



2018 Update: Hawai'i to Zero HIV Cure and Prevention Efforts

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HIV PrEP in Hawaii

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Disclosures

- Speaker have no disclosures

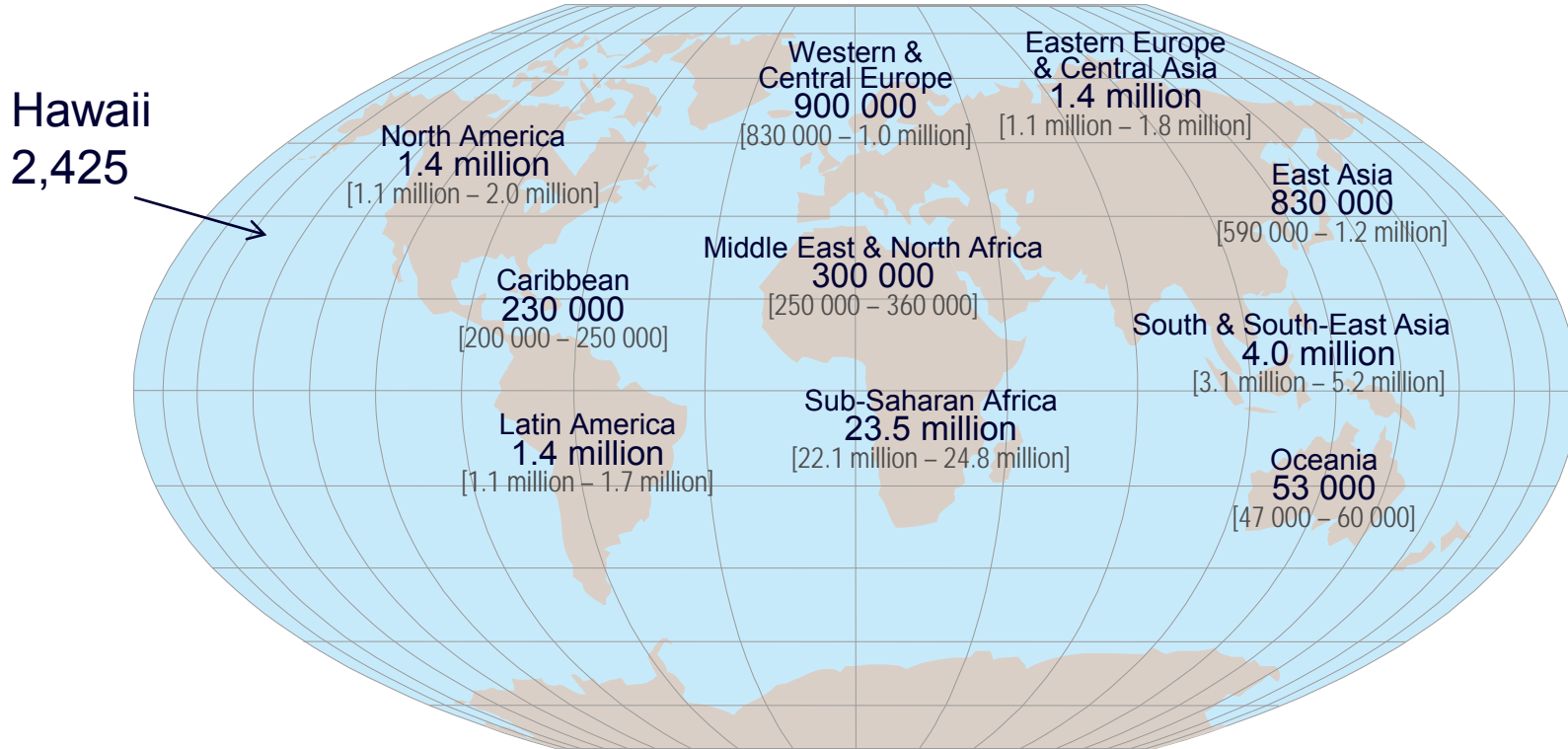
Can a Pill Prevent HIV?



Objective


- To discuss the magnitude of HIV infections in Hawaii and the number of at-risk individuals in our community
- To discuss the role of Pre-Exposure Prophylaxis (PREP) as HIV Prevention
- Understand how to identify at-risk individuals and how to prescribe PREP
- Learn about issues surrounding PREP from a PREP consumer

Adults and children estimated to be living with HIV



Total: 34.0 million [31.4 million – 35.9 million]

Estimated Incidence of HIV Infection, Overall, and by Sex, 2007-2010 — United States

	2007	2008	2009	2010
	<ul style="list-style-type: none"> • Approximately 100 New HIV infections reported to the State of Hawaii Department of Hawaii • 50 are locally detected <ul style="list-style-type: none"> • Majority had contact with a known HIV infected individual 			
	Total	53,200 (47,000–59,400)	47,500 (42,000–53,000)	45,000 (39,900–50,100)

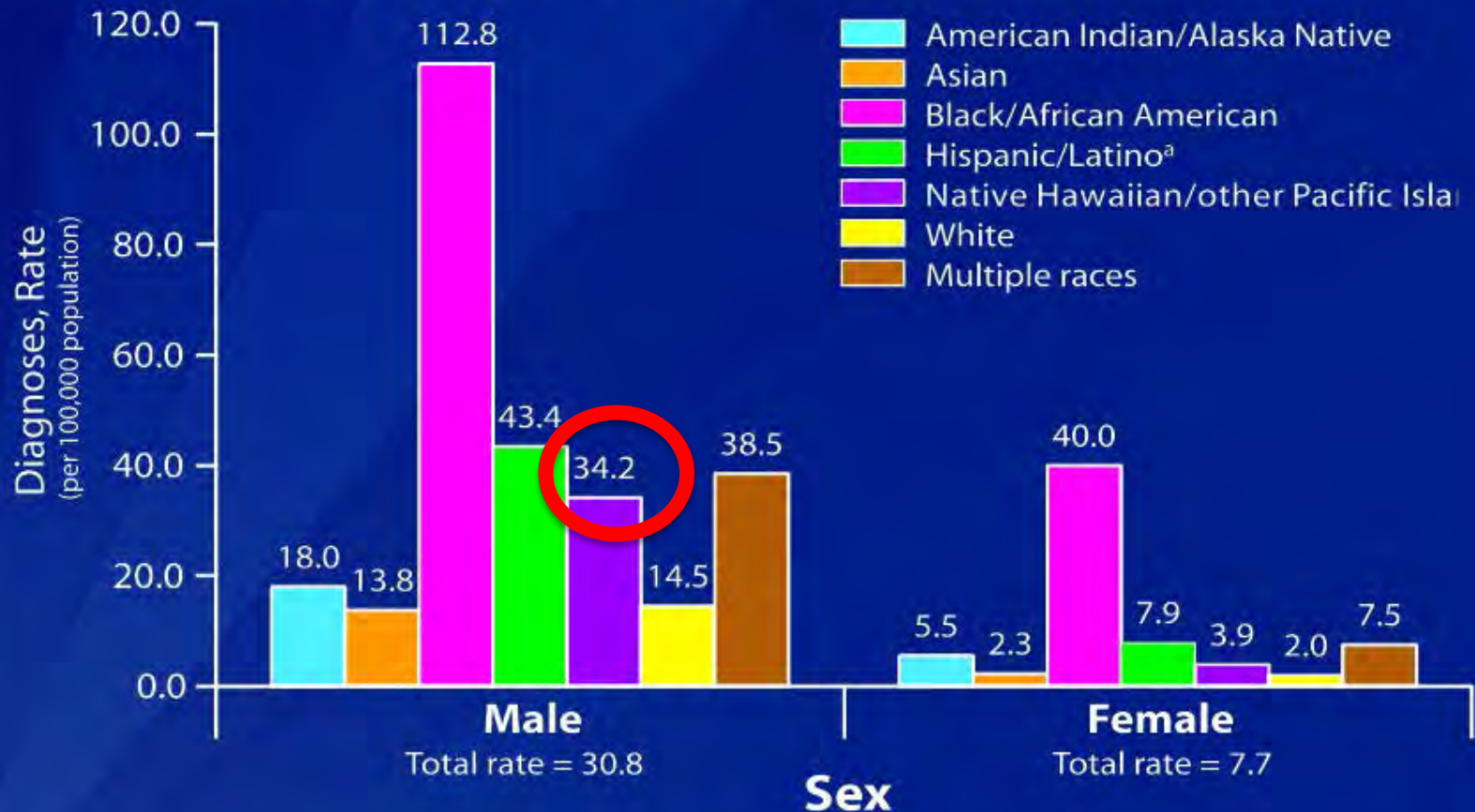
Note: Because column totals for estimated numbers were calculated independently of the values for the subpopulations, the values in each column may not sum to the column total.

^aCI = Confidence Interval. Confidence intervals reflect random variability affecting model uncertainty but may not reflect model-assumption uncertainty; thus, they should be interpreted with caution.

* Indicates significantly different ($p < 0.05$) from the 2008 estimate for the same group.



Rates of Diagnoses of HIV Infection among Adults and Adolescents, by Sex and Race/Ethnicity, 2011—United States



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting. Rates are per 100,000 population.

^a Hispanics/Latinos can be of any race.



What is PrEP?

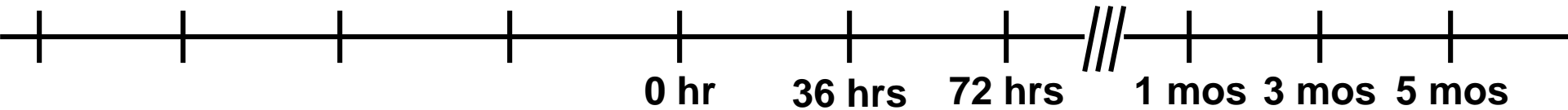
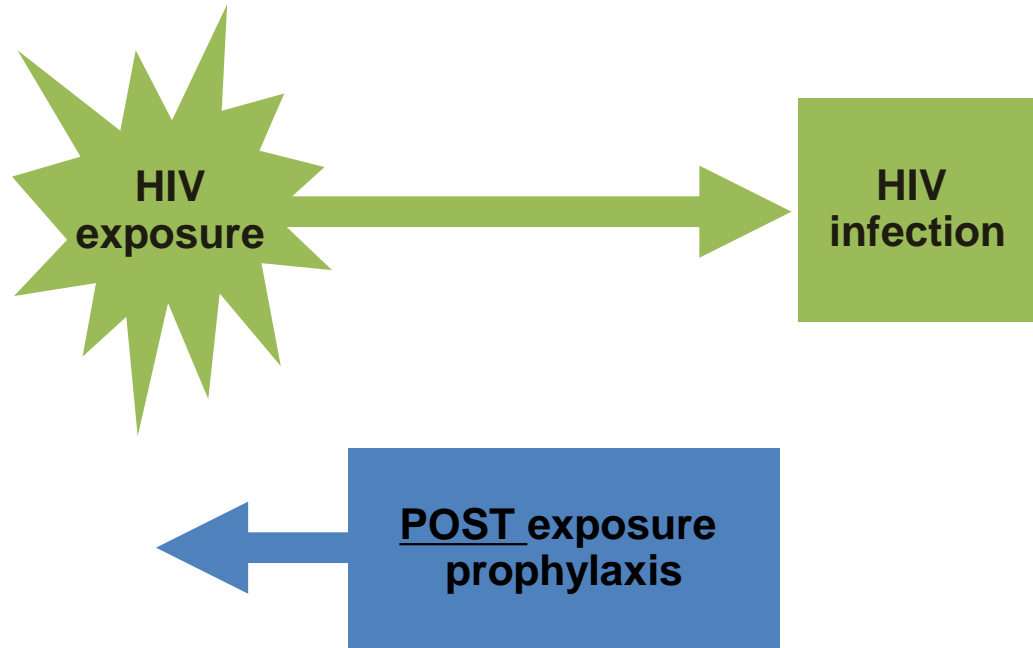
- A prevention strategy in which a high-risk individual takes medication regularly to prevent infection
- Tenofovir-emtricitabine (*Truvada*) approved for HIV PrEP by the FDA in July 2012
- Added benefits: provides some protection against HSV and hepatitis B



www.nytimes.com

Pre- vs Postexposure Prophylaxis

- After exposure to HIV, infection may become established
- Postexposure prophylaxis (initiated soon after exposure) reduces the chance of infection
- Pre-exposure prophylaxis begins treatment earlier (before exposure)



PrEP Trials Have Shown Efficacy in MSM, Heterosexual Men and Women, and IDUs

Trial	Population/Setting	Intervention	HIV Infections, n		Reduction in HIV Infection Rate, % (95% CI)
			PrEP	Placebo	
iPrEX ^[1] (N = 2499)	MSM, transgender women, 11 sites in US, South America, Africa, Thailand	TDF/FTC	36	64	44 (15-63)
Partners PrEP ^[2] (N = 4747)	Serodiscordant couples in Africa	TDF	17	52	67 (44-81)
		TDF/FTC	13		75 (55-87)
TDF2 ^[3] (N = 1219)	Heterosexual males and females in Botswana	TDF/FTC	9	24	62 (21-83)
Thai IDU ^[4] (N = 2413)	Volunteers from 17 drug Thai treatment centers	TDF	17	33	49 (10-72)

1. Grant RM, et al. N Engl J Med. 2010;363:2587-2599. 2. Baeten JM, et al. N Engl J Med. 2012;367:399-410. 3. Thigpen MC, et al. N Engl J Med. 2012;367:423-434. 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.

Disappointing Results of PrEP in Women: FEM-PrEP and VOICE

- FEM-PrEP: Study of oral TDF/FTC for 3900 high-risk women in Africa (2120 randomized)
 - Study ended early by DSMB due to lack of efficacy
 - 35 vs 33 new HIV infections in the placebo and TDF/FTC arms^[1]
 - TDF blood levels show that adherence was too low (< 40%)
- VOICE: Phase IIB placebo-controlled trial of > 5000 women in South Africa, Uganda, and Zimbabwe^[2]
 - Daily oral TDF; daily oral TDF/FTC; daily vaginal TFV 1% gel
 - DSMB stopped the daily oral TDF arm and daily vaginal gel arm for lack of efficacy
 - Daily oral TDF/FTC arm continued but recently shown to have low efficacy due to poor treatment adherence

1. Van Damme L, et al N Engl J Med. 2012 Jul 11. [Epub ahead of print].
2. Marrazzo J, et al. CROI 2013. Abstract 26LB.

PrEP Works, but Adherence Is Critical

Study	Efficacy Overall, %	Blood Samples With TFV Detected, %	Efficacy By Blood Detection of TFV, %
iPrEx ^[1]	44	51	92
iPrEx OLE ^[2]	49	71	NR
Partners PrEP ^[3]	67 (TDF) 75 (TDF/FTC)	81	86 (TDF) 90 (TDF/FTC)
TDF2 ^[4]	62	80	85
Thai IDU ^[5]	49	67	74
Fem-PrEP ^[6]	No efficacy	< 30	NR
VOICE ^[7]	No efficacy	< 30	NR

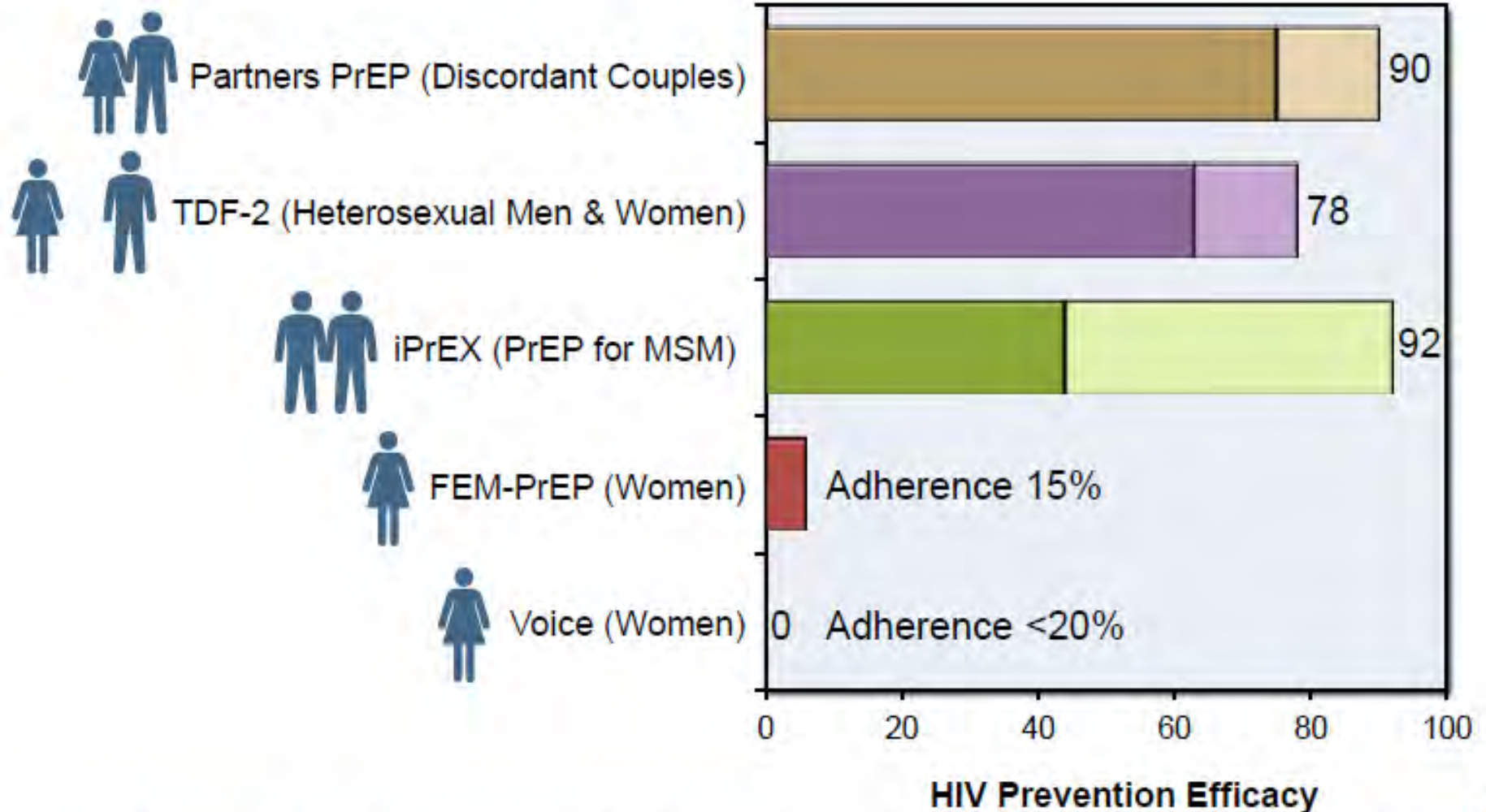
Among those who took PrEP (confirmed by tenofovir detection in blood) efficacy was 74-92%!

1. Grant RM, et al. N Engl J Med. 2010;363:2587-2599. 2. Grant RM, et al. Lancet Infect Dis. 2014; 14:820-829. 3. Baeten JM, et al. N Engl J Med. 2012;367:399-410. 4. Thigpen MC, et al. N Engl J Med. 2012;367:423-434. 5. Choopanya K, et al. Lancet. 2013;381:2083-2090. 6. Van Damme L, et al. N Engl J Med. 2012;367:411-422. 7. Marrazzo J, et al. CROI 2013. Abstract 26LB.

Why poor results in VOICE and FEM-PrEP?

- Why were there differences between these studies and the other TDF-based studies?
 - Very poor adherence.
 - Poor adherence in MSM may be more forgiving due to high TDF concentration in rectal tissue.

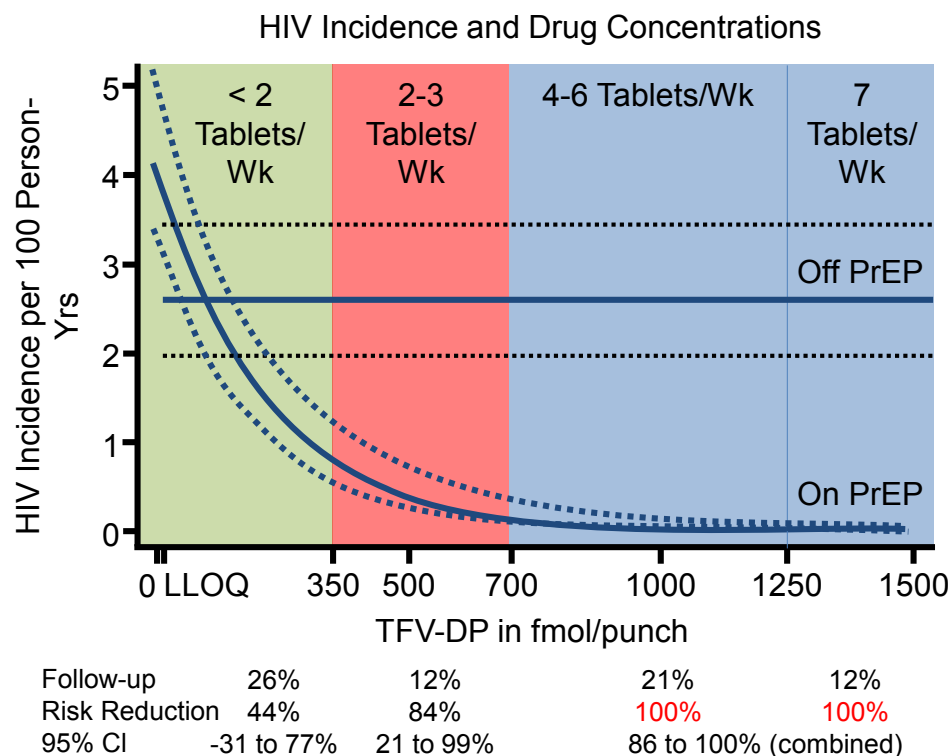
The Importance of Adherence



Oral PrEP Reduces HIV Incidence in MSM, Even With Incomplete Adherence

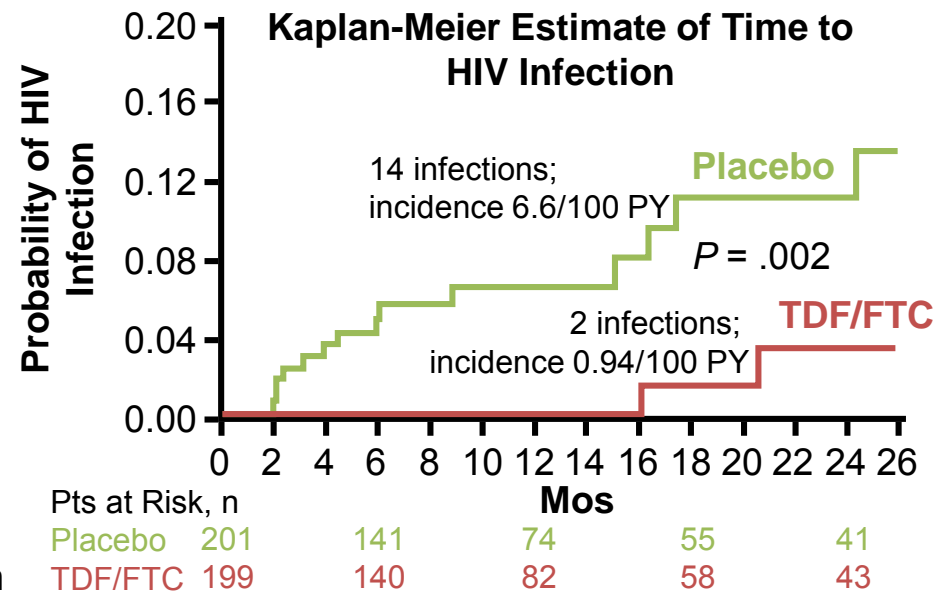
- iPreX OLE: open-label extension of iPrEX trial of daily TDF/FTC oral PrEP in MSM and transgender women (N = 1603)
- **100% adherence was not required** to attain full benefit from PrEP
 - **Benefit of 4-6 tablets/wk similar to 7 tablets/wk**
 - 2-3 tablets/wk also associated with significant risk reduction

Higher levels of sexual risk taking at baseline associated with *increased* adherence to PrEP



Ipergay: “On-Demand” Oral PrEP in High-Risk MSM

- Randomized double-blind trial of oral TDF/FTC* (n = 199) vs placebo (n = 201) in France
 - 2 tablets taken 2-24 hrs before sex
 - 1 tablet 24 hrs after sex
 - 1 tablet 48 hrs after sex
- Primary endpoint: HIV seroconversion
- **86%** reduction in risk seen in PrEP arm (95% CI: 40% to 99%, $P = .002$)
 - Number needed to treat for 1 yr to prevent 1 infection: **18**
 - Median of 16 pills taken per mo in each arm



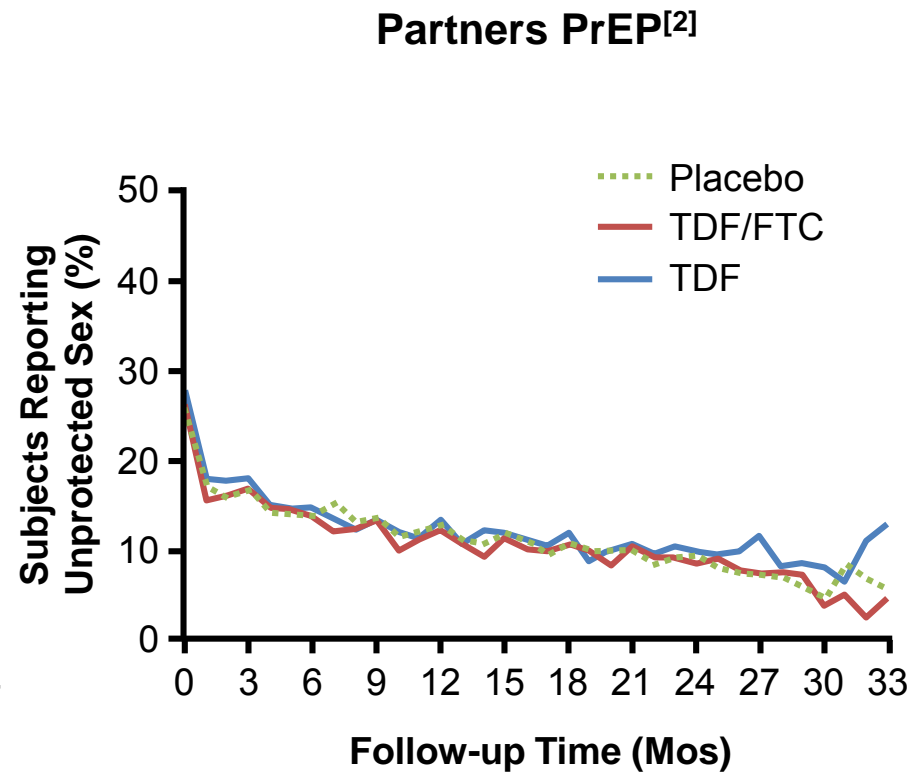
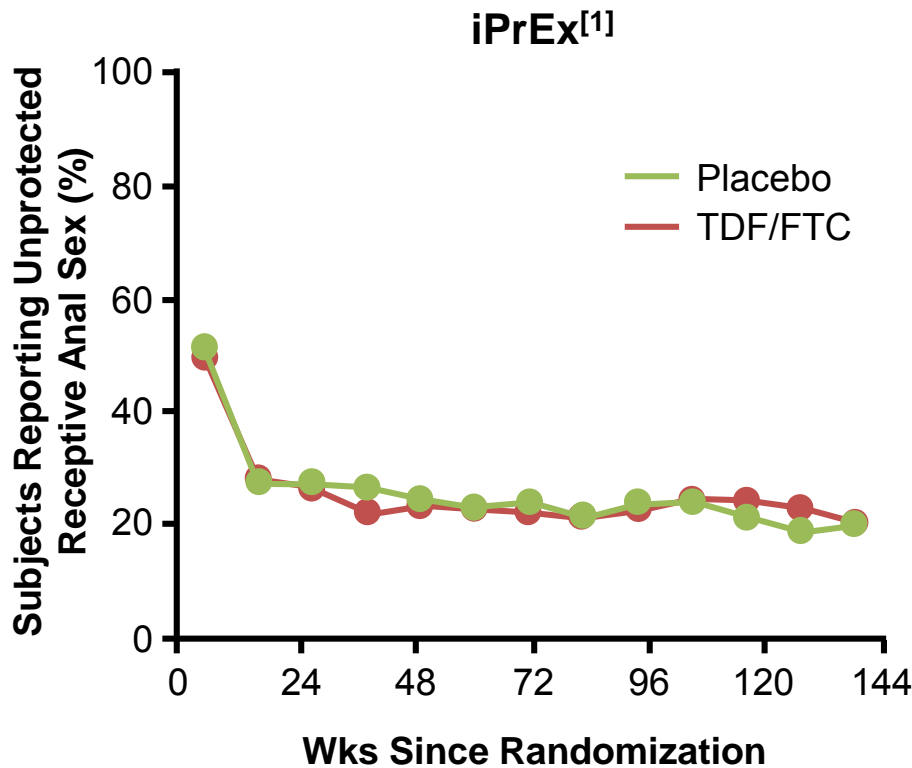
- In pts with infection, no tenofovir found in serum in last 2 visits
- 4 cases of acute HCV infection noted among lab abnormalities
- DSMB stopped trial early and recommended all participants start PrEP

*On-demand PrEP strategy not FDA approved.

Adverse Events

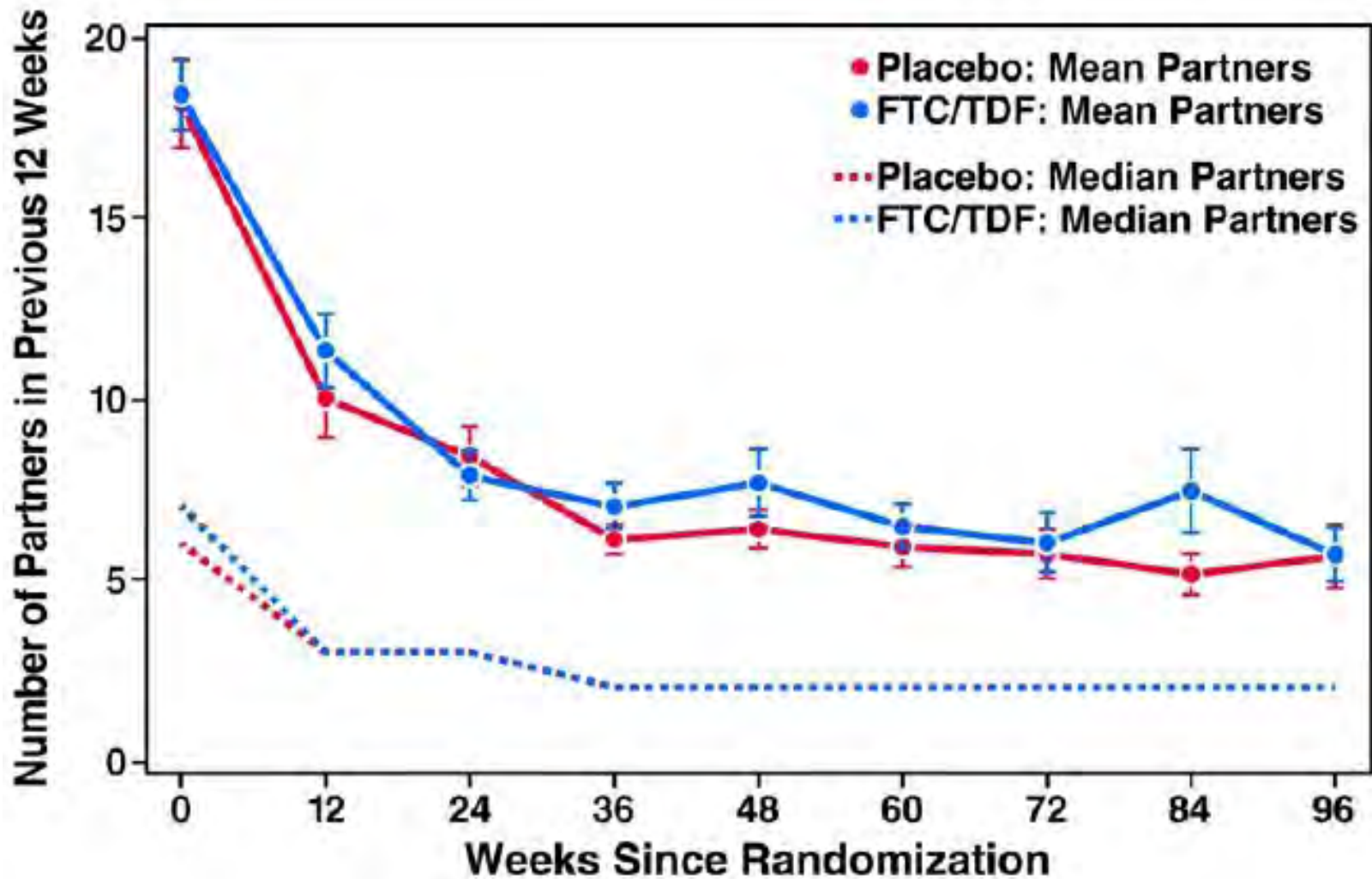
- Very few and mild AEs observed in PrEP trials^[1]
 - iPrEx: small but significant early nausea and weight loss^[2]
- Potential bone and renal toxicity
 - Known risk associated with TDF
- Potential for drug-resistant HIV infection
 - Infrequent in clinical trials but must exclude HIV infection

PrEP Trials Found *Decreasing* Risk Behavior Over Time



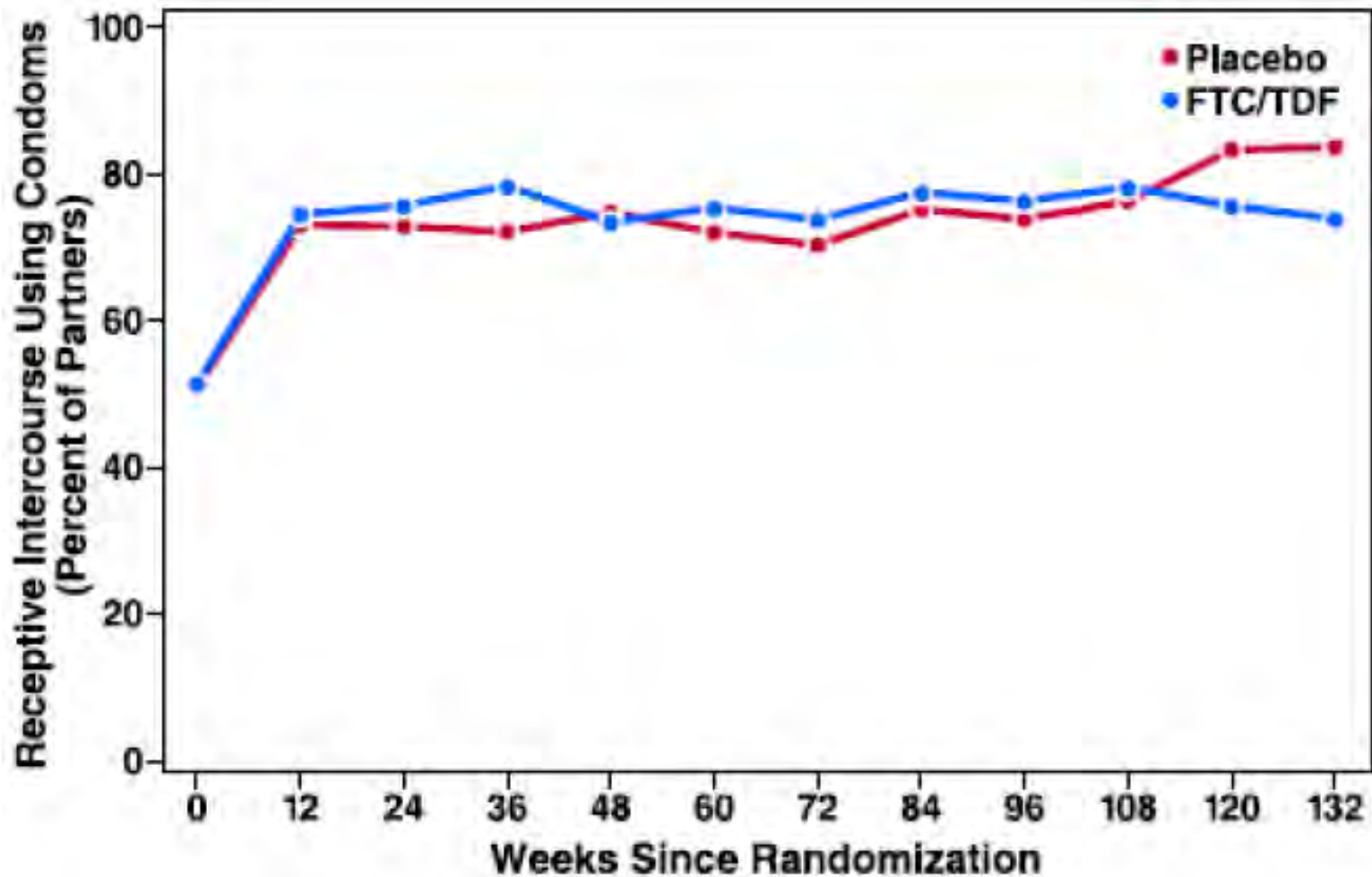
1. Grant RM, et al. N Engl J Med. 2010;363: 2587-2599.
2. Baeten JM, et al. N Engl J Med. 2012;367:399-410.

Risk Behavior: Partners decreased



NEJM, Nov 23, 2010

Risk Behavior: Condom use increased



CDC PrEP Guideline: For Which Patients Is PrEP Recommended?

- PrEP is recommended as one prevention option for the following adults at substantial risk of HIV acquisition
 - Sexually active MSM
 - Heterosexually active men and women
 - Injection drug users

	MSM	Heterosexual Women and Men	Injection Drug Users
Potential indicators of substantial risk of acquiring HIV infection	<ul style="list-style-type: none">▪ HIV-positive sexual partner▪ Recent bacterial STI▪ High number of sex partners▪ History of inconsistent or no condom use▪ Commercial sex work	<ul style="list-style-type: none">▪ HIV-positive sexual partner▪ Recent bacterial STI▪ High number of sex partners▪ History of inconsistent or no condom use▪ Commercial sex work▪ In high-prevalence area or network	<ul style="list-style-type: none">▪ HIV-positive injecting partner▪ Sharing injection equipment▪ Recent drug treatment (but currently injecting)

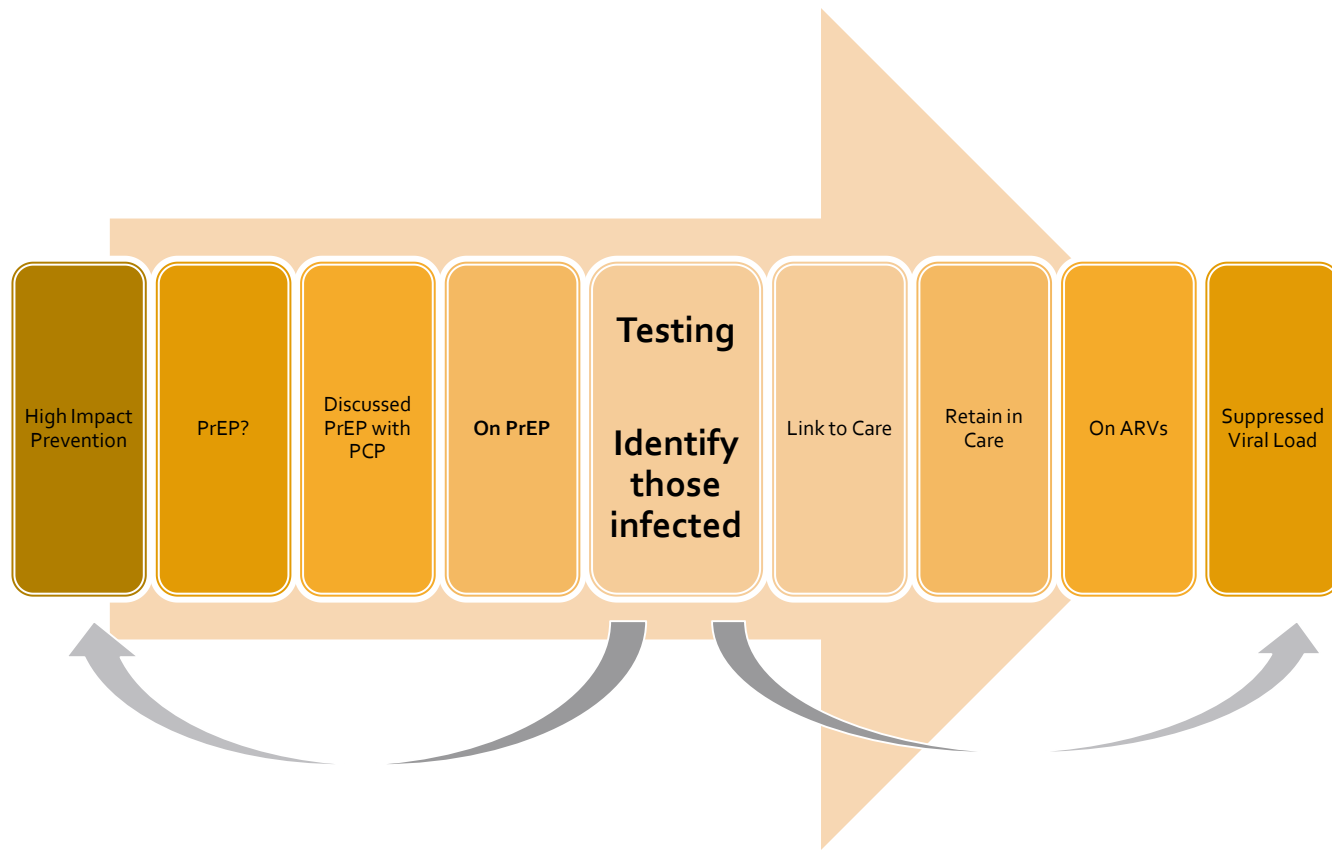
Goal



Epidemiologic Modeling

- HIV risk
 - 1 in 4 sexually active gay and bisexual men
 - 1 in 5 people who inject drugs
 - 1 in 200 heterosexual adults
- Overall, an estimated 1.23 million adults in the US would be considered at substantial risk of HIV and potentially eligible for PrEP
- For PREP to get Hawaii to Zero, approximately 3,000 individuals in Hawaii need to be on PREP

The HIV Neutral Continuum of Care



PrEP Navigation Services

- PrEP Education
- PrEP Screening
- PrEP Linkage to providers
- PrEP Ongoing Support (adherence, insurance, access, co-pay programs)

- **Life Foundation's Goal:** Link at least 100 new high-risk individuals to PrEP medication and support.

CDC PrEP Guidelines

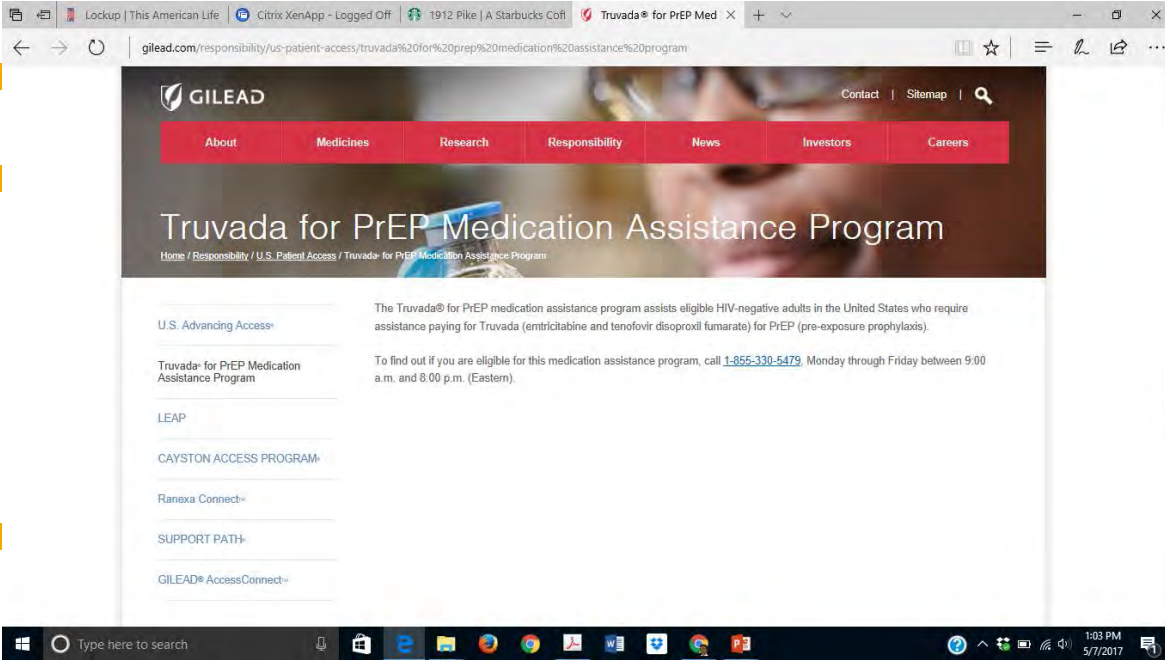
■ Before initiating PrEP:

- Document that HIV test is negative
- Confirm patient has substantial ongoing high risk for HIV
- Check creatinine clearance (kidney function)
- Screen for hepatitis B
- Screen for pregnancy

■ After PrEP initiated:

- Stress adherence continuously
- Check HIV status q 2-3 months
- Check kidney function in 3 months, then yearly
- HIV and STD regular testing

Who is Going to Pay for PrEP



The screenshot shows a web browser window displaying the Gilead website. The address bar shows the URL: gilead.com/responsibility/us-patient-access/truvada%20for%20prep%20medication%20assistance%20program. The page features a navigation menu with links for About, Medicines, Research, Responsibility, News, Investors, and Careers. The main heading is "Truvada for PrEP Medication Assistance Program". Below the heading, there is a list of programs: U.S. Advancing Access, Truvada for PrEP Medication Assistance Program, LEAP, CAYSTON ACCESS PROGRAM, Ranexa Connect, SUPPORT PATH, and GILEAD AccessConnect. The text on the page states: "The Truvada for PrEP medication assistance program assists eligible HIV-negative adults in the United States who require assistance paying for Truvada (emtricitabine and tenofovir disoproxil fumarate) for PrEP (pre-exposure prophylaxis). To find out if you are eligible for this medication assistance program, call 1-855-330-5479, Monday through Friday between 9:00 a.m. and 8:00 p.m. (Eastern)." The Windows taskbar at the bottom shows the time as 1:03 PM on 5/7/2017.

op

PrEP

On
PrEP

PrEP - Pre-exposure Prophylaxis

Need for Prophylaxis against STD	Z41.8
High risk sexual behavior	Z72.50
Exposure to HIV (suspected)	Z20.6
Exposure to STI (suspected)	Z20.2
High risk heterosexual behavior	Z72.51
High risk homosexual behavior	Z72.52
High risk bisexual behavior	Z72.53

Common PrEP-Related Billing Codes

ICD-9	Description
V69.2	High-risk sexual behavior
V01.79	Exposure to other viral diseases
ICD-10	Description
Z72.5	High-risk sexual behavior
Z20.82	Contact with and (suspected) exposure to other viral communicable diseases
CPT	Description
99401	Preventive counseling (15 minutes)
99402	Preventive counseling (30 minutes)
99403	Preventive counseling (45 minutes)
99404	Preventive counseling (60 minutes)

Challenges to Scale Up

- Education
 - Lack of public awareness
 - Lack of health promotion
 - Debunking stereotypes and myths
- Funding
 - Lack of incentives
- Manpower
 - Small number of PREP providers

Potential Solutions

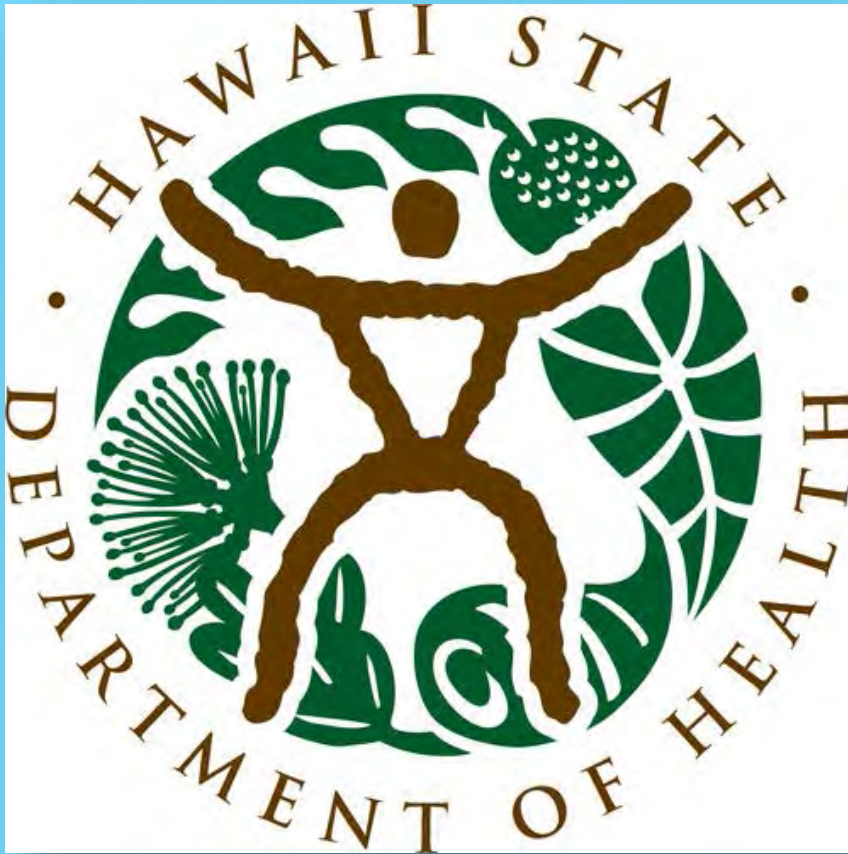
- DOH initiatives
- PREP focus among ASO's
 - Partnerships in delivering care
- Coming PREP Conference
- New meds coming
 - Rectal/vaginal gels
 - Availability of Tenofovir Alafenamide (TAF) → reduced risk of BMD and renal complications
 - Long-acting injectable PrEP (cabotegravir and rilpivirine injectables)



Hawai'i PrEP Working Group

- Collaboration between 7 agencies to raise awareness of PrEP in Hawai'i in all four counties.
- Message unification
- Address focus populations
- Address stigma

PrEP in DOH



- PrEP webpage
- PrEP provider list
- ASOs (all counties)
- Community partners
- Goals
 - to increase awareness and uptake of PrEP to both patients and providers
 - to ease the process of accessing PrEP

Search “prep Hawaii harm reduction”

The image shows a screenshot of a Google search page. The search bar contains the text "prep hawaii harm reduction". A blue callout box with a white border points to the search bar with the text "Type 'prep Hawaii harm reduction'". Below the search bar, the search results are displayed. The first result is titled "Harm Reduction Services Branch | Pre-exposure Prophylaxis (PrEP)" and is from the website "health.hawaii.gov/harmreduction/hiv-aids/pre-exposure-prophylaxis-prep/". A purple callout box with a white border points to this first result with the text "First website in Google search". The search results also show the number of results as "About 394,000 results (0.30 seconds)". The Windows taskbar is visible at the bottom of the screen, showing the search bar and various application icons.

prep hawaii harm reduction

All News Images Shopping Videos More Settings Tools

About 394,000 results (0.30 seconds)

Harm Reduction Services Branch | Pre-exposure Prophylaxis (PrEP)
health.hawaii.gov/harmreduction/hiv-aids/pre-exposure-prophylaxis-prep/

Pre-exposure prophylaxis, or PrEP, is a prevention option for people who are at high risk of getting HIV. It's meant to be used consistently, as a pill taken every day, and to be used with other prevention options such as condoms. Find out if PrEP is right for you. HIV PrEP Provider List - Hawaii Department of Health PrEP ...

Harm Reduction Services Branch | Hawaii PrEP Physician Directory
health.hawaii.gov/harmreduction/hiv-aids/pre...prep/hawaii-prep-physician-directory/

The list of physicians attached to this site is for informational purposes only. The DOH makes no representation about the professional qualifications of any of the physicians on the list. If any physician desires to be included on this list, that physician can contact the DOH at 808-733-4390 and the DOH will include that ...

Harm Reduction Services Branch | Hawaii Department of Health PrEP ...
health.hawaii.gov/harmreduction/...prep/hawaii-department-of-health-stdaids-preventi...

New York City Department of Health and Mental Hygiene PrEP and PEP Action Kit - PrEP Prescriber Check-list from Truvada® manufacture, Gilead. (1) Persons who think they might have HIV infection, AIDS, or other STDs should not rely on anything in this website to self-diagnose or treat, but should instead consult their ...

Harm Reduction Services Branch | Clinical Practice Supplement

2:13 PM 1/11/2018

PrEP DOH Webpage

The screenshot shows the Hawaii Department of Health's PrEP webpage. The page title is "PRE-EXPOSURE PROPHYLAXIS (PREP)". The main content area includes a list of resources with three callouts:

- [HIV PrEP Provider List](#) (pointed to by a blue callout: "Hawaii's PrEP provider list")
- [Hawaii Department of Health PrEP Guidelines](#)
- [PrEP Resources for Patients and Providers](#) (pointed to by a purple callout: "Patient and Provider resources")
- [PrEP Navigation Resources](#)
- [Is PrEP Right for Me? \(web survey\)](#) (pointed to by a red callout: "PrEP Survey")
- [Life Foundation PrEP Services](#)
- [CDC Press Release November 24, 2015](#)
- [CDC Resources](#)

The webpage also features a navigation menu with "Home", "About DOH", "Neighbor Island Offices", "News", and "Employment". The footer shows the Windows taskbar with the date 1/11/2018 and time 2:10 PM.

PrEP Provider Directory

Secure | <https://health.hawaii.gov/harmreduction/files/2015/01/HIV-PrEP-Provider-List-March-2017-Final.pdf>

Hawaii Pre-Exposure Prophylaxis (PrEP) Provider Directory

Oahu PrEP Providers

Provider	Address and Phone	Hours of Operation	Notes
Clifton Arrington, MD Emergency Room Physician	Straub Medical Center 888 South King Street Honolulu, Hawaii 96813 Phone: (808) 522-4000	Urgent Access/Walk-In Care Monday – Friday: 1:00 PM – 8:00 PM Saturday: 8:00 AM – 4:00 PM Sunday: 10:00 AM – 4:00 PM	For emergency assistance only. Not a primary provider. Work hours may vary. Accepted insurances: Most health insurances. Walk-ins accepted. No referral needed.
Heath Chung, MD James Joyner, MD Benjamin Thomas, MD Infectious Disease Medicine/Private Practice	Waterfront Plaza/Restaurant Row 500 Ala Moana Blvd, Suite 5300 Honolulu, Hawaii 96813 Phone: (808) 531-7111	Monday – Friday: 8:00 AM – 4:30 PM Saturday and Sunday Closed	Accepted insurances: Most health insurances except Multiplan. Appointment and walk-ins accepted.
Scott Denny, PA-C Internal Medicine/Infectious Disease Specialist	Kaiser Permanente Moanalua Medical Center 3288 Moanalua Road Honolulu, Hawaii 96819 Phone: (808) 432-7263 Website: https://healthy.kaiserpermanente.org/hawaii	Monday – Friday: 8:00 AM – 4:30 PM Saturday and Sunday Closed	Accepted insurance: Kaiser only Appointment only.
Michael Dukelow, MD	Hyatt Regency Waikiki Beach	Monday – Friday:	Accepted insurances: Aetna,

1:44 PM 5/10/2017

PrEP in combination with ART



- PrEP for high risk individuals
- ART for HIV-infected individuals
- Need ***everyone*** in order to be successful in reducing HIV
- Together we can help our goal in achieving **zero** HIV transmissions!

PrEP Consumer



PrEP is a new prevention method in which **people who do not have HIV** infection **take a pill daily to reduce their risk** of becoming infected.

- Melvin McCready Jadulang

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Kekoa Kealoha, Community Health Outreach &
PrEPatient Navigator & MSM Outreach,
Hawai'i Island HIV/AIDS Foundation
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Portions of Slides from:

- Carlos Malvestutto, MD, MPH; OSU Medical Center
- Katherine Marx, MS, MPH, FNP-BC; NY & NJ AIDS Education and Training Center
- Brian Wood, MD; University of Washington, Northwest AIDS Education and Training Center

Mahalo

Special thanks to

Hawai'i AIDS Education and Training Center

- Cyril Goshima
- Kevin Patrick



Hawaii Center for AIDS

- Cecilia Shikuma



Life Foundation

- Paul Groesbeck
- Heather Lusk
- Nandi Ishikawa



Department of Health Harm Reduction Services Branch

- Timothy McCormick
- Peter Whitarcar
- Glenn M. Wasserman



Mahalo