

What's New In PrEP?

The Role of Wisconsin's Statewide Action Planning Group

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Outline

- Practical Resources for Program Managers and Staff
- EHE and the Status Neutral Continuum of Care
- Innovations in PrEP Implementation
- Current PrEP Options and Innovations in PrEP products
 - Don't wait for new products!



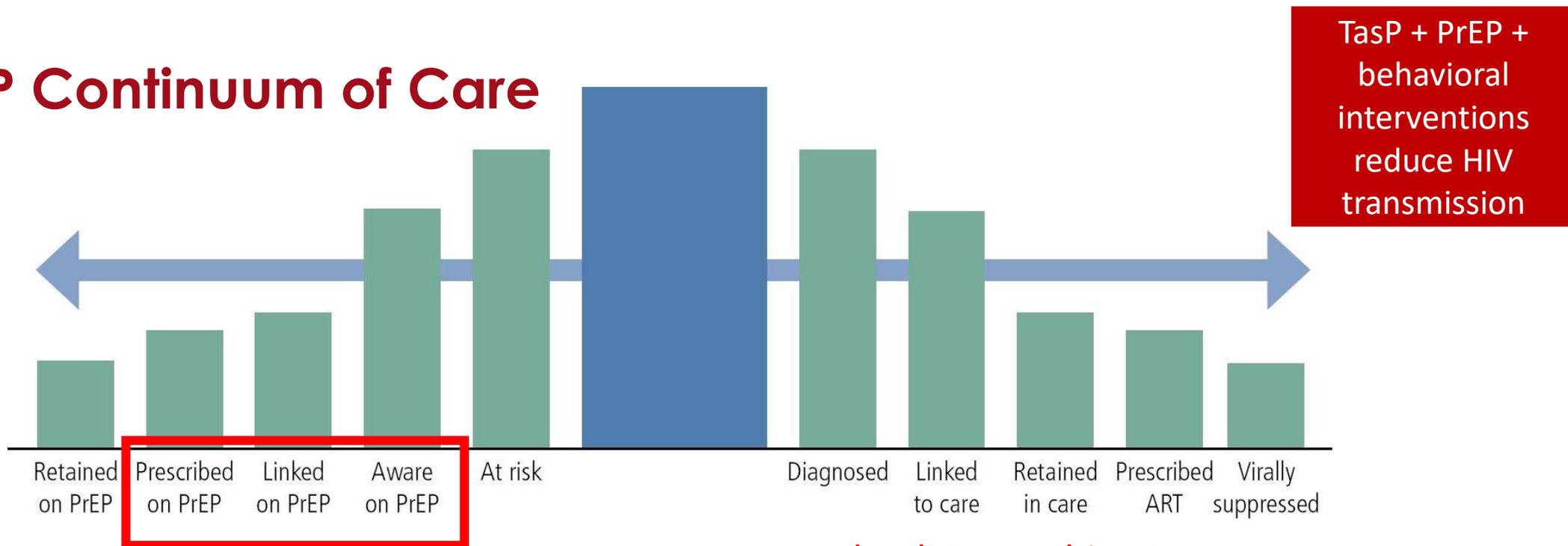
Resources for Practical Tools to Use for Program Planning and Staff Training

- CDC Website on PrEP Implementation (PrEP Basics & Effective Interventions Web Pages)
- AVAC – infographics and explanations biomedical interventions (HIV and COVID-19)
- NASTAD – many topics
- PleasePrEPme.org for PrEP Navigation
- Prime Health TeleHealth for TelePrEP Tools
- New York Health and San Francisco Health Dept for PrEP guidelines
- Fenway Institute and National LGBT Health Center for Staff Training
- WHO Implementation Tool 2019 with Phone App by JHPIEGO
- **Let Us know what resources you need!**

**Coming Soon!
SAPG Google
Drive Folder 2021
of PrEP Resources
and a Learning
Collaborative
Online Forum
developed by
WashU CBA,
MATEC WI, WI
Health Dept**

The EHE Goal: Reducing New Infections Requires Care Implementation Along The Status Neutral Continuum

PrEP Continuum of Care



PrEP Navigation

Office Visit + Labs + Medications

Federal Ryan White Program covers these costs

Challenges for PrEP Implementation: Who covers the costs?

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

Nunn et al. AIDS 2017

Innovations in PrEP Implementation:

Same-Day PrEP

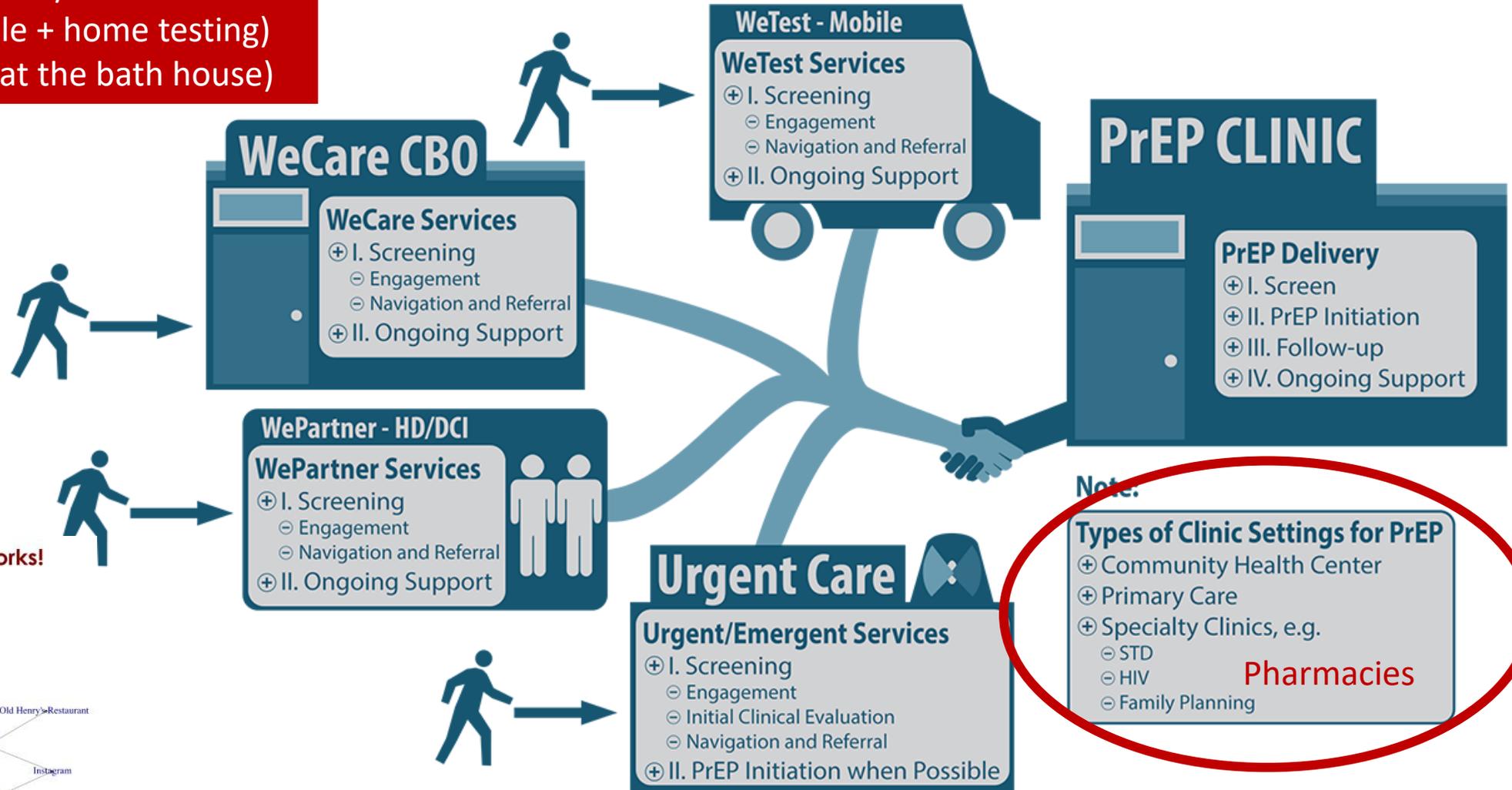
Integrated Testing & PrEP in Pharmacies

TelePrEP in clinics/CBOs/Pharmacies

PrEP at Home (with tele + home testing)

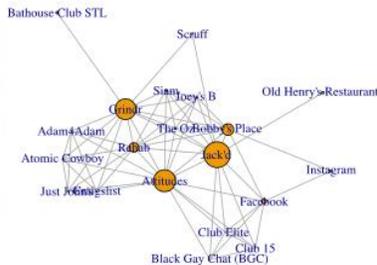
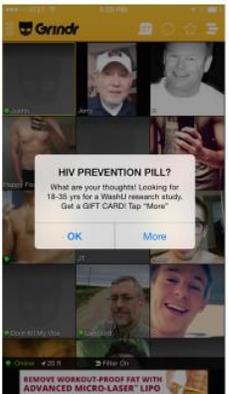
PrEP at Hotspots (i.e., at the bath house)

Must lay the foundation of PrEP Implementation NOW for the future PrEP products to have their benefit!

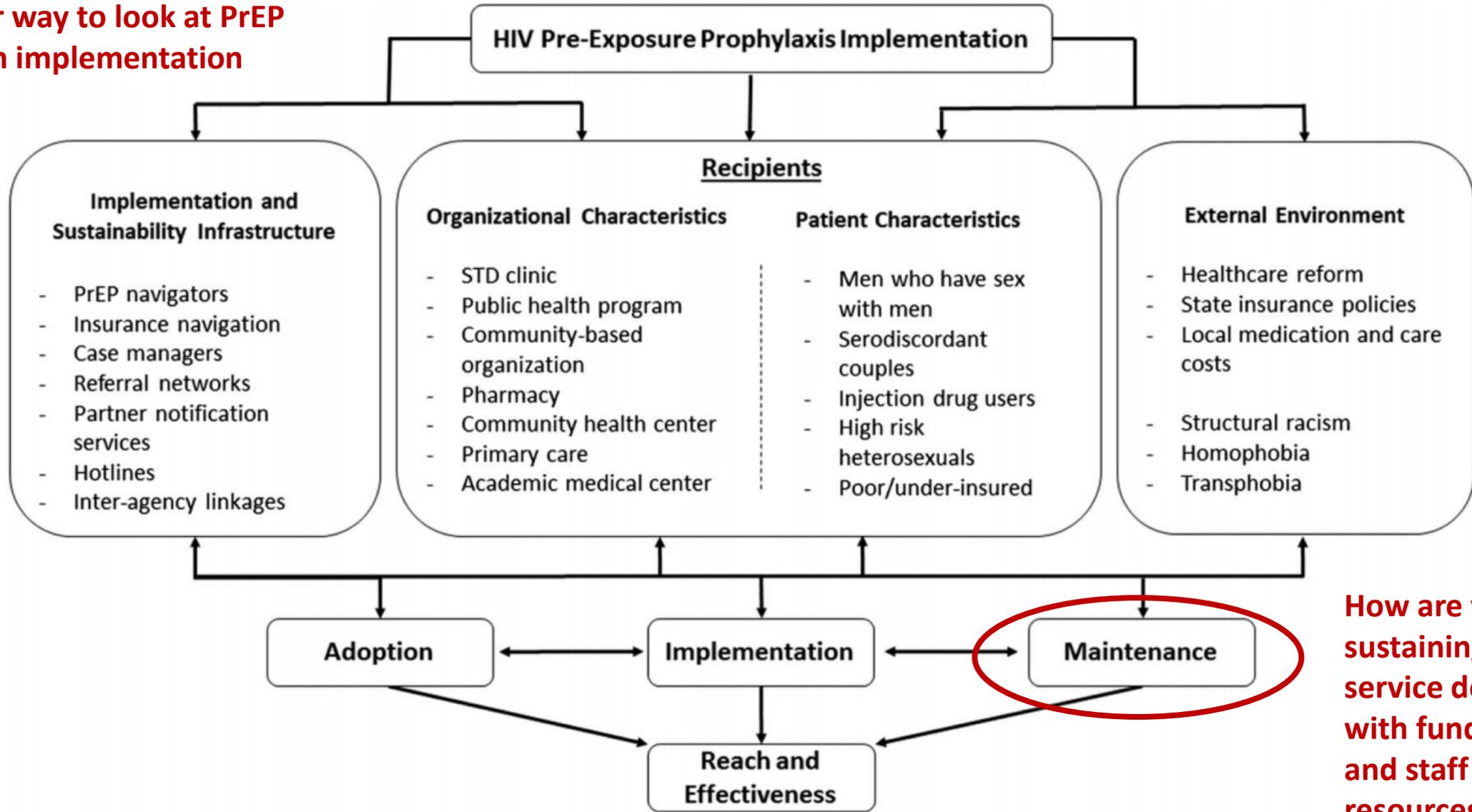


- Note:**
- Types of Clinic Settings for PrEP**
- ⊕ Community Health Center
 - ⊕ Primary Care
 - ⊕ Specialty Clinics, e.g.
 - ⊖ STD
 - ⊖ HIV
 - ⊖ Family Planning
- Pharmacies**

Implement among the social networks!



Another way to look at PrEP program implementation



How are you sustaining service delivery with funding and staff resources?

FIGURE 1. Ecosocial model of factors involved in PrEP implementation.

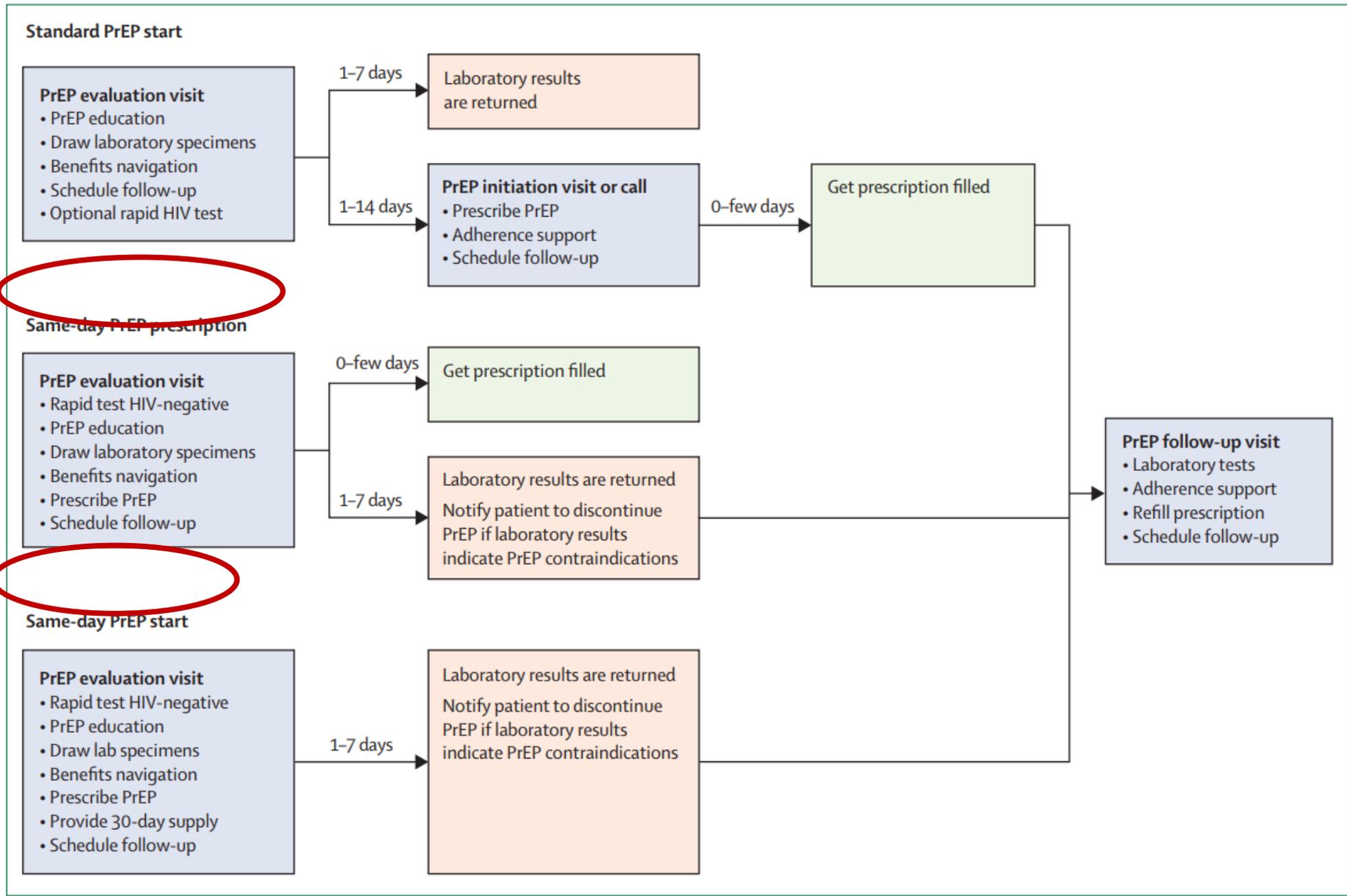


Figure: Standard versus same-day PrEP timelines
PrEP=pre-exposure prophylaxis.

**WI SAPG
Call to Action:**

**PrEP IS STANDARD
OF CARE
(it is equivalent to
not screening for
diabetes and
offering an aspirin
for someone at risk
of a heart attack)**

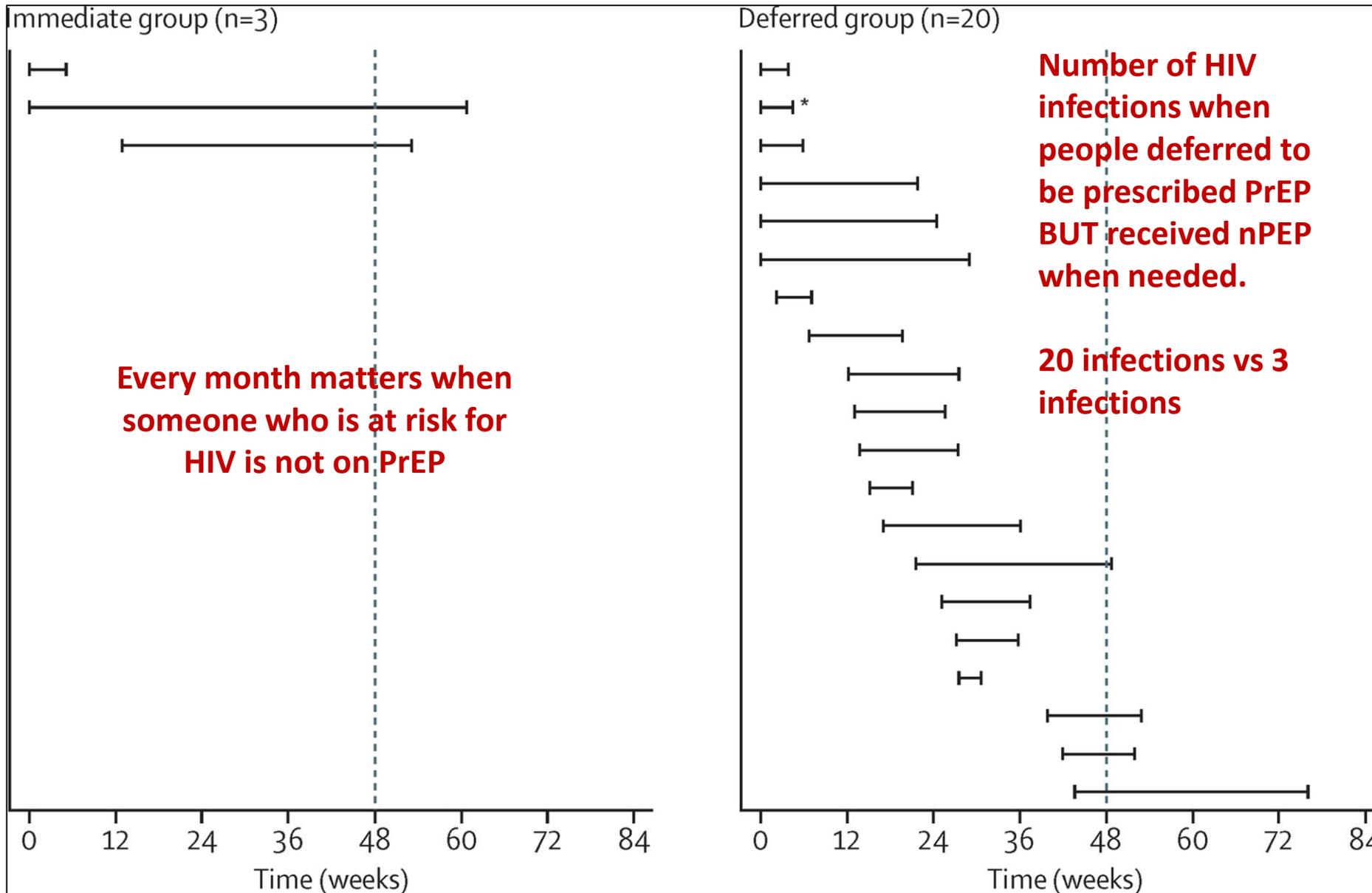
**Increase the
number of
competent
PrEP prescribers
(MD, DO, NP, PA,
Pharmacists)
who can take a
sexual history and
help to create safe
spaces for
community
members**

Table 1: Summary of Guidance for PrEP Use

Use this in your office!!!

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection	HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work	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	HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible	Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status		
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



Today's Options: PrEP Prescribing in 2020

- FDA approved AND CDC Guidance
 - Daily oral PrEP with TDF/FTC (**CDC, ~99% effective for sexual transmission; ~74% for IDU transmission**)
- FDA approved and no CDC Guidance
 - Daily oral PrEP with TAF/FTC
- No FDA approval and no CDC Guidance
 - On demand, event driven PrEP with TDF/FTC

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

Mayer et al. Lancet. July 2020

Kenneth H Mayer, Jean-Michel Molina, Melanie A Thompson, Peter L Anderson, Karam C Mounzer, Joss J De Wet, Edwin DeJesus, Heiko Jessen,



TDF/FTC vs TAF/FTC for PrEP

- DISCOVER Trial is the only trial on daily PrEP and TAF
- Trial did not include on demand, event driven PrEP
- Trial did not include cisgender men and women
- **TAF/FTC as PrEP is indicated in those with CrCl 30-60 mL/min** (vs TDF > 60 mL/min); FDA approved Oct 3, 2019
- PrEP providers are not aligned; TAF causes weight gain and dyslipidemia, has less data vs TDF, costly, not covered by insurance

Which medication should I prescribe for daily PrEP?

TDF/FTC (Truvada)

FDA approval: 2012



19 mm



EFFECTIVENESS

- ✓ for multiple populations

SAFETY

- Small ↓ in eGFR and BMD

COST

- \$1,845/month in 2019
- Generic in 2020

100

0

EFFECTIVENESS*

MSM & TRANS WOMEN

HETEROSEXUALS

PWID

SAFETY / 48 WKS

eGFR (mL/min)

HIP BMD

LDL (mg/dL)

BODY WEIGHT (kg)

-2.0

-0.99%

-6.5

+0



12.5 mm

TAF/FTC (Descovy)

FDA approval: 2019



EFFECTIVENESS

- ✓ for MSM and transwomen
- ? for other populations

SAFETY

- Small ↑ in LDL and weight

COST

- \$1,845/month in 2019

0

100



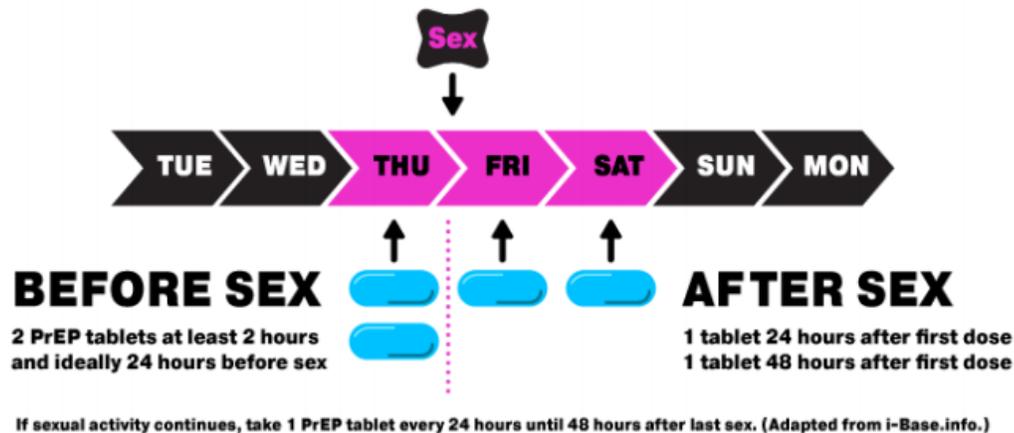
No CDC Guidance currently; guidance from local HDs (SF and NYC)

“On-Demand” Dosing for PrEP: Guidance for Medical Providers

Daily dosing is the only Food and Drug Administration (FDA)-approved schedule for taking pre-exposure prophylaxis (PrEP) to prevent HIV. Robust data support the intermittent or “on-demand” use of PrEP before and after sexual activity by cisgender gay, bisexual and other men who have sex with men. We provide guidance on the off-label but evidence-based use of on-demand PrEP.

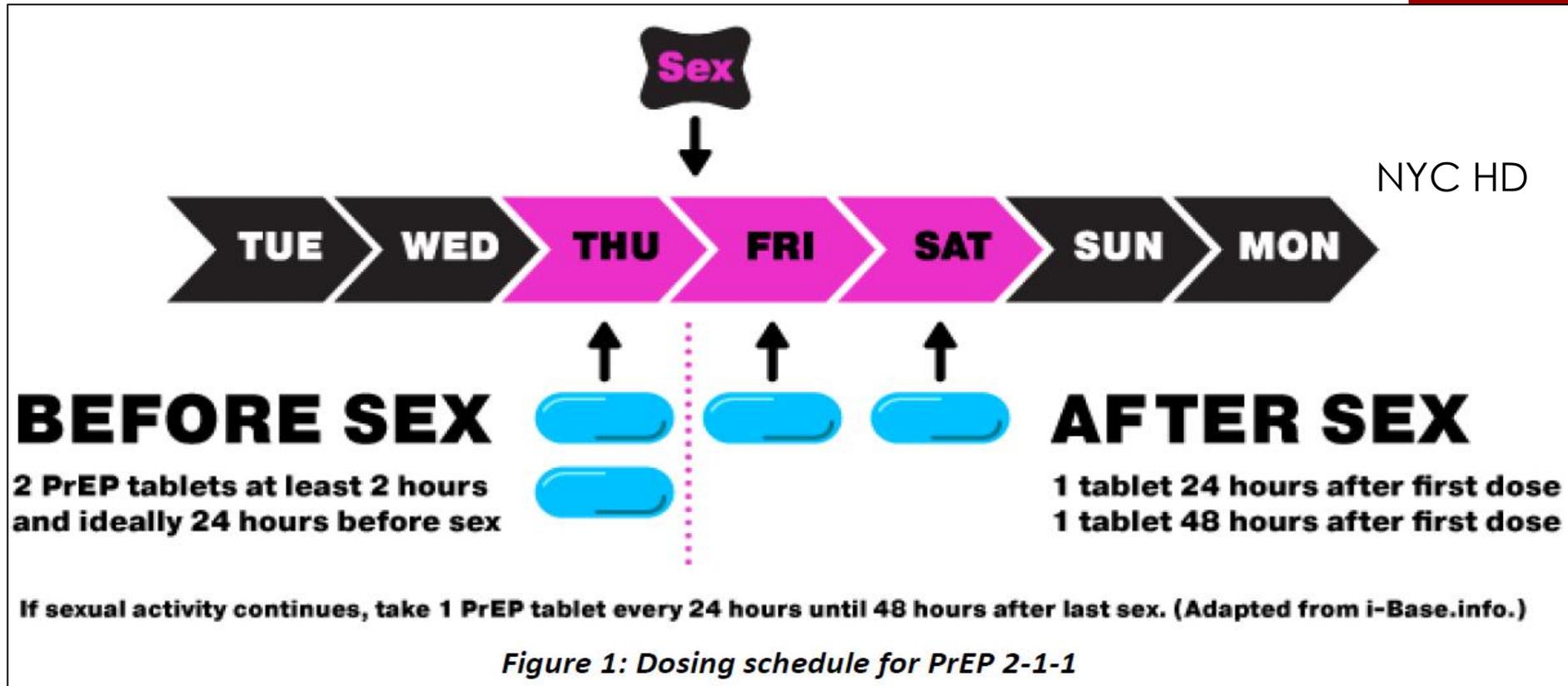
Recommended dosing for on-demand PrEP

The International Antiviral Society-USA supports the use of on-demand PrEP for gay, bisexual and other men who have sex with men, using a “2-1-1” schedule in which individuals take two tablets two to 24 hours before sex, one tablet 24 hours after the first dose, and another tablet 24 hours later. If they have sex again before the end of this 48-hour period, they should continue to take PrEP once every 24 hours until 48 hours after their last sexual episode. The next time they anticipate having sex, they should take a new pre-exposure dose of two pills — unless they last took PrEP at some point in the prior seven days, in which case they can initiate on-demand PrEP with a one-pill loading dose. (The San Francisco Department of Public Health also provides [guidance](#) on PrEP on demand.)



Molina JM, et al NEJM 2015 (IPERGAY); Antoni G, et al. Lancet HIV 2020; Molina JM, et al. Lancet HIV 2017; Molina JM, et al. IAS 2018 (Prevenir).

On Demand, Event Driven PrEP



- TDF/FTC only evaluated
- MSM only evaluated in large trials
- Not evaluation in cisgender men and women, and transgender women
- Do not prescribe in Hep B+ PrEP users



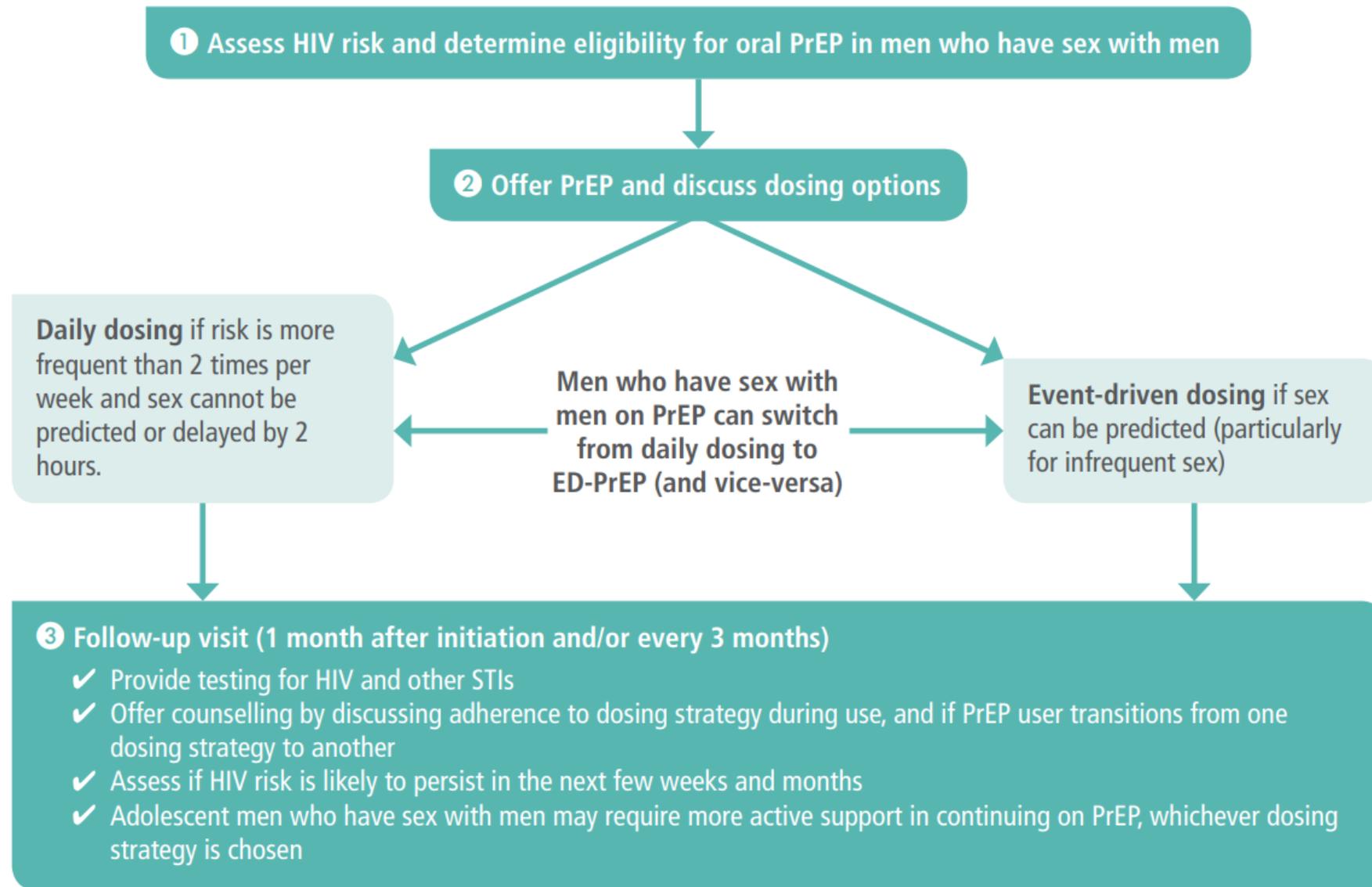
Table 2. When ED-PrEP could be considered

For whom is ED-PrEP appropriate?	For whom is ED-PrEP NOT appropriate?
<ul style="list-style-type: none">• a man who has sex with another man:<ul style="list-style-type: none">– who would find ED-PrEP more effective and convenient– who has infrequent sex (for example, sex less than 2 times per week on average)– who is able to plan for sex at least 2 hours in advance, or who can delay sex for at least 2 hours	<ul style="list-style-type: none">• cisgender women or transgender women• transgender men having vaginal/frontal sex• men having vaginal or anal sex with women• people with chronic hepatitis B infection.

WHO. Technical Brief 2019.

<https://apps.who.int/iris/bitstream/handle/10665/325955/WHO-CDS-HIV-19.8-eng.pdf?ua=1>

Fig. 2. Proposed algorithm for PrEP providers when considering how to offer ED-PrEP

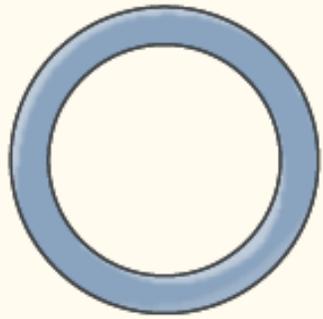


Innovation in PrEP products



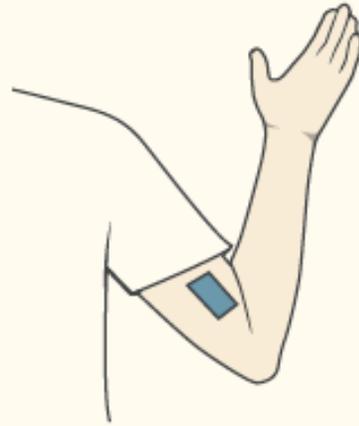
NIAID is funding research on 4 types of long-acting HIV prevention.

INTRAVAGINAL RING (IVR)



Polymer ring inserted into the vagina releases antiretroviral drug over time.

IMPLANT



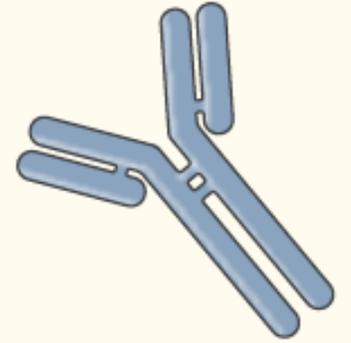
Device implanted in the body releases antiretroviral drug over time.

INJECTABLE



Long-acting antiretroviral drug is injected into the body.

ANTIBODY



Antibody is infused or injected into the body.

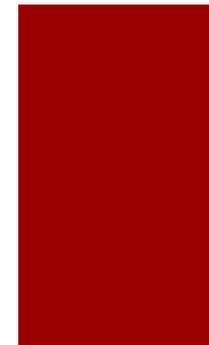
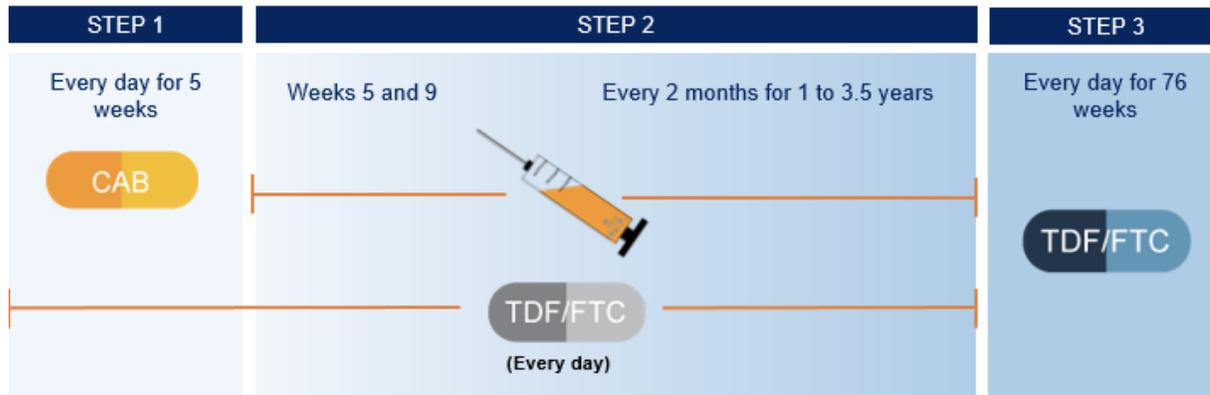
OPEN LABEL STUDIES

PRE-CLINICAL										PHASE I		PHASE III/IIIb		
Multipurpose Prevention Technologies (MPTs)														

DELIVERY SYSTEM	
	Oral pills
	Vaginal gel
	Vaginal ring
	Vaginal film
	Phosphate buffered saline
	Enema
	fast-dissolve insert
	Intrauterine device
	Vaginal tablet
	Rectal gel
	Long-acting injectable
	Micro-array patch
	Nano-fiber
	Subcutaneous injection
	Diaphragm
	Implant

ACTIVE DRUG			
	Tenofovir		Darunavir
	Broadly neutralizing antibody		Dapivirine
	Tenofovir disoproxil fumarate		Griffithsin
	Tenofovir Alafenamide		DS003 (BMS793)
	Tenofovir/emtricitabine		IQP-0528
	Tenofovir disoproxil fumarate/emtricitabine		5P12-RANTES
	Elvitegravir		Cabotegravir/GSK 744
	PC-1005		Monoclonal antibody
	Maraviroc		MK-2048
	Progestin		Tenofovir 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



Every 2-month muscular injection
 HPTN 084/083 stopped early; cisgender women and MSM/Transgender women
 As effective as daily oral PrEP (99%)
 Application for FDA approval 2021-2022

Every one-month vaginal ring for cisgender women
 Aspire/Hope
 30 - 63% protective
 Open label phase 3



1-year long-acting subcutaneous implant
 completed phase 1 trial in 12 humans



TelePrEP Resources:

<https://www.primehealthco.com/teleprep>

TELEPREP

Virtual Provider-led HIV Prevention Treatment

WHAT IS TELEPREP?
TelePrEP is an appointment for PrEP treatment with a healthcare provider over the internet. TelePrEP appointments provide the same quality of care and is convenient, secure, easy to use, and reduces time spent waiting and traveling to see the provider.

WHY USE TELEHEALTH FOR PREP?
PrEP treatment is personal to talk about. TelePrEP providers and staff are PrEP trained and experienced to talk to you about preventing HIV. The visit is private, there is no public waiting room, and you don't have to physically be where the provider is.

DEVICES FOR TELEPREP
A TelePrEP visit requires an audio (speaker & microphone) and typically a video connection:

- Computer
- Laptop
- Smartphone
- Tablet

HOW TO PREPARE FOR YOUR TELEPREP VISIT

- Good internet/data connection
- A private area with good lighting for your video visit
- Something to record information (pen & paper) and questions
- List your medications (& vitamins)
- Record your vitals before the visit: Height, weight, temperature, heart rate, blood pressure

WHAT ELSE DO I NEED TO KNOW ABOUT TELEPREP?

- HIV screening is needed every 3 months that can be done at a local laboratory or at home
- TelePrEP visits with the provider every 3 months
- Protection against other sexually transmitted disease
- Costs and assistance programs for medication and routine appointments
- Discuss what happens if you move out of the area and still need PrEP

PRIME HEALTH COLORADO



TelePrEP Implementation Planning Tool

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

Device

Internet / Cellular Service

Software or "App"

Camera

Microphone

Audio

Pictures instead of a audio-video

Texting / Email

Consent

Billing

Documentation / Workflow

In most cases, a smart phone, tablet, or personal computer is sufficient: Are your computers desktops or laptops? Will providers be using any other computer or device at any time?

You will need to be "connected". Depending on where you are physically located you may be able to use:
Cellular service: Your phone's cell service (e.g. Verizon, AT&T)
Internet: Wired or wireless (WiFi)
Satellite: Services will depend on the vendor's coverage

You may have an telemedicine platform associated with your EMR software provider: Check with your EMR provider to find out details
 If you have no existing platform:
 1- Join an existing telemedicine platform (see attached Telemedicine Platform Decision Matrix)
 2- Build your own platform – not quick or easy

If your work smart phone, tablet, or computer has a camera: Is the camera enabled to work on your work internet network? Are you able to use it while in the EMR? Are you able to use it off your work's internet network?
 If your device does not have a camera, you will need a compatible webcam to use with your device

If your smart phone, tablet, or computer has a microphone, try it. Is the sound quality adequate? Is the microphone enabled on your work internet browser?
 If your device does not have a microphone, you will need a compatible microphone to use with your device

If your smart phone, tablet, or computer has a speaker, try it. Is the area you will be working in private enough to use the speaker? Can you use headphones with your computer?
 If your device does not have a speaker or headphones, you will need to find a compatible audio device

Would you be willing to accept still pictures from clients?
 If yes, will you be able to do this through your TelePrEP platform? (see attached Telemedicine Platform Decision Matrix)

Are you open to receiving texts / emails?
 If yes, will you be able to do this through your TelePrEP platform? (see attached Telemedicine Platform Decision Matrix)

Consider verbal and/or written client consent for each TelePrEP consult. (see attached TelePrEP Consent Template)

Discuss billing and reimbursement with each of your payers. Reimbursement traditionally varies based on payer, state, and service line.

How will you document the TelePrEP session?
 Will your documentation system send a fax to a another provider?
 Can you submit TelePrEP patient education electronically?

CDC Capacity Building

This work has been funded by the Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention.

Request TA Today!

For CDC directly-funded organizations:

1. Check with your CDC Project Officer.
2. Submit a CBA Tracking System (CTS) request at [CDC.gov/CTS](https://www.cdc.gov/CTS).
3 Login credentials for current CRIS users will work in CTS.

For Organizations that are not directly-funded by CDC:

1. Contact the CDC-funded health department in your jurisdiction to submit a CTS request for your organization.
2. A list of health department CTS users, who can submit CTS requests on behalf of other organizations, can be found at the Health Department CTS Users tab at [CDC.gov/CTS](https://www.cdc.gov/CTS).

For assistance with CTS, contact cdccts@cdc.gov.

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