Based upon inputs to the model, PrEP provided little added benefit when all were true:
  - The HIV-infected male partner was on ART
  - Unprotected intercourse was limited to the period of ovulation
  - STIs were diagnosed and treated in both partners
- There was little absolute difference between any of the 4 strategies
- However, ART treatment of the HIV+ male partner drives the differences between strategies

Pregnancy Incidence and Outcomes Among Women Receiving PrEP Mugo JAMA 2014

- Randomized trial; 1785 HIV-serodiscordant heterosexual couples (the Partners PrEP Study).
  - Female partner was HIV uninfected
  - July 2008 – June 2013
  - Kenya and Uganda
  - Daily TDF (n = 598), FTC+TDF (n = 566), or placebo(n = 621)
- Differences in pregnancy incidence, birth outcomes, and infant growth were not statistically different for women receiving PrEP (TDF or FTC+TDF) compared with placebo at conception.
- Given that PrEP was discontinued when pregnancy detected and that CIs for the birth outcomes were wide, definitive statements about the safety of PrEP in the periconception period cannot be made based on this study.
- Although more studies are needed to determine the absolute safety of taking PrEP while attempting pregnancy and during the prenatal period, a foundation is being built pointing in the direction of safety

Not all persons with HIV are ready to start ART

- 772 serodiscordant couples in Partners PrEP study
- "Would you be willing to start ART if it would lower your chance of giving HIV to your partner"
  - HIV+ Men: 58% - Yes 42% - No
  - HIV+ Women: 70% Yes 30% No Heffron JAIDS 2012
- The HIV neg partner can not always depend on the fact that their partner is on ART with an undetectable VL and no resistance
- To rely on her male partner to protect her from acquiring HIV disempowers women, undermines her efforts to control her own risk, and may put her at risk of violence.
- Prep is yet another CHOICE, another tool for women to use to protect her own destiny, to have control over her risk of acquiring HIV without depending on her partner's behavior

PrEP (Like ART) Works When Taken

Study	HIV Protection Efficacy in Randomized Comparison,%	HIV Protection Efficacy when drug was detected in blood,%
Partners PrEP[1]	75	90
TDF2[2]	62	85
iPrEx[3]	44	92
Thai IDU[4]	49	73
FEM-PrEP[5] and VOICE[6]	No HIV protection	

2 additional trials of PrEP (FEM-PrEP and VOICE), both conducted among high-risk African women, did not demonstrate protection against HIV; in both trials, PrEP adherence was very low (< 30%)

1. Baeten JM, et al. N Engl J Med. 2012;367:399-410. 2. Thigpen MC, et al. N Engl J Med. 2012;367:423-434. 3. Grant RM, et al. N Engl J Med. 2010;363:2587-2599. 4. Choopanya K, et al. Lancet. 2013;381: 2083-2090. 5. Van Damme L, et al. N Engl J Med. 2012;367:411-422. 6. Marrazzo J, et al. CROI 2013. Abstract 26LB.

PrEP Safety

- Rates of death, serious adverse events, and laboratory abnormalities (including renal dysfunction) low and not significantly different between those receiving PrEP and those receiving placebo
- PrEP was well tolerated
  - Adverse events occurred in minority of subjects
  - GI adverse events (eg, nausea) more common in those receiving PrEP than placebo
    - Occurred in < 10% and primarily during the first month only (PrEP "start up" symptoms)
- PrEP associated with a small change (~ 1%) in bone mineral density but without increased risk of fracture

What is the risk of resistant virus?

Table 6: Evidence Summary— HIV Resistance Findings (TDF or FTC Drug Resistant Virus Detected)

Study	Outcome Analyses	
	Agent	Control
iPrEx	2 resistant viruses among 2 persons infected at baseline 0 resistant viruses among 36 persons infected after baseline	1 resistant virus among 8 persons infected at baseline 0 resistant viruses among 64 persons infected after baseline
US MSM Safety Trial	0 resistant viruses among 3 persons infected after baseline (in delayed arm before starting drug)	1 resistant virus among 1 person infected at baseline 0 resistant viruses among 3 persons infected after baseline
Partners PrEP	2 resistant viruses among 5 persons infected at baseline and randomly assigned to TDF 1 resistant virus among 3 persons infected at baseline and randomly assigned to TDF/FTC 0 resistant viruses among 27 persons infected after baseline	0 resistant viruses among 6 persons infected at baseline 0 resistant viruses among 51 persons infected after baseline
TDF2	1 resistant virus in 1 person infected at baseline 0 resistant viruses among 9 persons infected after baseline	1 resistant virus in 1 person infected at baseline (very low frequency and transient detection) 0 resistant viruses among 24 persons infected after baseline
FEM-PrEP	4 resistant viruses among 33 persons infected after baseline	1 resistant virus in 35 persons infected after baseline
West African Trial	0 resistant viruses among 2 persons infected while on TDF	NR
VOICE	NR	—
BTS	0 resistant viruses among 49 persons infected after baseline	

NR, not reported.

US Public Health Service

Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014

A Clinical Practice Guideline

May 2014

Table 1: Summary of Guidance for PrEP Use

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
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Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	Follow-up visits at least every 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment At 3 months and every 6 months thereafter, assess renal function Every 6 months, test for bacterial STIs		
	Do oral/rectal STI testing	Assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services

STI: sexually transmitted infection

Periconception, during Pregnancy and Breastfeeding

- Women without HIV who have sex partners with HIV during conception attempts
- Pregnancy is associated with an increased risk of HIV acquisition

  Mugo, Heffron et al *AIDS* 2011
- PrEP offers an additional tool to reduce risk of transmission during periconception, pregnancy and breastfeeding
  - FDA labeling and perinatal ART treatment guidelines permit this use
- PrEP trials with women medication was discontinued for those who became pregnant – no safety for exposed fetuses assessed
  - A single small study of periconception use of TDF in 46 uninfected women found no ill effects on pregnancy. Vernazza *AIDS* 2011

Periconception, during Pregnancy and Breastfeeding

- During conception attempts, pregnancy and breastfeeding HIV + partner should be on ART with undetectable VL
- Infants exposed to PrEP during lactation has not be well studied. However, data from infants exposed to TDF/FTC through breast milk suggest limited drug exposure.

Safety data from Pregnancy Registry

- Pregnancy Registry provides no evidence of adverse effects among fetuses exposed to TDF or FTC

  Antiretroviral Pregnancy Registry Dec 2013

- There have been no differences in the rates of birth defects for first-trimester compared with either later gestational exposures or with rates reported in the general population.

  daCosta, Machado et al. 2011;
  Watts, Huang et al. 2011;
  Knapp, Brogly et al. 2012;
  Floridia, Mastroiacovo et al. 2013

PrEP during pregnancy

- From studies of HIV+ women using tenofovir for treatment
  - No association with any adverse outcomes at birth
  - No association with preterm, SGA or adverse birth outcome
  - No association of TDF with teratogenicity
  - Minimal (0.4 cm) reduced mean length at month 12 ; significance uncertain

    Siberry AIDS 2012
- From studies of HIV-uninfected women using tenofovir as PrEP
  - Limited data from first trimester suggest no increased risk for poor birth outcomes and no delays in infant growth

    Mugo CROI 2012

HIV negative man planning pregnancy with an HIV positive female

- ART for the HIV positive female partner to achieve an undetectable viral load
- STI diagnosis and any indicated treatment for both partners before conception attempts
- Daily, oral doses of TDF/FTC beginning 1 month before a conception attempt and continuing for 1 month after
- Intravaginal insemination(either at home or in the clinic) with a fresh semen sample

OR

- Limit sex without a condom (natural conception) to peak fertility times identified by home or laboratory tests for ovulation.

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STI: sexually transmitted infection

Section 4 Patient Information Sheet – Acute HIV Infection

Information about Acute HIV Infection and PrEP

What is acute HIV Infection?

HIV stands for human immunodeficiency virus. This is the virus that causes AIDS.

Acute HIV infection is a name for the earliest stage of HIV infection, when you first get infected with the HIV virus. It is sometimes also called primary HIV infection. Many people with acute HIV infection have the following:

- A fever
- A tired feeling
- Swollen lymph nodes (also called lymph glands)
- Swollen tonsils (also called tonsillitis)
- A sore throat
- Joint and muscle aches
- Diarrhea
- A rash

These signs and symptoms of acute HIV infection can begin a few days after you are exposed to HIV

Baseline Assessment

- Document negative HIV status
- Baseline renal function (do not use if CrCl of <60 ml/min)
- Hepatitis B infection and vaccination status
- STI screen**

**Not included in the guidelines

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What to prescribe:

Table 9: Recommended Oral PrEP Medications

Generic Name	Trade Name	Dose	Frequency	Common Side Effects[66]
Tenofovir disoproxil fumarate (TDF)	Viread	300 mg	Once a day	Nausea, flatulence
Emtricitabine (FTC)[a]	Emtriva	200 mg	Once a day	Rash, headache
TDF + FTC	Truvada	300mg/200 mg	Once a day	—

[a] Not recommended alone; only for use in combination with TDF.

Section 2 PrEP Information Sheet

Pre-exposure Prophylaxis (PrEP) for HIV Prevention

Frequently Asked Questions

What is PrEP?

"PrEP" stands for **pre**exposure **p**rophylaxis. The word "prophylaxis" (pronounced pro fil ak sis) means to prevent or control the spread of an infection or disease. The goal of PrEP is to prevent HIV infection from taking hold if you are exposed to the virus. This is done by taking a pill that contains 2 HIV medications every day. These are the same medicines used to stop the virus from growing in people who are already infected.

Why take PrEP?

The HIV epidemic in the United States is growing. About 50,000 people get infected with HIV each year. More of these infections are happening in some groups of people and some areas of the country than in others.

Is PrEP a vaccine?

Section 3 Truvada Medication Information Sheet

Truvada Medication Information Sheet for Patients

Brand name: Truvada (tru va duh)

Generic name: tenofovir disoproxil fumarate and emtricitabine

Why is this medication prescribed?

- Truvada is one of several medications that are currently used to treat human immunodeficiency virus (HIV) and hepatitis B virus infection.
- Truvada is now being used to *prevent* HIV infection.
- Truvada is sometimes prescribed to some people who do not have HIV infection (for example, those who do not always use condoms or who have a sex partner that has HIV infection) to help reduce their chances of getting HIV infection
- When you take Truvada to prevent HIV infection, doctors refer to this use as "pre-exposure prophylaxis" or "PrEP".

How does Truvada (PrEP) help prevent HIV infection?

- HIV is a virus that attacks your body's immune cells (the cells that work to fight infections).
- The 2 medications that make up Truvada (tenofovir and emtricitabine) block important pathways that viruses use to set up infection.
- If you take Truvada as PrEP daily, the presence of the medication in your bloodstream can sometimes stop the virus from establishing itself and slow the spread of HIV in your body.
- By itself, PrEP with Truvada does not work all the time so you should also use condoms during sex for the most protection from HIV infection.

Section 5 Provider Information Sheet – PrEP during Conception, Pregnancy, and Breastfeeding

Information for Clinicians

Counseling Patients about PrEP Use During Conception, Pregnancy, and Breastfeeding

PrEP use may be one of several options to help protect the HIV-negative male or female partner in a heterosexual HIV-discordant couple during attempts to conceive[1,2].

DHHS Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission

Panel's Recommendations on Reproductive Options for HIV-Concordant and Serodiscordant Couples
For Couples who Want to Conceive *For Both Concordant (Both Partners are HIV-Infected)/Discordant Couples:* • Expert consultation is recommended so that approaches can be tailored to specific needs, which may vary from couple to couple (**AIII**). • Partners should be screened and treated for genital tract infections before attempting to conceive

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Follow-up Visit:

Box D: Key Components of Medication Adherence Counseling

Establish trust and bidirectional communication

Provide simple explanations and education

- Medication dosage and schedule
- Management of common side effects
- Relationship of adherence to the efficacy of PrEP
- Signs and symptoms of acute HIV infection and recommended actions

Support adherence

- Tailor daily dose to patient's daily routine
- Identify reminders and devices to minimize forgetting doses
- Identify and address barriers to adherence

Monitor medication adherence in a non-judgmental manner

- Normalize occasional missed doses, while ensuring patient understands importance of daily dosing for optimal protection
- Reinforce success
- Identify factors interfering with adherence and plan with patient to address them
- Assess side effects and plan how to manage them

Additional adherence support tools:

Box 6.1: Adherence Discussion

You are going to have to take the pill once a day, every day. Although this seems easy, we know that people forget to take their medicines, especially when they are not sick. It will be easier to take your medicine if you think through now some plans about how you'll do it. First, let's briefly discuss your experiences other times you might have taken medicine.

- *When you've taken medicines before, how did you remember to take them?
- Please tell me about any problems you had taking your pill.
- *What was most helpful for remembering to take them?

Box 6.2: Developing an adherence plan

OK, now let's come up with a plan for taking your medicine.

1. Scheduling

What is your schedule like during a typical week day?
At what point in the day do you think it would be easiest to take the pill? That is, is there a time when you are almost always at home, and not in too much of a rush?
How does your schedule differ on weekends?

2. Reminder devices

How will you remember to take the pill each day?
One way to remember is to take the pill at the same time that you are doing another daily task, such as brushing your teeth or eating breakfast. Which of your daily tasks might be used for this purpose? Try to pick something that happens every day. Sometimes we might pick something that is not always done on the weekends or during other days, and then we are more likely to forget. (For example, …. **One potential example follows**: sometimes I don't shave on Saturdays, but I always brush my teeth, so linking taking the medicine to brushing my teeth might be better than linking it to shaving.) It also helps to store the pills near the place where you perform this daily task.
Some people use a reminder device to help them remember. Do you have any reminder devices that you have used in the past? For example, watches, beepers, or cell phones.

3. Organizational skills

Follow-up visit:

Box E: Key Components of Behavioral Risk-Reduction Counseling

Establish trust and 2-way communication

Provide feedback on HIV risk factors identified during sexual and substance use history taking

- Elicit barriers to, and facilitators of, consistent condom use
- Elicit barriers to, and facilitators of, reducing substance abuse

Support risk-reduction efforts

- Assist patient to identify 1 or 2 feasible, acceptable, incremental steps toward risk reduction
- Identify and address anticipated barriers to accomplishing planned actions to reduce risk

Monitor behavioral adherence in a non-judgmental manner

- Acknowledge the effort required for behavior change
- Reinforce success
- If not fully successful, assess factors interfering with completion of planned actions and assist patient to identify next steps

Risk Assessment

- PrEP should be part of an integrated harm reduction strategy.
- Clinicians should regularly discuss their patients risk for pregnancy, STDs, HIV transmission, abuse.
- Persons with HIV should be asked about their partner's risks
- Persons without HIV should be asked about their partner's risks and HIV status

Attempting Pregnancy or Pregnant women on Prep

- Consider more frequent visits, possibly monthly. For HIV testing and close monitoring for adherence
- Woman trying to get pregnant should come in for unscheduled visit if missed menses.
- If pregnant report to Antiretroviral Pregnancy Registry
  - http://apregistry.com/
  - Phone: 800-258-4263
  - Fax: 800-800-1052
- Post Partum options
  - Discuss risks/benefits of breastfeeding on PrEP
  - strict condom use
  - HIV+ partner's viral load undetectable
  - formula feeding and continuing PrEP for own health post partum.

Billing: ICD 10 codes

- Contact with or Exposure to viral HIV/AIDS virus V01.79
- Exposure to an STD V01.89

Truvada.com

- Free drug assistance for uninsured
- Free HIV and HBV testing
- Free resistance testing for those who seroconvert while on Truvada

PrEP Patient Assistance Program

Social Security #: ___ ___ ___ – ___ ___ – ___ ___ ___ ___	Date of Birth: MM DD YYYY _____ /_____ / _____	Gender: M ☐ F ☐	Resides in U.S/U.S. territories: YES ☐ NO ☐

Primary Contact:_____ Relationship:_____ Phone Number: _____

Applicant Financial Information

Current Annual Household Income: $_____ Number in Household (circle one): **1 2 3 4 5 6** _____

Please include current documentation for all sources of income (eg, tax return, W2, last 2 pay stubs, etc).

☐ **Applicant is insured** (Please fill out all the applicable insurance information below. Attach copy (front and back) of applicant insurance card.)

☐ **Applicant is uninsured** (No health insurance through any public or private payer.) Complete **"Additional Insurance Information"** below.

3 Statement of Medical Necessity

Statement of Medical Necessity for Financially Needy Applicants. To the best of my knowledge, this applicant has no coverage (including Medicaid or other public programs) for TRUVADA. I certify that the medication(s) listed above are medically indicated for this applicant and that I will be supervising the applicant's treatment. I certify that I am prescribing TRUVADA for PrEP as part of a risk reduction strategy for HIV prevention for this applicant. I certify that the applicant has been tested for HIV infection and found to be HIV negative, and regular HIV testing will be conducted as part of the applicant's care plan. As part of my applicant's eligibility, I agree to periodically verify continued use of Gilead medication and resubmit current prescriptions.

SIGN HERE **Prescriber Signature:**_____ **Date:**_____

Applications are considered complete only if they include all of the following:

- Front and Back Pages of Enrollment Form
- Applicant as well as Prescriber Signatures and Dates
- Documentation of Income Sources and Residency
- Copy of Prescription

When complete, **FAX** application and documentation to: **1-855-330-5478**

Gilead Sciences, Inc.
Medication Assistance Program
P.O. Box 13185
La Jolla, CA 92039-3185
TEL: 1-855-330-5479 | FAX: 1-855-330-5478

Steps for a national agenda for Prep implementation

- Educational campaign to increase awareness for persons who might benefit from PrEP use
- Educational campaign to train providers interested in offering PrEP to their patients
  - Systematic training in medical, family planning, HIV, and OB/GYN clinics
- Monitor PrEP use and its health impact
- Disburse information on models of implementation
- Disburse information on clinical research
- Ensure insurance policies reimburse billing codes
- Coverage for uninsured needs to be worked out: lab costs, coverage for visit etc.

Patient Information Sites

- **Project Prepare Website: www.projectprepare.net**
- http://www.prepwatch.org/#women
- **Centers for Disease Control and Prevention: http://www.cdc.gov/hiv/prep/**
- **Project inform: http://www.projectinform.org/pdf/orderprepbooklets**
  - **A new option for safer loving for women in Spanish and English**
- **San Francisco Department of Public Health: www.prepfacts.org**
- **PrEP watch: http://www.prepwatch.org/#guidance**
- Bay Area Perinatal AIDS Center: Positive Reporductive Outcomes for Men: hiv.ucsf.edu/care/perinatal/pro_men.html

National HIV/AIDS Clinicians' Consultation Center

UCSF – San Francisco General Hospital

Perinatal HIV Hotline (888) 448 - 8765

National Perinatal HIV Consultation & Referral Service

Advice on testing and care of HIV-infected pregnant women and their infants

Referral to HIV specialists and regional resources

Warmline (800) 933 - 3413

National HIV Telephone Consultation Service

Consultation on all aspects of HIV testing and clinical care

PEPline (888) 448 - 4911

National Clinicians' Post-Exposure Prophylaxis Hotline

Recommendations on managing occupational exposures to HIV and hepatitis B & C

HRSA AIDS ETC Program & Community Based Programs, HIV/AIDS Bureau
& Centers for Disease Control and Prevention (CDC)

www.nccc.ucsf.edu