

PrEP in 2019

State of the Science
& Challenges Ahead





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School of Medicine

As of 1 Oct 2018, Dr. Hurt serves as UNC site PI for a Gilead-funded study of PrEP (DISCOVER, comparing FTC/TAF vs FTC/TDF).

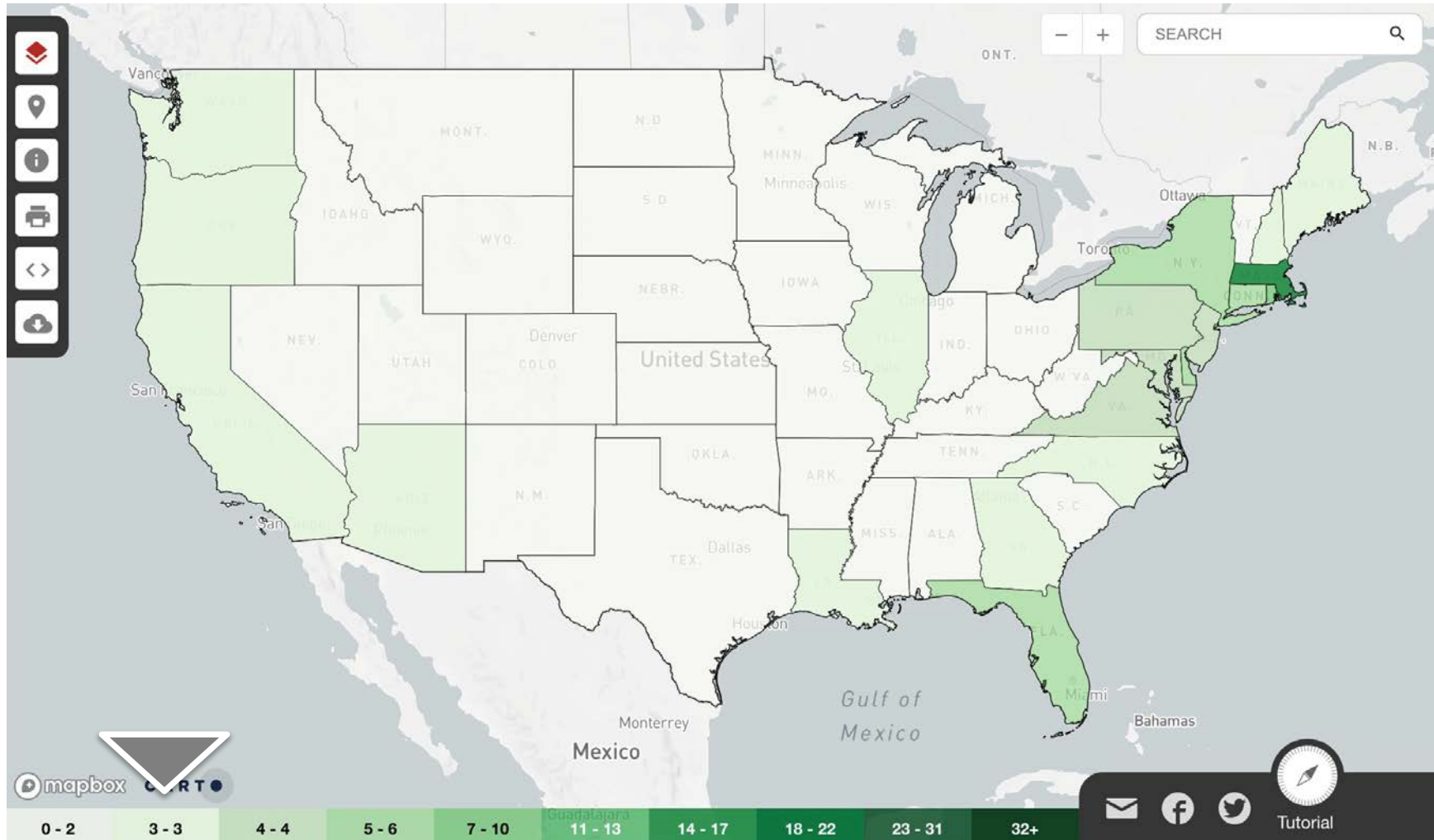
Dr. Hurt is supported by the Centers for Disease Control and Prevention (ELC-2017-J3), Health Resources and Services Administration (U1OHA30535), Eunice Kennedy Shriver National Institute of Child Health & Human Development (U19HD089881), the National Institute on Drug Abuse (UG3DA044823), and the National Institute of Allergy and Infectious Diseases (P30AI50410, UM1AI069423, UM1AI068619).

The views expressed are not necessarily those of CDC, HRSA, or the NIH.

Objectives

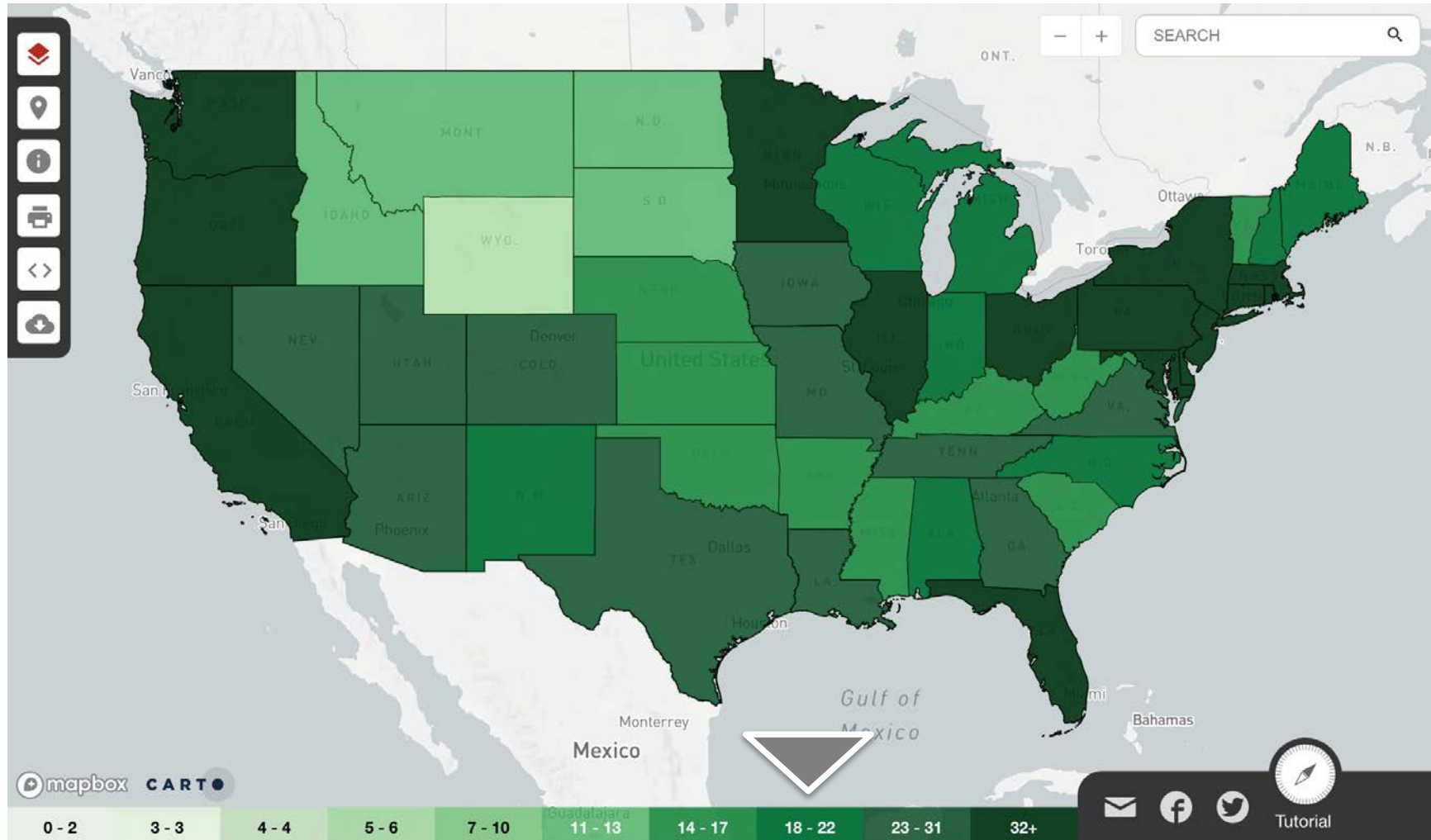
- Describe current trends in PrEP access and uptake in the US
- Explain what the “pipeline” for biomedical prevention looks like as of 2019
- Outline the challenges in PrEP science that our CFAR PrEP Scientific Working Group is well-positioned to address

PrEP users per 100,000 population, 2012



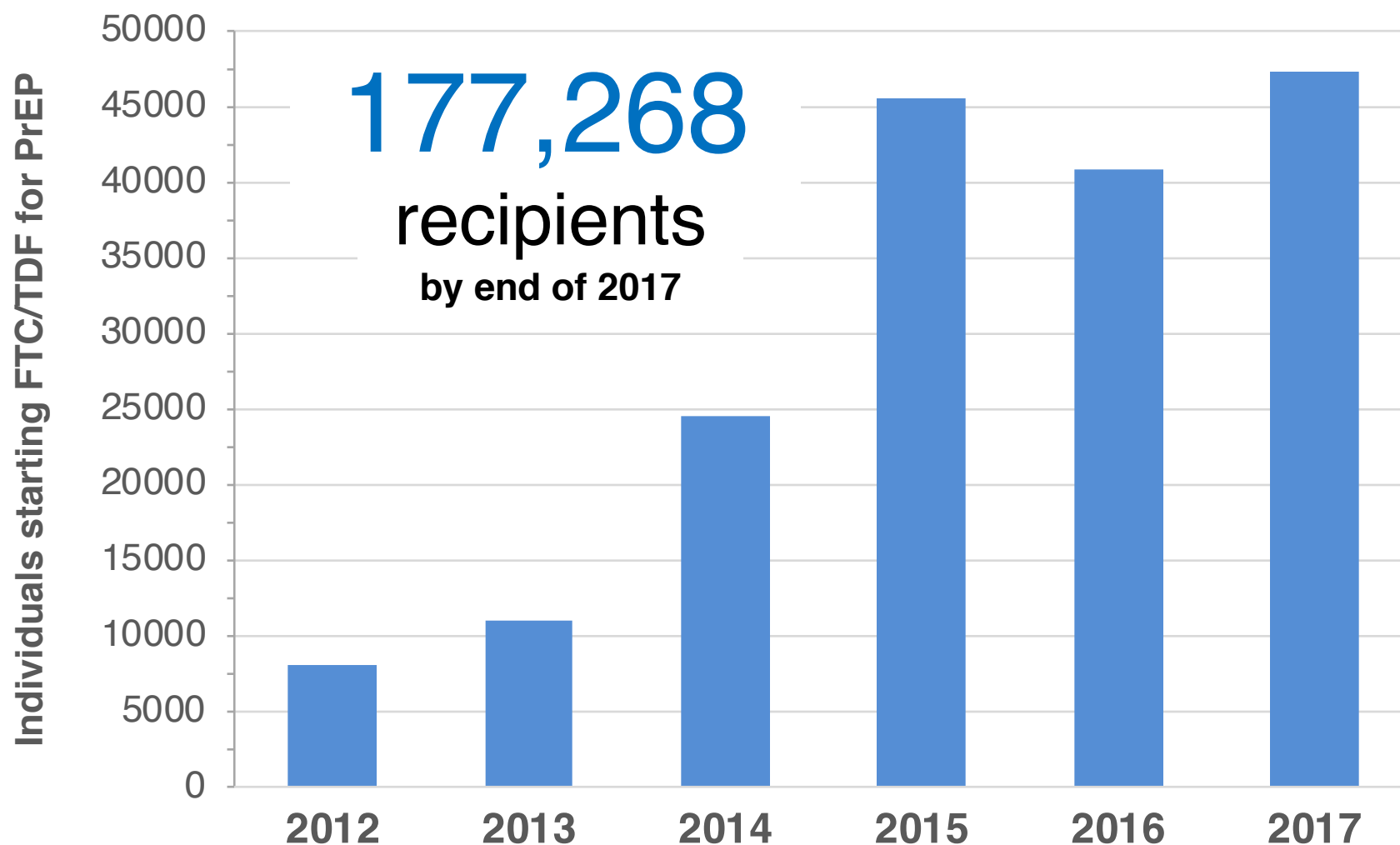
NC: 3 per 100,000

PrEP users per 100,000 population, 2017

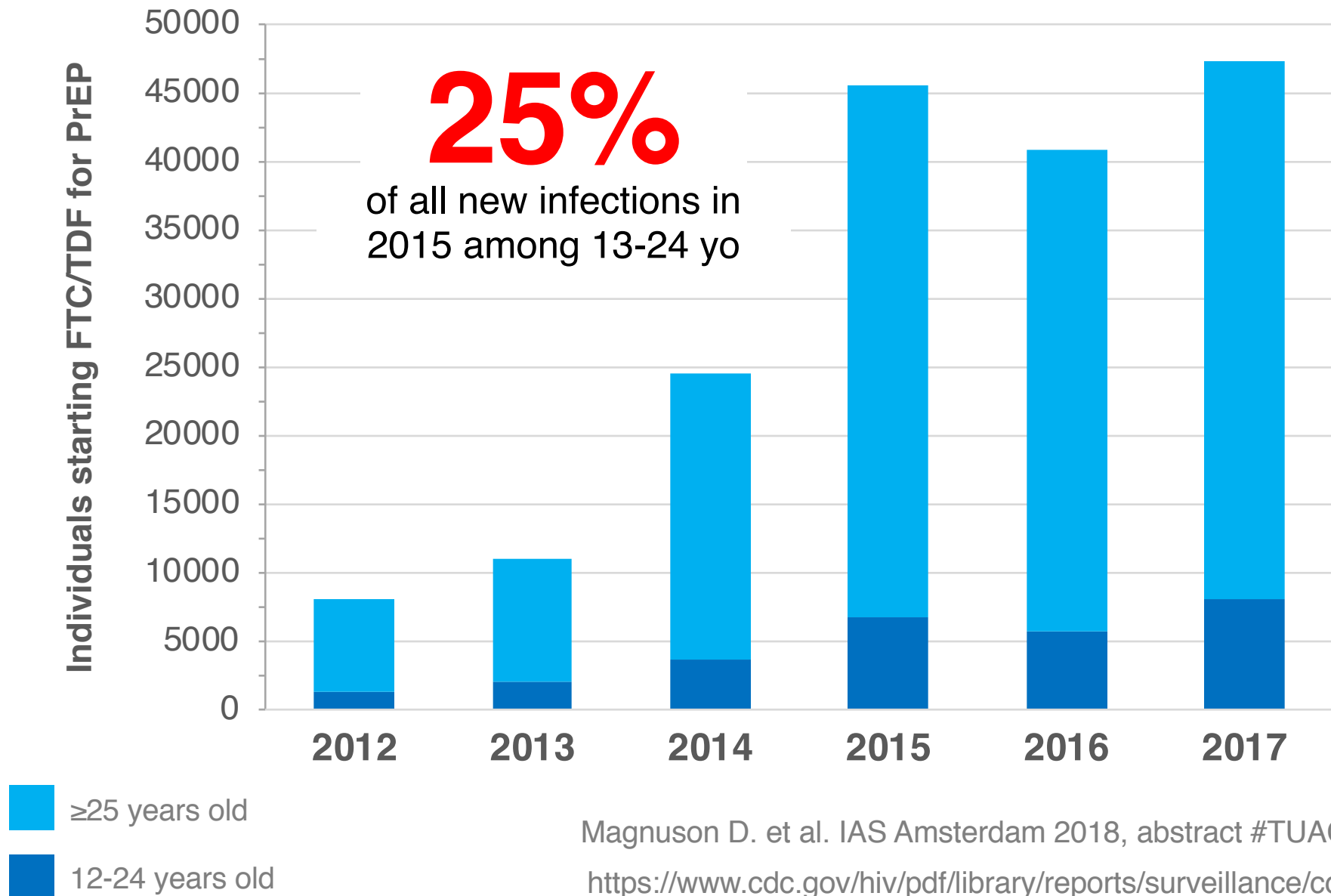


NC: 21 per 100,000

PrEP has taken off in the US...



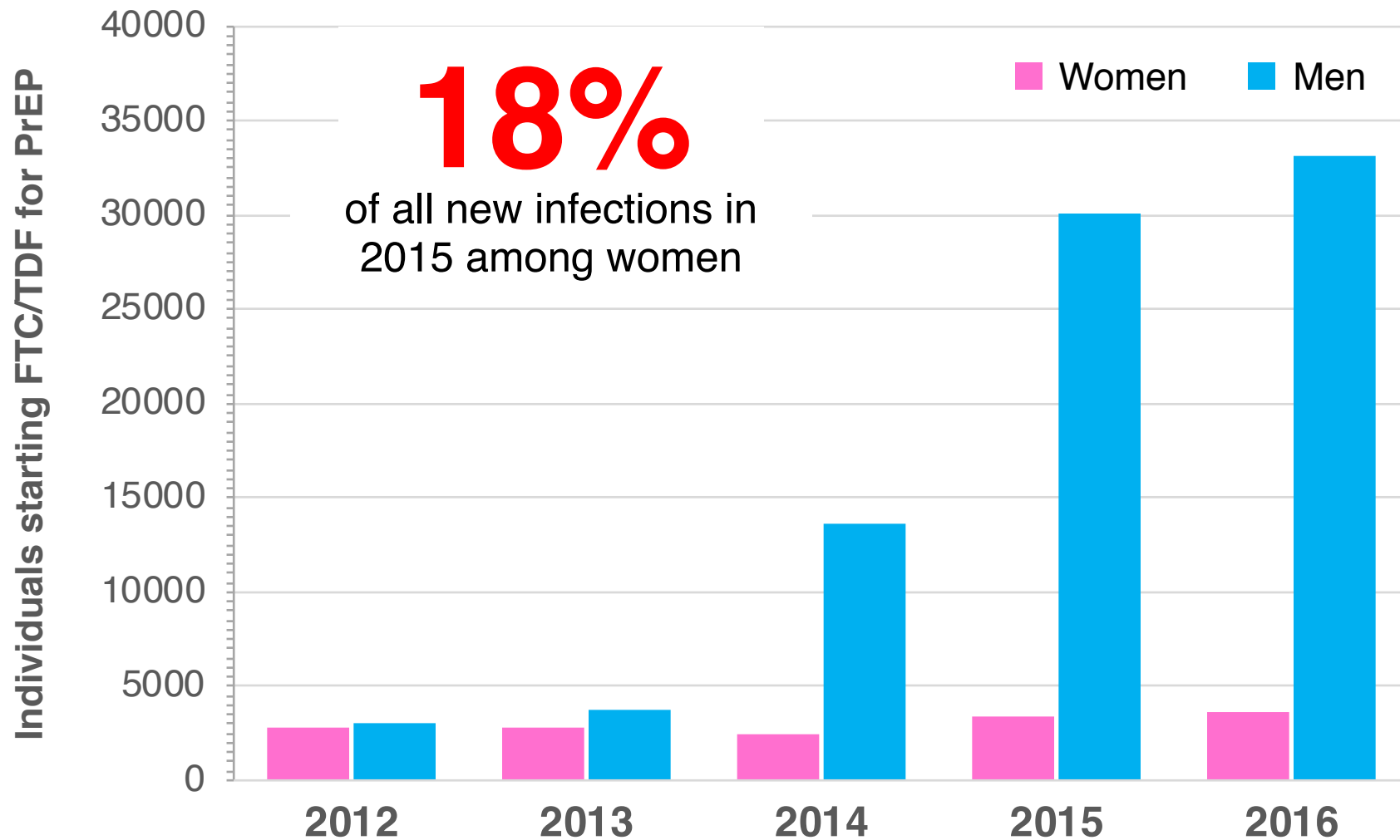
...but its distribution remains uneven...



Magnuson D. et al. IAS Amsterdam 2018, abstract #TUAC0305

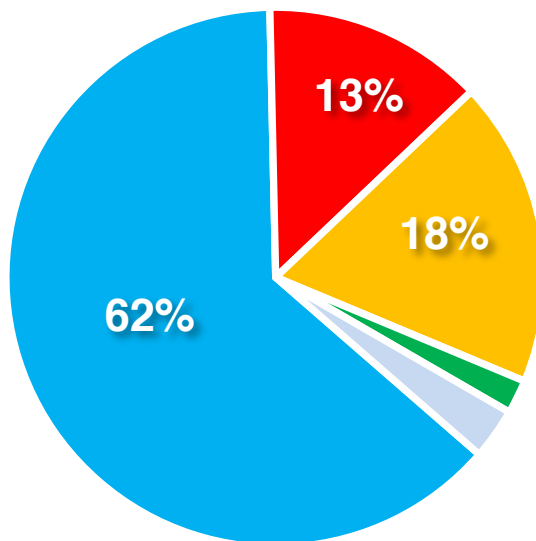
<https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-23-1.pdf>

...but its distribution remains uneven...

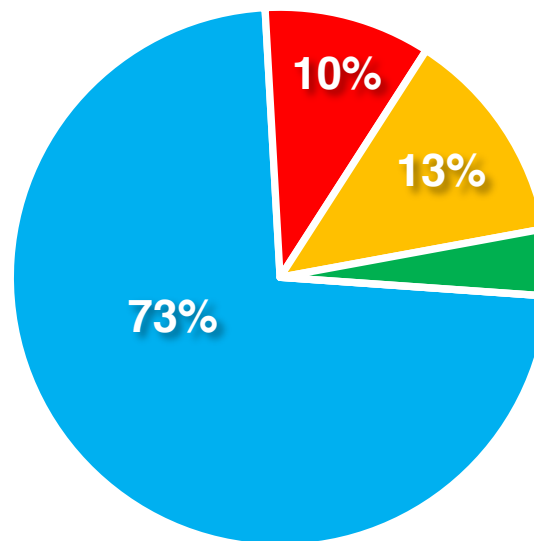


...and it's not reaching those most at risk

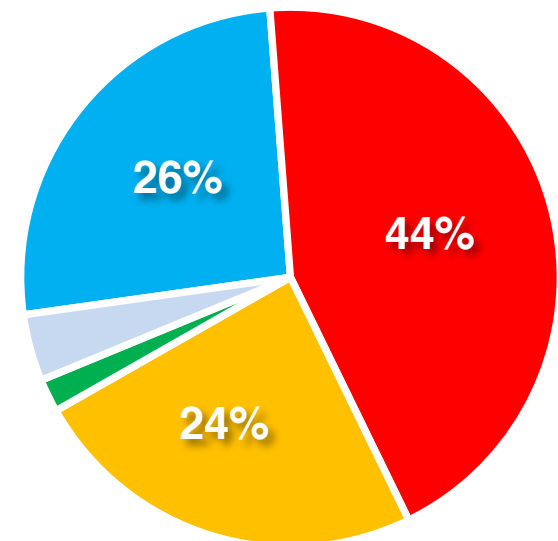
US Population
2015



PrEP Utilization
Sept 2016



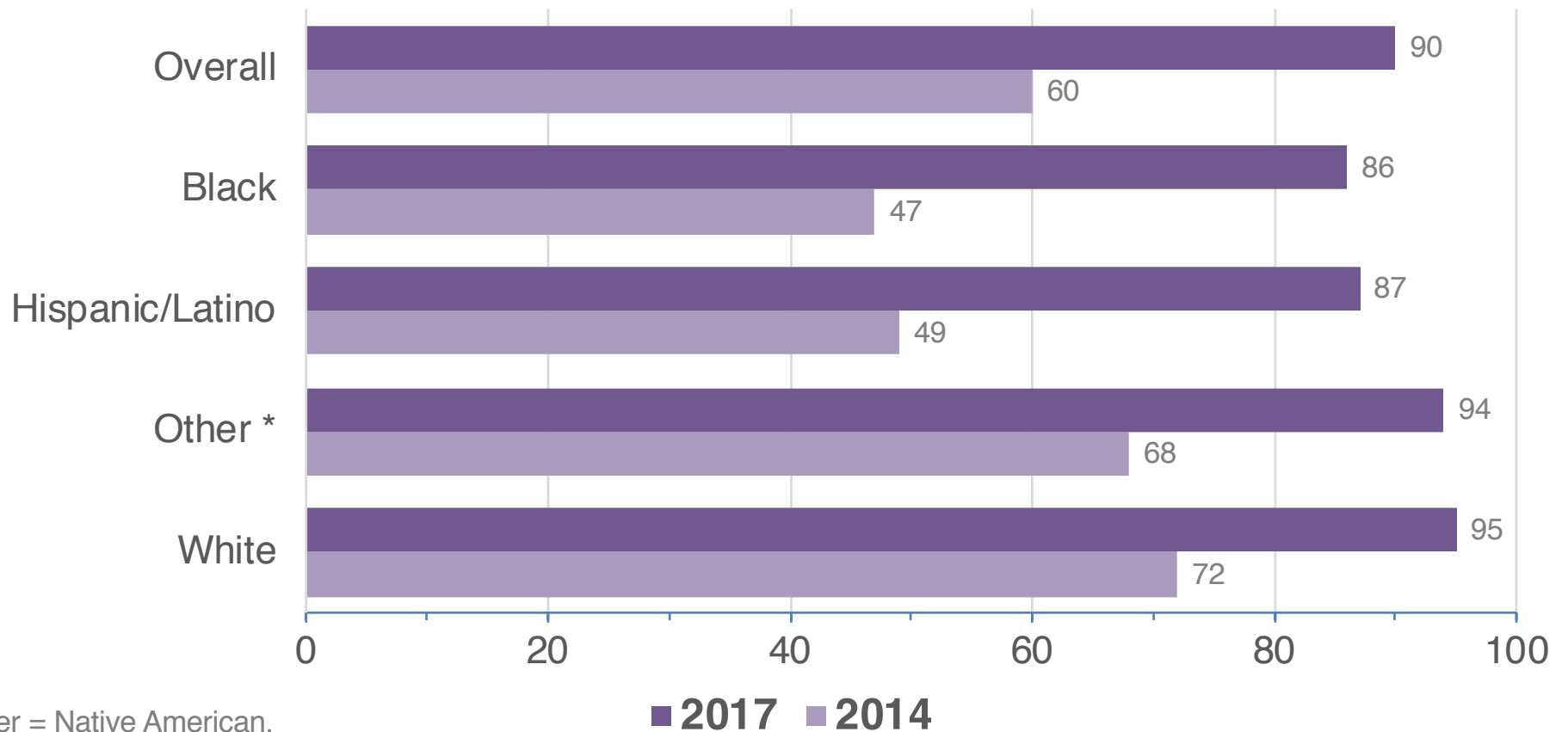
New Infections
2015 (estimated)



■ Black ■ Hispanic ■ Asian ■ Multi/Other ■ White

New data show racial disparities persist

NHBS MSM: % aware of PrEP

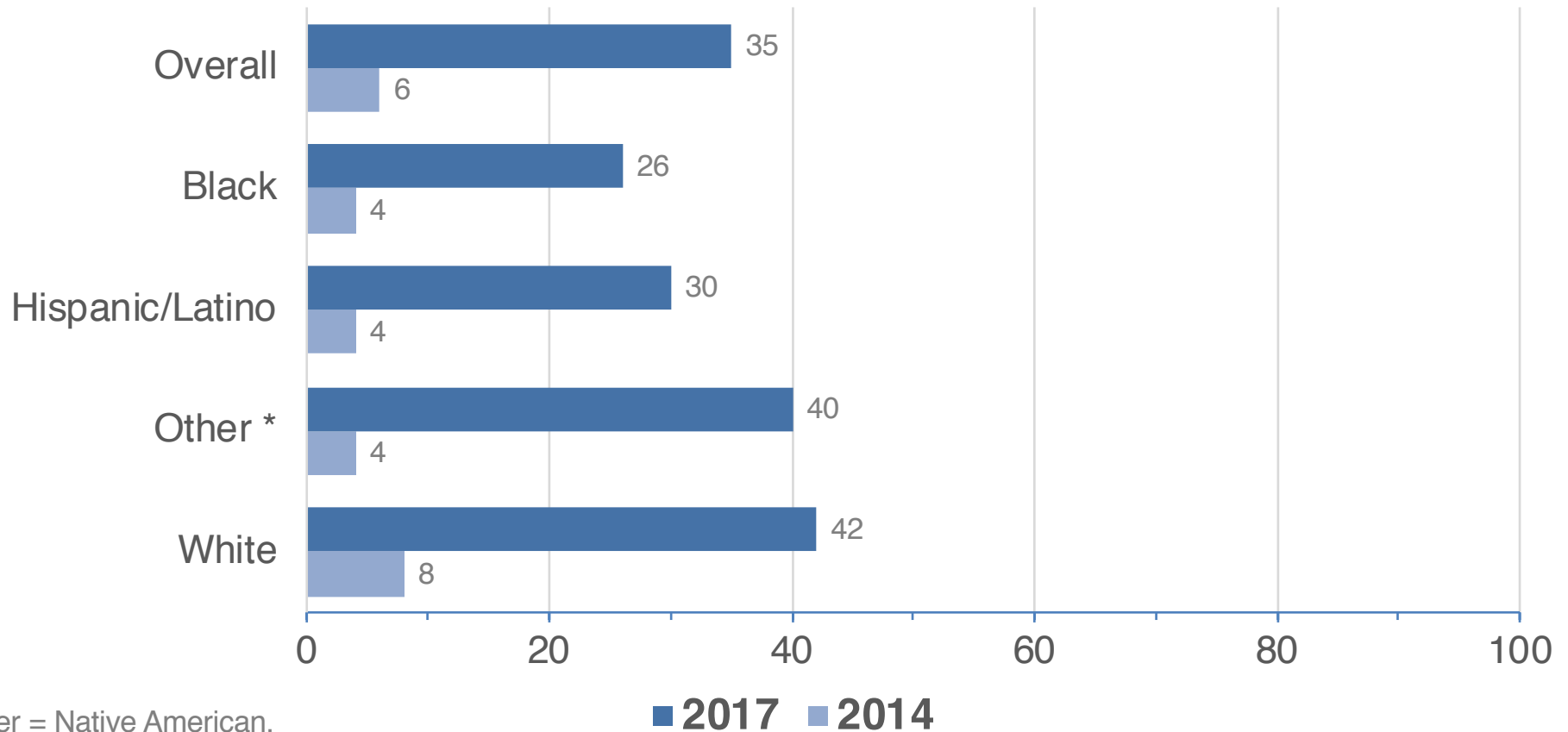


Other = Native American,
Asian/Pacific Islander, Multiple Races

National HIV Behavioral Surveillance MSM Cycles — Finlayson T. et al. CROI 2019, abstract 972
<http://www.croiconference.org/sessions/changes-hiv-prep-awareness-and-use-among-men-who-have-sex-men-2014-vs-2017>

New data show racial disparities persist

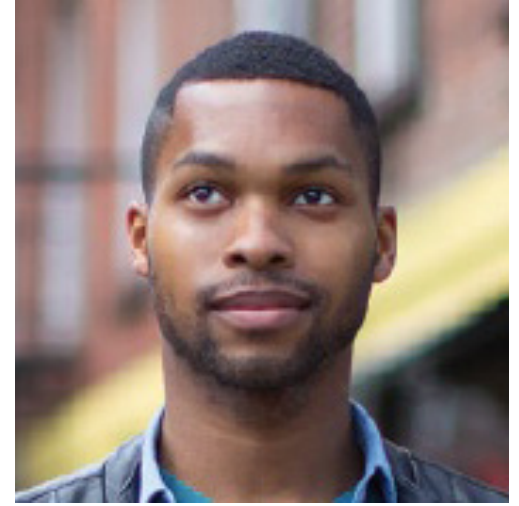
NHBS MSM: % reporting PrEP use in past 12m



Other = Native American,
Asian/Pacific Islander, Multiple Races

National HIV Behavioral Surveillance MSM Cycles — Finlayson T. et al. CROI 2019, abstract 972
<http://www.croiconference.org/sessions/changes-hiv-prep-awareness-and-use-among-men-who-have-sex-men-2014-vs-2017>

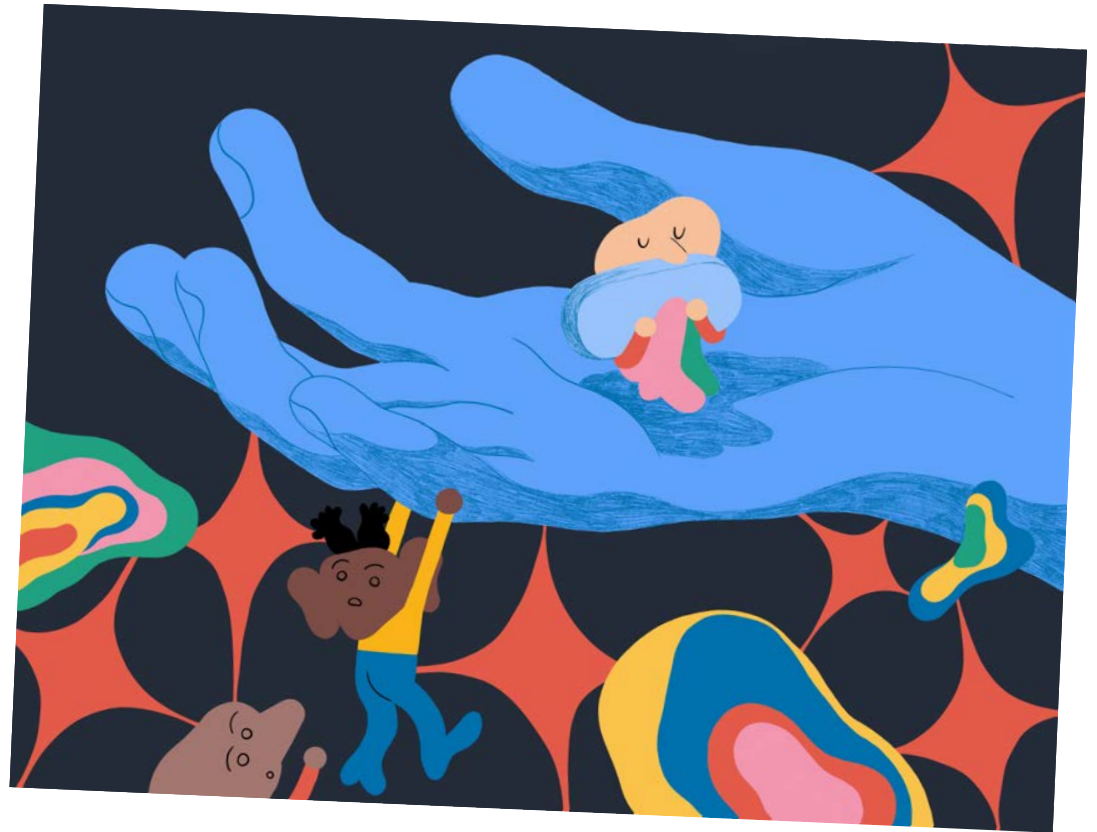
PrEP is now a matter of social justice...



...which requires addressing privilege...



via Instagram



Artwork by Amanda Baeza for Quartz
1 June 2018

<https://qz.com/1288341/has-prep-use-finally-reached-critical-mass/>

...and affordability of biomedical prevention



per month if paid
totally out-of-pocket

(excluding lab costs & provider fees)




Break the Patent → <https://slate.com/human-interest/2018/05/act-up-is-challenging-gilead-to-make-truvada-more-accessible.html>

TAF lawsuits → <https://www.latimes.com/business/la-fi-gilead-hiv-drug-lawsuit-20180509-story.html>

TAF patent → <https://www.i-mak.org/wp-content/uploads/2018/12/Roadmap-SE-Report-on-TAF-2018-05-07F.pdf>

Oral PrEP is poised for additional growth



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Draft Recommendation Statement

Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis

This opportunity for public comment expired on December 26, 2018 at 8:00 PM EST

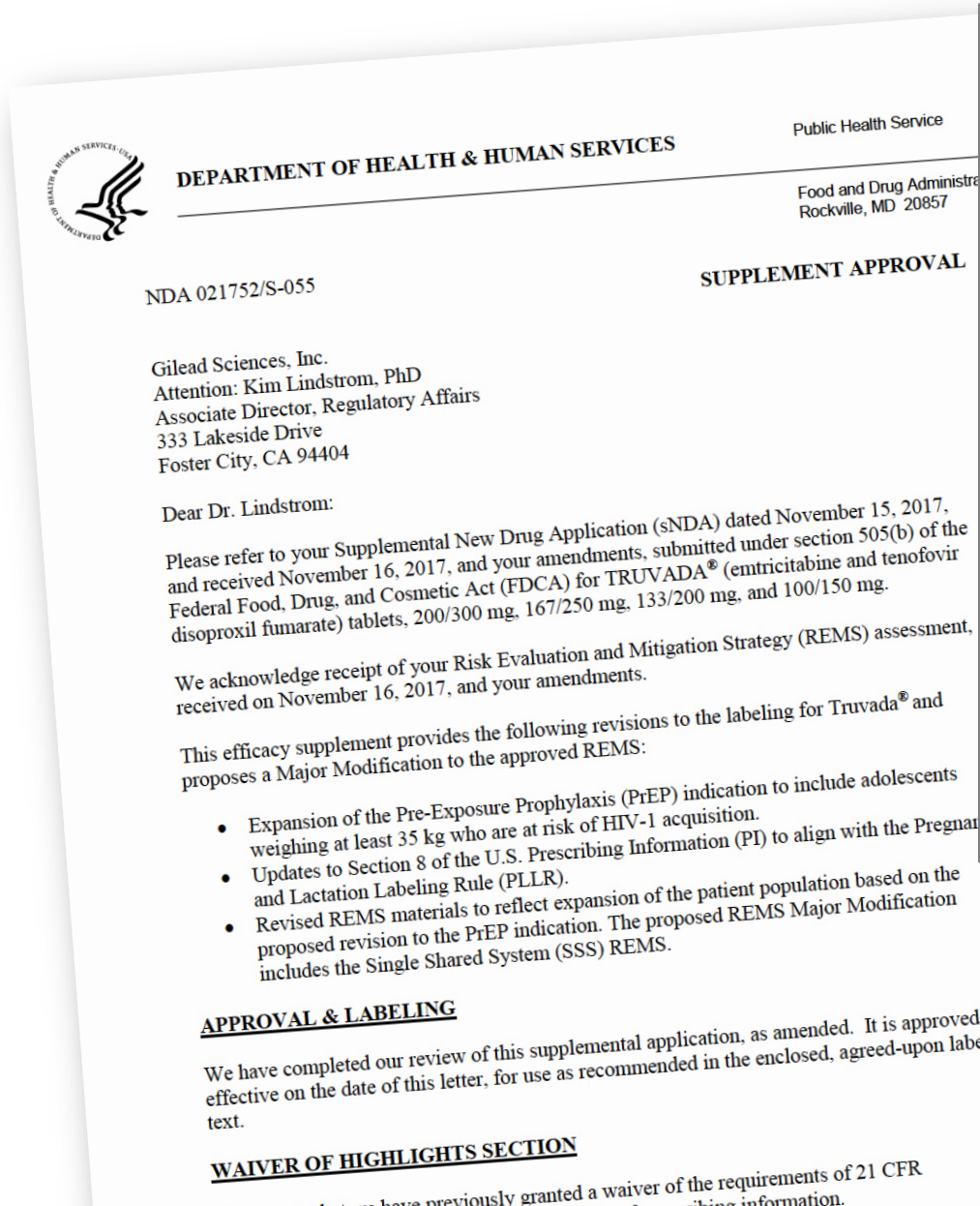
Note: This is a Draft Recommendation Statement. This draft is distributed solely for the purpose of receiving public input. It has not been disseminated otherwise by the USPSTF. The final Recommendation Statement will be developed after careful consideration of the feedback received and will include both the Research Plan and Evidence Review as a basis.

Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Draft: Recommendation Summary

Population	Recommendation	Grade (What's This?)
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.	A

Oral PrEP is poised for additional growth



Indicated... in combination with safer sex practices ... to reduce the risk of sexually acquired HIV-1 in at-risk adults **and adolescents weighing at least 35 kg.**

15 May 2018

<https://www.accessdata.fda.gov/>

But what's the right tone in messaging?



Los Angeles



Washington State



New South Wales, Australia



NYC



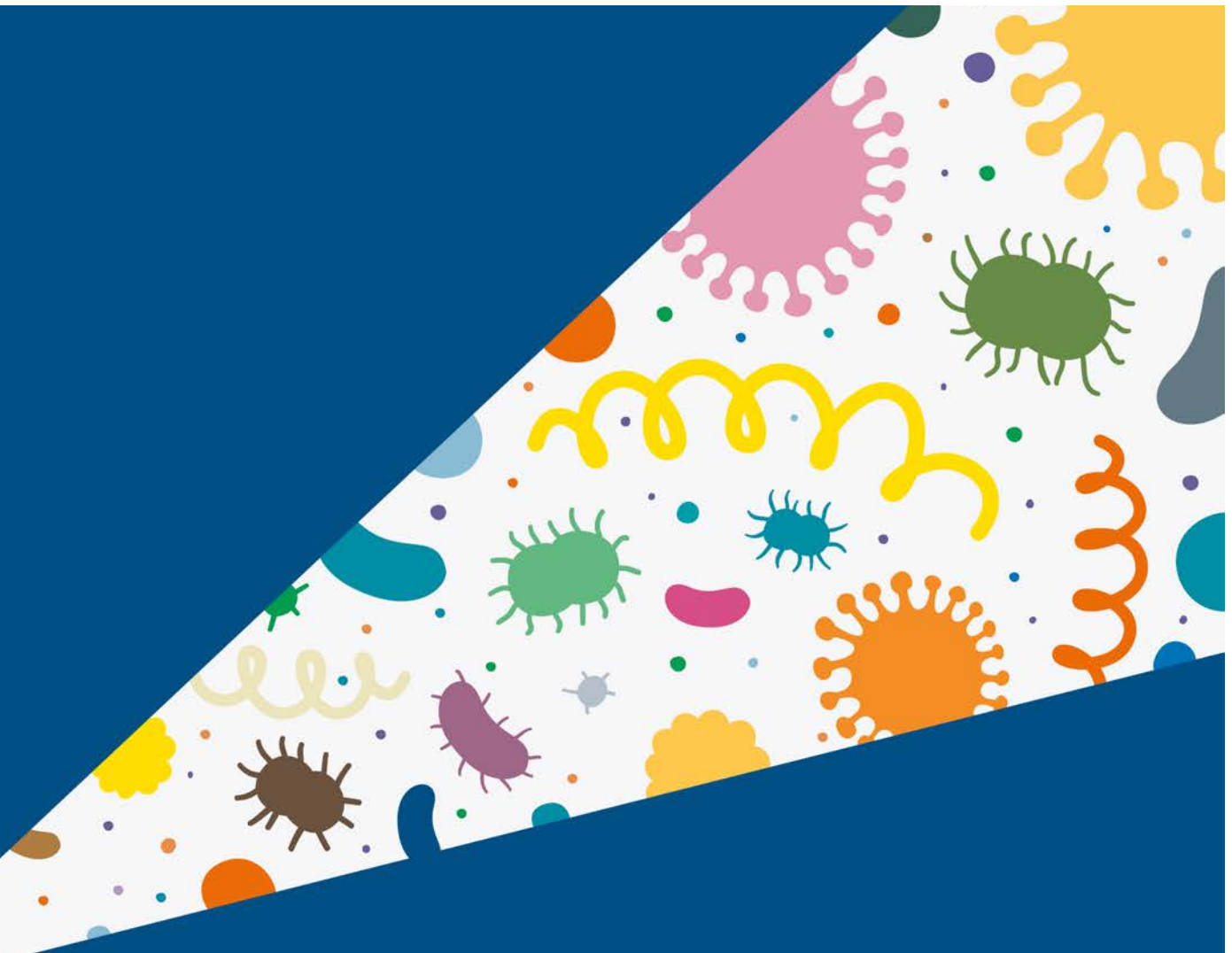
Chicago



North Carolina



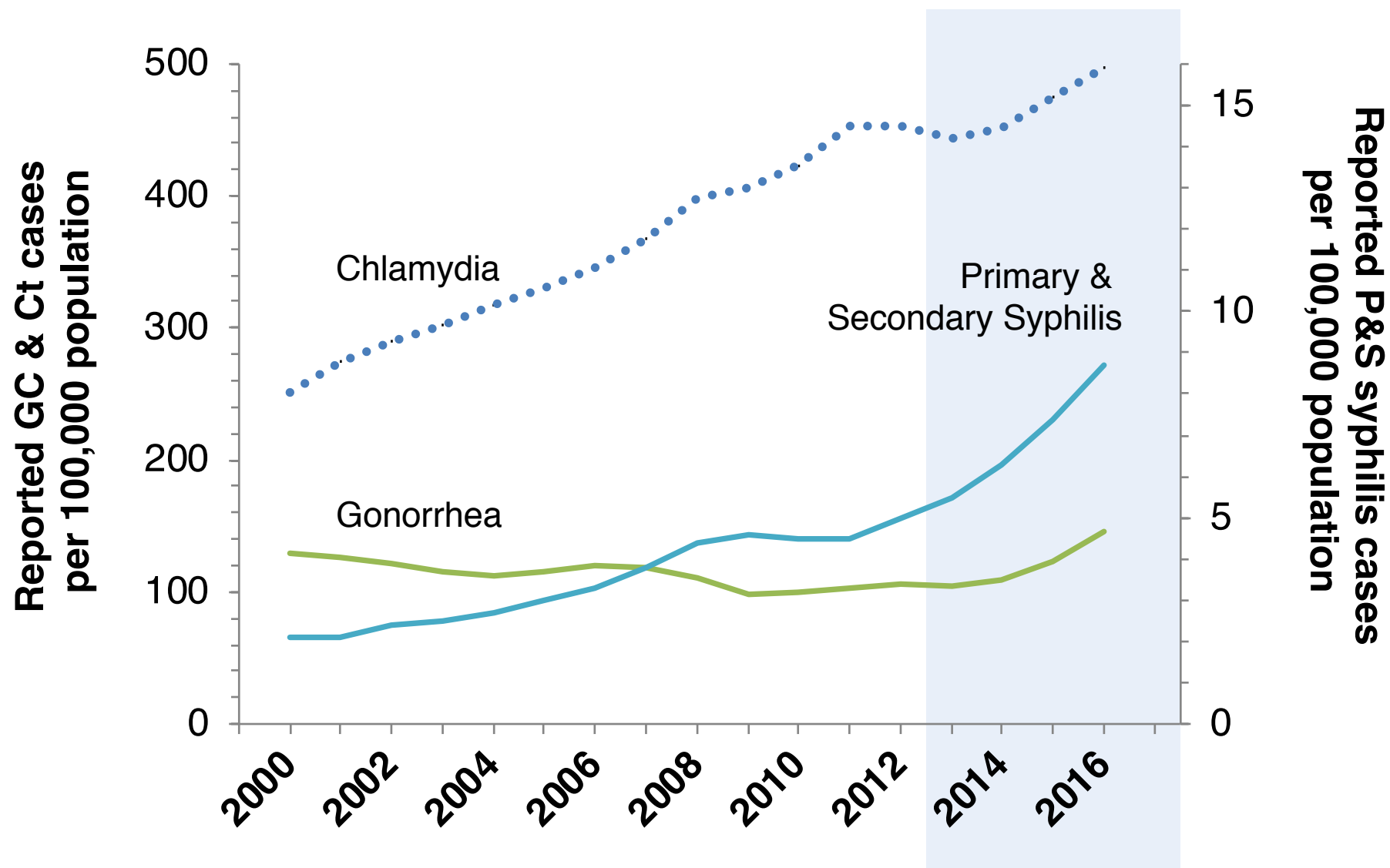
Melbourne, Australia



<https://mosaicscience.com/story/hiv-prep-truvada-prevention-sti-std-lgbtqi-gay-condom-pride/>

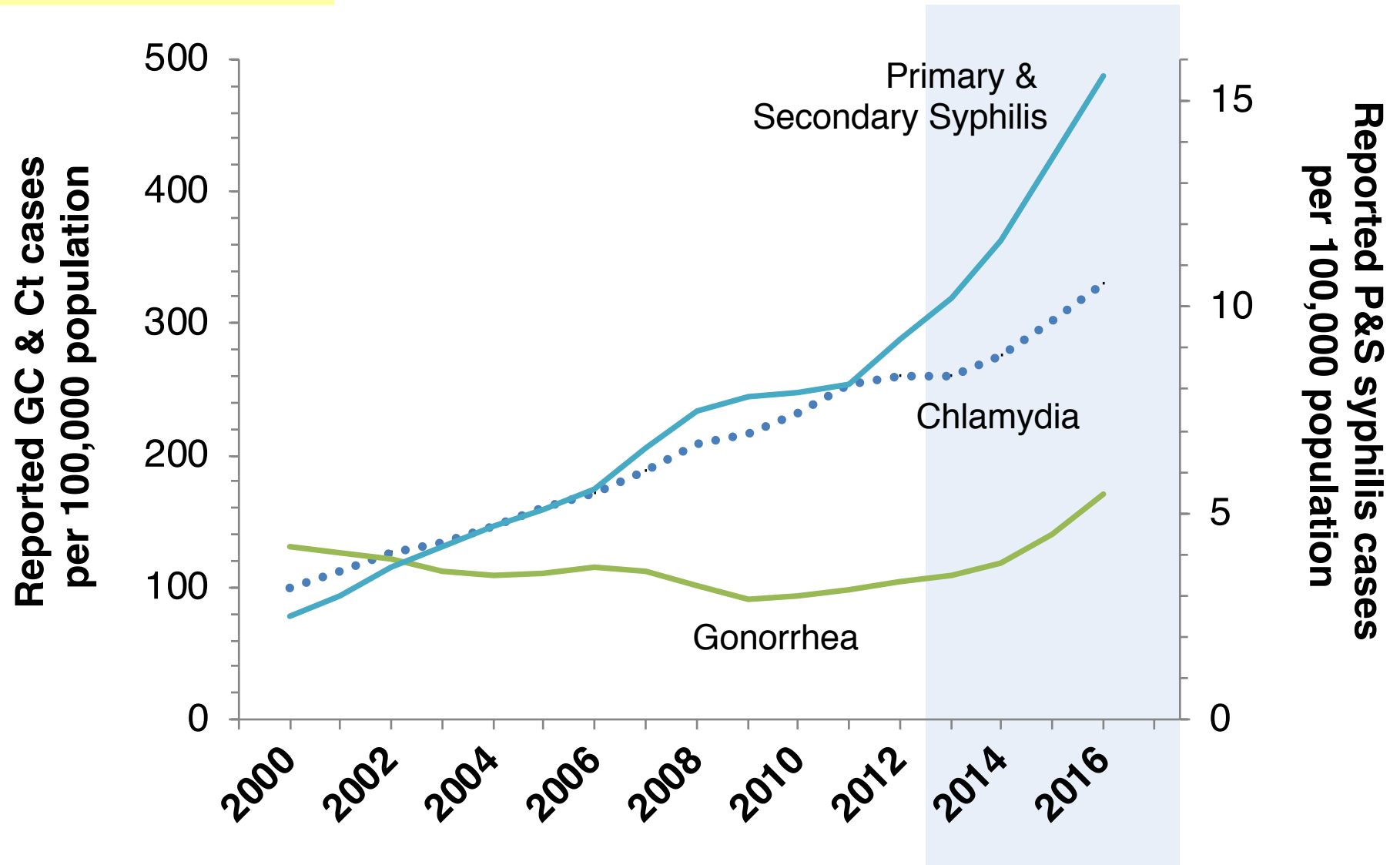
STIs in United States, 2000-2016

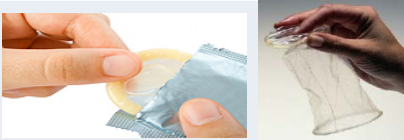













All Americans, all ages

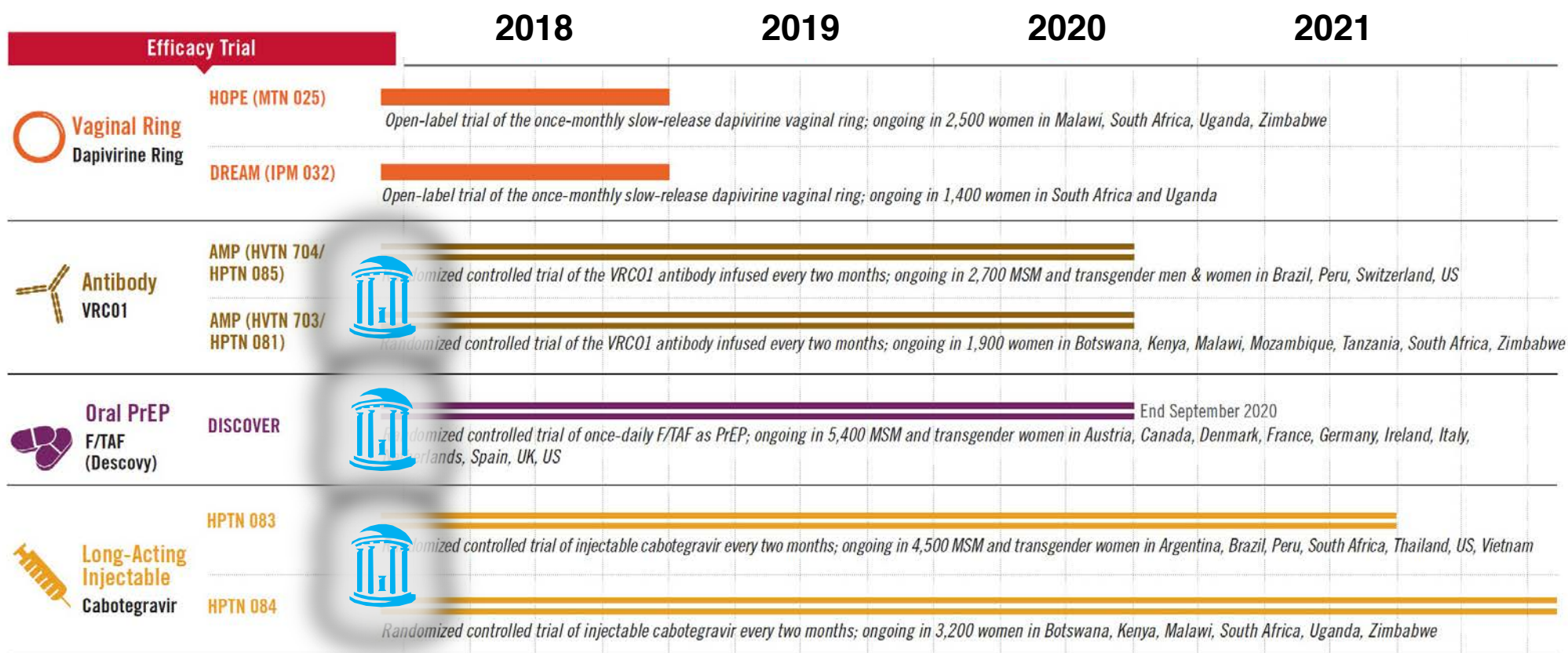


STIs in United States, 2000-2016

Men, all ages



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



 Open-label
 Randomized Controlled
 Open-label and Randomized
 Ongoing

AVAC

Global Advocacy for HIV Prevention

TAF non-inferior to TDF for MSM & TGW...

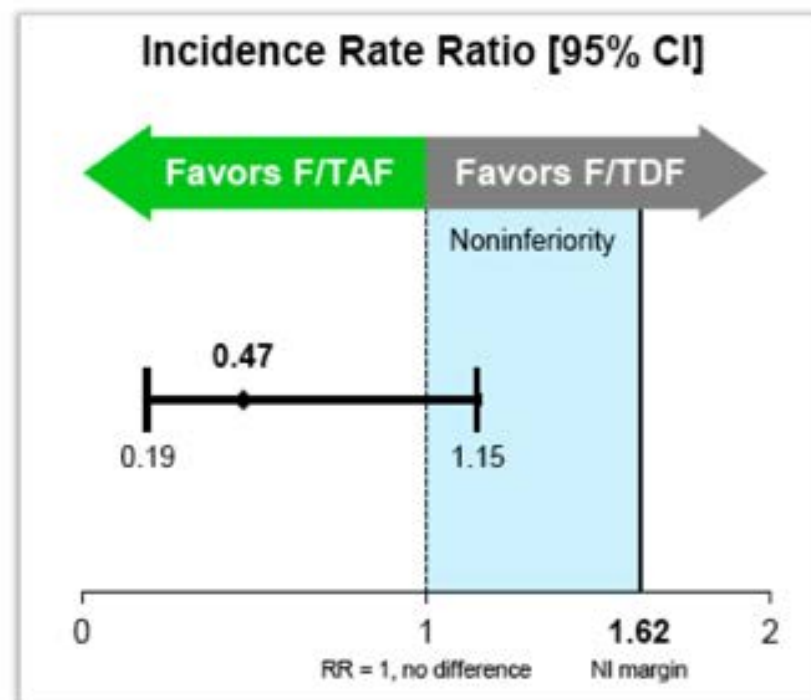
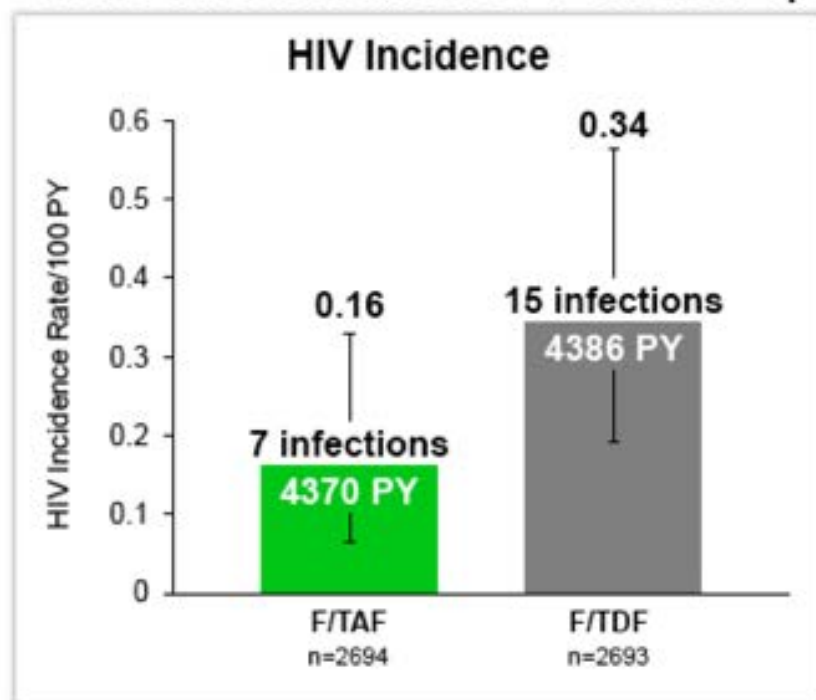


emtricitabine /
tenofovir alafenamide



emtricitabine /
tenofovir disoproxil

22 HIV infections in 8756 PY of follow-up



5313 MSM
74 transgender women

Hare B. et al. CROI 2019, abstract 104
http://www.natap.org/2019/CROI/croi_21.htm

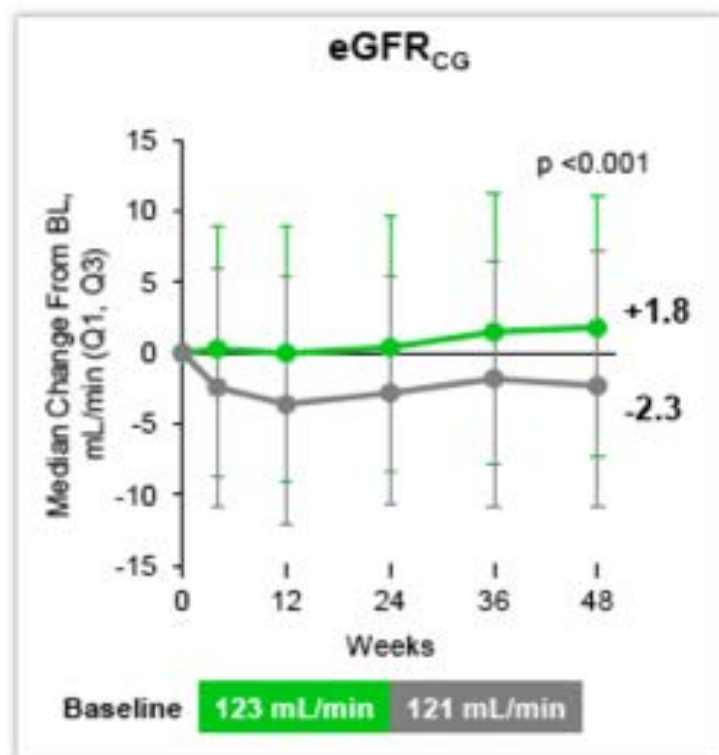
...without kidney or bone density issues



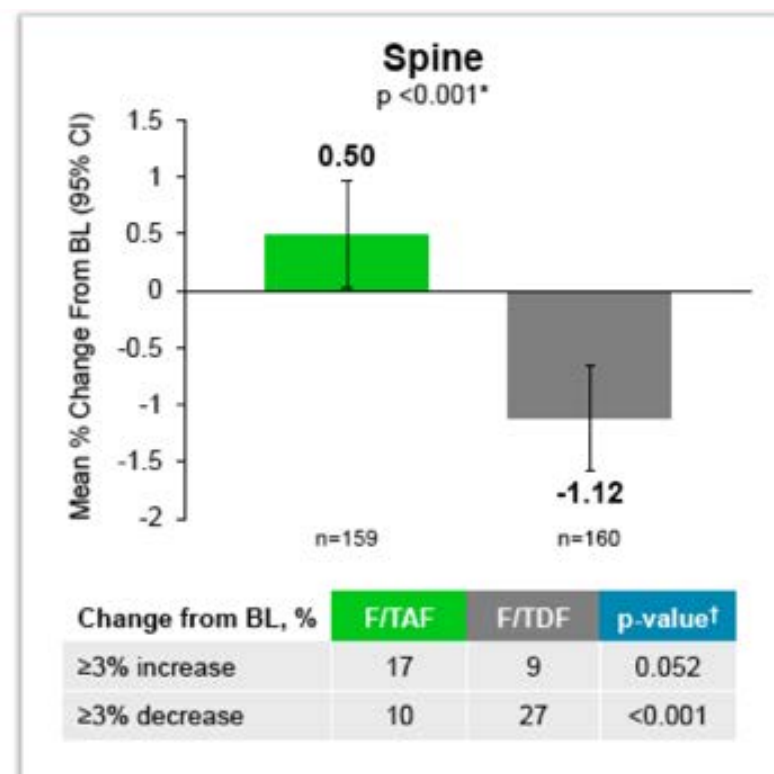
emtricitabine /
tenofovir alafenamide



emtricitabine /
tenofovir disoproxil



F/TAF **F/TDF**



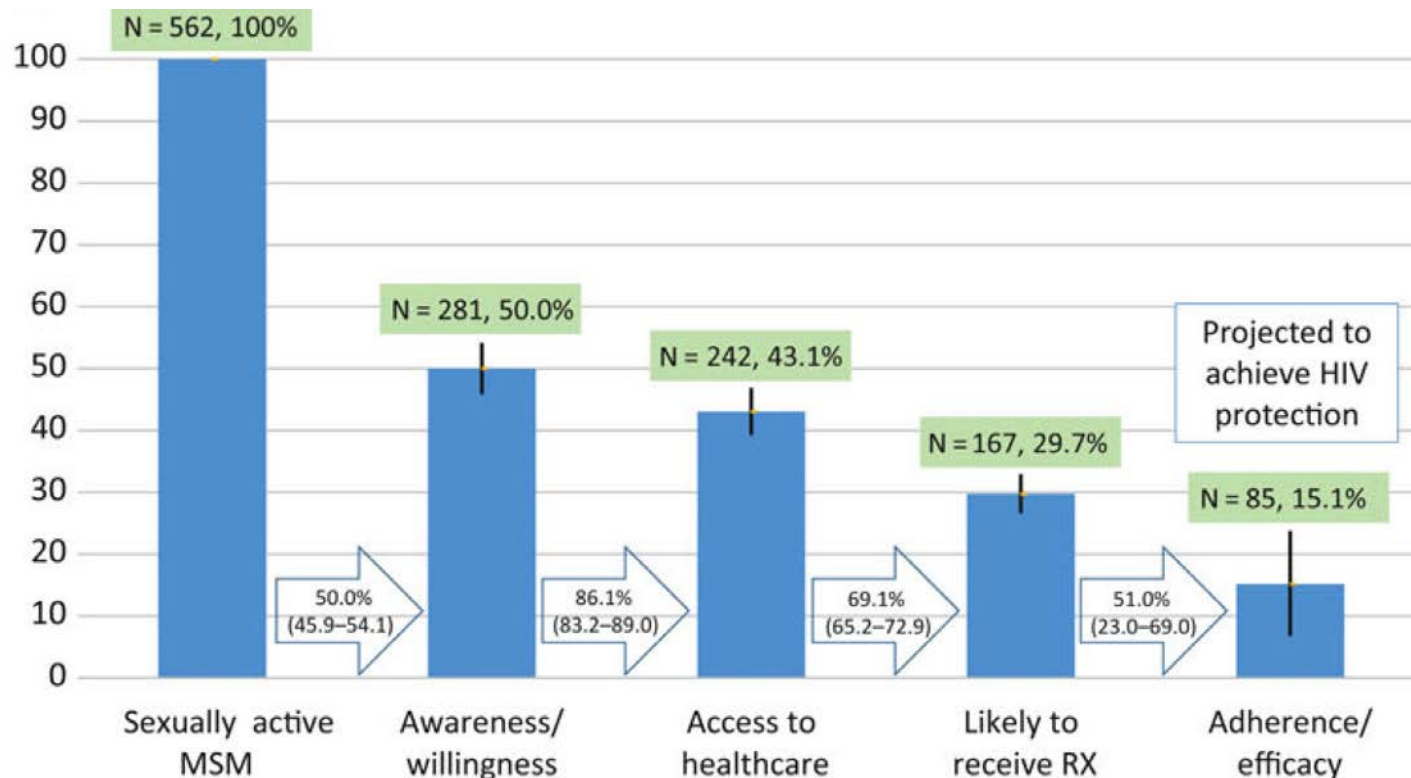
BMD

Baseline vs. Week 48



**Six big
challenges
that UNC is
well-positioned
to address**

#1: Measuring PrEP “success”

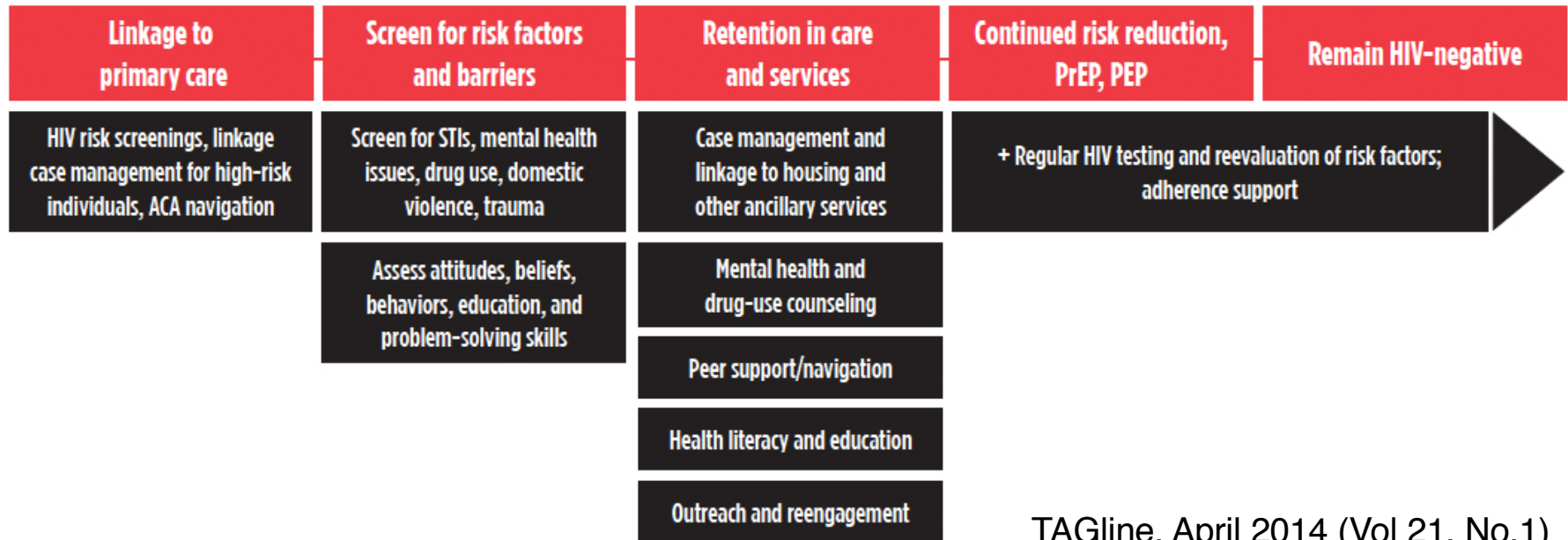


Suggested reading:

- Nunn AS, [Brinkley-Rubinstein L](#), et al. Defining the HIV pre-exposure prophylaxis care continuum. *AIDS*. 2017 Mar 13;31(5):731-734. PubMed PMID: 28060019.
- Kelley CF, et al. Applying a PrEP Continuum of Care for Men Who Have Sex With Men in Atlanta, Georgia. *Clin Infect Dis*. 2015 Nov 15;61(10):1590-7. PubMed PMID: 26270691.
- Haberer JE. Current concepts for PrEP adherence in the PrEP revolution: from clinical trials to routine practice. *Curr Opin HIV AIDS*. 2016 Jan;11(1):10-7. PubMed PMID: 26633638.

#2: Characterizing barriers and intervening

HIV-NEGATIVE

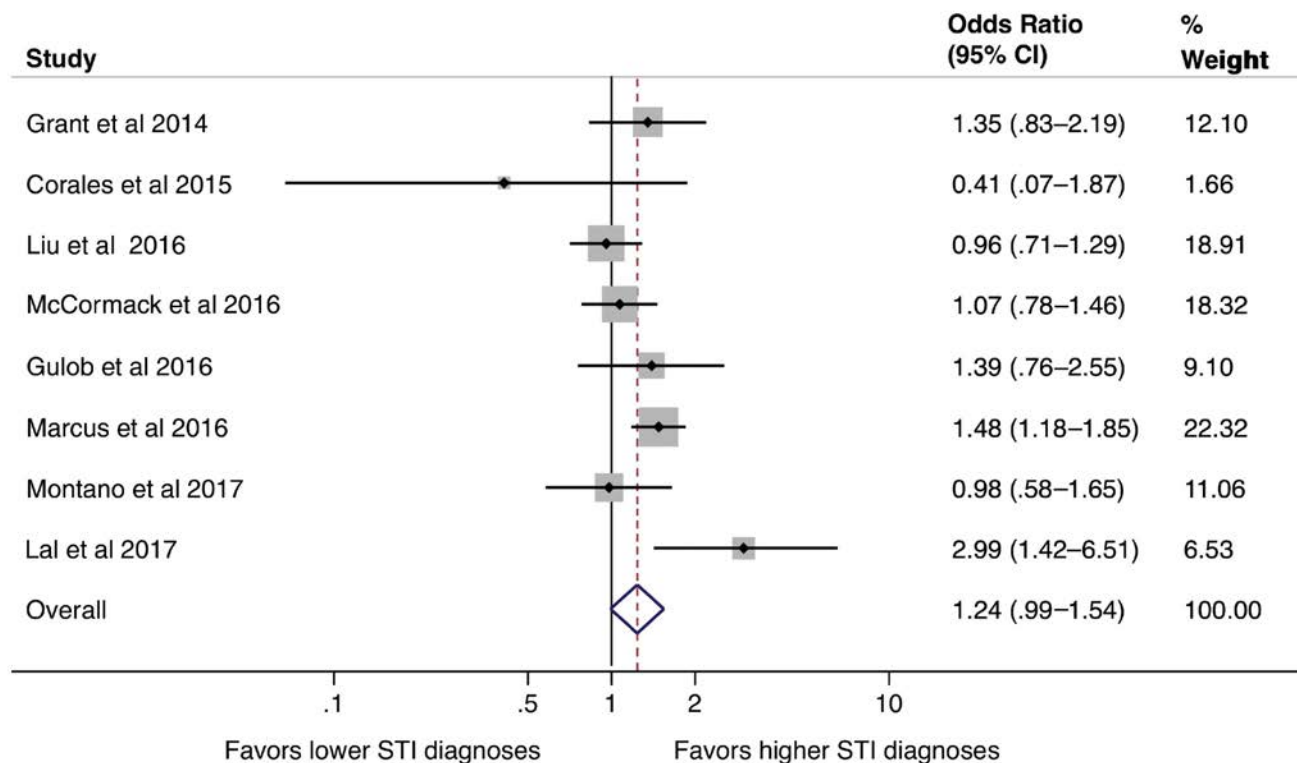


TAGline, April 2014 (Vol 21, No.1)

Suggested reading:

- Sullivan PS, Siegler AJ. Getting pre-exposure prophylaxis (PrEP) to the people: opportunities, challenges and emerging models of PrEP implementation. *Sex Health*. 2018 Nov;15(6):522-527. PubMed PMID: 30476461.
- Jenness SM, et al. Addressing Gaps in HIV Preexposure Prophylaxis Care to Reduce Racial Disparities in HIV Incidence in the United States. *Am J Epidemiol*. 2018 Oct 11. PubMed PMID: 30312365.
- Touger R, Wood BR. A Review of Telehealth Innovations for HIV Pre-Exposure Prophylaxis (PrEP). *Curr HIV/AIDS Rep*. 2019 Jan 30. [Epub ahead of print] Review. PubMed PMID: 30701404.

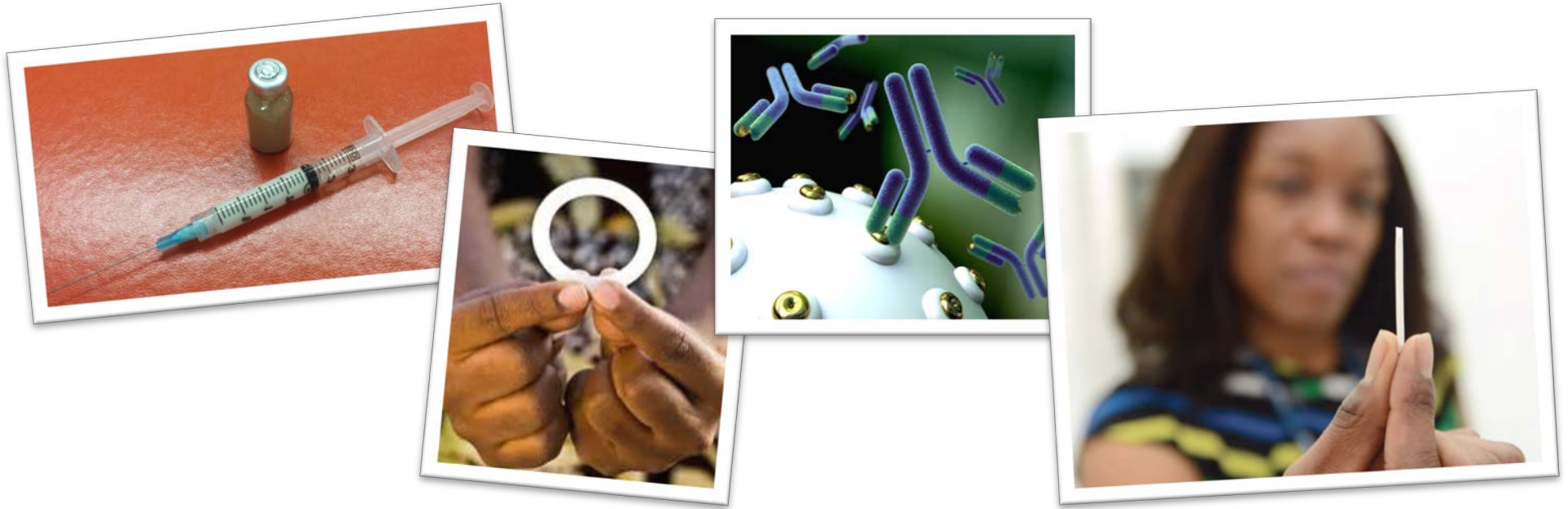
#3: Disentangling STIs and PrEP



Suggested reading:

- Traeger MW, et al. Effects of Pre-exposure Prophylaxis for the Prevention of HIV Infection on Sexual Risk Behavior in Men Who Have Sex With Men: A Systematic Review and Meta-analysis. *Clin Infect Dis*. 2018 Aug 16;67(5):676-686. PubMed PMID: 29509889.
- Marcus JL, et al. Risk Compensation and Clinical Decision Making - The Case of HIV Preexposure Prophylaxis. *N Engl J Med*. 2019 Feb 7;380(6):510-512. PubMed PMID: 30726699.
- Jenness SM, et al. Incidence of Gonorrhea and Chlamydia Following Human Immunodeficiency Virus Preexposure Prophylaxis Among Men Who Have Sex With Men: A Modeling Study. *Clin Infect Dis*. 2017 Sep 1;65(5):712-718. PubMed PMID: 28505240.

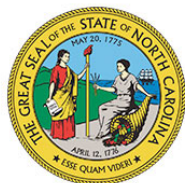
#4: Staying ahead of the curve with PrEP 2.0



Suggested reading:

- [Kovarova M](#), [Benhabbour SR](#), Massud I, [Spagnuolo RA](#), Skinner B, Baker CE, [Sykes C](#), [Mollan KR](#), [Kashuba ADM](#), García-Lerma JG, [Mumper RJ](#), [Garcia JV](#). Ultra-long-acting removable drug delivery system for HIV treatment and prevention. *Nat Commun*. 2018 Oct 8;9(1):4156. PMID: 30297889.
- Flexner C, Thomas DL, Swindells S. Creating demand for long-acting formulations for the treatment and prevention of HIV, tuberculosis, and viral hepatitis. *Curr Opin HIV AIDS*. 2019 Jan;14(1):13-20. PubMed PMID: 30394948.
- Patel RR, Crane JS, López J, Chan PA, Liu AY, Tooba R, James AS. Pre-exposure prophylaxis for HIV prevention preferences among young adult African American men who have sex with men. *PLoS One*. 2018 Dec 28;13(12):e0209484. PubMed PMID: 30592756.

#5: Leveraging big(ger) data



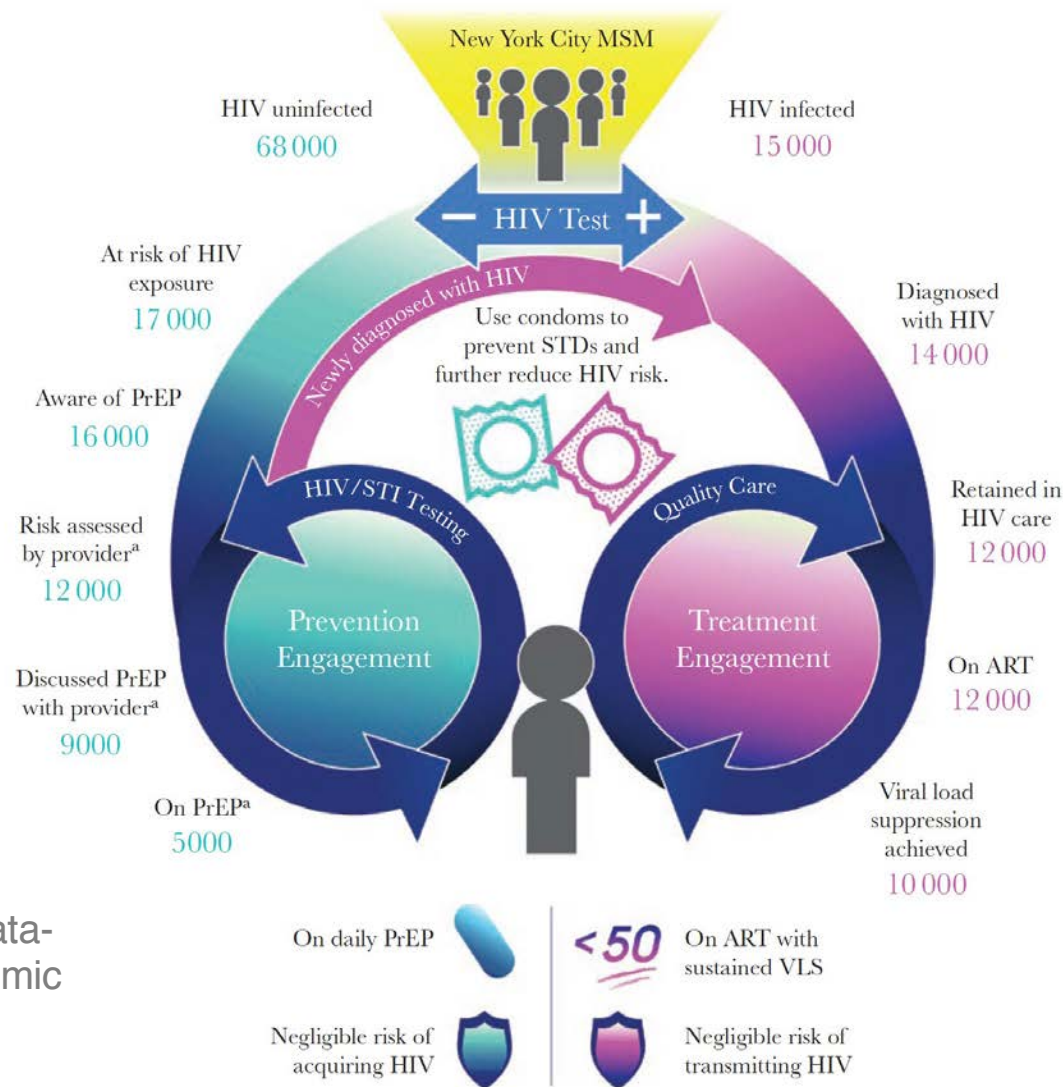
NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES

“Component B”



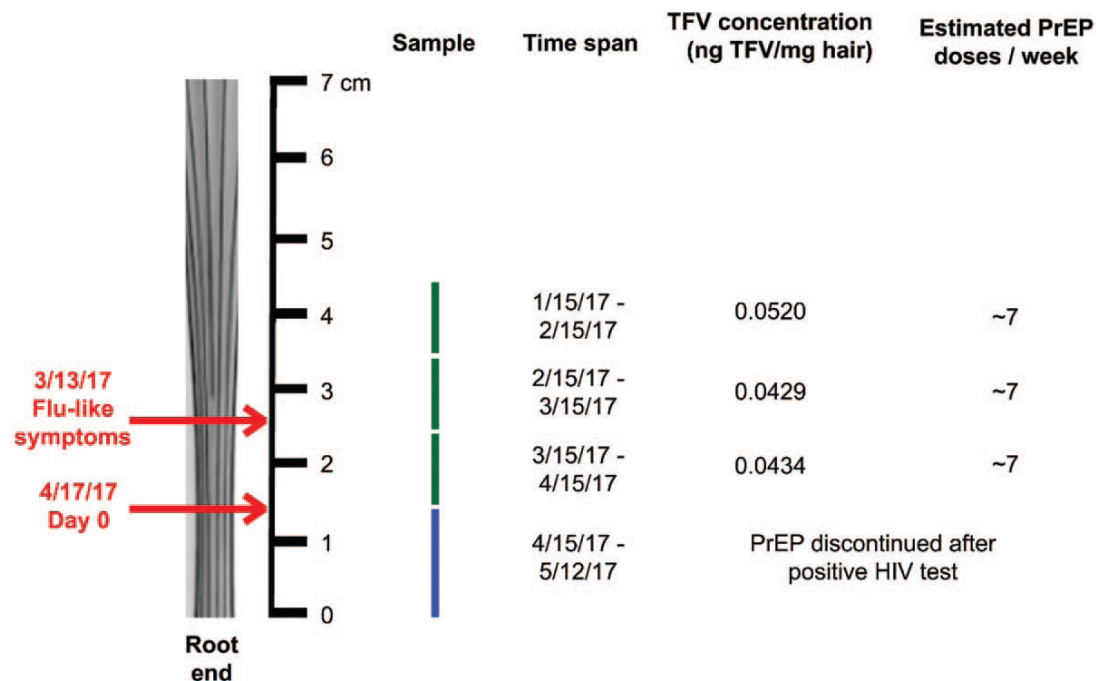
Suggested reading:

- Bradley H, Rosenberg ES, Holtgrave DR. Data-Driven Goals for Curbing the U.S. HIV Epidemic by 2030. *AIDS Behav.* 2019 Feb 22. [Epub ahead of print] PubMed PMID: 30796638.
- Myers JE, et al. Redefining Prevention and Care: A Status-Neutral Approach to HIV. *Open Forum Infect Dis.* 2018 May 2;5(6):ofy097. PubMed PMID: 29977957.



People at risk of HIV exposure **taking daily PrEP** and people with HIV **with sustained viral load suppression** have negligible risk of acquiring or transmitting HIV.

#6: Perfecting the evaluation of failure



Suggested reading:

- Smith DK, Switzer WM, Peters P, Delaney KP, Granade TC, Masciotra S, Shouse L, Brooks JT. A Strategy for PrEP Clinicians to Manage Ambiguous HIV Test Results During Follow-up Visits. *Open Forum Infect Dis*. 2018 Jul 21;5(8):ofy180. PubMed PMID: 30568989.
- Thaden JT, Gandhi M, Okochi H, [Hurt CB](#), McKellar MS. Seroconversion on preexposure prophylaxis: a case report with segmental hair analysis for timed adherence determination. *AIDS*. 2018 Jun 1;32(9):F1-F4. PubMed PMID: 29683856.

bit.ly/FMC31519



Let's discuss...

- Strategic priorities for UNC?
- Where do you think things are headed?