





A Pill for Prevention

Understanding HIV Pre-Exposure Prophylaxis



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I have no conflicts of interest in relation to this presentation.

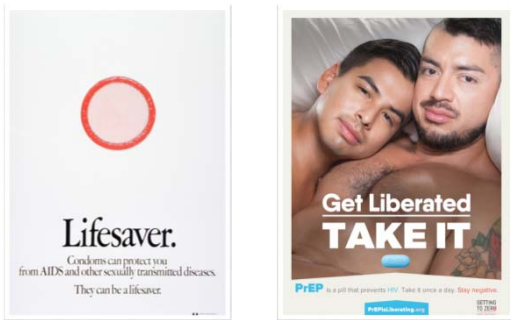
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The views expressed are not necessarily those of the NIH.

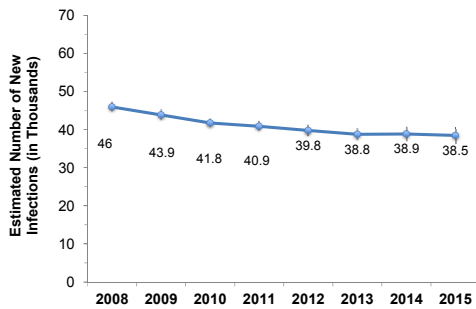
Overview

- A bit of epidemiology for context
- Oral PrEP: how good is good?
- Uptake, access, and equity
- Special populations
 - Cisgender women trying to conceive
 - Persons who inject drugs
- What's in the pipeline
- Questions

Change may be difficult for many of us



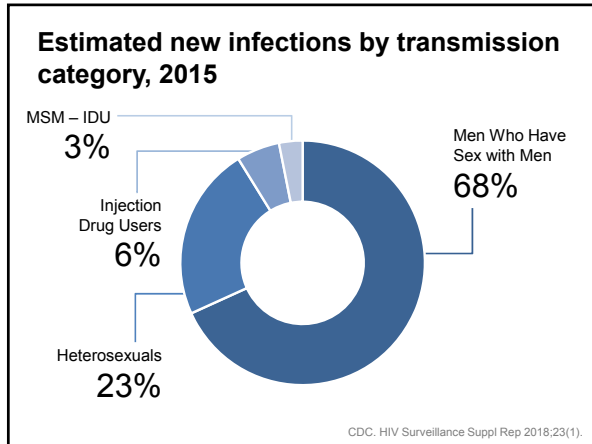
HIV incidence in United States, 2008-2015 By CD4 model (new in 2017)

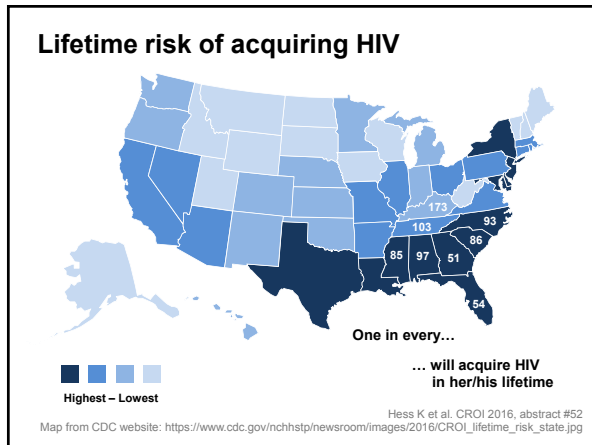


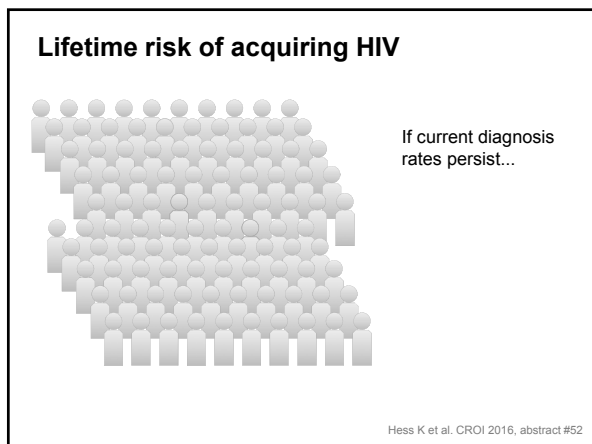
Hall HI et al. JMIR Public Health Surveill 2017 Feb 3;3(1):e8.
Satcher Johnson A et al. JAIDS 2017 Oct 1;76(2):116-22
CDC. HIV Surveillance Suppl Rep 2018;23(1)

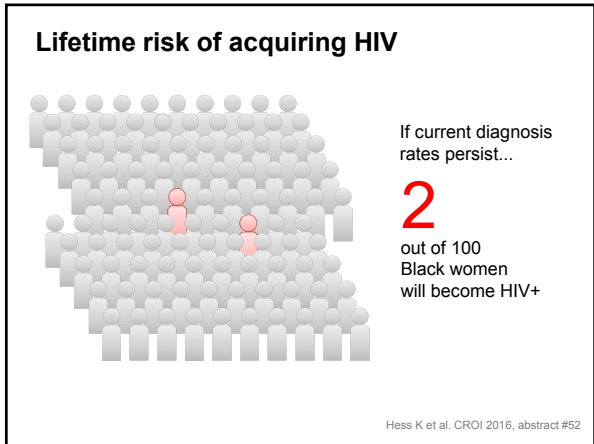
Do we really need additional strategies?

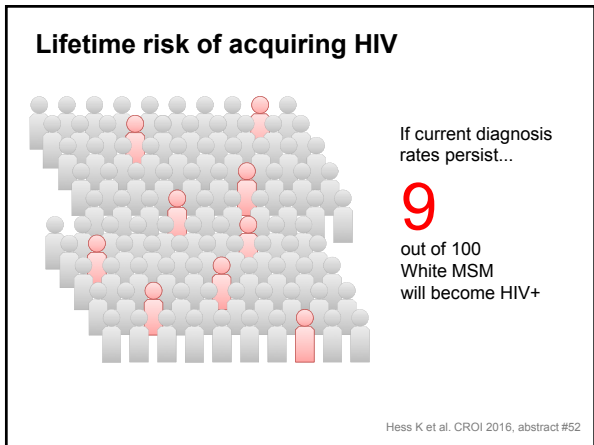


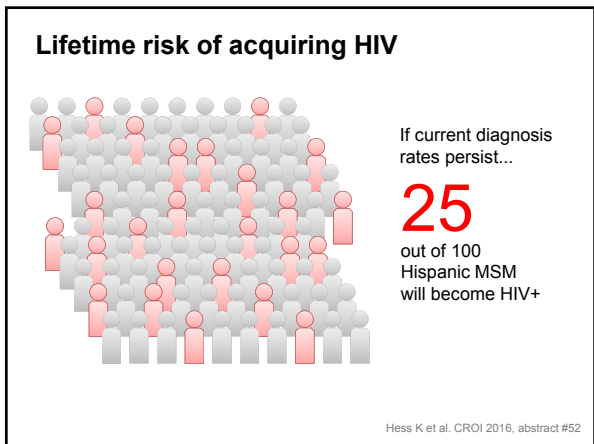


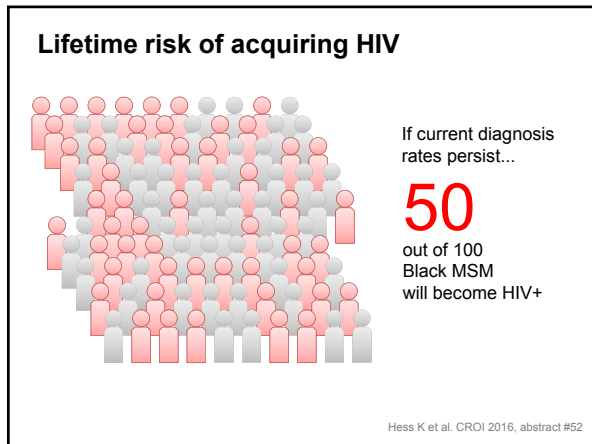


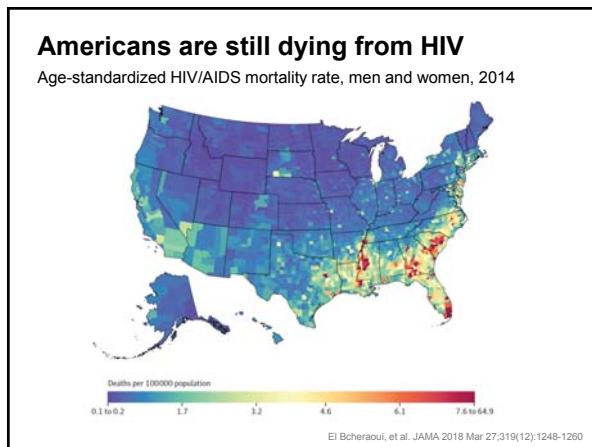


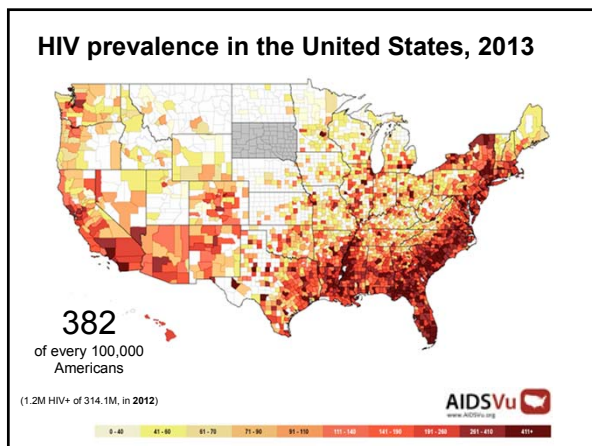


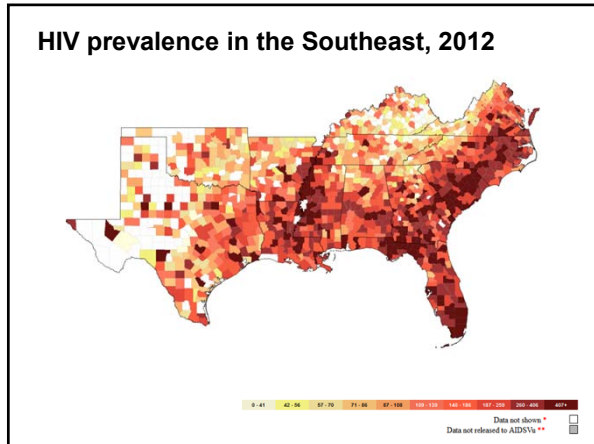


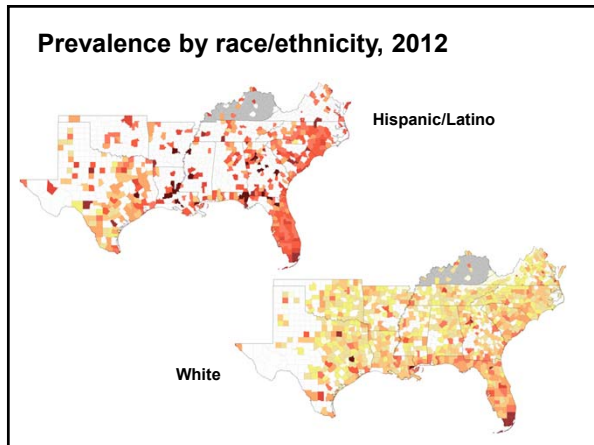


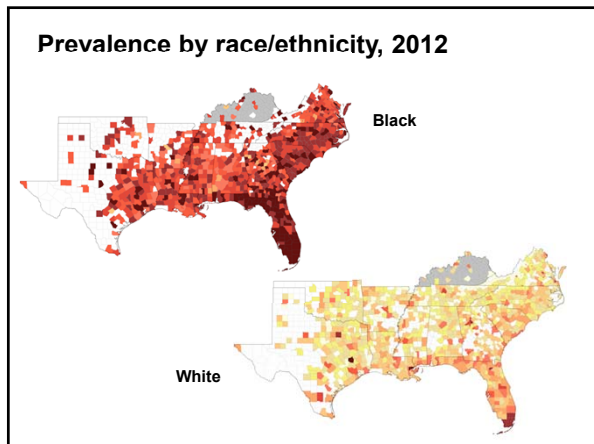












Access to meds is essential for prevention



Treatment as prevention



PrEP
(and PEP)

What is pre-exposure prophylaxis?

Use of antiretroviral medications **before** an exposure, to reduce the risk of becoming infected

Tenofovir disoproxil fumarate (TDF) is the most studied agent for PrEP

- Properties of drug allow infrequent dosing
- Few drug-drug interactions
- Safe and well tolerated

FDA approved in 2012
USPHS guideline in 2014
(emtricitabine / TDF = **Truvada**)





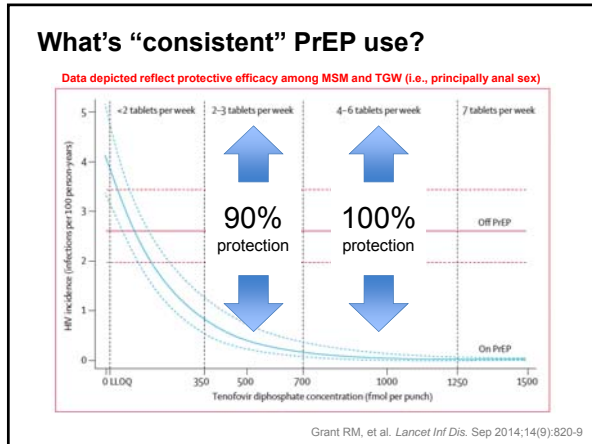
When taken consistently, oral PrEP reduces risk of HIV infection as much as

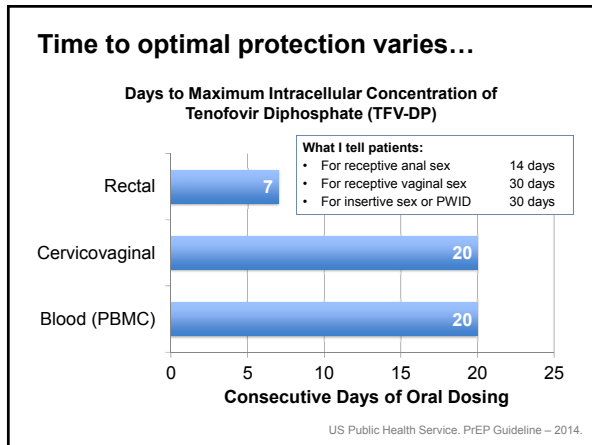
90-100%

among cisgender MSM, heterosexual men & women, and transgender women.

(84% among PWID)

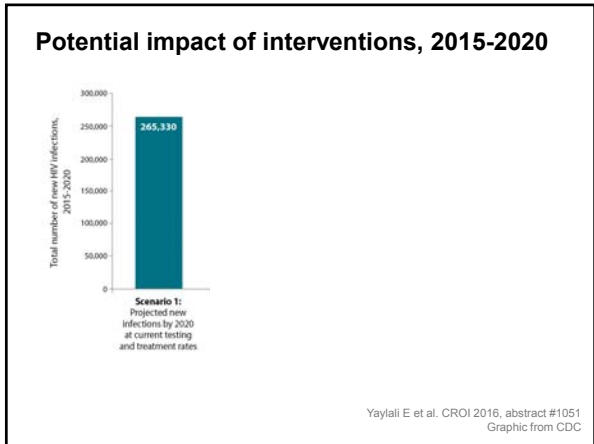
Grant RM, et al. *NEJM*. Dec 2010;363(27):2587-99
Baeten JM, et al. *NEJM*. Aug 2012;367(5):399-410
Grant RM, et al. *Lancet Inf Dis*. Sep 2014;14(9):820-9
Martin M, et al. *AIDS*. Apr 2015;29(7):819-24

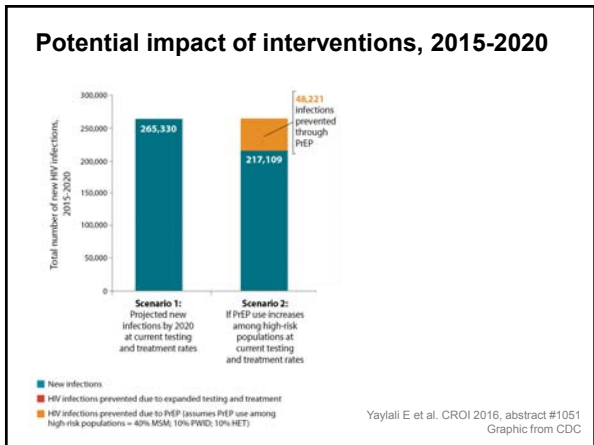


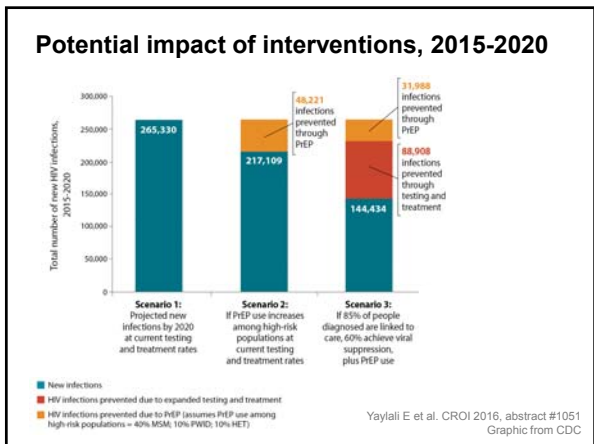


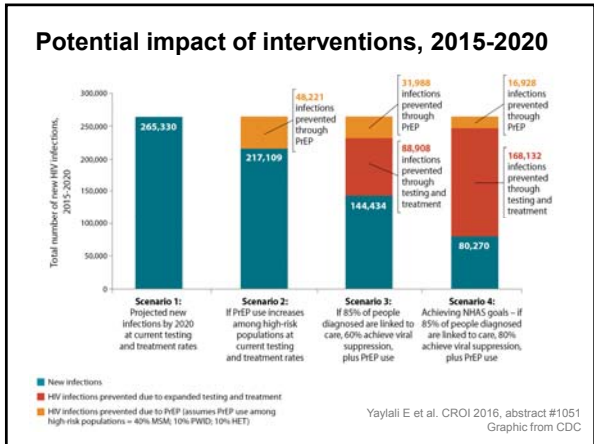
Key points

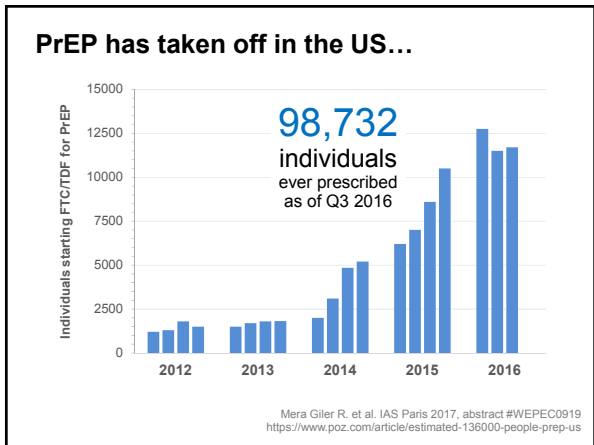
- Daily dosing affords greatest protection
- Occasional missed dose probably OK (less OK for women...)
- Nonadherence creates opportunities for infection

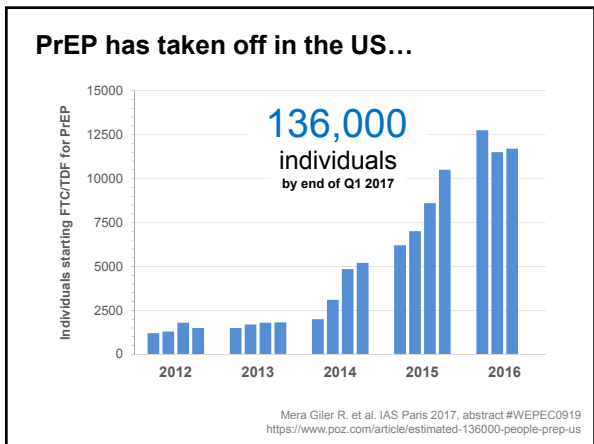


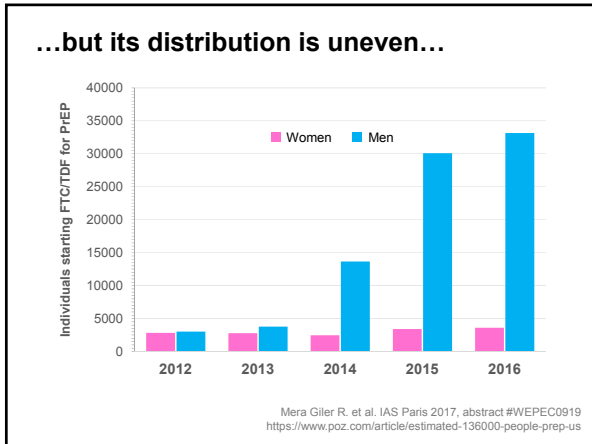


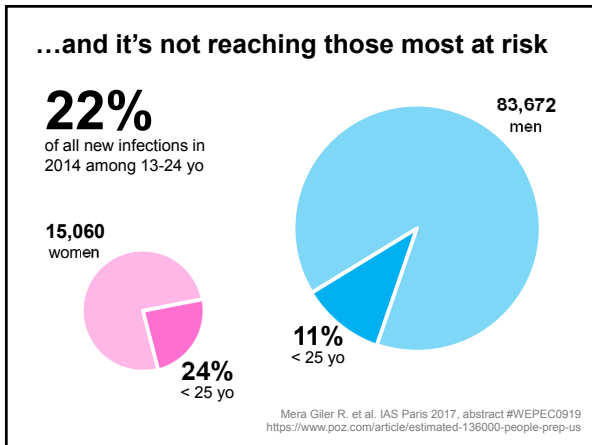


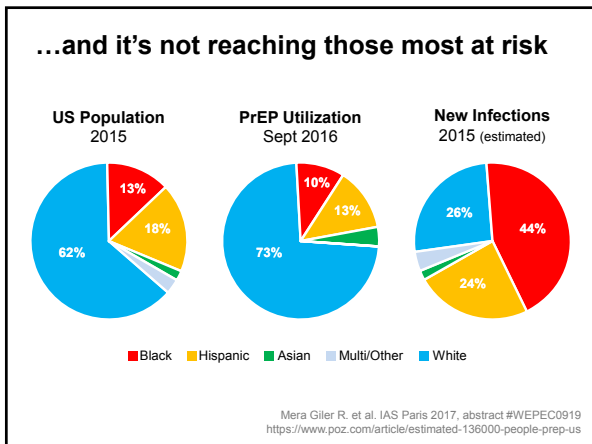


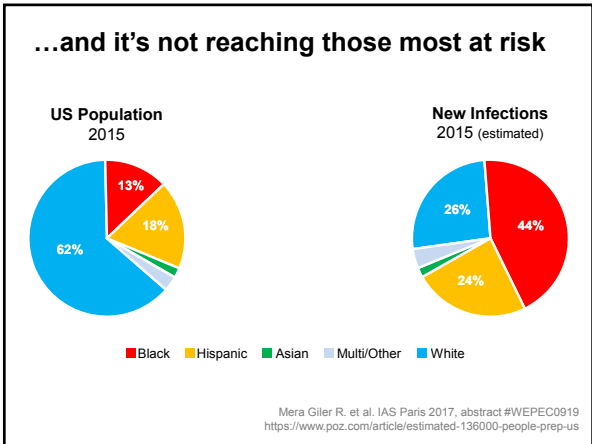


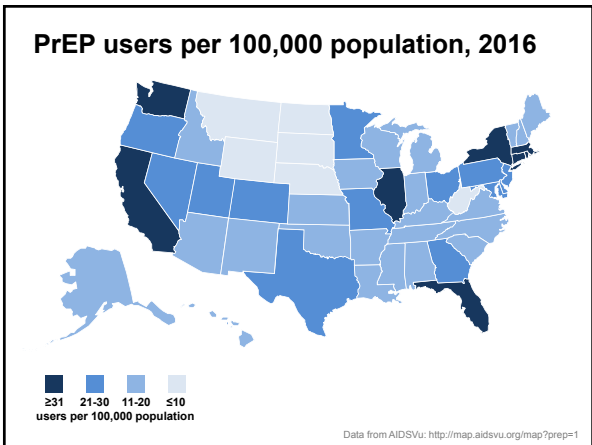


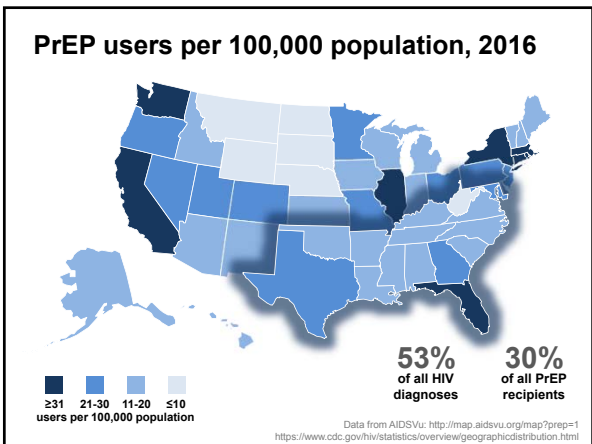


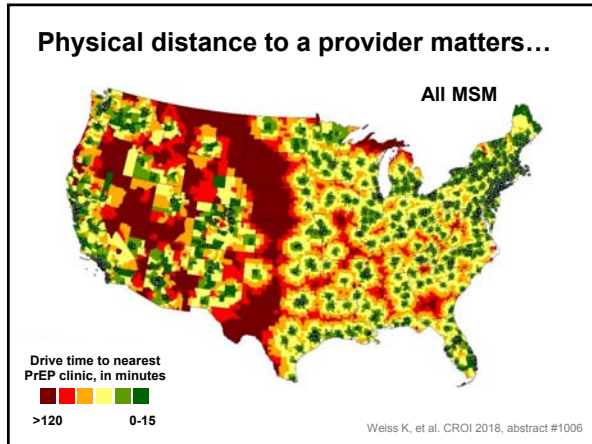


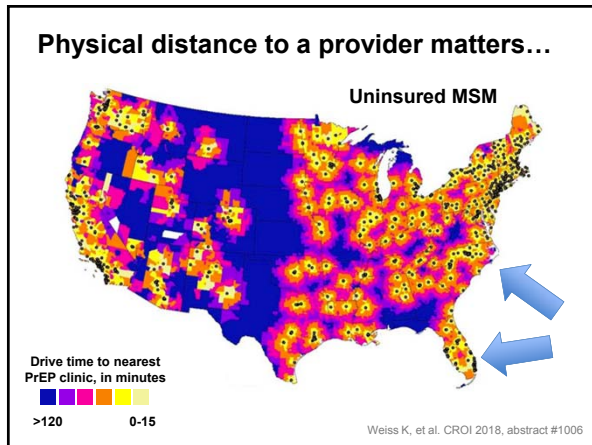












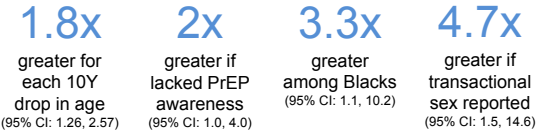


...but it doesn't tell the whole story

US PrEP Demo Project

Miami, SF, DC – 2012-2014

Adjusted odds of loss to follow-up by week 12 were:



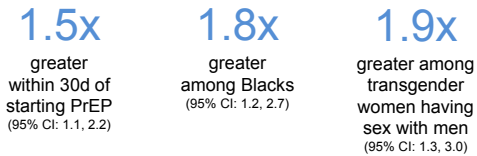
Doblecki-Lewis S, et al. CROI 2018, abstract #1013

...but it doesn't tell the whole story

SF Primary Care Clinics

Fifteen public clinics throughout city – 2013-2017

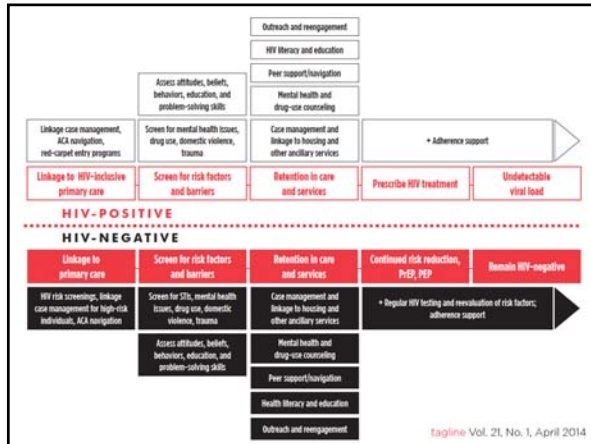
Adjusted hazard of discontinuing PrEP was:



Doblecki-Lewis S, et al. CROI 2018, abstract #1013

Take-home messages on access & equity

- Efforts to support early retention are critical
- Young people need more support if they are to adhere to PrEP and be retained in care
- Poorer retention among Blacks is another sign of structural barriers they face day-to-day
- Providers need to inquire about social marginalization and offer additional support



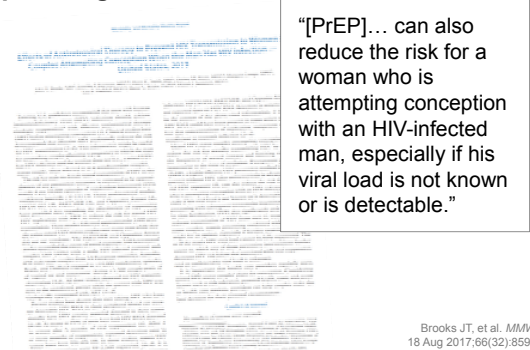




PrEP for special populations



CDC acknowledges PrEP in conception planning

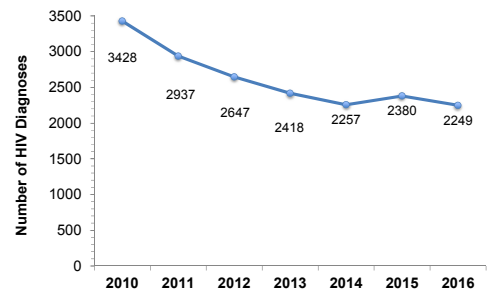


“[PrEP]... can also reduce the risk for a woman who is attempting conception with an HIV-infected man, especially if his viral load is not known or is detectable.”

Brooks JT, et al. *MMWR*. 18 Aug 2017;66(32):859-60

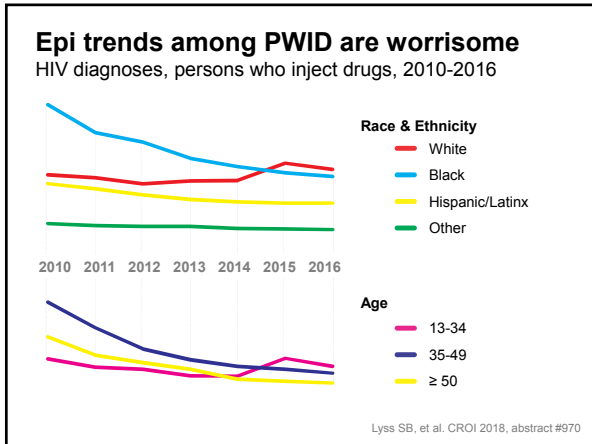
Epi trends among PWID are worrisome

HIV diagnoses, persons who inject drugs, 2010-2016




Year	Number of HIV Diagnoses
2010	3428
2011	2937
2012	2647
2013	2418
2014	2257
2015	2380
2016	2249

Lyss SB, et al. *CROI* 2018, abstract #970



Bangkok Tenofovir Study

Persons who inject drugs









June 2005 - June 2012 (endpoint reached Nov 2011)

49% preventive efficacy among all participants (95% CI: 9.6, 72.2; modified intention-to-treat)














83.5% preventive efficacy among participants with excellent adherence (n=849; defined as ≥97.5%)

Martin M, et al. AIDS. 2015 Apr 24; 29(7):819-24



Pregnancy Prevention	Pregnancy Prevention	HIV Prevention
Education & behavior modification	Education & behavior modification	Behavior modification
Condoms	Condoms 	Condoms
Rings	Rings 	Rings
Birth control pill & injection	Birth control pill & injection 	PrEP (oral & injectable)
"Morning-after pill"	"Morning-after pill" 	Post-exposure prophylaxis
Spermicide	Spermicide 	Topical microbicides
Implantable birth control	Implantable birth control 	Broadly neutralizing Abs Implantables
Vasectomy/Tubal Ligation	Vasectomy/Tubal Ligation	Vaccination

Adapted from HPTN

Pregnancy Prevention	HIV Prevention
Education & behavior modification	Education & behavior modification
Condoms 	Condoms 
Rings 	Rings 
Birth control pill & injection 	PrEP (oral & injectable) 
"Morning-after pill" 	Post-exposure prophylaxis 
Spermicide 	Topical microbicides 
Implantable birth control 	Broadly neutralizing Abs Implantables 
Vasectomy/Tubal Ligation 	Vaccination

Adapted from HPTN

PrEP 2.0 is coming...



FTC / TAF



dapivirine ^{NNRTI}



cabotegravir-LA ^{INI}



broadly neutralizing
monoclonal
antibodies
(bnAbs)

The big picture



PrEP is a **proven, well-tolerated, highly effective** tool for HIV prevention when taken every day.



Questions?


Please email me!

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EXTRA SLIDES

Safety of FTC/TDF in pregnancy is clear




FTC/TDF is category B¹

No evidence of birth defects among babies born to mothers taking TDF for HIV¹

No data suggesting PrEP is unsafe in pregnancy or lactation²

1 Wang L, et al. *Clin Infect Dis*. 2013 Dec;57(12):1773-81
2 Mofenson LM, et al. *AIDS*. 2017 Jan 14;31(2):213-232

Efficacy of PrEP in pregnancy is unknown



Risk of HIV acquisition higher during pregnancy & post-partum¹

Women who became pregnant in PrEP trials stopped FTC/TDF²

CDC/USPHS 2014³

- Ensure male partner undetectable
- Begin PrEP 1 month before, continue for 1 month after conception attempt

1 Thomson KA, et al. *J Infect Dis*. 2018 Mar 5. [ePub ahead of print]
2 Mofenson LM. *PLoS Med*. Sep 2016;13(9):e1002133
3 CDC/USPHS 2014 PrEP Guideline – Clinical Providers' Supplement

Efficacious, but may be too expensive...

Estimation of the cost-effectiveness of HIV prevention services for people who inject drugs in the United States: A randomized program

Bernard CL, et al. *PLoS Med.* 2017 May 27;14(5):e1002312

Scaling up services to 50% coverage among US PWID...

OAT	22,000 infections averted \$18,000 / QALY
NSP	35,000 infections averted \$25,000 / QALY
Test & Treat	6,700 infections averted \$27,000 / QALY
PrEP	37,000 infections averted \$300,000 / QALY
