



Seeing the Forest AND the Trees: TelePrEP as a Point of Access for Health Centers: Background

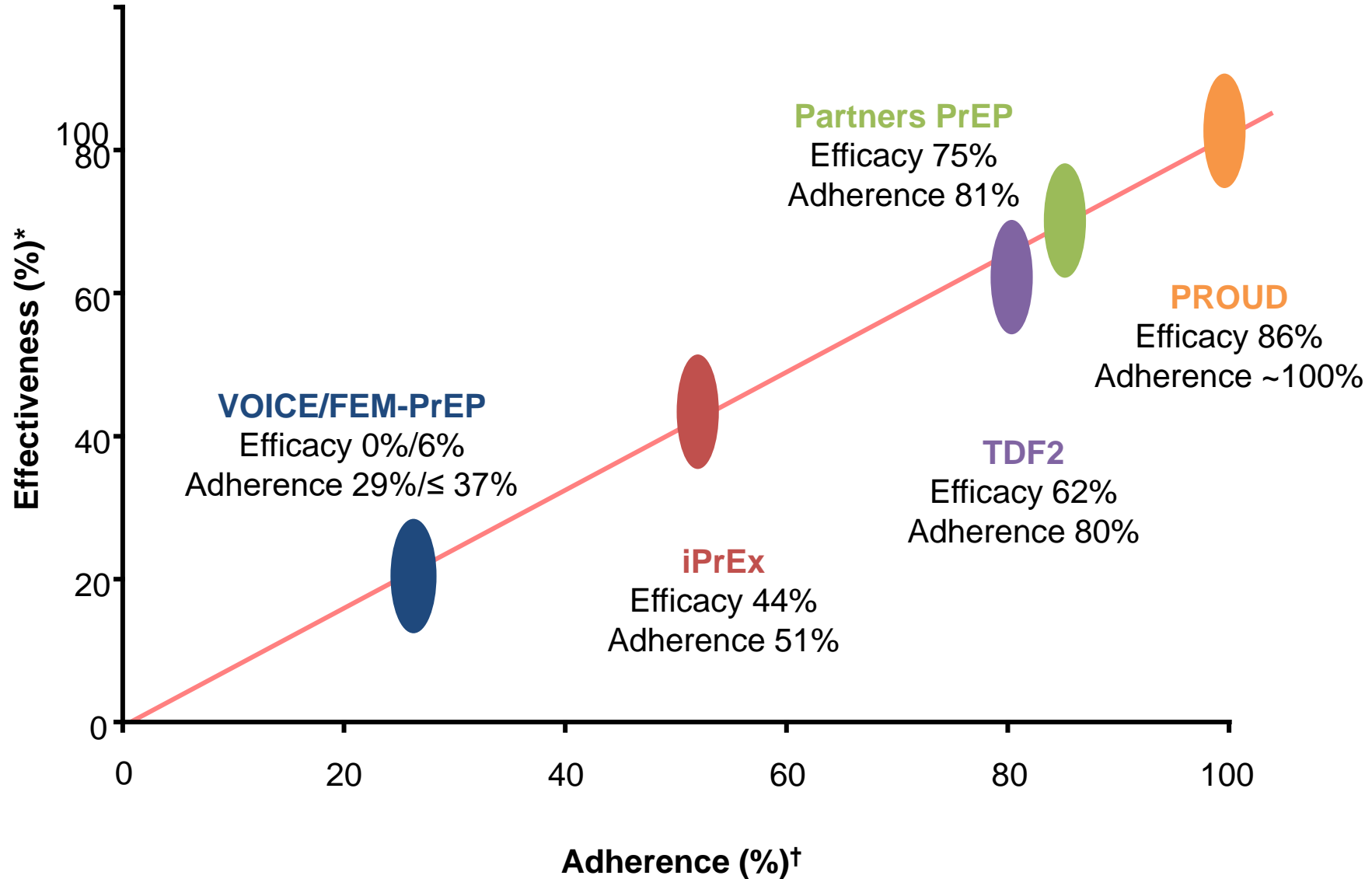
Kenneth H. Mayer, M.D.

NACHC CHI

August 22nd, 2021

thefenwayinstitute.org

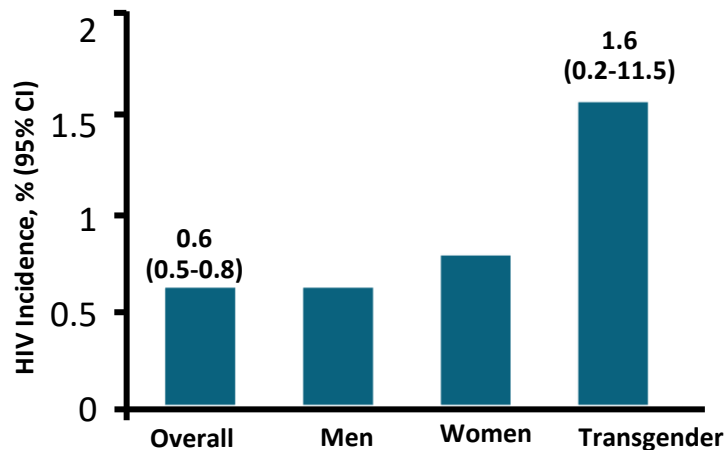
Tenofovir/Emtricitabine for PrEP: Effectiveness Improves With Adherence



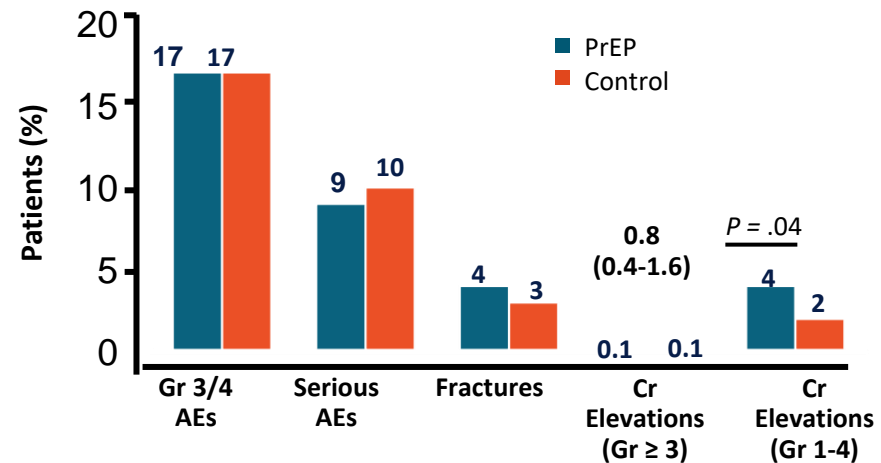
Real-World Efficacy and Clinical Trial Safety of PrEP

■ 46 PrEP demonstration projects ¹

- Overall incident HIV infections: n = 91^[1]
- Occurred > 30 days after last PrEP dose: n = 27
- Occurred < 3 mos after starting PrEP: n = 17
- Comparable to HIV incidence in active arms of clinical trials

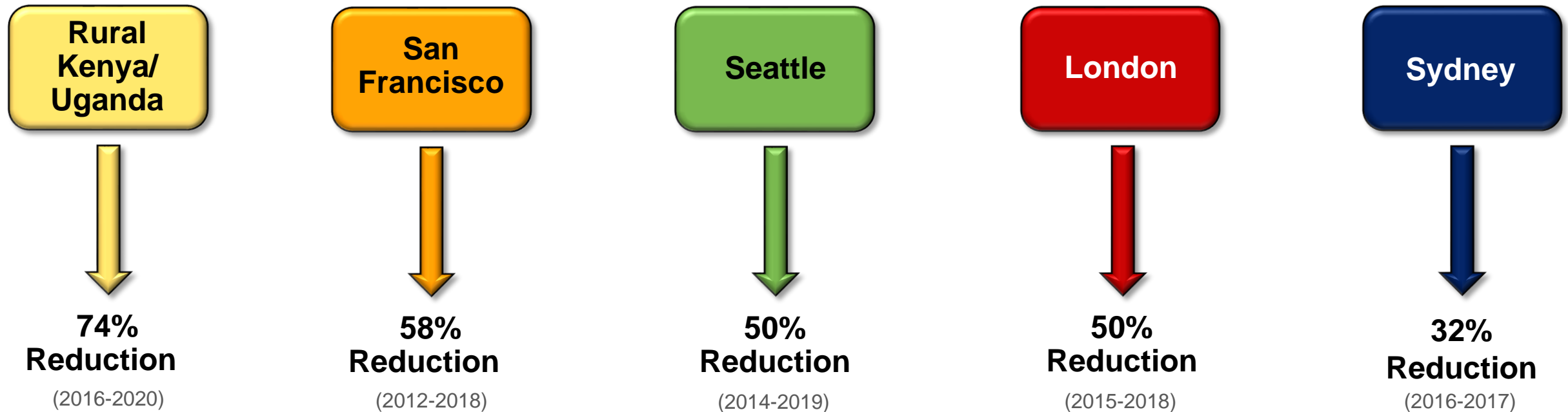


Meta-Analysis of 13 Randomized Daily Oral PrEP Trials (n = 15,678)^[2]



Scaling up PrEP and Treatment has led to decreased HIV spread

Population-Level Reductions in HIV Risk in Diverse Settings



Koss C, et al. *PLoS Med.* 2021;18(2):e1003492.

Buchbinder SP, et al. *J Acquir Immune Defic Syndr.* 2019;82(suppl 3):S176-S182.

Seattle & King County and the Infectious Disease Assessment Unit. HIV/AIDS Epidemiology Report 2020, Volume 89.

Public Health England. Health Protection Report. 2019;13(31).

Grulich A, et al. *Lancet HIV.* 2018;5:e629-e637.

Preventing HIV Transmission: The PrEP Gap in the United States

~1.2 Million Americans Are Likely to Benefit From PrEP

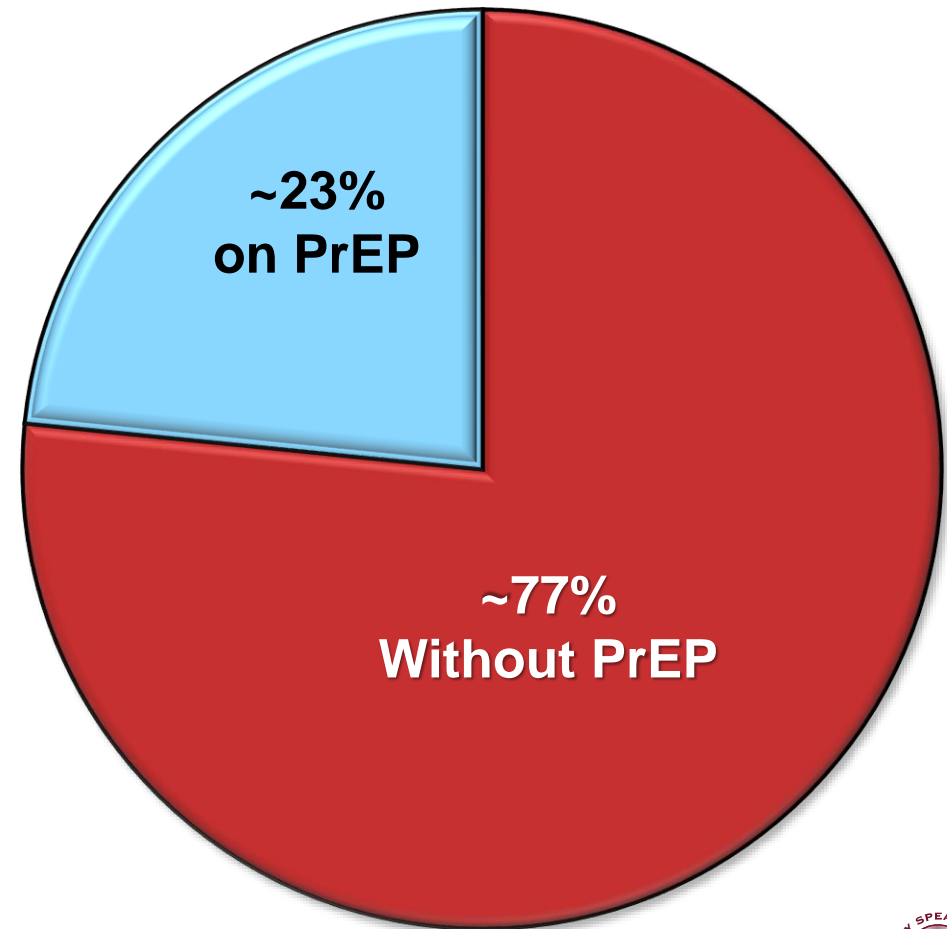
1 in 4 sexually active MSM: 814,000
1 in 5 PWID: 73,000
1 in 200 heterosexual adults: 258,000

Gap Between PrEP Awareness, Willingness, and Use

American Men's Internet Survey
(n=4475 MSM PrEP eligible; 2017)

81% Aware → 60% Willing To Use → 20% Used PrEP

People With an Indication for PrEP (2019)



PrEP coverage in 2017 and 2018 was 13% and 18%, respectively.

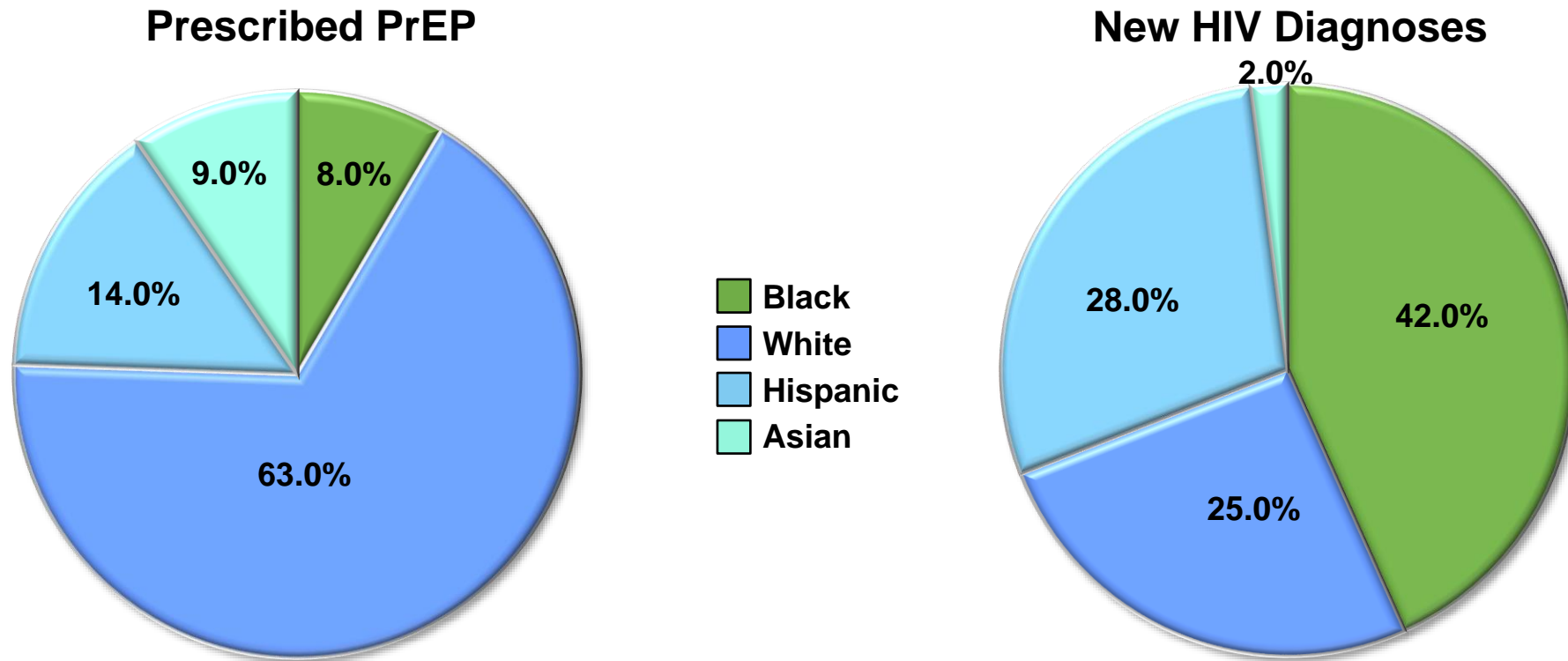
Harris NS, et al. *MMWR Morb Mortal Wkly Rep.* 2019;68:1117-1123.

Sullivan PS, et al. *J Int AIDS Society.* 2020;23:e25461.

CDC. *HIV Surveillance Supplemental Report 2021.* <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2021.

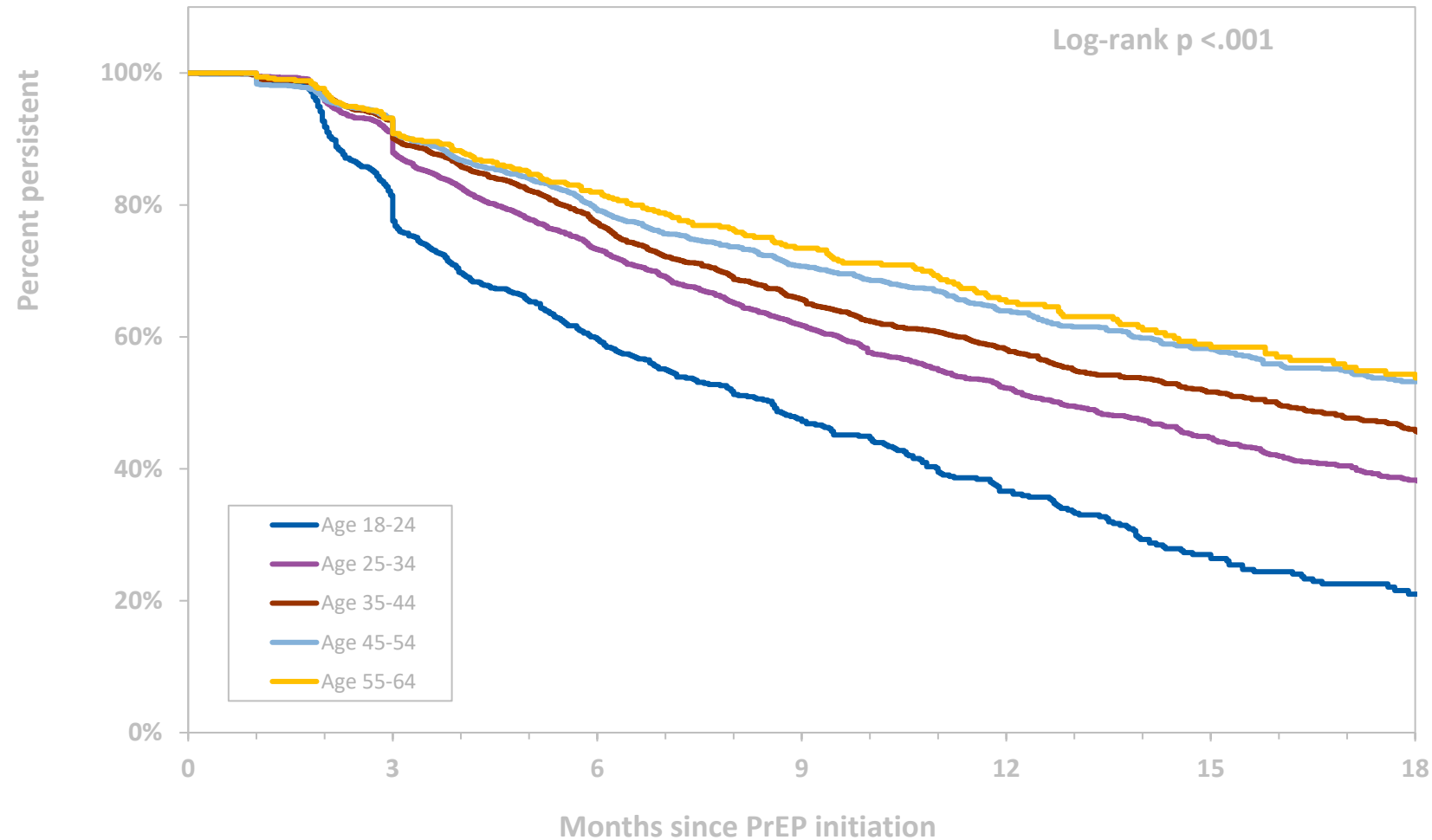
New PrEP Starts in the United States (2019): Prescription Database

**23% of Persons With Indications for PrEP Were Prescribed PrEP
(278,718 of 1,216,210 with indications for PrEP)**



**Blacks and Hispanics account for 70% of new HIV diagnoses,
but their use of PrEP was relatively low during 2019**

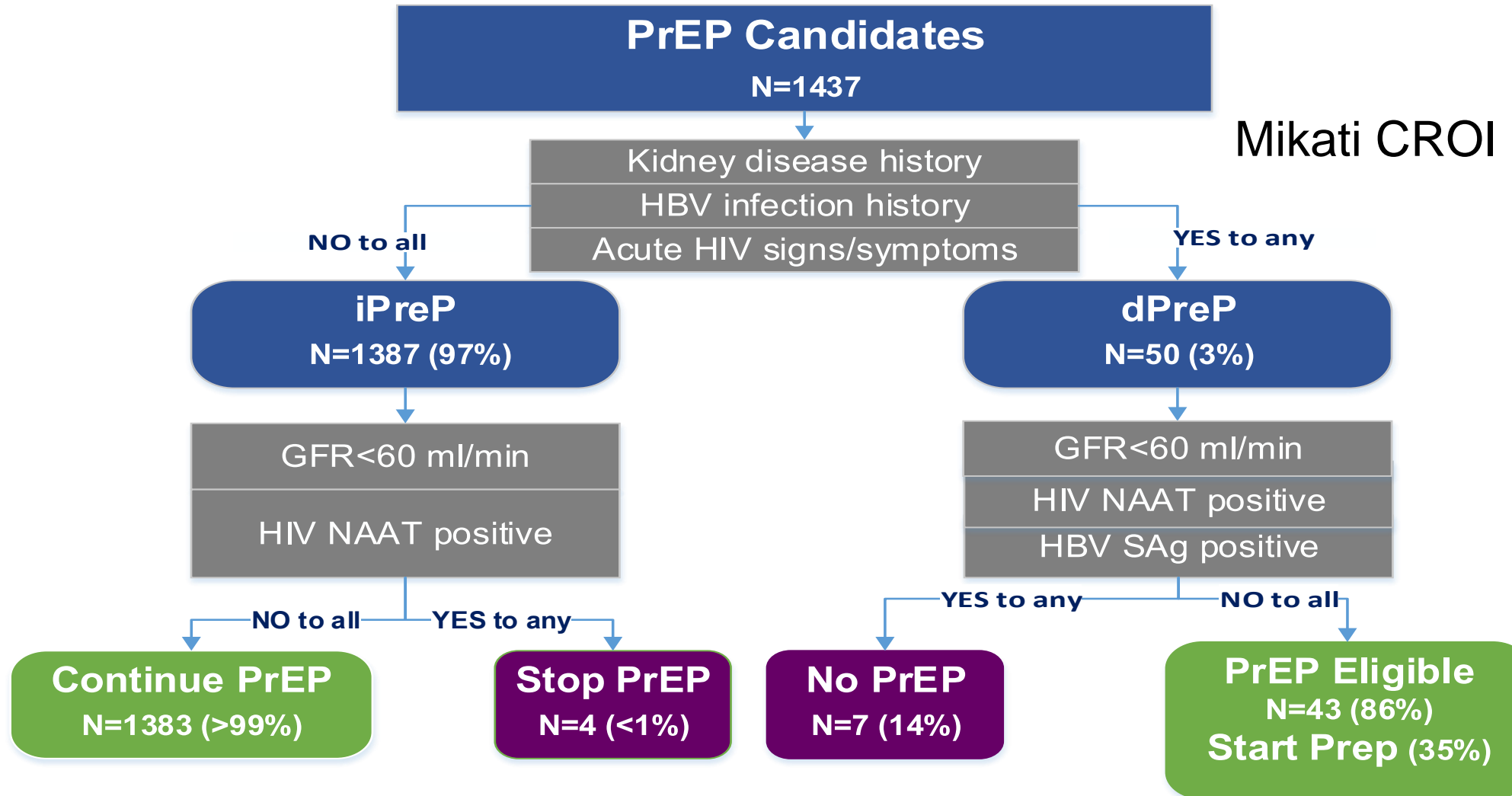
Even among commercially insured PrEP users, PrEP persistence attenuates over time



Immediate PrEP (iPrEP) is Feasible

NYC Sexual Health Clinics, Jan 2017-June 2018

Mikati CROI 2019 #962

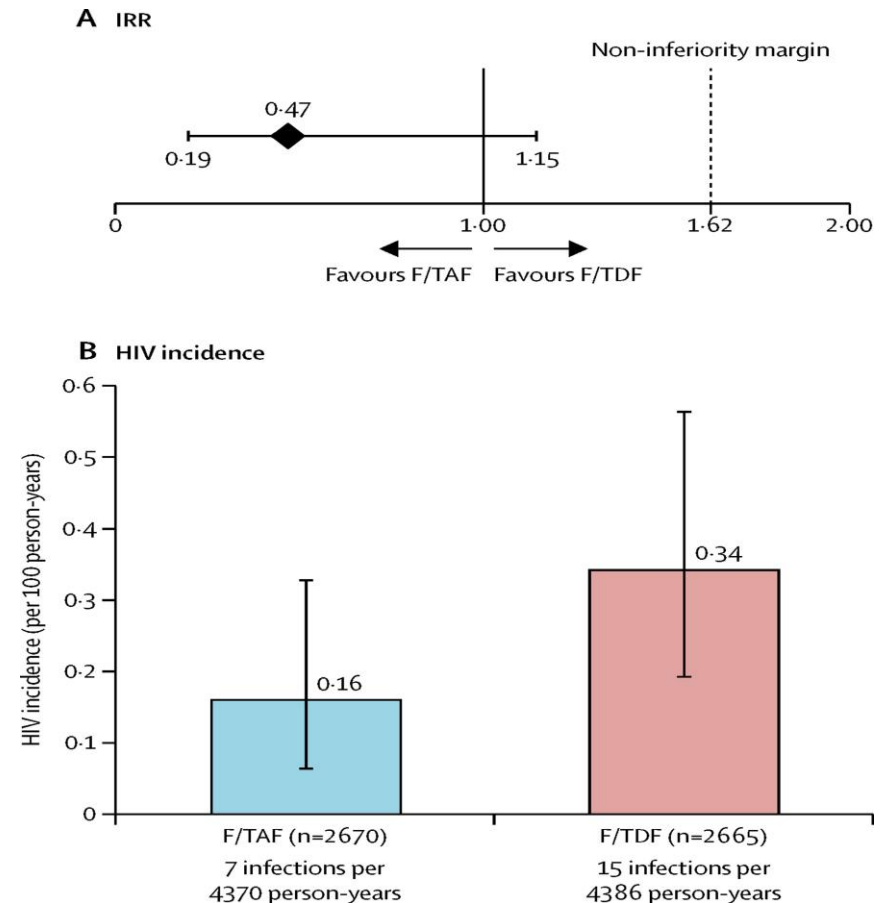


“PrEP 1.5”

- Daily TAF/FTC as effective as TDF/FTC in MSM/TGW
- Less change in bone and renal endpoints from baseline compared to TDF/FTC
- Discontinuations 36 (1%) TAF/FTC and 49 (2%) TDF/FTC
- ↑ weight gain and ↓ favorable lipid profile with TAF/FTC compared to TDF/FTC
- **Cost may be a consideration**
- Other new modalities are on demand PrEP and Dapivirine ring

Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial

Kenneth H Mayer, Jean-Michel Molina, Melanie A Thompson, Peter L Anderson, Karam C Mounzer, Joss J De Wet, Edwin DeJesus, Heiko Jessen, Robert M Grant, Peter J Ruane, Pamela Wong, Ramin Ebrahimi, Lijie Zhong, Anita Mathias, Christian Callebaut, Sean E Collins, Moupali Das, Scott McCallister, Diana M Brainard, Cynthia Brinson, Amanda Clarke, Pep Coll, Frank A Post, C Bradley Hare



HIV Incidence with 2:1:1

Global HIV Incidence: 0.11/100 PY (95% CI: 0.04-0.23) (6 cases)

Mean Follow-up of 22.1 months and 5633 Person-Years

Rate of study discontinuation: 14.4/100 PY

Treatment	Follow-Up Pts-years	HIV Incidence per 100 Pts-years (95% CI)	IRR (95%CI)
TDF/FTC Daily	2583.25	0.12 (0.02 – 0.34)	0.99
TDF/FTC On Demand	2553.68	0.12 (0.02 – 0.34)	(0.13-7.38)

361 HIV-infections averted*

* assuming an incidence of 6.6/100 PY as observed in the Placebo group of the ANRS Ipergay study

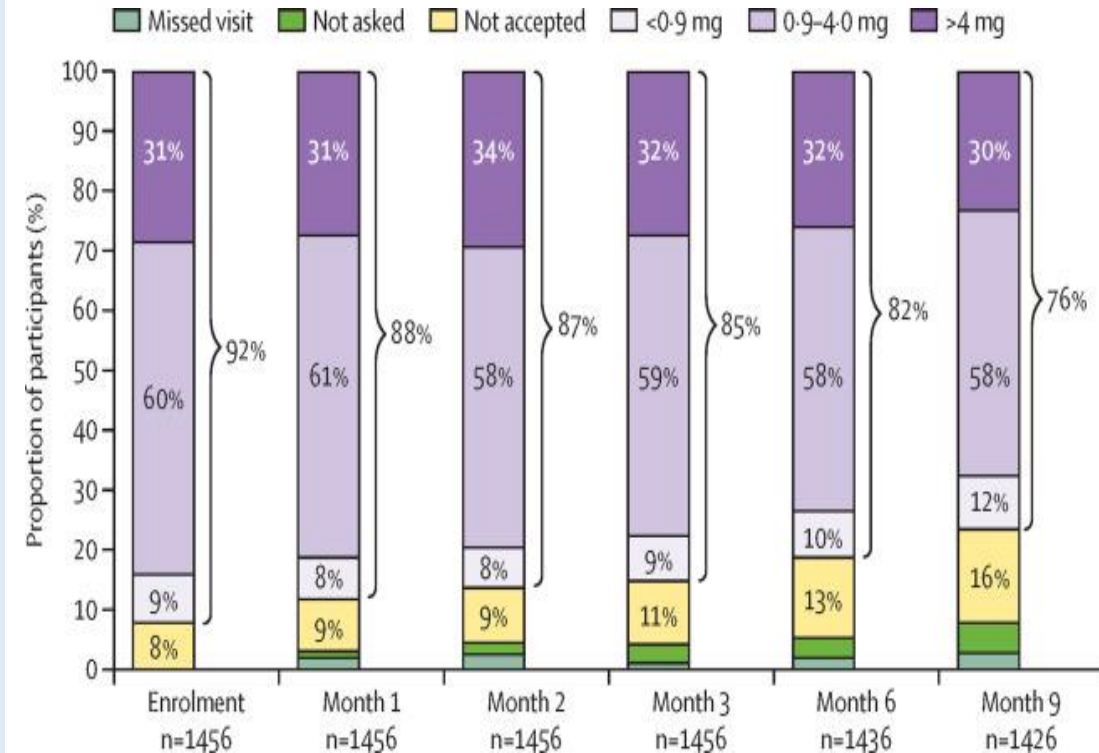
Intravaginal ring news

Key messages

- Women who continued used the rings
 - 73% took the ring at every visit
 - 89% returned rings had PK data supporting use in previous month
 - Dapivirine released significantly higher than during the placebo controlled trial
- EMA approved monthly 25mg DPV ring
- WHO recommended
- 3 month rings likely and several multi-purpose rings in development

Safety, uptake, and use of a dapivirine vaginal ring for HIV-1 prevention in African women (HOPE): an open-label, extension study

Jared M Baeten, Thesla Palanee-Phillips, Nyaradzo M Mgodi, Ashley J Mayo, Daniel W Szyldo, Gita Ramjee, Brenda Gati Mirembe, Felix Mhlanga, Portia Hunidzarira, Leila E Mansoor, Samantha Siva, Vanesha Govender, Bonus Makanani, Logashvari Naidoo, Nishanta Singh, Gonasagrie Nair, Lameck Chinula, Urvi M Parikh, John W Mellors, Iván C Balán, Kenneth Ngure, Ariane van der Straten, Rachel Scheckter, Morgan Garcia, Melissa Peda, Karen Patterson, Edward Livant, Katherine Bunge, Devika Singh, Cindy Jacobson, Yuqing Jiao, Craig W Hendrix, Zvavahera M Chirenje, Clemensia Nakabiito, Taha E Taha, Judith Jones, Kristine Torjesen, Annalene Nel, Zeda Rosenberg, Lydia E Soto-Torres, Sharon L Hillier, Elizabeth R Brown, for the MTN-025/HOPE Study Team*



HIV incidence	2.7/100pyrs (95%CI 0.9-3.8)
Counterfactual	4.4/100pyrs (95%CI 3.2-5.8)
Suggests reduction	39% (95%CI 14-65)

Injectable Cabotegravir

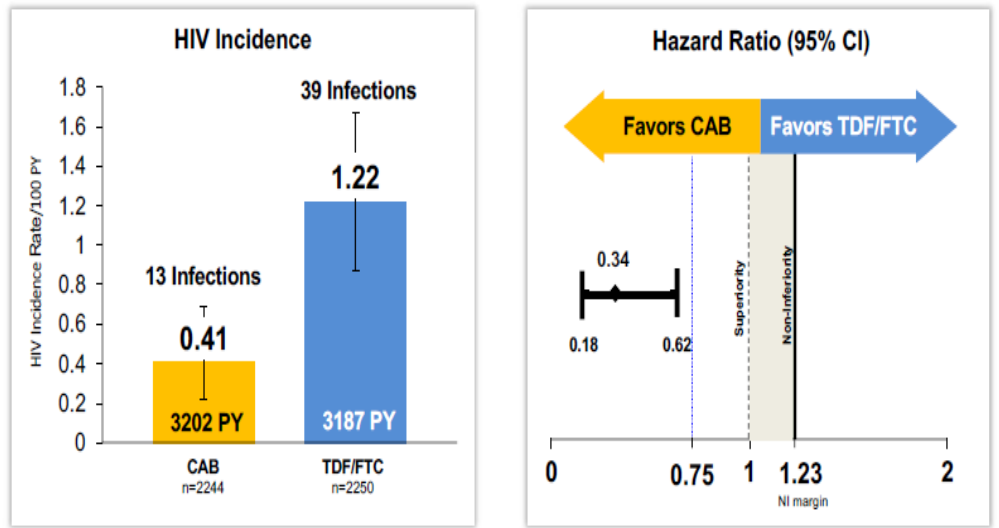
Primary outcome: HIV incidence

40 infections over 3892 person-years
Pooled HIV incidence 1.03 (0.73, 1.4) per 100 person-years



HIV Incidence CAB vs. TDF/FTC

52 HIV infections in 6389 PY of follow-up
1.4 (IQR 0.8-1.9) years median per-participant follow-up
Pooled incidence 0.81 (95%CI 0.61-1.07) per 100 PY



	CAB	TDF/FTC
HIV infections	4	36
Person-years	1,953	1,939
HIV incidence (95% CI)	0.2 (0.06, 0.52)	1.86 (1.3, 2.57)

Wald test z statistic – 4.20, efficacy stopping bound (z scale) – 3.61

- Pooled incidence in both trials lower than previously observed in the community
- Both trials showed superiority of CAB-LA against a highly effective TDF/FTC control
- CAB-LA well tolerated despite injection site reactions



Next Generation PrEP

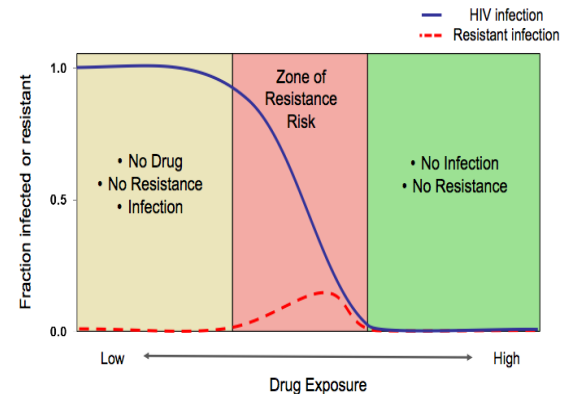
PRE-CLINICAL										PHASE I		PHASE III/IIIb	DELIVERY SYSTEM		ACTIVE DRUG			
															Tenofvir		Darunavir	
															Broadly neutralizing antibody		Dapivirine	
															Tenofvir disoproxil fumarate		Griffithsin	
Multipurpose Prevention Technologies (MPTs)															Tenofvir Alafenamide		DS003 (BMS793)	
															Tenofvir/emtricitabine		IQP-0528	
															Tenofvir disoproxil fumarate/emtricitabine		5P12-RANTES	
															Elvitegravir		Cabotegravir/GSK 744	
															PC-1005		Monoclonal antibody	
															Maraviroc		MK-2048	
															Progestin		Tenofvir alafenamide/emtricitabine	
															MK-8591		Ferrous gluconate	
															Acyclovir-Zovirax		Polyamino-Polycarboxylic acid	
															SPL7013-VivaGel		Levonorgestrel	
															Ascorbic acid		Ethinyl estradiol	
															Betulonic acid		Different drugs being investigated	

* This formulation is for a 3-month vaginal ring

In Efficacy Trials: Islatravir: a pill monthly and Lenacapravir: subQ injection every 6 months

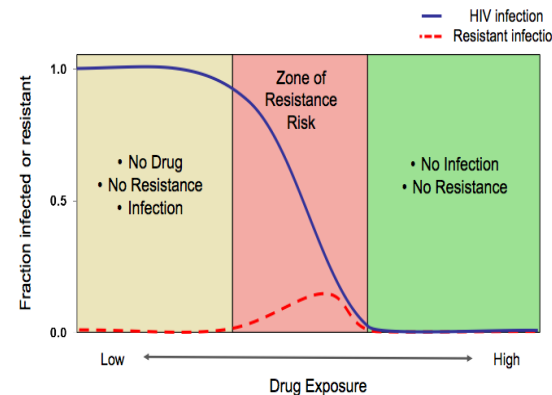
Less frequent and alternative dosing

YES!	More thought needed
Improved adherence	Understanding PK and stopping and starting
Less frequent reminding	Managing frequency and place of clinic visits
Fewer healthcare visits	Service distribution models and service providers
Discretion	Still need to consider intimacy & other SRH needs, eg timing with LARC



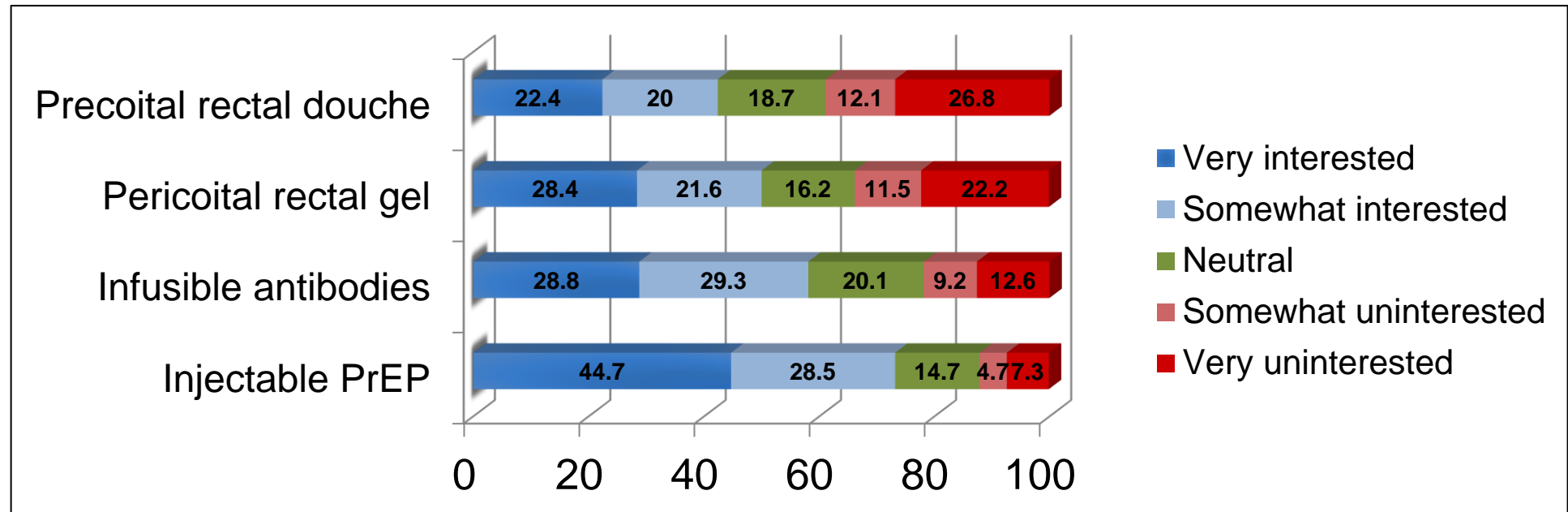
LA injectables PrEP: Pros and Cons

YES!	More thought needed
Improved adherence	Understanding the “long tail” implications
Less frequent reminding	Access when travelling or away from home base
Community-based healthcare?	Accredited administrators – trained individuals to administer
Discreet – easier to keep private than pills	Still need to consider intimacy & other SRH needs, eg timing with LARC



Product Interest in On-Line Sample of YMSM

(N=4638; Biello et al, AIDS Behav, 2017)



- Most endorsed reasons for NOT being interested
 - Injectable PrEP: Concerned about long-acting side effects (51.8%)
 - Infusible antibodies: Do not like idea of IV infusions (62.7%)
 - Pericoital gel: Think it would be messy (45.2%)
 - Precoital rectal douche: Think it would be messy (41.8%)

PrEP use among MSM is associated with high rates of bacterial STIs

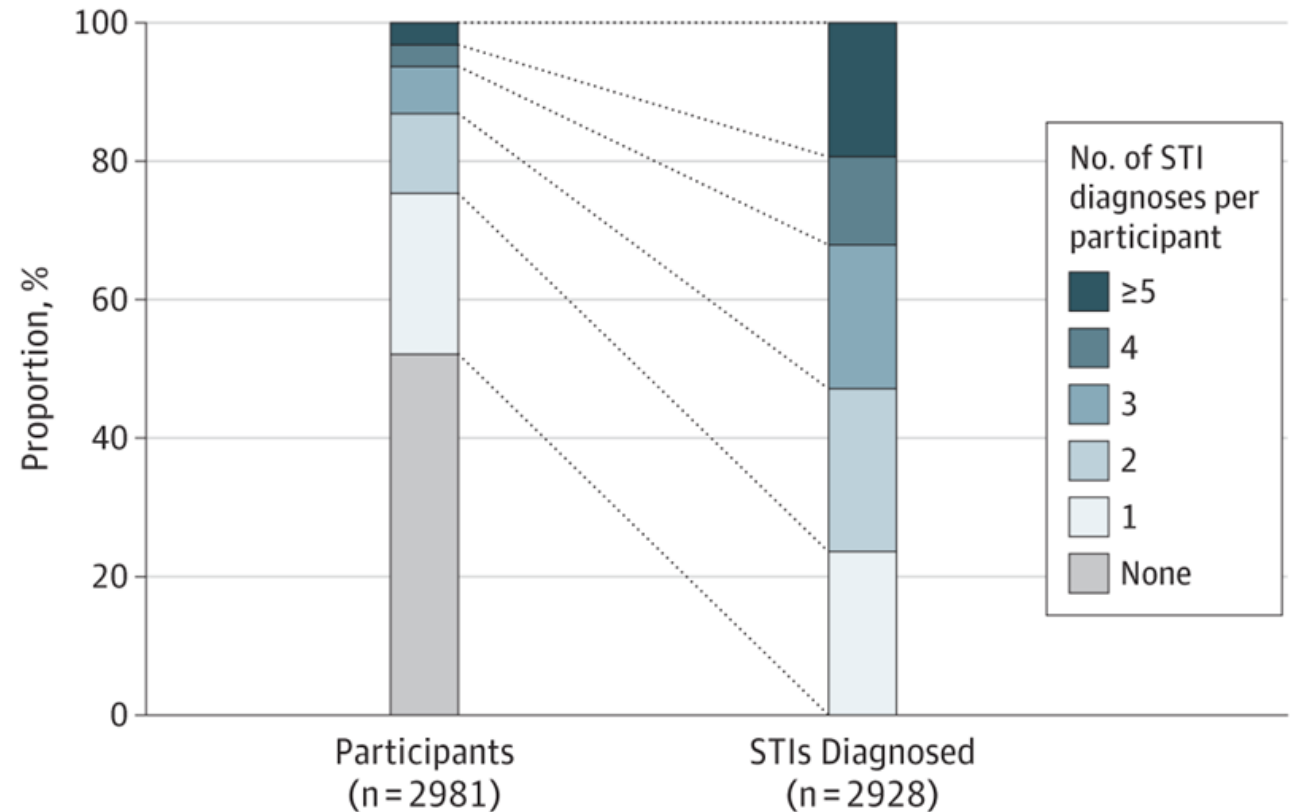
PrEPX: open-label study in Victoria, Australia (n=4275 MSM)

STI incidence: 91.9 per 100 person-years

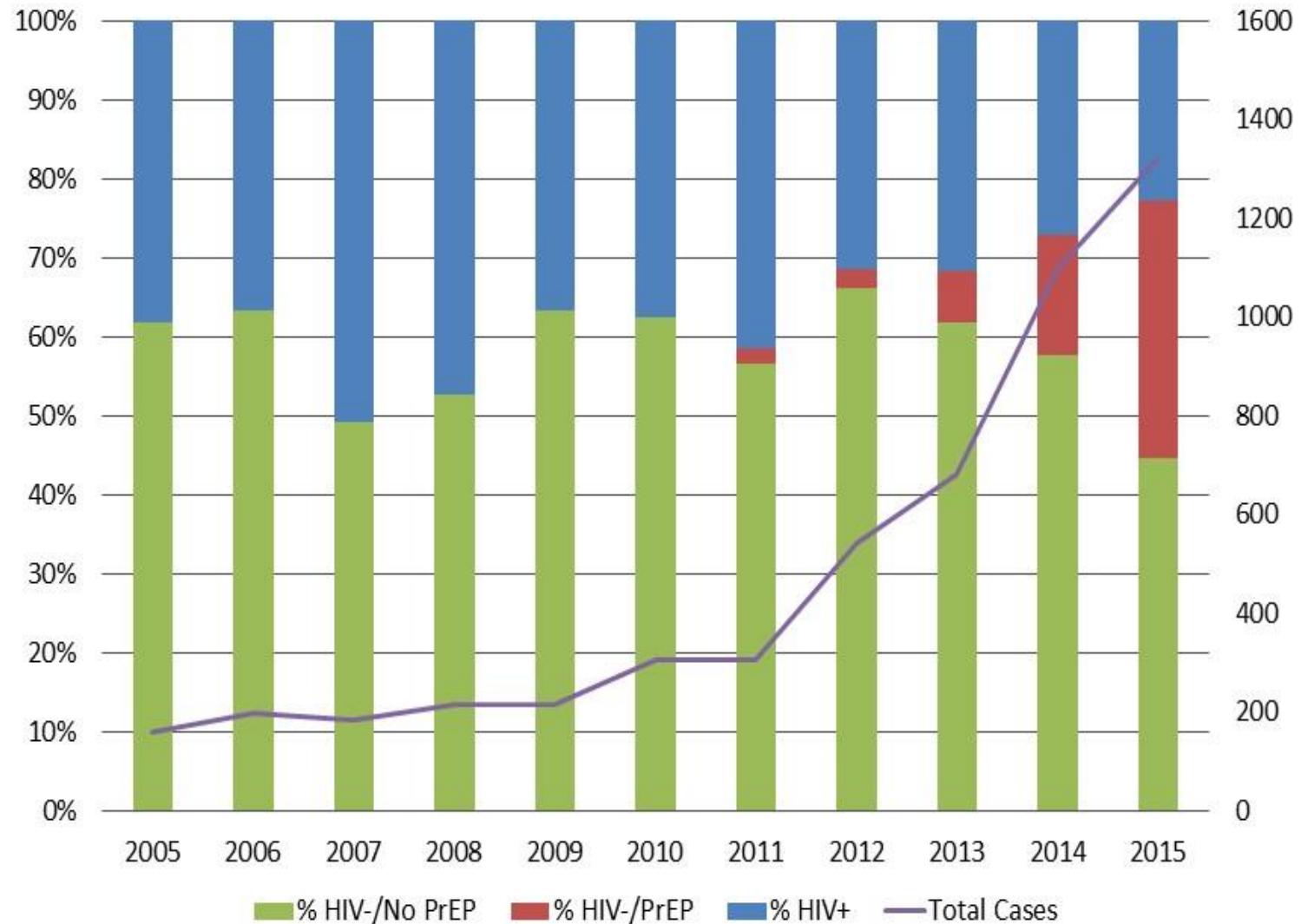
25% participants accounting for 76% of all STIs

STI incidence increased by 12% after adjusting for increased testing

Frequent STI screening is important



Frequency of Bacterial STI infection, by HIV status and PrEP Use, among Male Patients, Fenway Health



Mayer, OFID, 2017

More than U=U and PrEP

- Social media
- Sex Networking sites
- In US, ACA
- Extragenital Screening

Schillinger, CROI, 2018

Purview paradox: contradictory beliefs about which providers will prescribe PrEP

(Krakower, AIDS and Behavior, 2014)



HIV providers:

Primary care providers
are in the best position
to prescribe PrEP



Primary care providers:

It would not be feasible
to prescribe PrEP

PrEP as a gateway to care: Fenway Health

Primary care utilization by PrEP users and non-users—
Fenway Health, 2012-2016 (N=5,857)

Flu vaccination	1.57 (1.47-1.67)
Tobacco screening	1.13 (1.09-1.16)
Depression screening	1.18 (1.15-1.22)
Hemoglobin A1c or glucose testing	1.83 (1.75-1.92)
Hemoglobin A1c testing	0.89 (0.79-1.01)
Glucose testing	2.03 (1.93-2.14)

Prevalence ratios obtained from Poisson models with generalized estimating equations. Adjusted models included age, gender, race/ethnicity, insurance type, and year, with diabetes, hypertension, and overweight/obesity additionally included in models for hemoglobin A1c and glucose testing.

Sexual Health in the SARS-CoV-2 Era

Jack L. Turban, MD, MHS; Alex S. Keuroghlian, MD, MPH; and Kenneth H. Mayer, MD

More than 200 000 people have died of severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) infection, leading to widespread concern regarding physical morbidity and mortality. The sexual health implications, however, have received little focus. On the basis of existing data, it appears all forms of in-person sexual contact carry risk for viral transmission, because the virus is readily transmitted by aerosols and fomites. This has resulted in broad guidance regarding physical distancing, with substantial implications for sexual well-being. Given the important role of sexuality in most people's lives, health care providers (HCPs) should consider counseling patients on this topic whenever possible. This is an unprecedented and stressful time for HCPs; facilitating brief conversations and referrals to relevant resources (Table) can help patients maintain sexual wellness amid the pandemic.

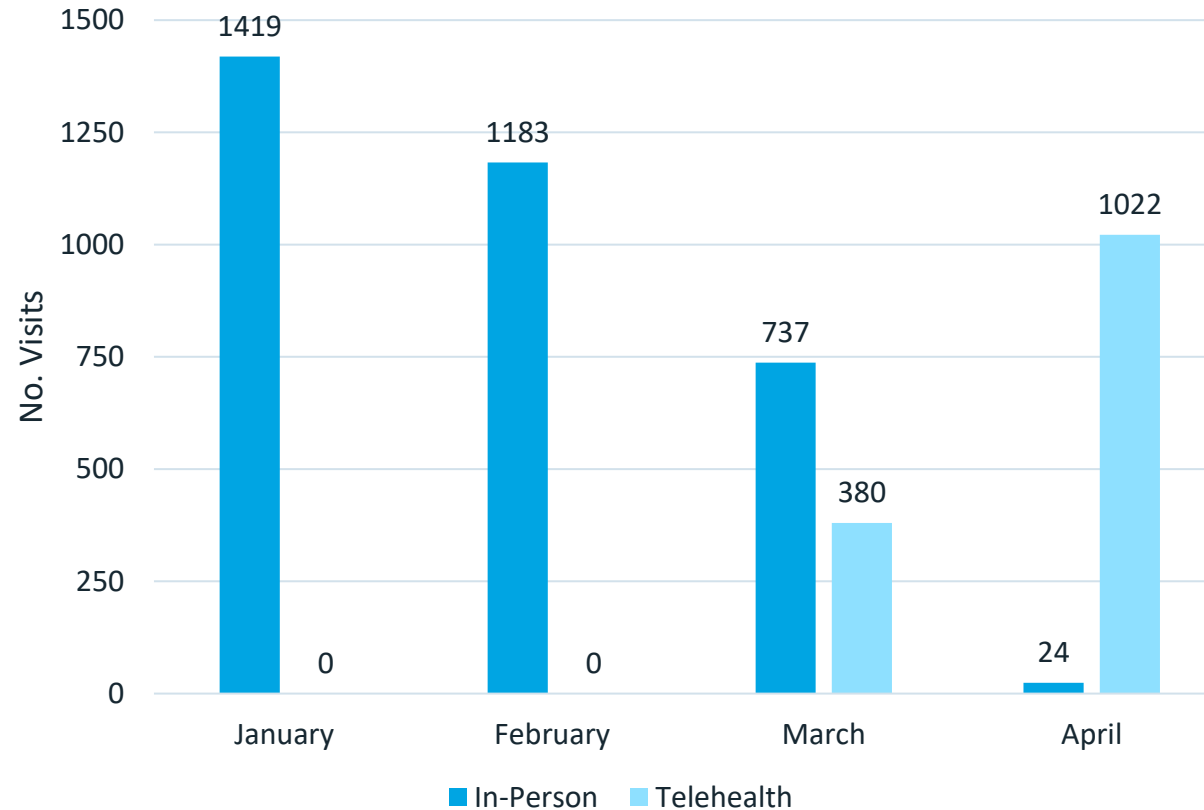
**CURRENT EVIDENCE SUGGESTS THAT ALL
IN-PERSON SEXUAL CONTACT CARRIES
TRANSMISSION RISK**

transmission owing to the virus' stability on common surfaces and propensity to propagate in the oropharynx and respiratory tract.

PSYCHOLOGICAL EFFECTS OF SEXUAL ABSTINENCE

Sexual expression is a central aspect of human health but is often neglected by HCPs. Messaging around sex being dangerous may have insidious psychological effects at a time when people are especially susceptible to mental health difficulties. Some groups, including sexual and gender minority (SGM) communities, may be particularly vulnerable to sexual stigma, given the historical trauma of other pandemics, such as AIDS. Abstinence recommendations may conjure memories of the widespread stigmatization of SGM people during the AIDS crisis. For the population at large, a recommendation of long-term sexual abstinence is unlikely to be effective, given the well-documented failures of abstinence-based public health interventions and their likelihood to promote shame (8).

A major shift from in-person visits to tele-PrEP occurred during the pandemic

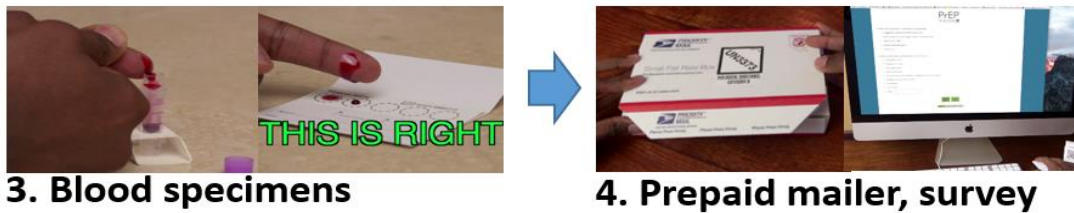


Krakower et al. OACLB0104

Providing tailored, appropriate care

Home care system for PrEP could reduce clinician visits from 4/year to 1/year

<https://vimeo.com/138977095>



Participant Test Summary Form PrEP@ Home

Participant Information		<input checked="" type="radio"/> Optimal <input type="radio"/> Elevated <input type="radio"/> High
Participant Name	Doe John E	Date Specimens Collected
	Last First MI	6/13/2016
Participant Initials	D J E	Date Specimens Tested
		6/17/2016
Section 1: HIV Testing		
HIV	Oraquick	<input checked="" type="radio"/> Interpretation: Non-Reactive HIV test
Section 2: Symptomatic Screening for Acute HIV		
Fever, Swollen Glands, Sore Throat, Muscle and Joints Aches and Pains,		<input checked="" type="radio"/> Interpretation: No Acute HIV symptoms

5. Results report to clinician



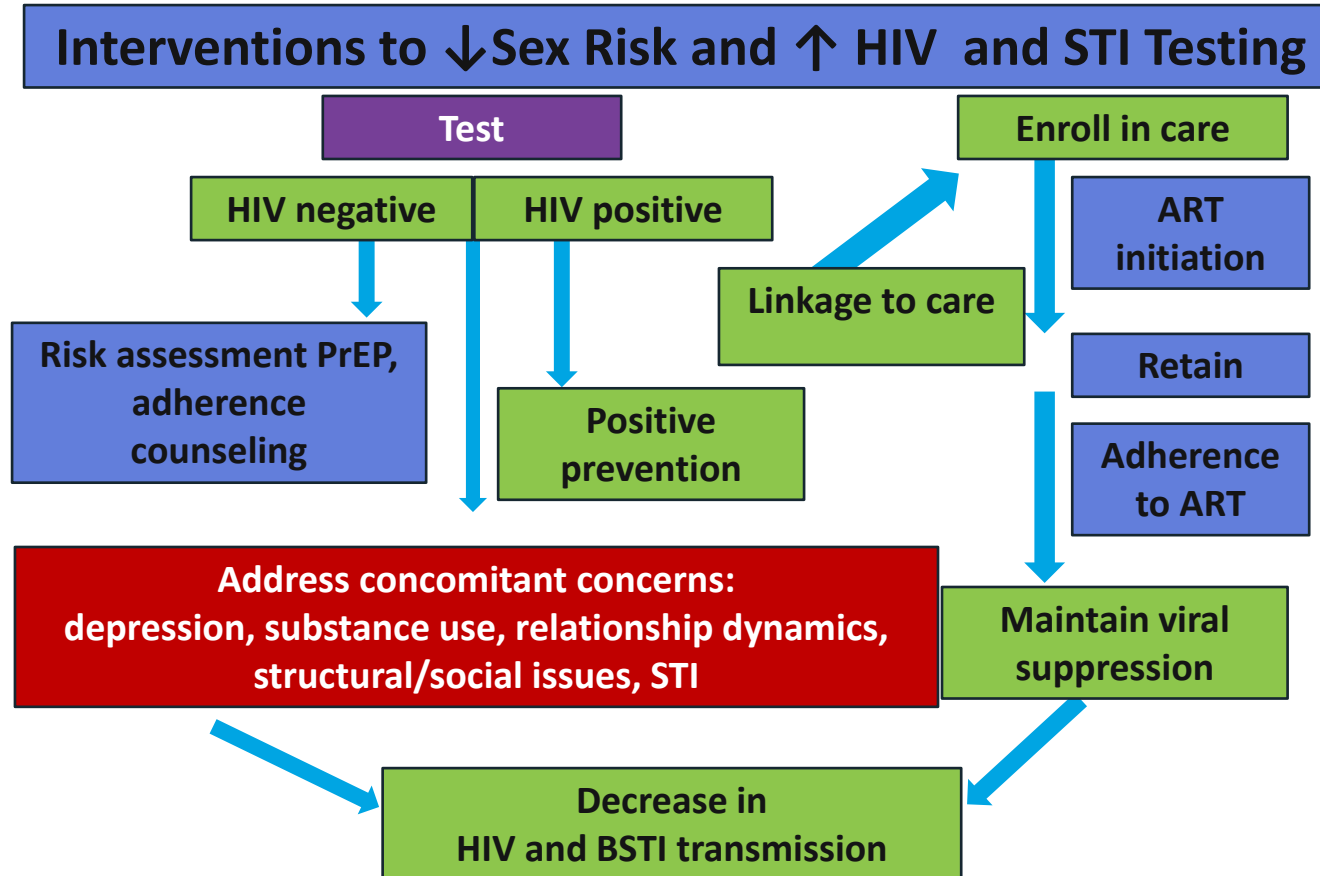
6. Rx, care as needed

Siegler AJ, Mayer KH, Liu AY, Patel RR, Ahlschlager LM, Kraft CS, et al. Developing and assessing the feasibility of a home-based PrEP monitoring and support program. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America. 2018;Jul 4.

Conclusions

- The uptake of PrEP biobehavioral HIV prevention modalities has been suboptimal to date.
- The development of new approaches will offer opportunities for less frequent dosing, culturally congruent modes of delivery, and the possibility of MPTs.
- Insufficient adherence and uptake are not exclusively due to dislike of daily pill taking, but more options are likely to increase uptake
- The SARSCoV-2 Pandemic has accelerated the use of tele-PrEP
- For PrEP to achieve its promise, social/structural and individual behavioral issues (ranging from poverty, violence/victimization, to depression and substance use) must be addressed.

Need to think holistically



Thank You

Jared Baeten
Rachel Baggaley
Linda-Gail Bekker
Chris Beyrer
Katie Biello
Marcy Gelman
Chris Grasso
Beatriz Grinsztejn
Alex Keuroghlian
Doug Krakower
Ken Levine
Julia Marcus

Jeanne Marrazzo
Sheena McCormack
Rupa Patel
Robert Remien
Aaron Siegler
Patrick Sullivan
NIAID, NIMH, NIDA,
NICHD, CDC, HRSA,
Mass DPH, Gilead,
ViiV, MAC AIDS
Foundation



Prescribing PrEP in CHCs

Rupa Patel, MD MPH
PrEP Program Director
Associate Professor, Division of Infectious Diseases
8/2021

GETTING TO
ZERO
ONE PERSON
AT A TIME.



St. Louis
STI/HIV Prevention
Training Center

Objectives



- Prescribing PrEP (CDC 2017 Guidelines)
- The Virtual PrEP Care Continuum
- **PrEP as TDF/FTC in a person at risk (gay/bisexual/MSM/TG women/cisgender men & women) for HIV with CrCl > 60 mL/min**

Cases we see in PrEP clinics...

- A 26 yo White man asks you about PrEP. He heard about it at the club. But then has seen it on the “about me section” on Grindr and Jack’d.
- A 40 yo Black woman comes to your clinic to ask you about PrEP because she saw an Ad on TV about it.

PrEP Prescribing Options in 2021

- **FDA approved**
 - Daily oral PrEP with TDF/FTC (Truvada and generic)
 - ~99% effective for sexual transmission
 - ~74% for IDU transmission
 - All populations
 - > 60 mL/min
 - Daily oral PrEP with TAF/FTC (Descovy)
 - Cannot prescribe for cisgender women
 - >30 mL/min
- **Not FDA approved:** On demand, event driven, 2-1-1 PrEP with TDF/FTC

Use this in your office!!!

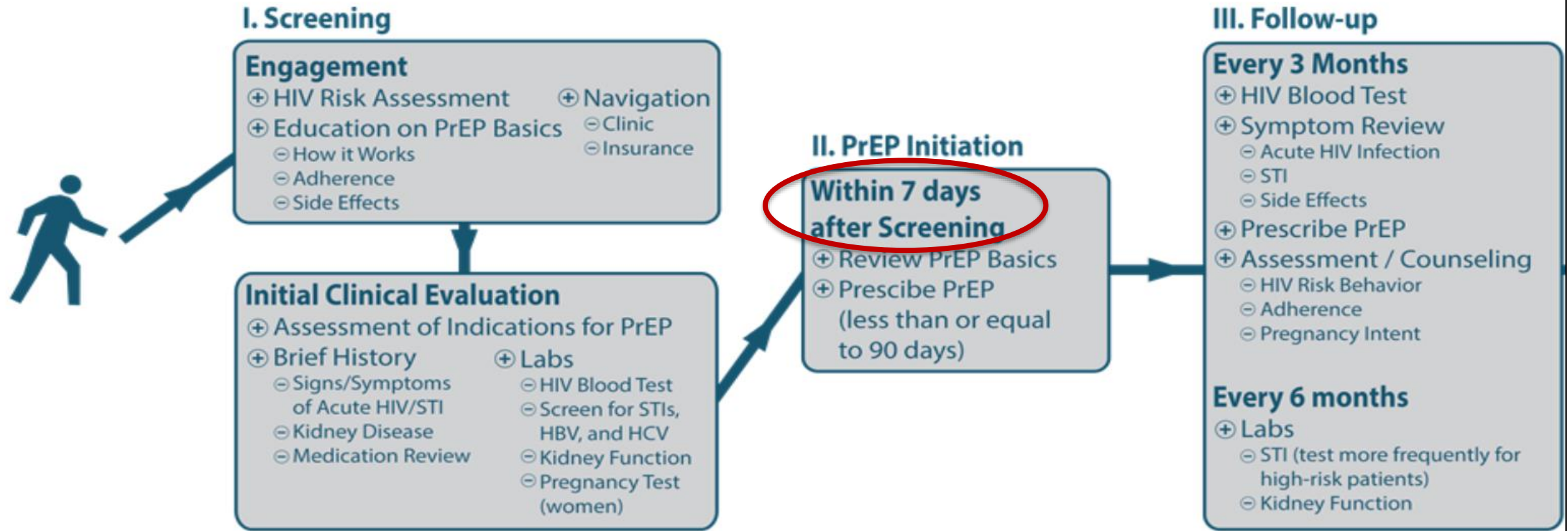
Table 1: Summary of Guidance for PrEP Use

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection	<p>HIV-positive sexual partner</p> <p>Recent bacterial STI</p> <p>High number of sex partners</p> <p>History of inconsistent or no condom use</p> <p>Commercial sex work</p>	<p>HIV-positive sexual partner</p> <p>Recent bacterial STI</p> <p>High number of sex partners</p> <p>History of inconsistent or no condom use</p> <p>Commercial sex work</p> <p>In high-prevalence area or network</p>	<p>HIV-positive injecting partner</p> <p>Sharing injection equipment</p> <p>Recent drug treatment (but currently injecting)</p>
Clinically eligible	<p>Documented negative HIV test result before prescribing PrEP</p> <p>No signs/symptoms of acute HIV infection</p> <p>Normal renal function; no contraindicated medications</p> <p>Documented hepatitis B virus infection and vaccination status</p>		
Prescription	<p>Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply</p>		
Other services	<p>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</p> <p>At 3 months and every 6 months thereafter, assess renal function</p> <p>Every 6 months, test for bacterial STIs</p>		
	<p>Do oral/rectal STI testing</p>	<p>Assess pregnancy intent</p> <p>Pregnancy test every 3 months</p>	<p>Access to clean needles/syringes and drug treatment services</p>

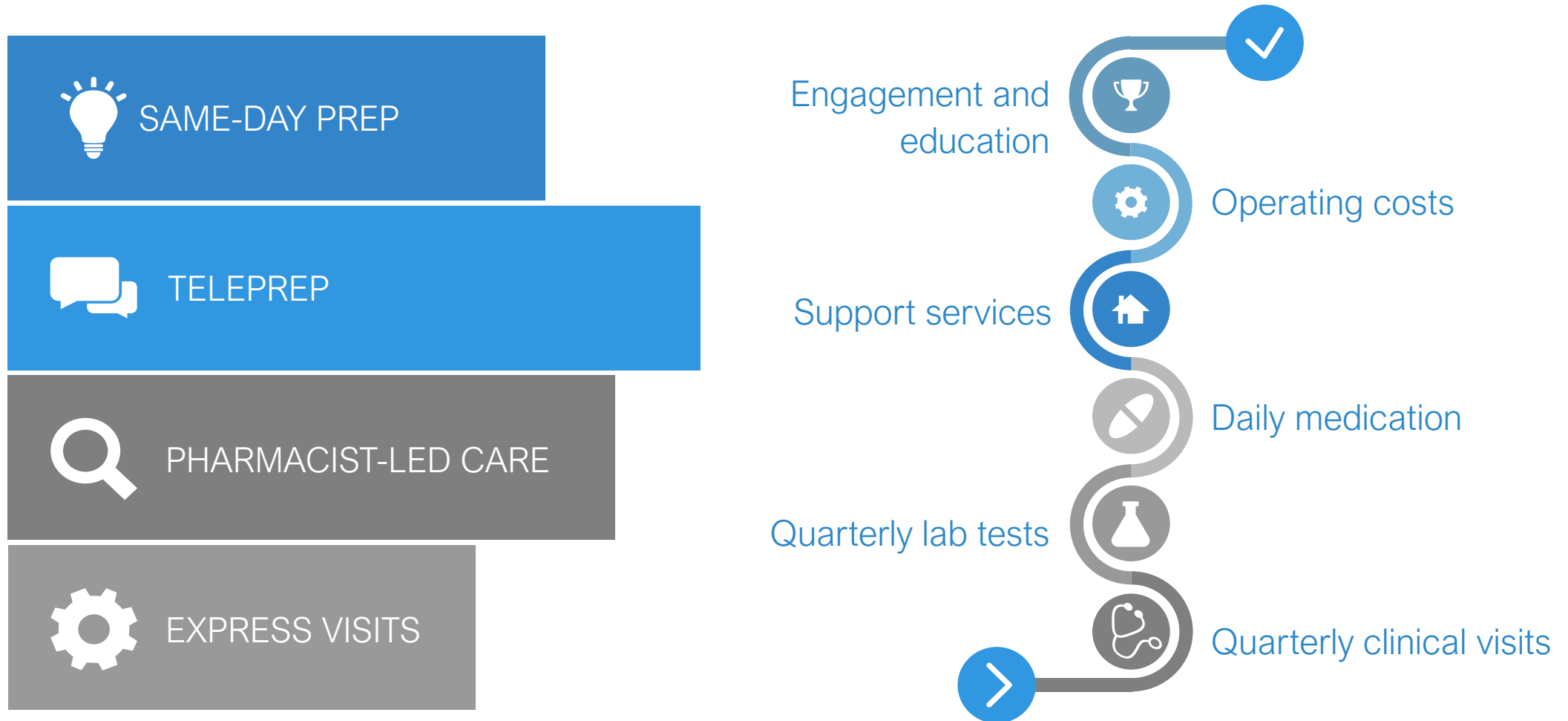
STI: sexually transmitted infection

Providing Care within the PrEP Care System

The PrEP Care System encompasses three phases: Screening, PrEP initiation, and Follow-Up.



Delivery Strategies



Same day PrEP is standard of care

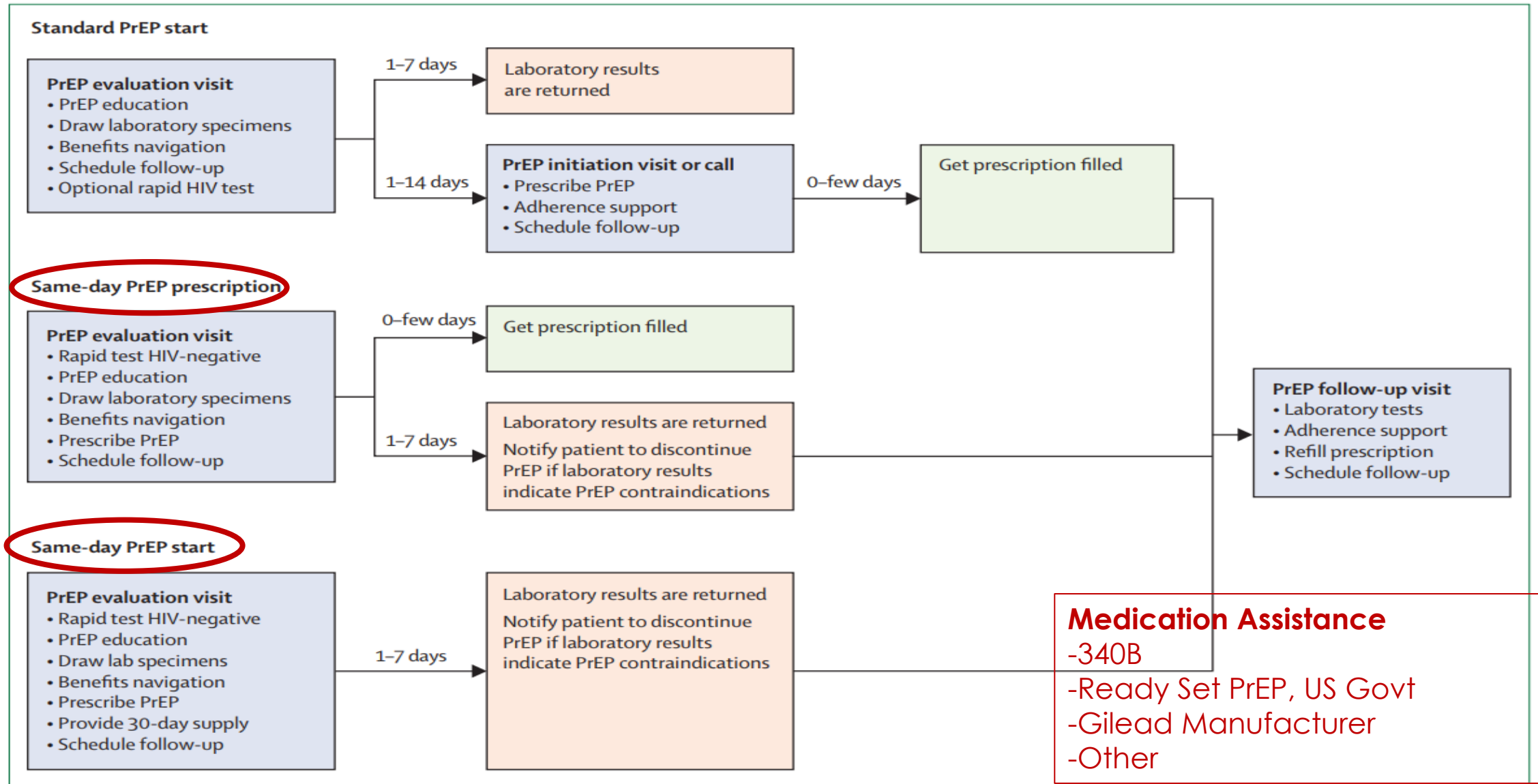
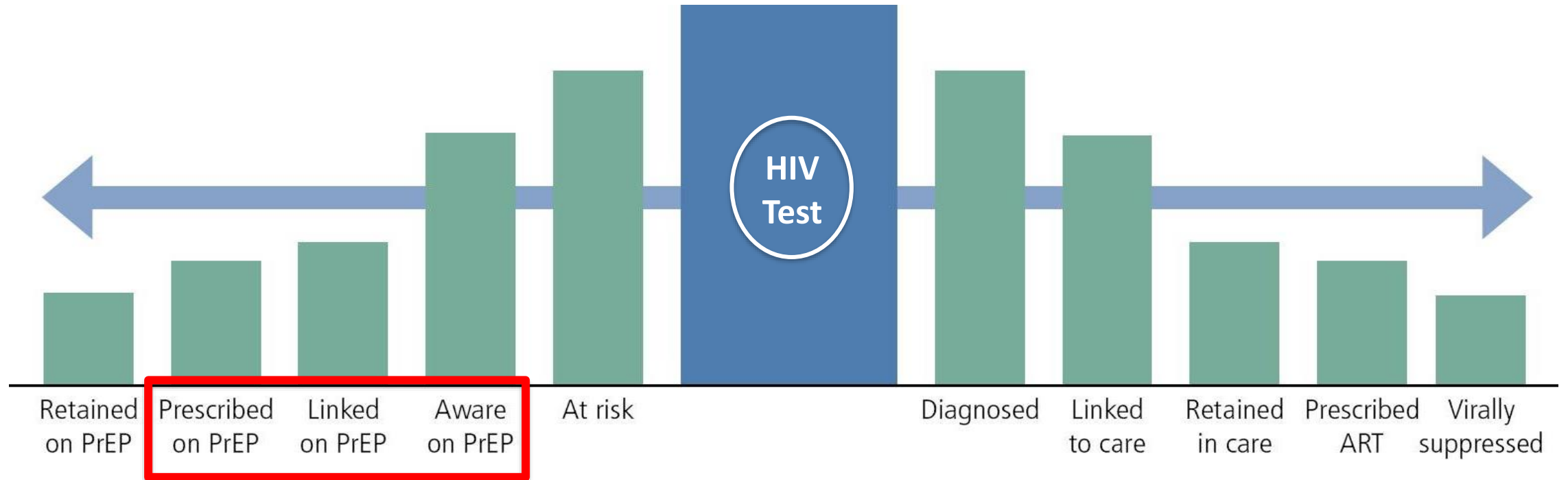


Figure: Standard versus same-day PrEP timelines
PrEP=pre-exposure prophylaxis.

Status Neutral Continuum

Virtual PrEP Care Continuum



Self Testing HIV/STI/Cr Labs

Source: Buchbinder and Liu, Topics in Antiviral Medicine, 2018

Nunn et al. AIDS 2017

TelePrEP



[HIV](#) [Hepatitis](#) [Other STDs](#) [Find Services](#) [About Us](#) [For Service Providers](#)



The Power of Prevention in the Palm of Your Hand

Consumer Support: (319) 930-9093

Provider Support: (515) 443-0341

[Home](#) [Directory](#) [TelePrEP](#) [Info for Providers](#) [Resources](#) [Blog](#)

prepiowa@gmail.com

TELEPREP

HIV prevention can be hard. Getting PrEP shouldn't be.

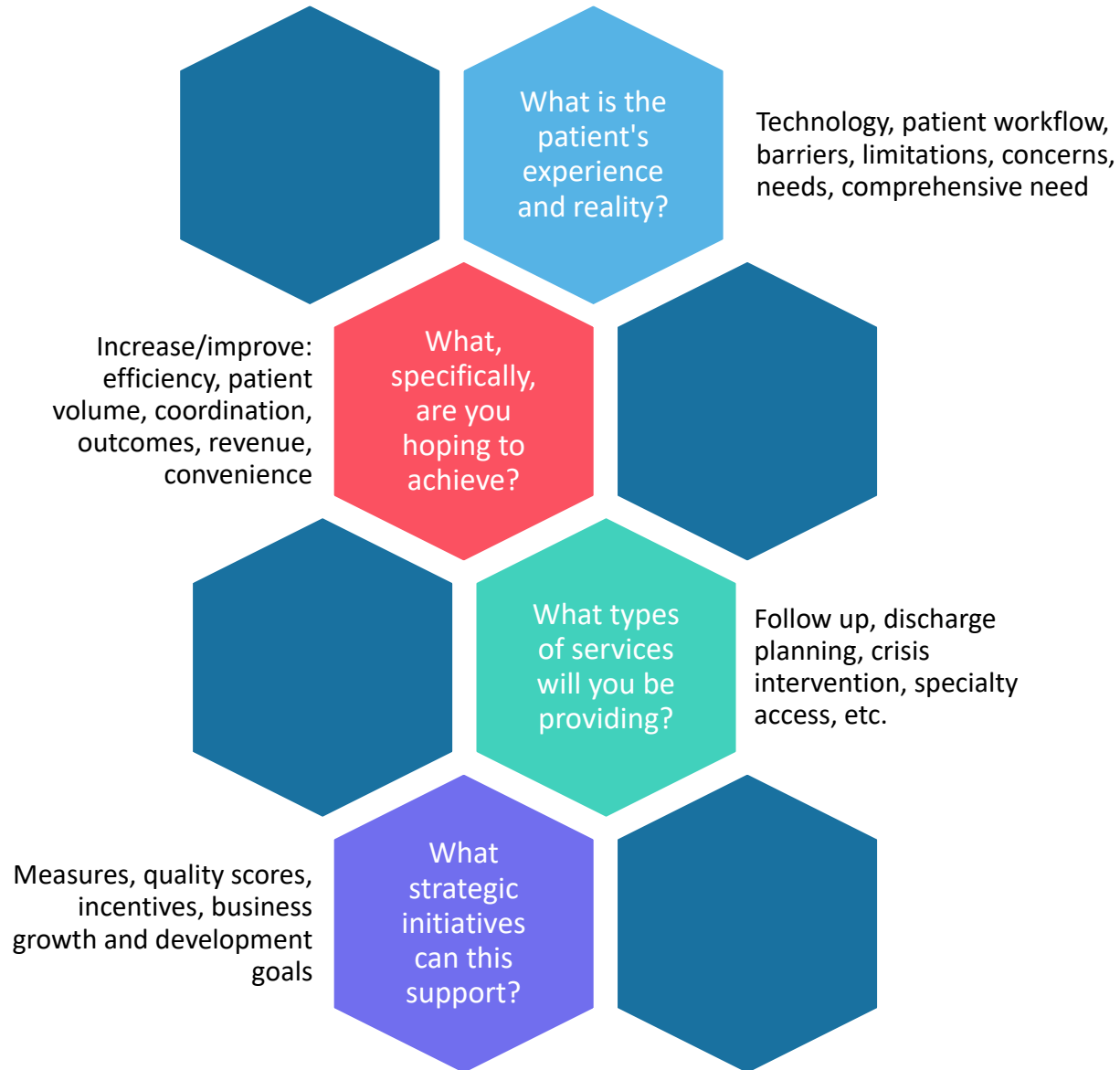
TelePrEP is an in-home (or wherever you want to be) telemedical delivery model for PrEP in Iowa. Patients visit with a Pharmacist using a HIPAA compliant (secured) app on a smartphone, laptop, or tablet. Labs can be obtained locally by visiting an outpatient lab site or utilizing Iowa's extensive network of public health providers.

risk of infection by 92–99% for those who take it daily as prescribed.

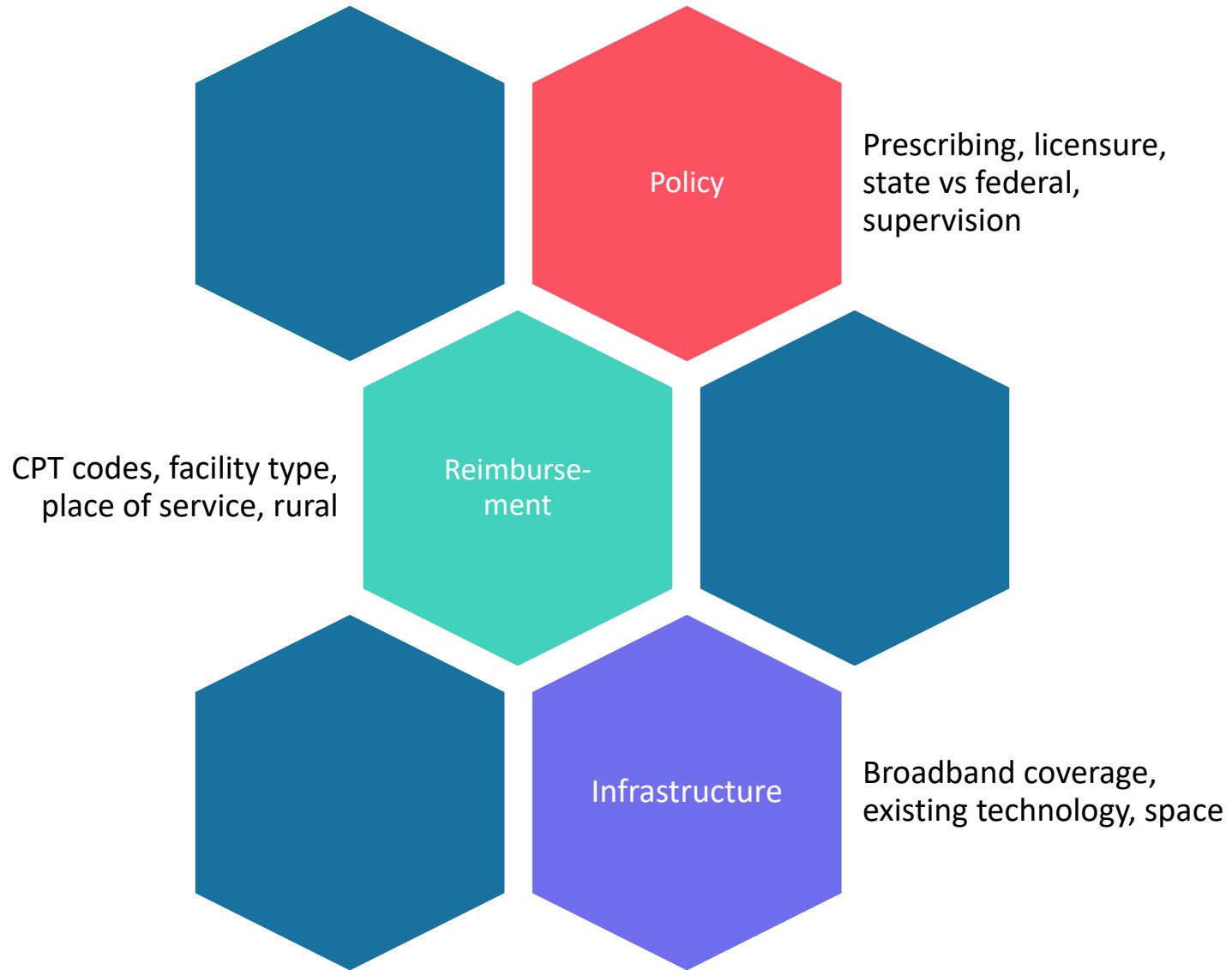


Hoth AB et al. STD 2019

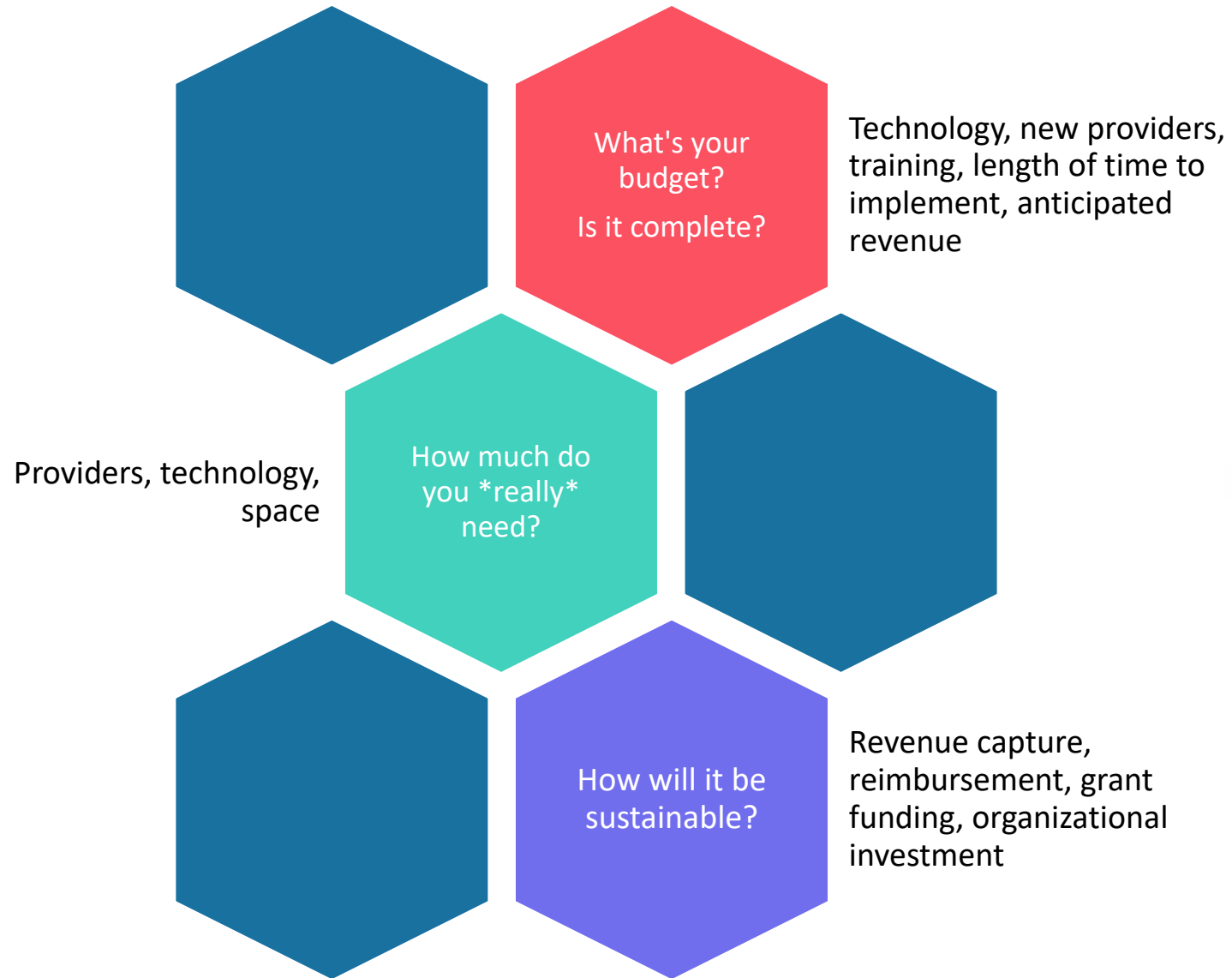
Touger R et al. Curr HIV/AIDS Rep 2019



STRATEGY



PREPARATION



RIGHT SIZING



IMPLEMENTATION

Components of a Program

- Intake
- Documentation and Consent
- Scheduling
- Rooming
- Diagnosing
- Treatment: Initial vs Follow up;
Medical vs Behavioral
- Vitals
- Labs
- Prescribing
- Care coordination
- Emergency procedures
- Reportable events





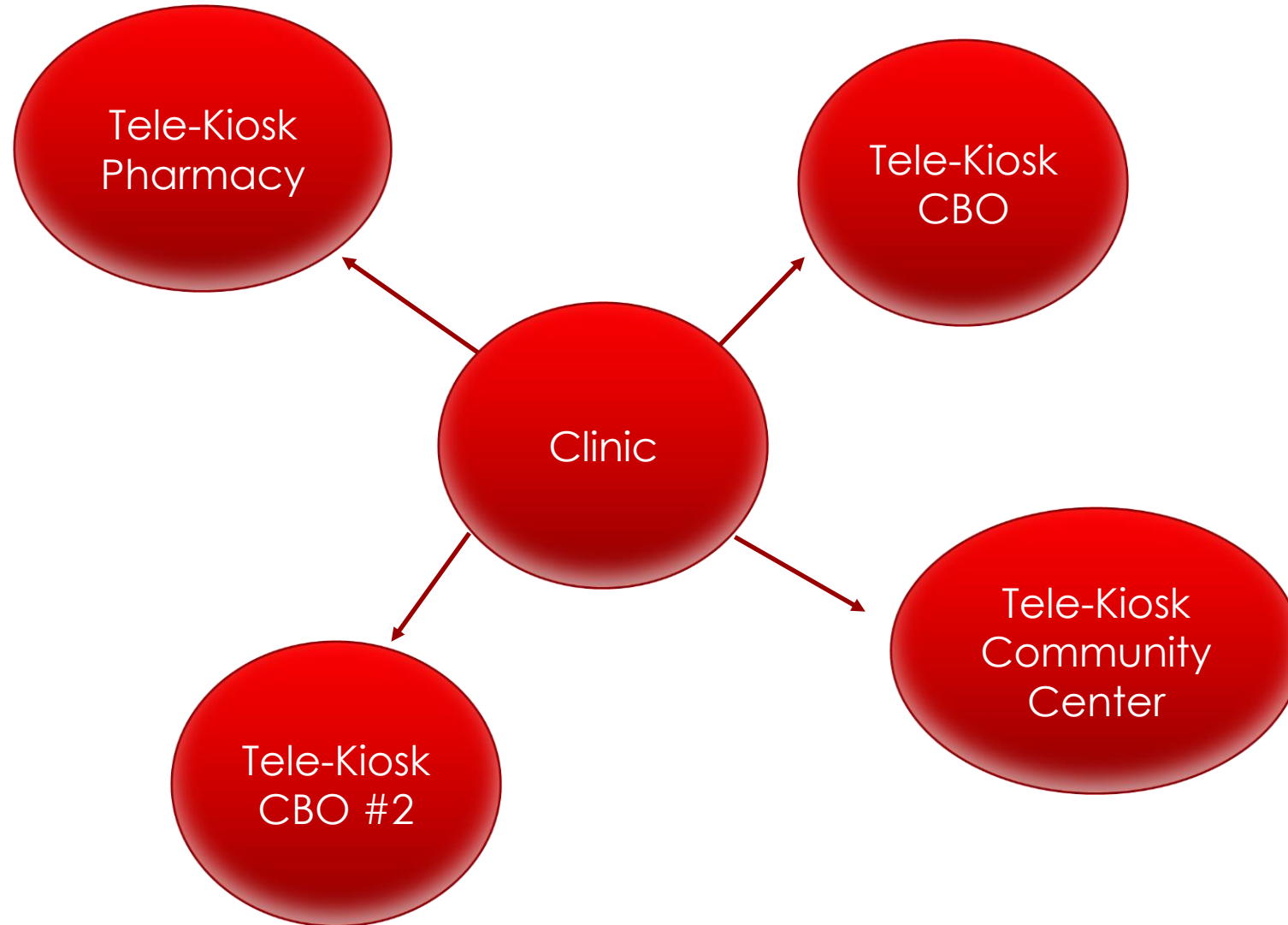
TelePrEP Implementation Planning Tool

Questions for Program Managers about Equipment and Resources Needed to Provide TelePrEP



Addressing Digital Poverty

-creating safe spaces with internet & devices





Free/Low-Cost Telehealth Support Resources



Free Computer Skills Training Programs:

Give Computers/PCs for People:

Virtual Courses with Certification
[pcsforpeople.org/digital-learning/](https://www.pcsforpeople.org/digital-learning/)

Ben Van Wienen

Digital Literacy Instructor

bvanwienen@pcsforpeople.com

651-419-4563 ext 165

St. Louis County Library:

1-on-1 Classes with a Trainer

[scl.org/book-a-trainer](https://www.scl.org/book-a-trainer)

314-994-3300

Urban League of Metropolitan St. Louis:

Computer Literacy Training Sessions

[ulstl.com/business-training-center.html](https://www.ulstl.com/business-training-center.html)

Rosalyn Taylor

St. Louis City Division Contact

rtaylor@urbanleague-stl.org

(314) 615-3610



Connection Devices:

Give Computers/PCs for People:

Low Cost Desktops, Laptops, and Internet
[pcsforpeople.org](https://www.pcsforpeople.org)

Belville, IL: 618-215-3787

Kansas City, MO: 816-559-7077

St. Louis County Library:

Free Chromebook and Hotspot Rentals

[slcl.org/computerkits](https://www.slcl.org/computerkits)

314-994-3300

St. Louis Public Library:

Free Chromebook and Hotspot Rentals

[slpl.org/hotspots-chromebooks/](https://www.slpl.org/hotspots-chromebooks/)

314-241-2288



Emergency Broadband Benefit and Lifeline Programs for Free Internet and Phone Services:

Access Wireless:

Unlimited Texts/Data/Minutes

[accesswireless.com/lifeline](https://www.accesswireless.com/lifeline)

1-888-900-5899

Assurance Wireless:

Smartphone, 100 GB Hotspot Data, Unlimited

Texts/Data/Minutes

[assurancewireless.com/apply-now](https://www.assurancewireless.com/apply-now)

1-888-321-5880

Life Wireless:

Smartphone, Monthly Cell Service

[lifewireless.com/enroll](https://www.lifewireless.com/enroll)

573-751-3234

SafeLink Wireless:

Unlimited Text/Data/Minutes, 10-15 GB Hotspot
Data

[safelinkwireless.com/Enrollment/Safelink/en/Web/
www/default/index.html#!/newHome](https://www.safelinkwireless.com/Enrollment/Safelink/en/Web/www/default/index.html#!/newHome)

1-800-723-3546

Standup Wireless:

Unlimited Text/Minutes, 10 GB Data

[standupwireless.com/apply-now/](https://www.standupwireless.com/apply-now/)

1800-544-4441

Q Link:

Tablet, Unlimited Text/Data/Minutes

[qlinkwireless.com/signup/g-6-717/](https://www.qlinkwireless.com/signup/g-6-717/)

1-855-754-6543

Terra Com Wireless:

Unlimited Text, 500 Minutes, 4.5 GB Data

[terracomwireless.com/enter_zip.php](https://www.terracomwireless.com/enter_zip.php)

1-888-716-8880

Tempo:

Unlimited Text/Minutes, 4.5 GB Data

[mytempo.com/lifeline-wireless/](https://www.mytempo.com/lifeline-wireless/)

1-833-998-3676

TAG Wireless:

Smartphone, Unlimited Text/Minutes, 500MB Data

[tagmobile.com/#tab1](https://www.tagmobile.com/#tab1)

1-866-959-4918



Lessons Learned with TelePrEP

- Lack of a safe space (i.e., lives with people, need to establish private space at work)
- Digital poverty: device + internet
- Converting to telephone visits & regulations
- Requires flexibility in appt times and duration
- Higher show rates (i.e., use of phones (video/telephone appt), calls from cars, calls from work)
- Delays between visit, lab testing, script, medication dispensing, starting PrEP
- Incorporating different lab testing options (home/self, CBO, clinic, lab near home)
- Tele-support staff & tele-counseling

National Resources

- CDC PrEP/PEP Hotline
 - 855-448-7737
 - <http://www.cdc.gov/hiv/living/treatment/hotline.html>
- UCSF Clinical Consultation Center (CCC)
PrEPline
 - 855-448-7737 (11 a.m. – 6 p.m. EST)
 - <http://nccc.ucsf.edu/clinical-resources/pep-resources/pep/>



CDC Capacity Building Assistance

- For technical assistance
 - Contact your local CBA
 - Place a CTS request via your health department or CBO

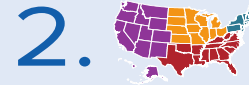
The CBA Provider Network includes four major components:



1. National Training: A standardized national training program will increase the knowledge, skills, and competencies of HIV prevention staff. Based on feedback from HIV prevention providers, web-based and classroom-based training will now be provided separately, though the eLearning and Classroom training providers will also collaborate to deliver trainings that blend online and classroom learning.

Track A: Electronic Learning (eLearning) Training Center
Funded organizations: ETR Associates, Inc. and HealthHIV

Track B: Classroom Learning Training Center
Funded organization: Cicatelli Associates, Inc.



2. Regional Technical Assistance: To provide more personalized support and facilitate long-term working relationships, technical assistance will now be tailored and delivered to meet capacity building needs within four geographic regions: Northeast, South, Midwest, and West. These providers will work together to develop and implement jurisdictional CBA plans for CDC-funded health departments and CBOs in each region. Each region will have a team of three technical assistance providers – one for each of the following three tracks:

	Funded Organizations			
	Northeast	South	Midwest	West
Track A: Clinical HIV Testing and Prevention for Persons with HIV	Primary Care Development Corporation	My Brother's Keeper	San Francisco Community Health Center (formerly Asian and Pacific Islander Wellness Center)	Denver Health and Hospital Authority (Denver Prevention Training Center)
Track B: Nonclinical HIV Testing and Prevention for HIV Negative People	University of Rochester	Latino Commission on AIDS	Washington University	City & County of San Francisco Department of Public Health
Track C: Integrated HIV Activities and Structural Interventions	New York City Department of Health & Mental Hygiene	National Alliance of State & Territorial AIDS Directors	AIDS United	Public Health Foundation Enterprises, Inc. (California Prevention Training Center)



3. Continuous Quality Improvement and Sustainability for CBOs: This new distance-learning program, developed in response to input from CBOs, will help senior and mid-level program managers at CDC-funded CBOs improve the quality of their programs and the sustainability of their organizations. The program will include expert instruction, mentoring, and resource sharing as well as peer-to-peer learning and support opportunities.

Funded organization:
 Asian and Pacific Islander American Health Forum

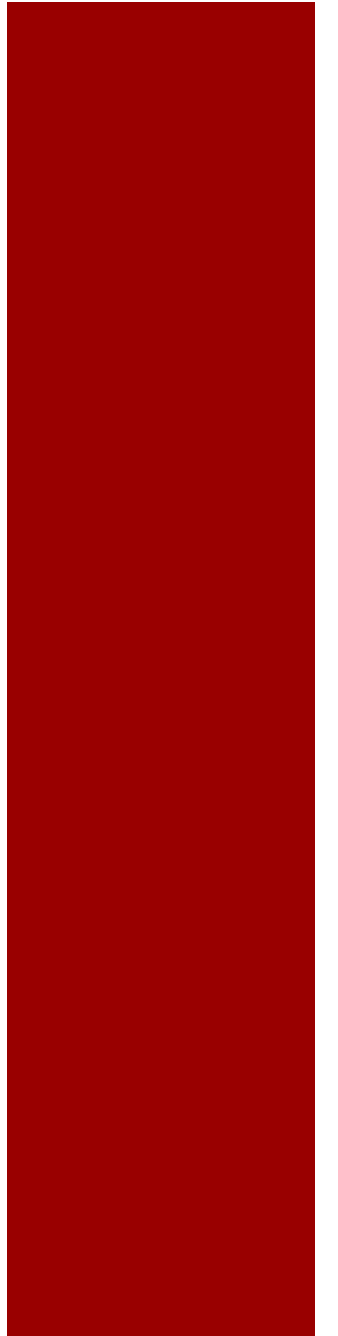


4. Marketing and Administrative Support for CBA Provider Network: This provider will focus on marketing to increase awareness and utilization of the CBA program and administrative support to facilitate coordination, communication, and collaboration across the CBA Provider Network.

Funded organization:
 University of Missouri - Kansas City

Thank you!!

Questions?





Seeing the Forest and the Trees: TelePrEP as a Point of Access for Health Centers Resources and Planning for the Future

Kevin L. Ard, MD, MPH

thefenwayinstitute.org

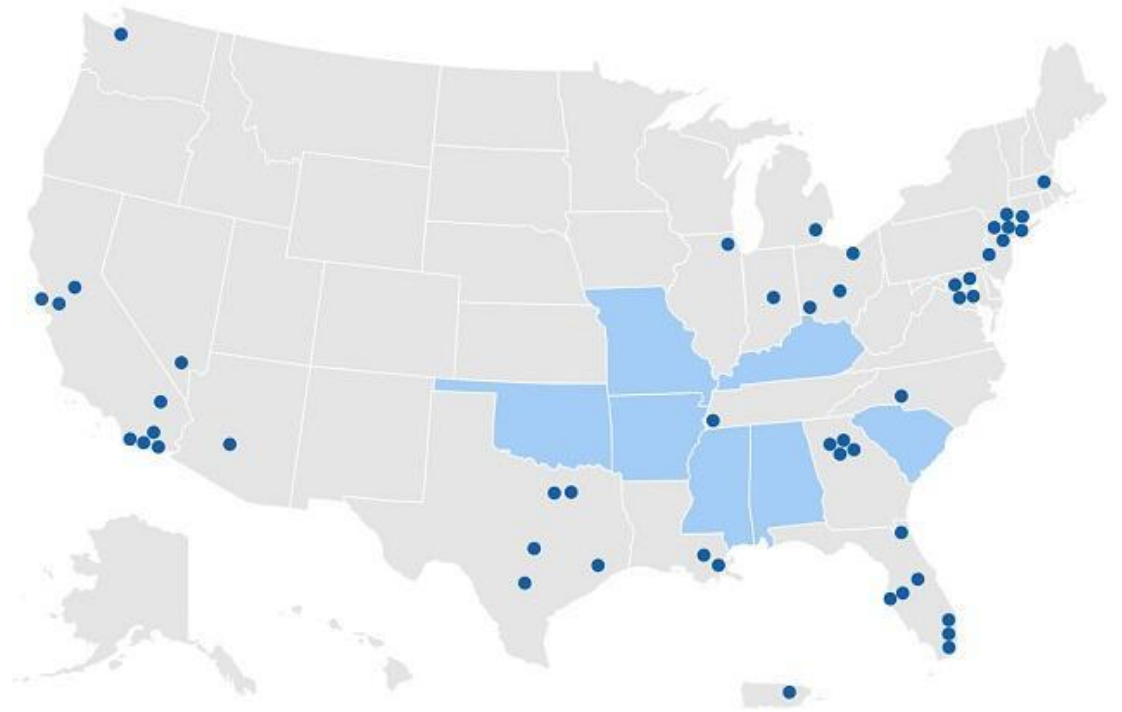
Outline

- Health center's perspectives on HIV prevention and TelePrEP: Recent data
 - TelePrEP resource for health centers
 - Planning for the future: TelePrEP and long-acting injectable agents
-

HIV prevention in health centers

PrEP readiness assessments coupled with virtual PrEP training for health centers in 2020

- Distinct versions for staff and leaders
- Completed by 364 of 412 participants (88%)
- Participants located in 15 states and Washington, DC, representing 29 of 57 (51%) of Ending the HIV Epidemic (EHE) priority areas



Example question from staff readiness assessment

34. If your health center had additional resources to support PrEP, which of the following would represent the best use of those resources? Check all that apply.

- Hiring a non-clinical staff member to help patients obtain PrEP medication through enrollment in assistance programs/benefits navigation.
- Hiring a non-clinical staff member to help patients taking PrEP adhere to the medication and follow-up visits.
- Hiring a physician to provide PrEP.
- Hiring a nurse practitioner to provide PrEP.
- Hiring a physician's assistant to provide PrEP.
- Hiring a clinical pharmacist to provide PrEP.
- Purchasing PrEP medications to dispense to patients for same-day PrEP initiation.
- Providing professional development/continuing education opportunities for clinicians prescribing PrEP.
- Establishing a tele-PrEP program to improve PrEP access and adherence.
- Providing training and technical assistance to create a more welcoming and inclusive clinical environment for patients who are at high risk for HIV (e.g., MSM and transgender women).
- Participating in community events to raise awareness of PrEP and engage community members in PrEP care.
- Providing PrEP services at off-site locations (e.g., community-based organizations).
- Establishing a syringe service program, where legally permissible, which incorporates PrEP.
- Enhancing the electronic medical record to facilitate identification of PrEP candidates, provide decision support for HIV testing, and facilitate PrEP follow-up testing.

Key findings from the readiness assessments

- 91% considered HIV prevention a priority for their health center
 - 74% worked at health centers that provided PrEP
 - Most considered their health centers welcoming to populations disproportionately affected by HIV, though perceptions differed by population:
 - Black/African-American patients: 95%
 - Hispanic/Latinx patients: 94%
 - Gay and bisexual men: 91%
 - People who inject drugs: 89%
 - Transgender and gender diverse people: 87%
-

Key findings from the readiness assessments, continued

- **Major barriers:**

- Staff: Lack of outreach/engagement for people at risk for HIV (23%)
- Leaders: Patients' willingness to take PrEP (24%)

- **Best uses of additional resources:**

- Staff: Establishing a telePrEP program (56%)
 - Leaders: Establishing a telePrEP program (64%), training/TA on welcoming environments for people at risk for HIV (64%)
-

TelePrEP

Telemedicine for HIV Prevention



NATIONAL LGBTQIA+ HEALTH
EDUCATION CENTER

A PROGRAM OF THE FENWAY INSTITUTE



www.lgbtqiahealtheducation.org

Best practices for telePrEP

Clinicians and PrEP programs can take key steps to overcome challenges to telePrEP and maximize the availability and benefits of this care delivery option..

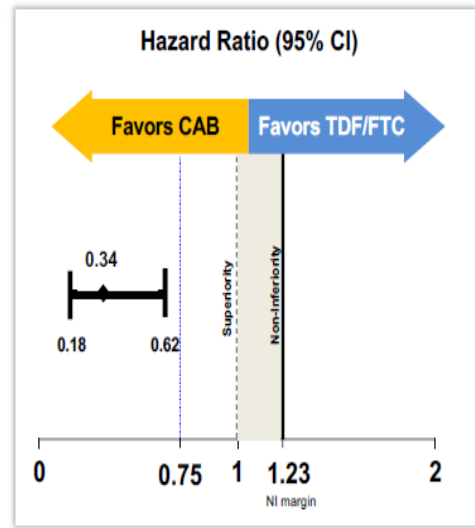
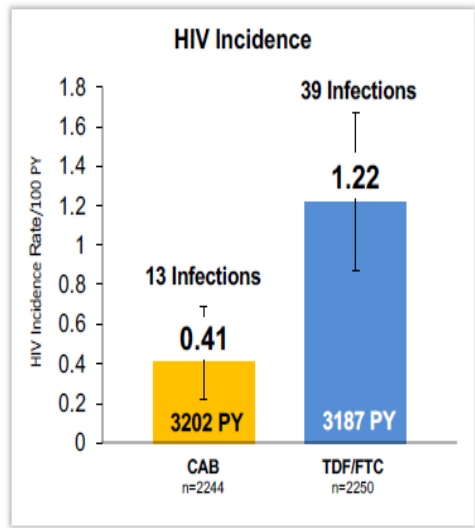
- Clinicians should follow best practices in telemedicine, including ensuring that they conduct telePrEP visits over secure connections, from a private setting and, if video is used, with a professional background [11].
- For physical examinations in which a medical chaperone would be present during an in-person visit (e.g., examination of the genitals to evaluate a genital ulcer), consider engaging a video chaperone. This could be a healthcare worker at the same location as the clinician or a healthcare worker who joins the videoconference from another location.
- TelePrEP should maintain the HIV, STI, and other PrEP-related testing schedule recommended by CDC [1]. Options for testing as part of telePrEP include:
 - **Visits for specimen collection only, with all other aspects of PrEP care provided by telemedicine.** This may be the least expensive option for some patients who rely on publicly-funded HIV and STI testing.
 - **Home delivery of test kits.** In this strategy, patients self-collect specimens, package them, and mail them to a clinic or laboratory for processing. In a pilot study of home self-testing, a majority of participants preferred at-home testing to clinic visits, and

Injectable Cabotegravir



HIV Incidence CAB vs. TDF/FTC

52 HIV infections in 6389 PY of follow-up
1.4 (IQR 0.8-1.9) years median per-participant follow-up
Pooled incidence 0.81 (95%CI 0.61-1.07) per 100 PY



CI, confidence interval

Primary outcome: HIV incidence

40 infections over 3892 person-years
Pooled HIV incidence 1.03 (0.73, 1.4) per 100 person-years

	CAB	TDF/FTC
HIV infections	4	36
Person-years	1,953	1,939
HIV incidence (95% CI)	0.2 (0.06, 0.52)	1.86 (1.3, 2.57)

Wald test z statistic – 4.20, efficacy stopping bound (z scale) – 3.61

- Pooled incidence in both trials lower than previously observed in the community
- Both trials showed superiority of CAB-LA against a highly effective TDF/FTC control
- CAB-LA well tolerated despite injection site reactions



Draft guidance on cabotegravir for PrEP includes HIV viral load assays.

Draft for Public Comment

Table 7 Timing of CAB PrEP-associated Laboratory Tests

Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	When Stopping CAB
HIV*	X	X	X	X	X	X
Syphilis	X			MSM^/TGW~ only	Heterosexually active women and men only	MSM/TGW only
Gonorrhea	X			MSM/TGW only	Heterosexually active women and men only	MSM/TGW only
Chlamydia	X			MSM/TGW only	Heterosexually active women and men only	MSM/TGW only
Pregnancy	Persons with childbearing potential	Persons with childbearing potential	Persons with childbearing potential			Persons with childbearing potential

* HIV-1 viral load assay

X all PrEP patients

^ men who have sex with men

~ persons assigned male sex at birth whose gender identification is female

Cabotegravir may require changes to existing telePrEP models.

Step in PrEP care	Amenable to fully virtual care?	Potential solutions
Risk assessment and counseling	Yes	None needed
Benefits navigation	Probably, depending upon the documentation required	None needed
Medication administration	No - Intramuscular injection in the gluteus every 2 months	Community-based administration, home health visits
Baseline and monitoring laboratory studies	No – There is no FDA-approved home HIV viral load assay	New assay development/validation, hybrid care models

Incorporating cabotegravir into community-based PrEP models may improve access.



TEXT "PREP" TO 978.604.6937

Swiping right? Get PrEP!

GLASS provides a continuum of confidential services to LGBTQ+ Youth of Color ages 18-29 including same-day PrEP, STI testing, and treatment.

EVERY WEDNESDAY | 3:00 - 7:00 P.M. | AT OUR TWO LOCATIONS
75R Amory St, Boston, MA • 1 Grant St, Suite 100, Framingham, MA

GLASS   MASSACHUSETTS GENERAL HOSPITAL  JRI | Leader in Social Justice

Open to all regardless of ability to pay. Learn more at JRI.ORG/PREPATGLASS or email OUTREACH@JRI.ORG



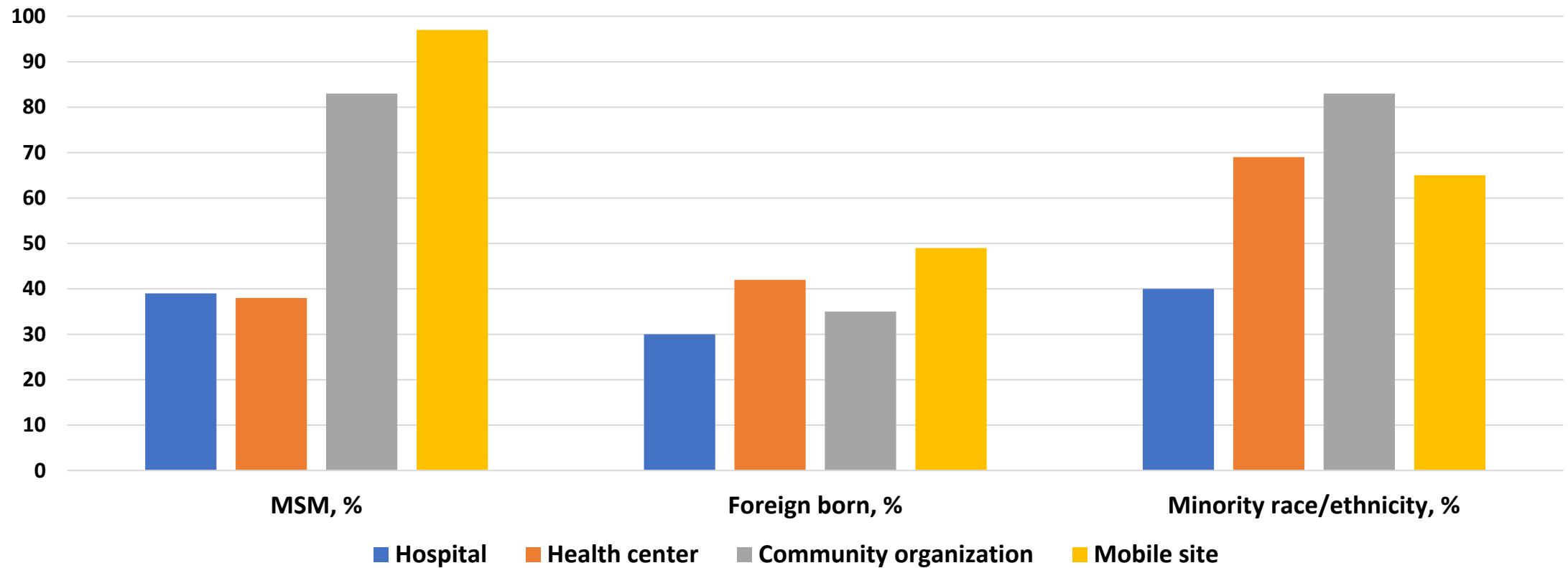
PrEP on a mobile unit in Miami



PrEP at a drop-in center for LGBTQIA+ youth in Boston

Community sites reach different populations than clinical sites.

Patient characteristics in Boston STI program by site, 2019



Summary

- In a recent survey, health center employees in EHE priority areas identified telePrEP as a priority for program development.
- Online resources for telePrEP exist. Go to www.lgbtqiahealtheducation.org.
- Cabotegravir's mode of administration and laboratory monitoring may pose new challenges for telePrEP.