TasP, U=U, PrEP and the Pandemic

Staying on Task to End the HIV Epidemic in the Midst of the COVID-19 Pandemic

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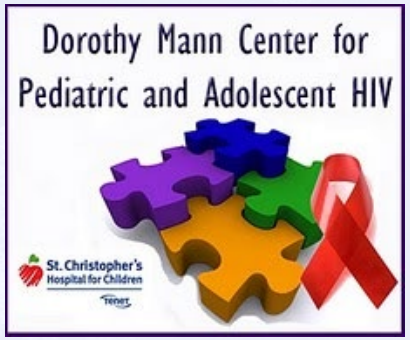
Drexel University College of Medicine



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COLLEGE OF MEDICINE

Disclosure

- Speakers Bureau Gilead Sciences

How Can We Avoid Missed Opportunities to Educate Patients about U-U & Support Adherence ?

Case I

- 35 y/o, AA, heterosexual, male with HIV, dx'd 8 years ago.
- Patient's son was infected with HIV perinatally, his wife died of HIV shortly before their diagnosis.
- Started ARV therapy at diagnosis and has had an undetectable viral load consistently for 8 years.
- Father has struggled with grief, depression and shame/stigma since his and his son's diagnosis.
- Despite consistent f/u with HIV care, he only learned about U=U in consultation with his son's HIV provider.
- Father cries when he learns about U=U

Case II

- 20 year old, Latinx, heterosexual cis-gender female, diagnosed HIV+ at age 15.
- Long history of depression and also struggles with shame and stigma surrounding her HIV diagnosis.
- Years of struggle with adherence to ARV therapy.
- After several months of discussion about U=U, patient re-starts ARV therapy, achieves nearly a year of undetectable viral loads,discloses her diagnosis to s sexual partner for the first time since her diagnosis.

How Can We Avoid Missed Opportunities for HIV Testing, Treatment and Prevention?

At the Primary Care Office…

- 19 year old college bound male
- Self identifies as YMSM
- "Out" to himself, his family, community and his provider since the age of 15.
- Seen for health maintenance apt. at which time he reports that he is sexually active and that he uses condoms 100% of the time
- HIV test is deferred since it was negative the previous year.
- Urine GC/Chl sent that day was negative.
- 6 months later he has a positive rapid HIV test at a local health fair.

At The HIV Clinic…

- HIV infection is confirmed and patient has an AIDS diagnosis…
- On intake his history reveals that he exclusively has receptive anal sex and occasional performs oral sex
- Intake Labs at the HIV Clinic:
  - RPR: 1:128
  - Urine GC/Chl: Negative
  - Throat GC/Chl: Positive for Gonorrhea
  - Rectal GC/Chl: Positive for both Gonorrhea and Chlamydia

How Can We Avoid Missed Opportunities for HIV Testing, Treatment and Prevention?

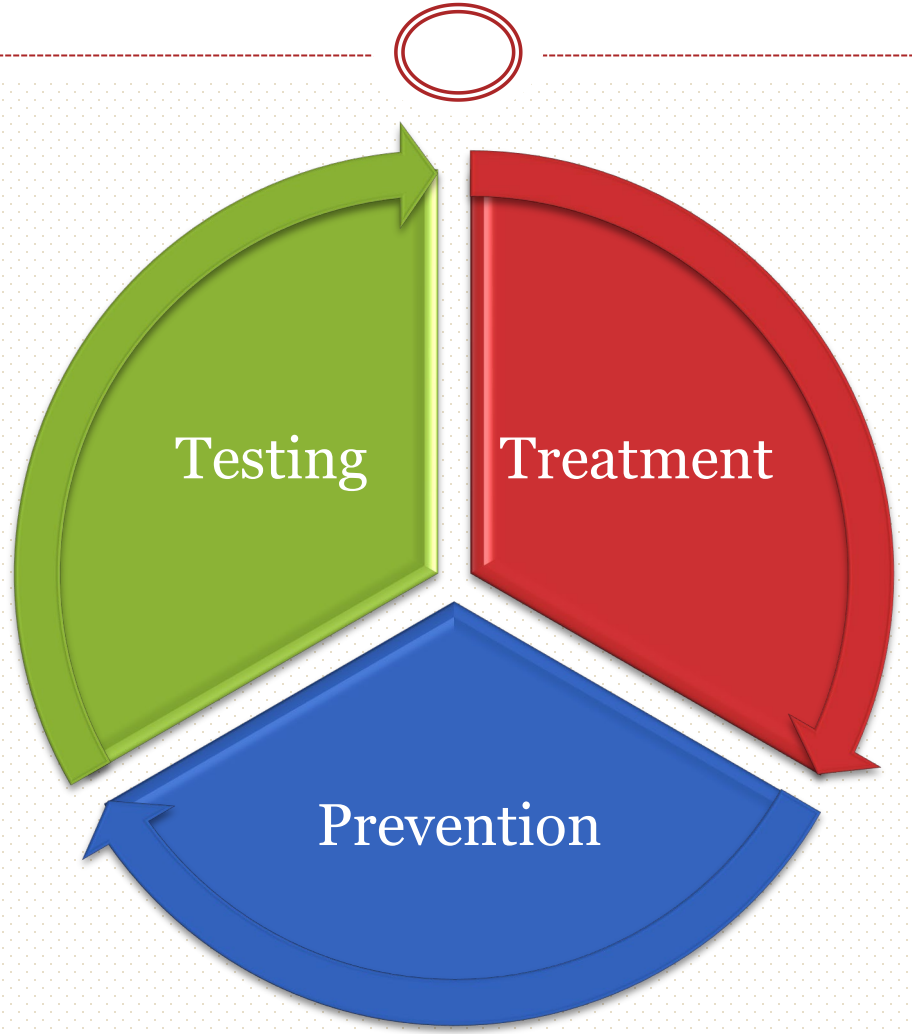
Potential PrEP Candidates in the ED or Urgent Care Centers

- 22 year old male presents to ED with rectal discharge, discomfort for 3 days. He was afebrile with normal vital signs.
- Denies recent history of any signs/symptoms suggestive of acute retroviral syndrome such as fever, fatigue, swollen lymph nodes/tonsils, sore throat, joint and muscle aches, vomiting, diarrhea, or rash.
- Last sexual contact was 5 days ago. Multiple new male partners in the last 4-6 weeks.
- He has heard of PrEP but did not think he needed it.
- ED: Rapid HIV-, HIV RNA viral load, RPR, CBC, Hep B panel, Hep C AB, CMP, Triple screen for GC and chlamydia.
- Started on PEP regimen Tenofovir disoproxil fumarate/Emtricitabine plus Dolutegravir.
- F/U in PrEP clinic 5 days later.

PrEP Clinic Risk Assessment

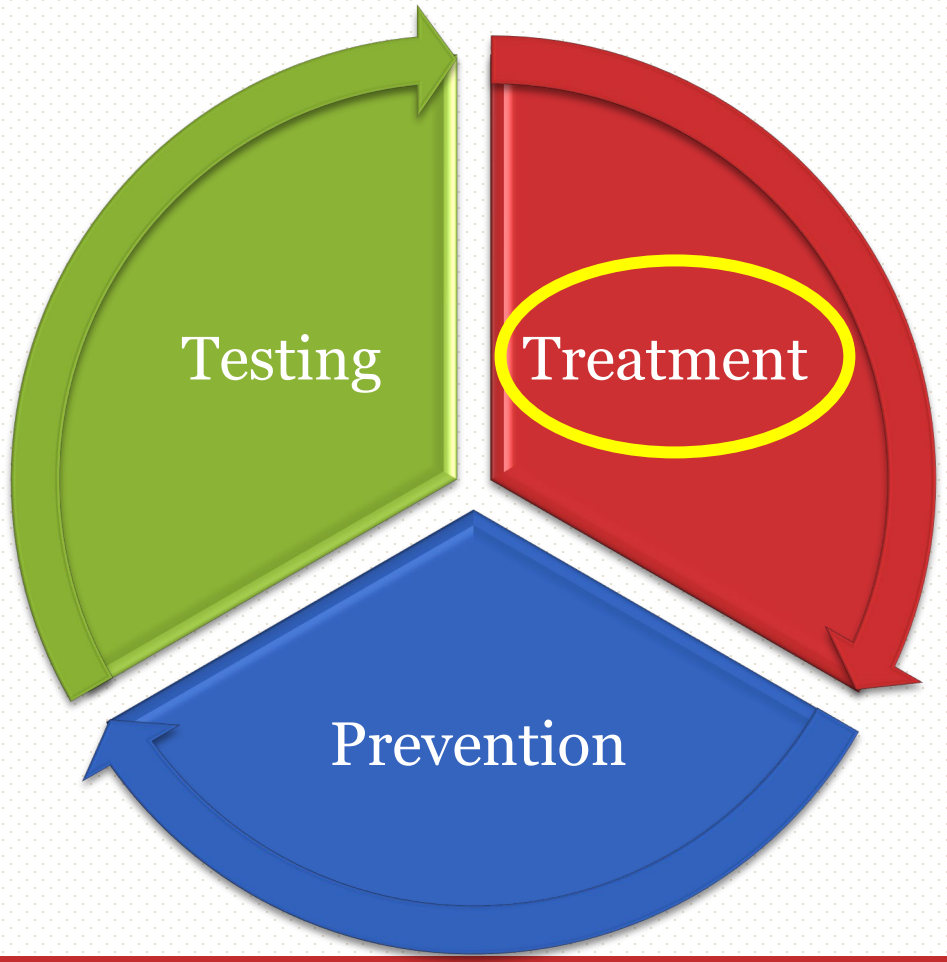
- Identifies as male
- Preferred pronouns-he, him, his,
- Attracted to males,
- Sexual debut age 21
- Describes himself as an “exclusive bottom” mostly condomless,
- Performs and receives oral sex always condomless.
- Uses mostly social media apps like JACK’D, Grindr and Instagram to meet partners.
- 25 Total lifetime partners
- + history of transactional sex as recent as 1 month ago.
- No previous history of STIs but he has also not been screened. Always denied sexual activity during medical appointments.

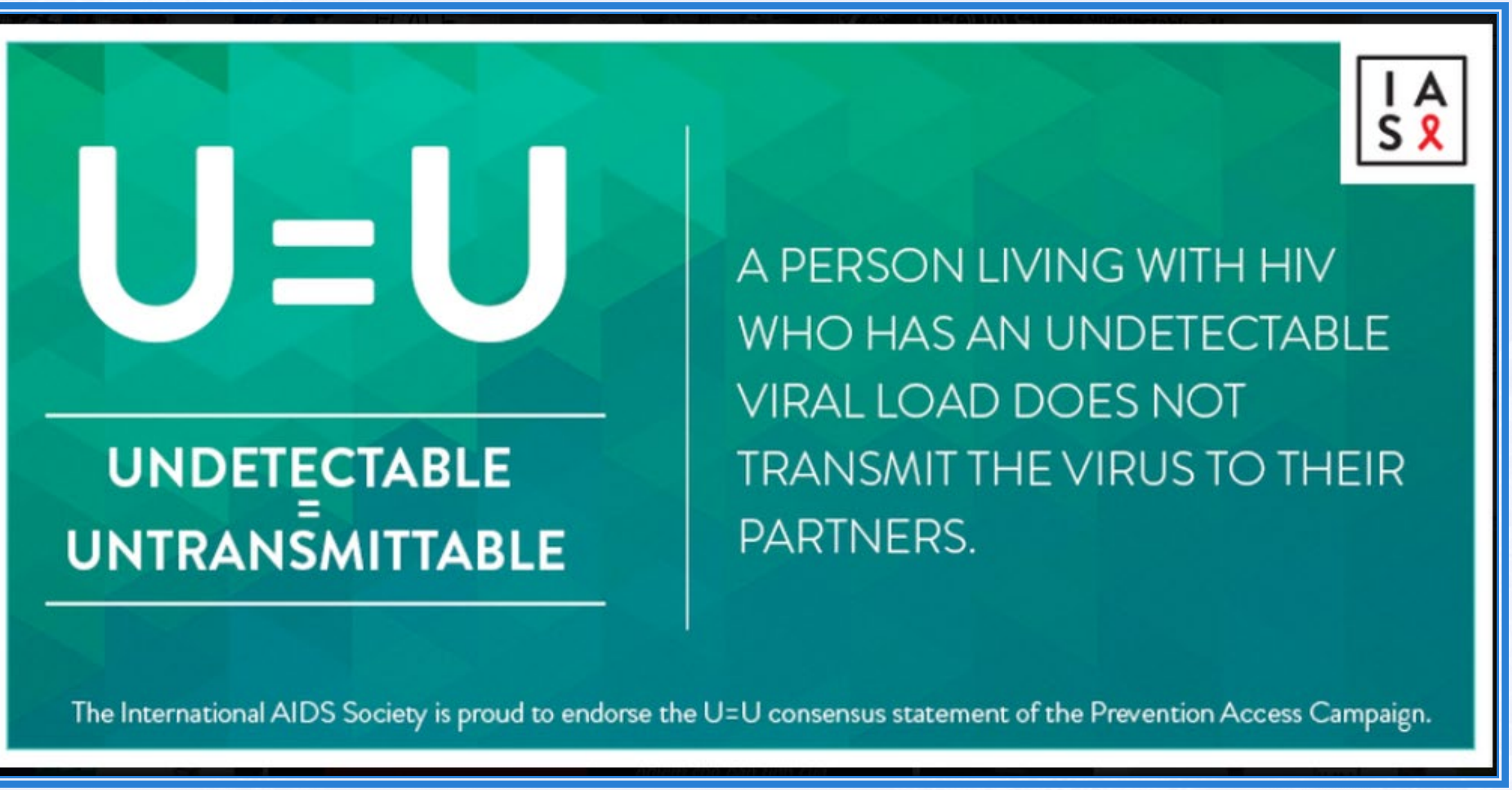
The Path to Ending the HIV Epidemic



The Path to Ending the Epidemic

Treatment




U=U
UNDETECTABLE
=
UNTRANSMITTABLE
A PERSON LIVING WITH HIV WHO HAS AN UNDETECTABLE VIRAL LOAD DOES NOT TRANSMIT THE VIRUS TO THEIR PARTNERS.
IAS
The International AIDS Society is proud to endorse the U=U consensus statement of the Prevention Access Campaign.

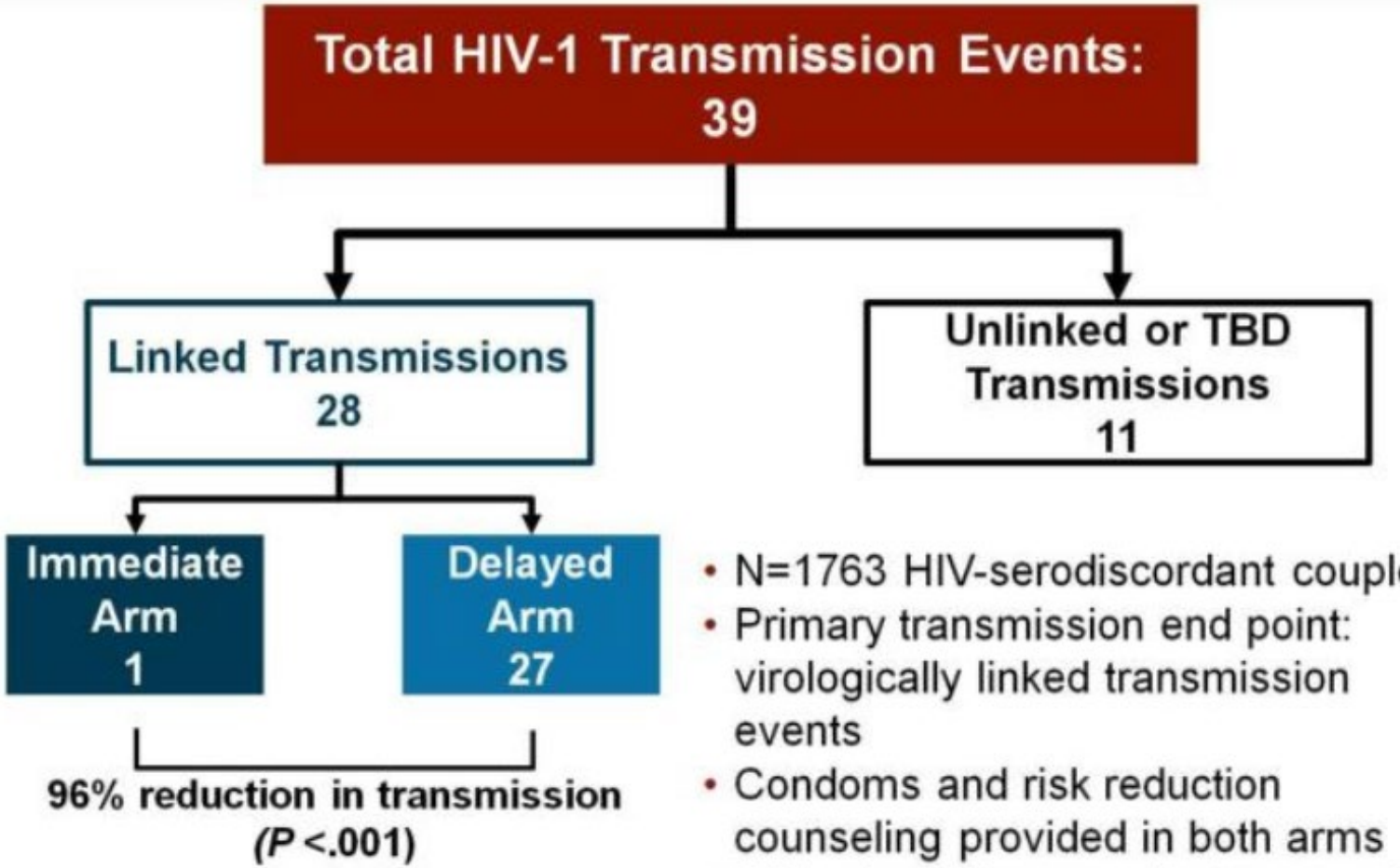
U=U News


THE BODY
The Complete HIV/AIDS Resource
The Washington Post
nam aidsmap
Newsweek
THE LANCET
a&u
AMERICA'S AIDS MAGAZINE
CBS EVENING NEWS
CATIE
Canada's source for HIV and hepatitis C information
CNN
NBC NEWS
US
DailyMail.com
POZ
The New York Times
VICE
NEW YORK POST
BangaloreMirror
JEZEBEL
POSITIVE LITE.COM
Canada's Online HIV Magazine
[imstilljosh]
malaymail online
MEDICAL Brief
Africa's Medical Media Digest
BARBADOS TODAY
CGTN
CHINA GLOBAL TELEVISION NETWORK
China.org.cn
BuzzFeed
healthline
U.S.News & WORLD REPORT
REDBOOK
QUEERTY
My Fabulous Disease
Mark S. King
BHEKISISA
MD
THE HUFFINGTON POST
LA WEEKLY
plus
ADVOCATE
CNBC

- A recent international survey of more than 1,000 providers
  - only 77% of ID specialists, 42% of primary care physicians talked to patients about U=U when informing them of their undetectable viral load
- Reasons given for not discussing U=U included
  - Disbelief in that HIV risk is actually mitigated.
  - Perception that U=U runs counter to personal responsibility.
  - Concerns about “patients’ behavior” and perception that patients will misunderstand the information.

Zuniga JM. Inconsistent clinician communication of the evidenced based U=U messaging to people living with HIV. *J Int Assoc Provid AIDS Care. (In Press)*

HPTN 052: Antiretroviral Therapy as Prevention



- N=1763 HIV-serodiscordant couples
- Primary transmission end point: virologically linked transmission events
- Condoms and risk reduction counseling provided in both arms
- 97% of couples were heterosexual

Cohen MS, et al. *N Engl J Med*. 2011;365:493-505.[3]

PARTNER Study

"Partners of People on ART – A New Evaluation of the Risks"

- Observational study of serodiscordant couples with HIV+ partner on ART to evaluate the risk of transmission

888 couples in primary analysis
(38% MSM)

58,000 condomless sex acts

17% of HIV- MSM
18% of HIV+ MSM
Had STI during f/u

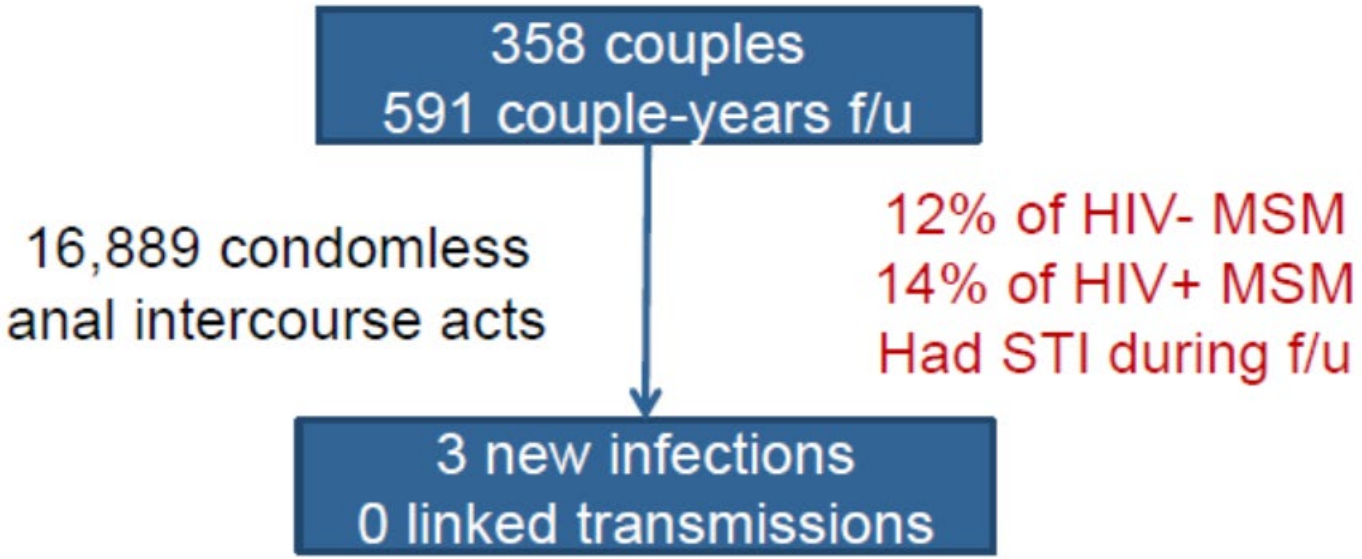
11 new infections
0 linked transmissions

Rate of within-couple transmission =
0 (95% CI: 0-0.30/100 couple-years)

Rodger et al, *JAMA* 2016

Opposites Attract

- Observational study of MSM sero-discordant couples in Australia, Thailand, Brazil



Rate of within-couple transmission =
0 (95% CI: 0-0.62/100 couple-years)

Grulich A, et al, IAS 2017

Providers should discuss U=U with all patients living with HIV

Sarah K Calabrese and Kenneth H Mayer

Lancet HIV, The, 2019-04-01, Volume 6, Issue 4, Pages e211-e213, Copyright © 2019 Elsevier Ltd

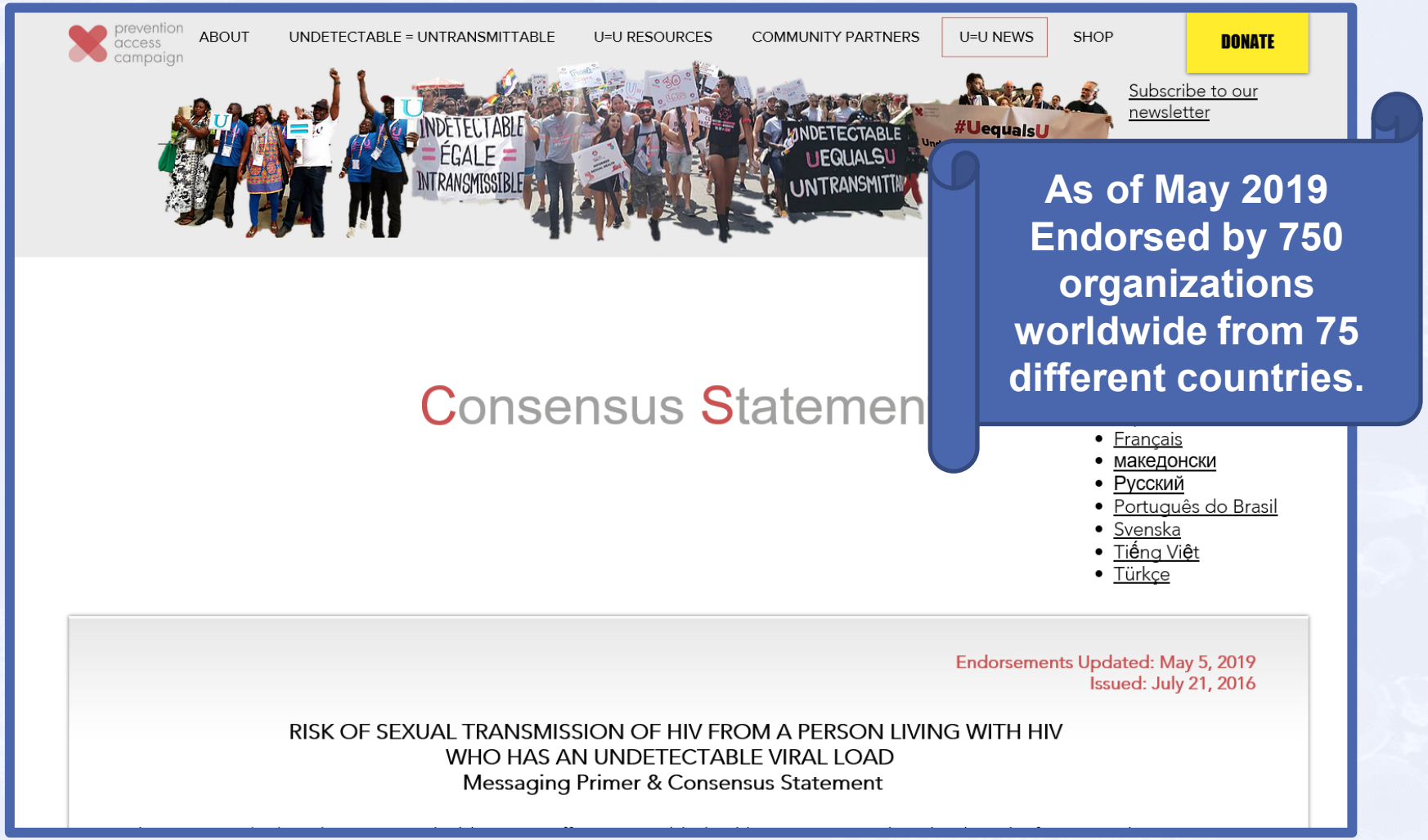
	Enrolled sample	Study design	Number of condomless sex acts	Number of new HIV infections		
				Total	Phylogenetically linked	Phylogenetically linked when HIV-positive partner virally suppressed
HPTN 052 (2016)[3]	1763 serodifferent couples; 98% male–female couples	Two-arm trial with HIV-positive partner randomised to early or delayed ART	..	78 19 in early-ART group; 59 in delayed-ART group	46* 3 in early-ART group; 43 in delayed-ART group	0
PARTNER1 (2016)[4]	1166 serodifferent couples; 888 in analysis subset; 62% male–female couples	Observational	55 193 total; 34 214 in male–female couples; 20 979 in male–male couples†	11	0	0
PARTNER2 (2018)[1]	972 serodifferent male–male couples; 783 in analysis subset	Observational	76 991	15	0	0
Opposites Attract (2018)[5]	358 serodifferent male–male couples	Observational	12 447 counted when HIV-positive partner virally suppressed and HIV-negative partner not on PrEP	3	0	0

For a systematic review and meta-analysis of earlier relevant research, see Attia et al (2009).[6] U=U=undetectable=untransmittable. ART=antiretroviral therapy. PrEP=pre-exposure prophylaxis. *Viral linkage status not determined for six of 78 infections. †Estimates calculated by averaging the number of within-couple condomless sex acts self-reported by each serostatus subgroup within each couple type.

***Table*: Evidence for U=U 2016–18**

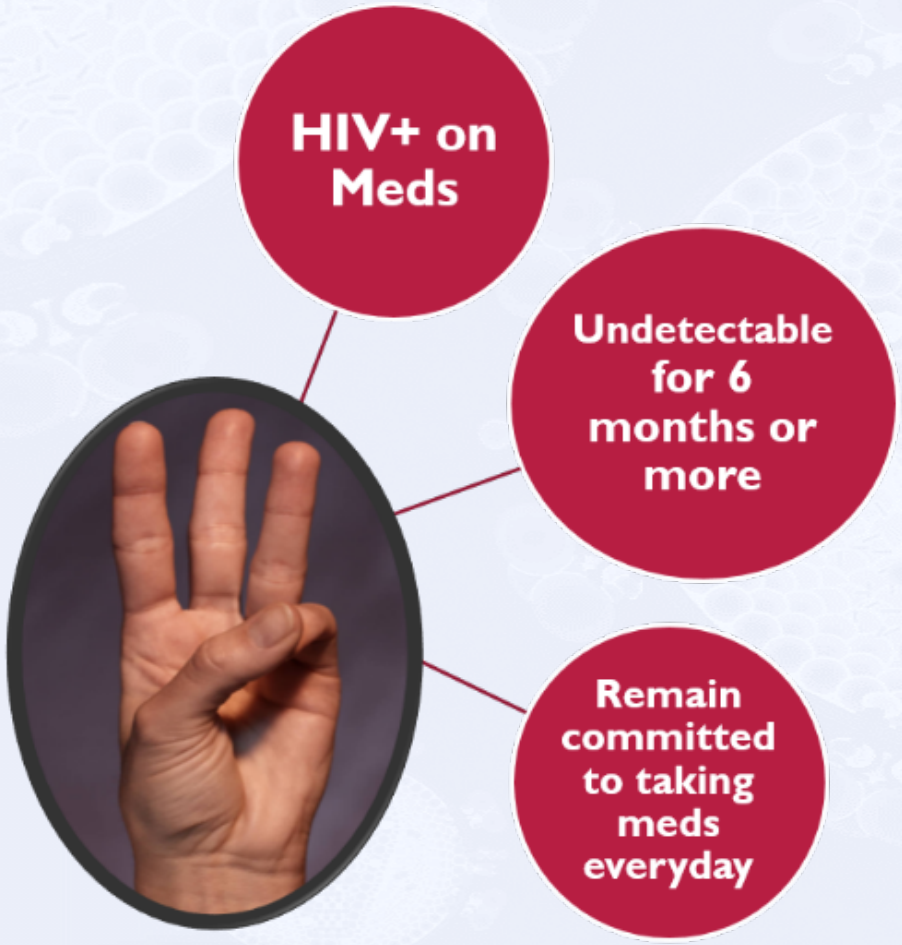
The Road to U=U

- **Earliest prelude to U=U Mid-Late 90s**
  - Quinn,TC et al. N Engl J Med 2000; 342: 921-929, Observational study of 415 serodiscordant heterosexual couples-0 transmissions if VL < 1,500 copies /ml
  - Conner, EM et al. N Engl J Med 1994; 331: 1173-1180, Randomized, placebo controlled trial showing that HIV+ pregnant women on AZT alone had 70% reduction in MTCT of HIV infection.
- **ART builds firm ground U=U Mid to Late 2000s**
  - IAttia, s et al. *AIDS* 2009; 23 (11): 1397-1404. A larger systematic review and meta-analysis involving 11 cohorts, 5,021 HIV-serodiscordant heterosexual couples. Zero transmissions when partner with HIV on ART had VL <400 copies/ml
- **Swiss Statement 2008**
  - First to bravely propose that virologically suppressed patients do not transmit HIV to their sexual partners to wide criticism
- **HTPN 052 presents first compelling scientific support for U=U 2011**
  - First large clinical trial evaluating transmission among discordant couples is stopped early as it is clear that transmission is substantially less likely if HIV+ partner is on ARV therapy and consistently suppressed
- **Universal HIV Treatment 2012**
  - US treatment guidelines recommend treatment for all people living with HIV and specifically cite the compelling HTPN052 data as a factor supporting this recommendation
- **Prevention Access Campaign 2016**
  - U=U slogan makes its debut and presents a consensus statement boldly presenting U=U to a worldwide audience.
- **US falls in line with U=U 2016-2018**
  - New York City health officials become the first in the US to endorse U=U
  - CDC send “Dear Doctor Letter” endorsing U=U
  - WHO endorses U=U

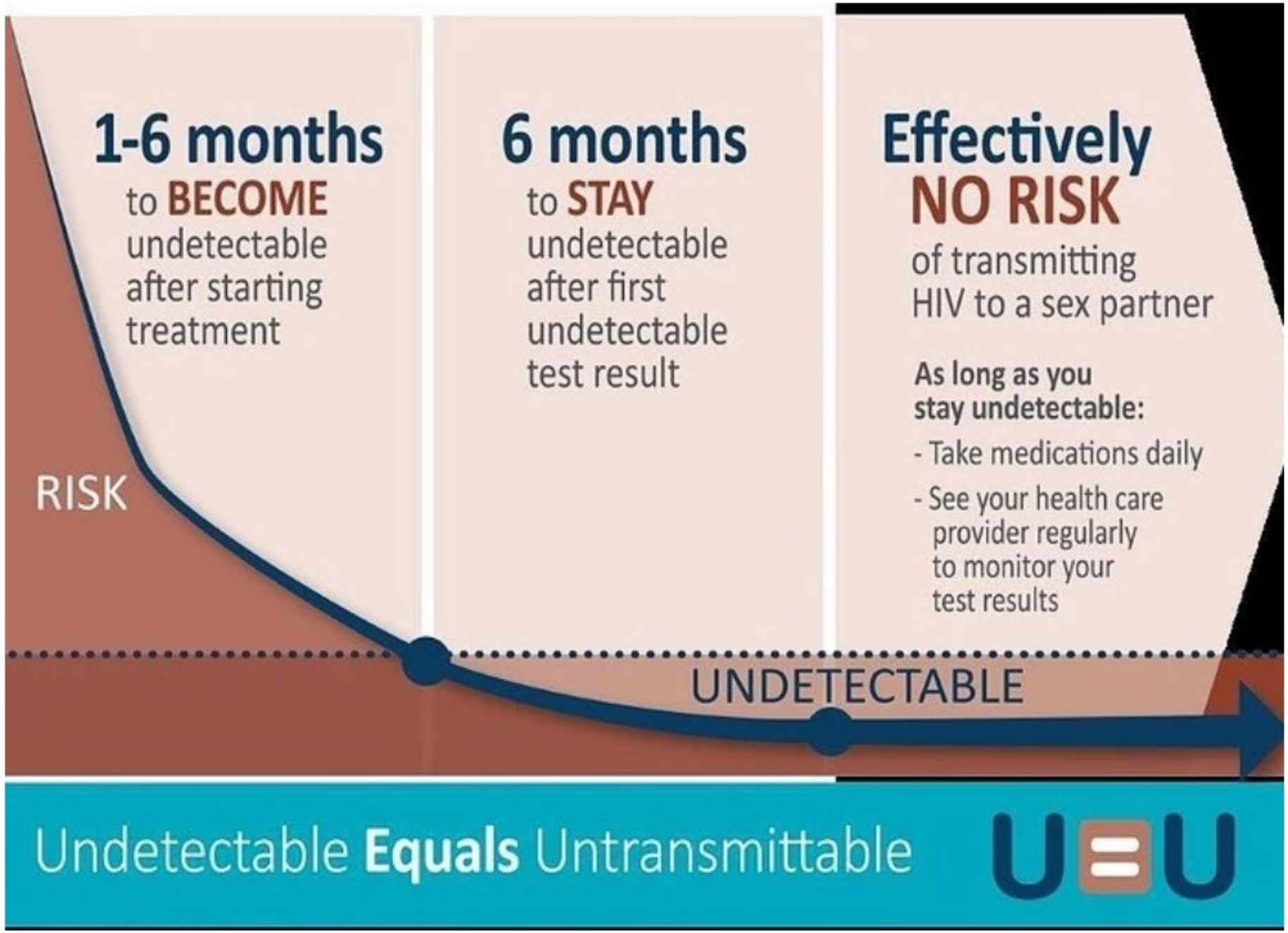


As of May 2019 Endorsed by 750 organizations worldwide from 75 different countries.

Counseling Patients about U=U



- Be sure to discuss time to viral suppression
- Counsel that good engagement in care and regular viral load testing is essential in achieving, maintaining & validating U=U status
- Discuss how adherence challenges impact U=U
  - Make a plan on what to do if adherence challenges arise.
    - PEP/PrEP?


1-6 months
to BECOME
undetectable
after starting
treatment
6 months
to STAY
undetectable
after first
undetectable
test result
Effectively
NO RISK
of transmitting
HIV to a sex partner
As long as you
stay undetectable:
- Take medications daily
- See your health care
provider regularly
to monitor your
test results
RISK
UNDETECTABLE
Undetectable Equals Untransmittable
U=U

Counseling Patients about U=U

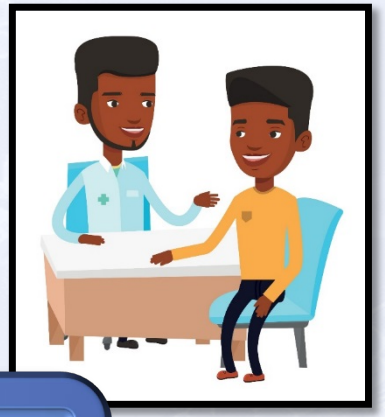
- Help patient to understand that they get on the road to U=U by starting ARV therapy, but that they reach and maintain their U=U status by regularly documenting undetectable viral loads.
  - Once a person is undetectable for 6 months or more, DHHS guidelines recommend viral load testing every 3-4 months.
  - If viral suppression and immunologic status is stable for >2 years, viral load testing can be extended to every 6 months
  - If patient stops ARV therapy than U=U status is lost, until re-established.

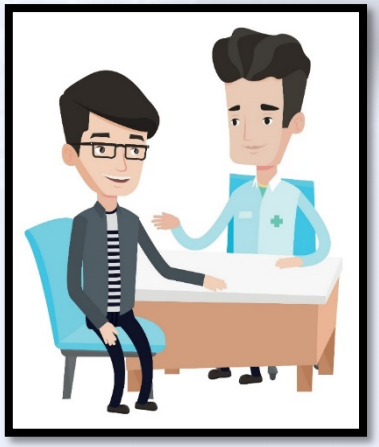
Counseling Patients about U=U

- ***Additional considerations***
  - Patients should be reminded that while U=U means that a partner will be safe from HIV infection, unprotected sexual encounters still can result in the acquisition of other STIs, so routine/regular screening for STIs is still recommended.
  - U=U messaging applies to sexual transmission only.
    - No data regarding U=U and HIV exposure from needle sharing
    - U=U does not apply to mother to child transmission of HIV through breastfeeding

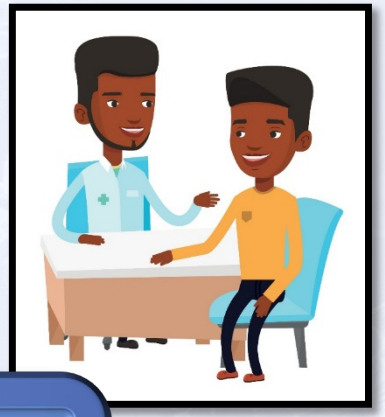
Counseling Partners about U=U

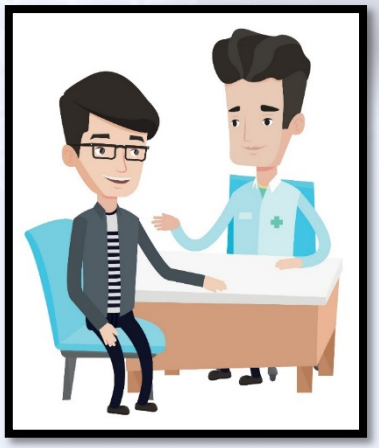
- Partners of people with HIV should be fully counseled about U=U with full description of its caveats
- Partners should be supported and empowered around initiating and maintaining open dialogue with their partner around ARV medication adherence, engagement in HIV care and regular measurements of viral loads.
- Partners should have a plan of action if they feel that their partner's U=U status is in question ie., or if they have other partners outside of the relationship.
  - Condoms
  - PEP
  - PrEP

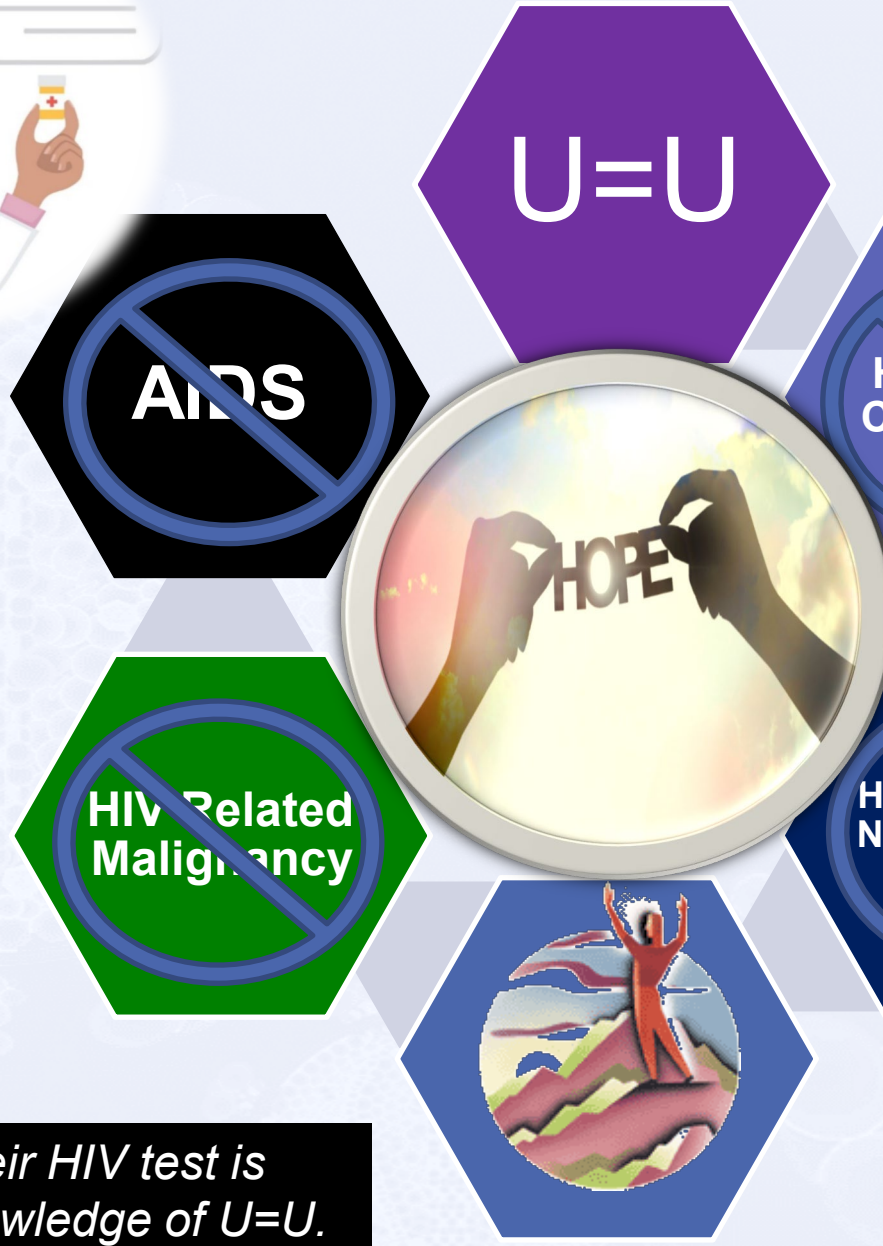




What happens when a person receives a positive HIV test result means everything.







A person who has just heard that their HIV test is positive should never leave without knowledge of U=U.

Potential Benefits of U=U

Energizing Hope, Fight Stigma & End the HIV Epidemic

- Motivates patients to promptly initiate, achieve and maintain an undetectable viral load
- Can help to mitigate internalized HIV stigma
- Can help to alleviate psychosocial stress anxiety related to potential transmission to sexual partner.
  - *Sex without fear.*
- More community awareness of U=U means, less stigma and more motivation for people to get tested, get in to care, achieve and maintain suppressed viral load, all which can lead to decreased community viral load and decreased incidence.

prevention access campaign

UNDETECTABLE = UNTRANSMITTABLE

U=U

#UEQUALSU

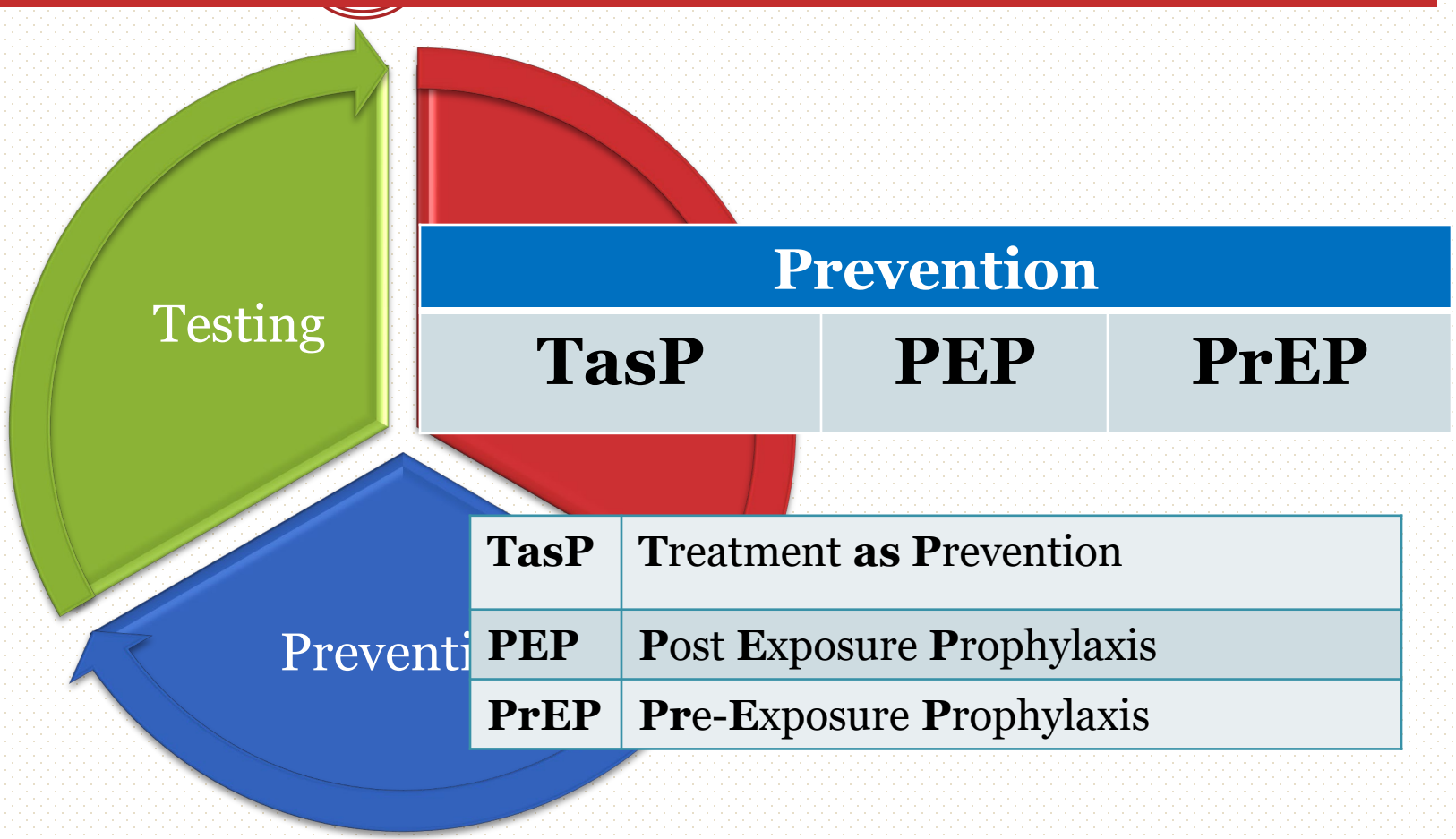
www.uequalsu.org

"You are the gatekeepers of the science that let us [people living with HIV] know that we are not infectious," Bruce Richman, CEO of Prevention Access Campaign, said during his presentation. "People living with HIV must know that [U=U] is possible for them."


UNDETECTABLE = UNTRANSMITTABLE
U=U
#UEQUALSU
www.uequalsu.org

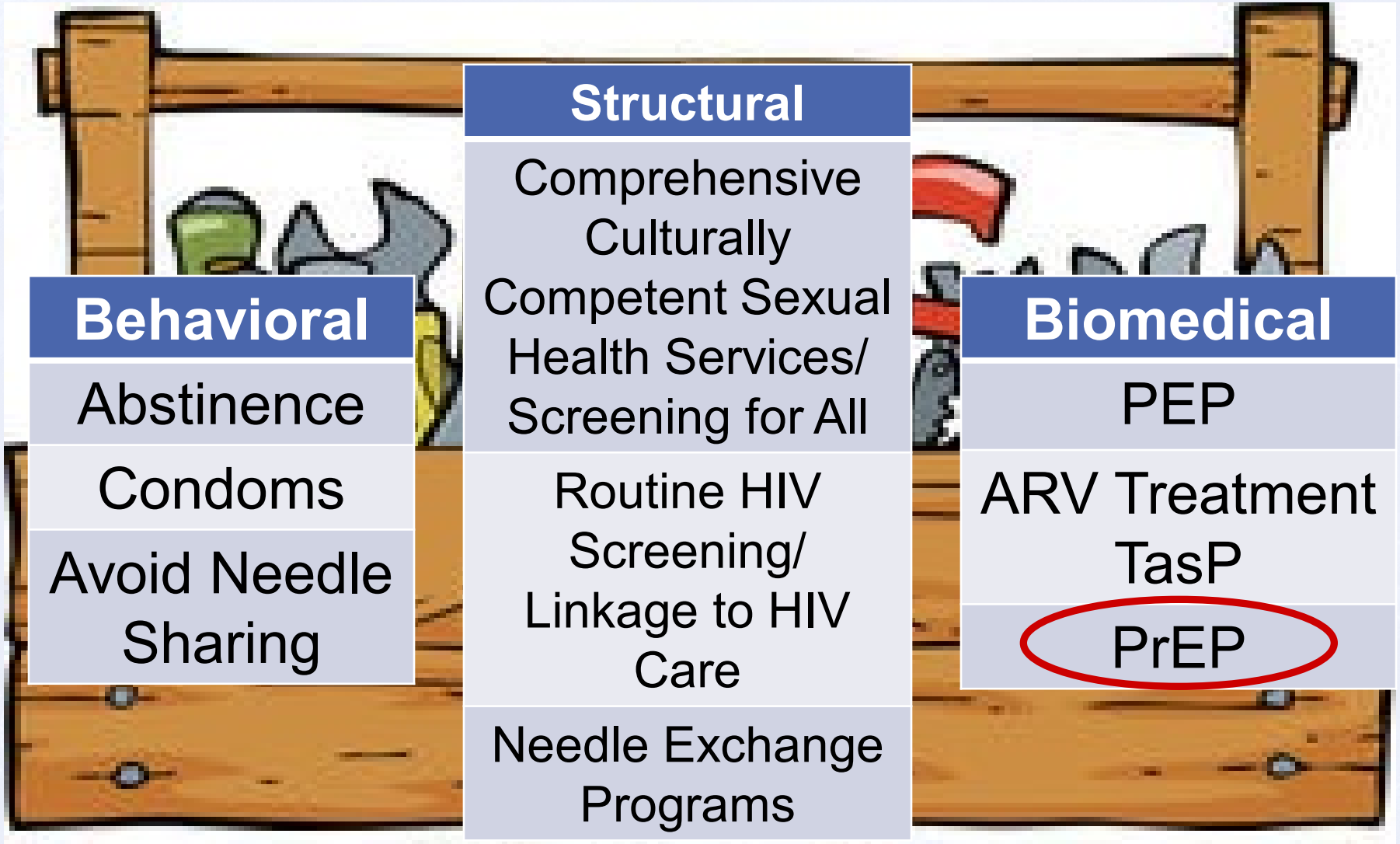
The Path to An HIV-Free Generation

Prevention



TasP	**T**reatment **as P**revention
PEP	**P**ost **E**xposure **P**rophylaxis
PrEP	**Pr**e-**E**xposure **P**rophylaxis

HIV Prevention Toolbox



Pre-Exposure Prophylaxis

HIV Prevention IS Possible!!!

- **What is PrEP?**
  - Pre-exposure prophylaxis
  - PrEP, antiretroviral medication that is taken daily by a high risk HIV-negative patient *in combination with safer sex practices* with the goal of preventing HIV infection.
  - There are currently two, FDA approved, co-formulated tablet that contains tenofovir disoproxil fumarate and emtricitabine (TDF-FTC) and tenofovir alafenamide and emtricitabine (TAF-FTC).

Potential Candidates for PrEP

HIV- Individuals with Partners with HIV

OR

Individuals without HIV who engage in sexual activity in a high-prevalence area or social network AND have one or more of the following risk factors:

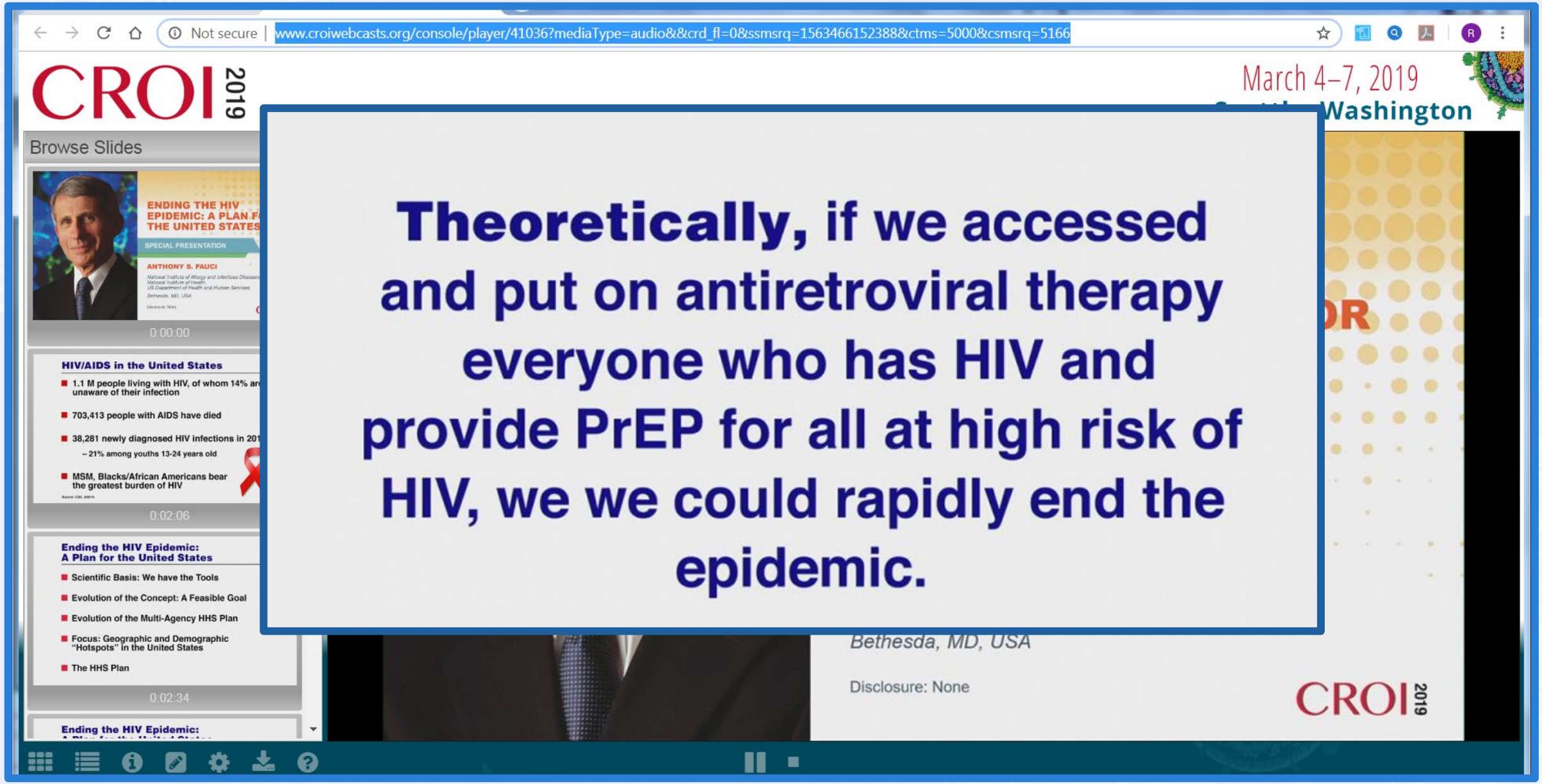
Partner of Unknown HIV Status	Inconsistent Condom Use
Diagnosis of STI	Transactional Sex
Use of illicit drugs or alcohol dependence	Incarceration

Potential Candidates for PrEP

- MSM who engage in unprotected anal intercourse
- Individuals in sero-discordant sexual relationships, esp during attempts to conceive
- Transgender Individuals
- People who inject drugs, including those injecting hormones
- Stimulant drug use, esp methamphetamine
- Individuals with ≥ 1 anal STI in the last 12 months
- Individuals prescribed PEP with on-going high risk exposure to HIV infection and or a history of multiple courses of PEP
- Individuals engaging in transactional sex

Potential PrEP Candidates Among Youth

- Adolescent victims of sexual assault
  - ♀♂ PEP more than once
  - YMSM PEP once!!
  - ♀♂ Developmental delay
- Adolescent perpetrators of sexual assault
- Adolescent patient's with history concerning for sex trafficking/transactional sex
- Adolescents with STIs
  - Any female with a diagnosis of PID
  - YMSM diagnosed with an anal STI in last 12 months
- Transgender youth
- Adolescents with substance abuse injection drug use, including those who inject hormones
- Adolescents with mental health disorders that may lead to increased levels of high risk sexual behaviors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CROI 2019
March 4–7, 2019
Washington
Browse Slides
ENDING THE HIV EPIDEMIC: A PLAN F
THE UNITED STATES
SPECIAL PRESENTATION
ANTHONY S. FAUCI
0:00:00
HIV/AIDS in the United States
1.1 M people living with HIV, of whom 14% ar
unaware of their infection
703,413 people with AIDS have died
38,281 newly diagnosed HIV infections in 201
– 21% among youths 13-24 years old
MSM, Blacks/African Americans bear
the greatest burden of HIV
0:02:06
Ending the HIV Epidemic:
A Plan for the United States
Scientific Basis: We have the Tools
Evolution of the Concept: A Feasible Goal
Evolution of the Multi-Agency HHS Plan
Focus: Geographic and Demographic
"Hotspots" in the United States
The HHS Plan
0:02:34
Ending the HIV Epidemic:
Theoretically, if we accessed and put on antiretroviral therapy everyone who has HIV and provide PrEP for all at high risk of HIV, we we could rapidly end the epidemic.
Bethesda, MD, USA
Disclosure: None
CROI 2019

US and Global Health Guidelines Recommend PrEP in Combination with Safer-Sex Practices to Help Reduce the Risk of Sexually Acquired HIV-1 in Adults at High Risk

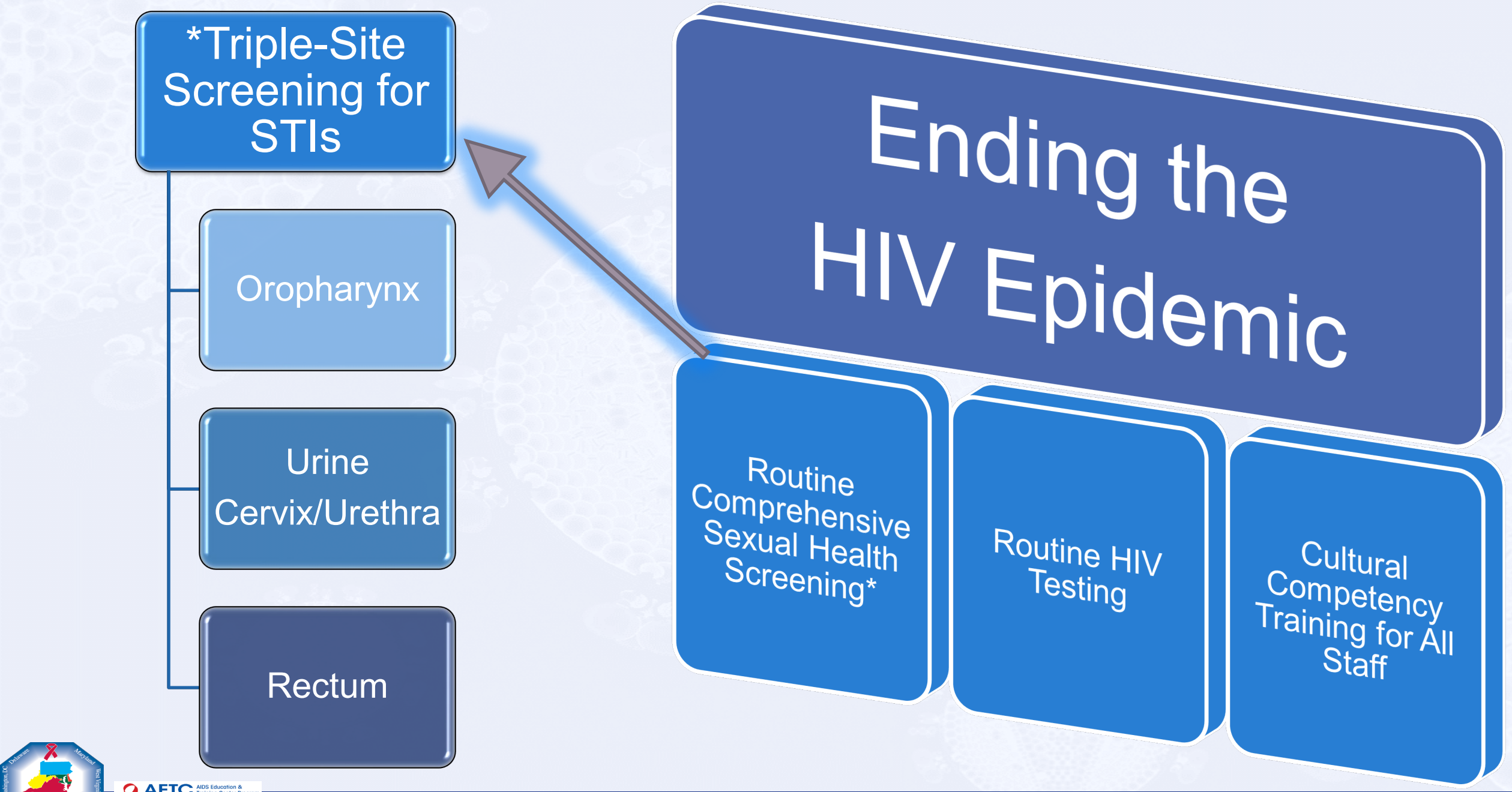
CDC
Centers for Disease Control and Prevention

WHO
World Health Organization

US National HIV/AIDS Strategy

IAS-USA
International Antiviral Society-USA

ACOG
The American College of Obstetricians and Gynecologists


*Triple-Site Screening for STIs
Oropharynx
Urine Cervix/Urethra
Rectum
Ending the HIV Epidemic
Routine Comprehensive Sexual Health Screening*
Routine HIV Testing
Cultural Competency Training for All Staff


STERILE
TIGHTEN SECURELY
Name: Doe, John
Date:
Time:
Room No.
Doctor:
Instructions:
urine for GC/Chl
Doe, John
Patient Name
Rectal
Date
Doe, John
Urine GC/Chl
Doe, John
Patient Name
throat
Date
Patient ID#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2013-01-31

Douglas S. Krakower, Patricia Solleveld, Ken Levine, Kenneth H. Mayer

IAC 2020 Virtual July 6-10 SF
Reported by Jules Levin

IMPACT OF COVID-19 ON HIV PREEXPOSURE PROPHYLAXIS CARE AT A BOSTON COMMUNITY HEALTH CENTER

Douglas S. Krakower, Patricia Solleveld, Ken Levine, Kenneth H. Mayer

Abstract OACLB0104

Methods

- Fenway Health: community health center, LGBTQIA+
- Electronic health records data
  - PrEP refill lapses (i.e., no refill before end of prior Rx)
  - New PrEP starts
  - HIV/STI testing
  - Telehealth
- Jan 1, 2020 to April 30, 2020
- Assess patient factors associated with PrEP refill lapses in April 2020 (Chi-square tests)

Krakower et al. OACLB0104

Douglas S. Krakower, Patricia Solleveld, Ken Levine, Kenneth H. Mayer

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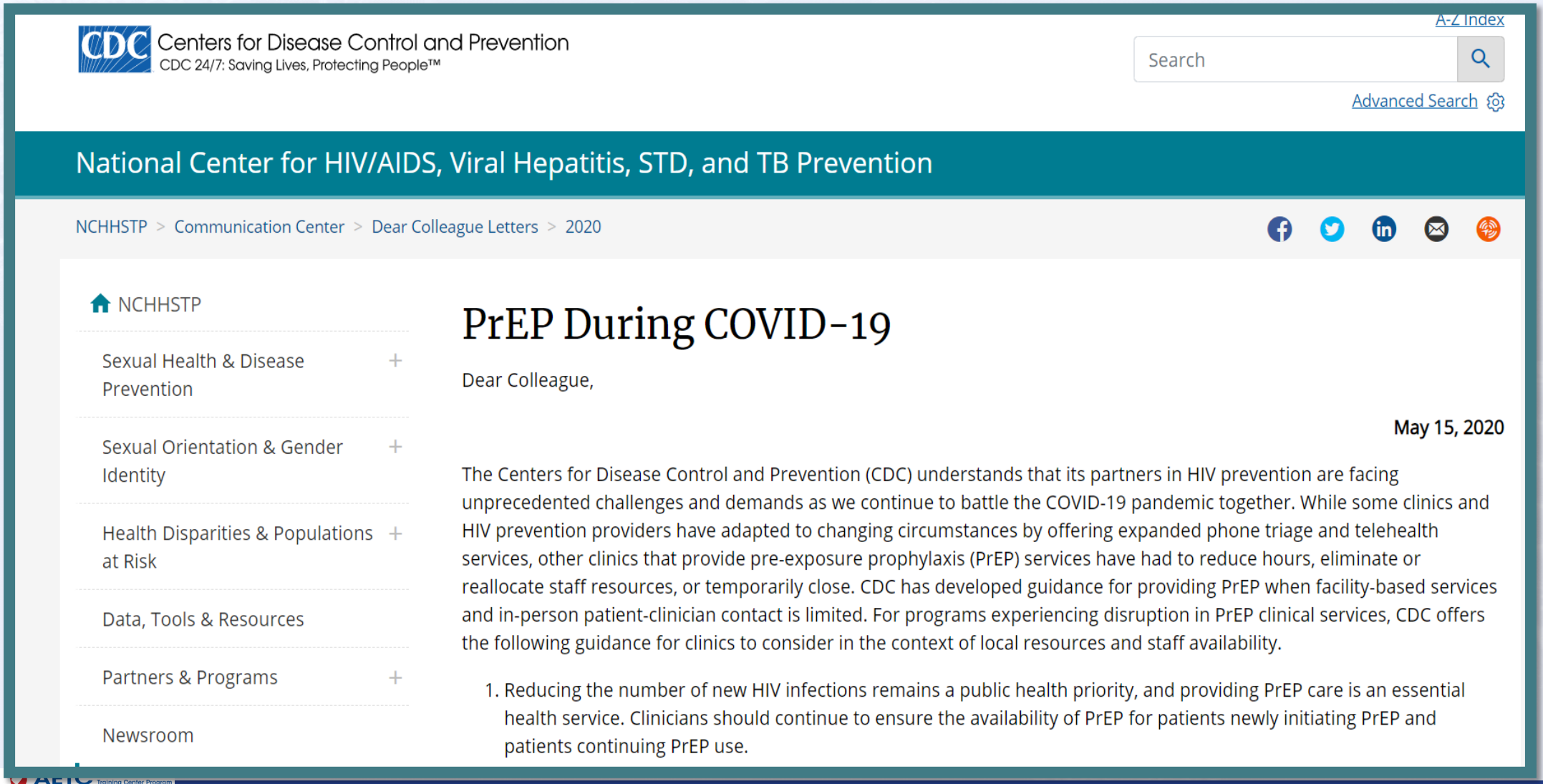
IMPACT OF COVID-19 ON HIV PREEXPOSURE PROPHYLAXIS CARE AT A BOSTON COMMUNITY HEALTH CENTER

Douglas S. Krakower, Patricia Solleveld, Ken Levine, Kenneth H. Mayer
Abstract OACLB0104

- Between January –April 2020
  - New PrEP starts decreased by 72% (122 per mo to 34 per mo)
  - PrEP refill lapses increased by 191% (140 lapses/mo to 407 lapses/mo)
  - Refill lapses associated with being younger than 27 y/o, non-white, Latinx, publically insured
  - Overall the # of clients receiving PrEP services declined by 18%
  - Testing for HIV, GC and chlamydia decreased by 85% (1,058/mo to 158/mo)
    - The rate of clients testing positive for these STIs increased slightly form 12% to 16%.

CDC Guidance on Providing PrEP Services in the time of COVID



CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

A-Z Index

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- Sexual Orientation & Gender Identity +
- Health Disparities & Populations at Risk +
- Data, Tools & Resources
- Partners & Programs +
- Newsroom

PrEP During COVID-19

Dear Colleague,

May 15, 2020

The Centers for Disease Control and Prevention (CDC) understands that its partners in HIV prevention are facing unprecedented challenges and demands as we continue to battle the COVID-19 pandemic together. While some clinics and HIV prevention providers have adapted to changing circumstances by offering expanded phone triage and telehealth services, other clinics that provide pre-exposure prophylaxis (PrEP) services have had to reduce hours, eliminate or reallocate staff resources, or temporarily close. CDC has developed guidance for providing PrEP when facility-based services and in-person patient-clinician contact is limited. For programs experiencing disruption in PrEP clinical services, CDC offers the following guidance for clinics to consider in the context of local resources and staff availability.

1. Reducing the number of new HIV infections remains a public health priority, and providing PrEP care is an essential health service. Clinicians should continue to ensure the availability of PrEP for patients newly initiating PrEP and patients continuing PrEP use.

CDC Guidance on Providing PrEP Services in the time of COVID

Issued May 15, 2020

- Acknowledged the concern of many that PrEP services will be significantly disrupted by COVID 19 health care disruptions
- Affirms that **PrEP care is an essential health care service**.
- Encourages the use of home specimen collection kits to facilitate PrEP starts and continuation of established PrEP services during COVID 19 lockdowns
- Use Oral saliva kits for HIV testing also encouraged when other more sensitive tests are not available
- Encouraged 90 scripts instead of 1 month supply and 2 refills to minimize pharmacy trips
- Establish alternative plans for patient to continue to receive PrEP services care site is shut down

Important Considerations for Supporting PrEP Patients In the Midst of the COVID19 Pandemic

- Try to collect more than one method of contacting patient phone, email.
  - Utilize text messaging whenever possible.
- How has COVID changed daily life for you?
  - Help patient problem solve around adherence problems possibly created by COVID19 life changes.
- Does lockdown change patient's HIV risk?
- Consider "Labs Only" in-person appointments. Conduct the bulk of the appointment via Telehealth if possible.
- Partner with EDs and urgent care sites to identify high risk candidates for PrEP and encourage a PEP to PrEP plan when possible.
- PrEP navigation services are key to keep people engaged with taking PrEP particularly during a pandemic.
- Encourage pharmacy delivery services.
  - Housing location changed due to COVID? Pharmacy switch?
- Educate patients routinely about the symptoms of STIs and acute HIV infection.

MOLECULAR TESTING LABS

At-Home PrEP Continuation Panels

May 15: CDC releases new guidance on PrEP screening when clinic access is limited.

Molecular can ship all the supplies necessary for on-going PrEP and general sexual health monitoring directly to your door.

Basic PrEP
HIV
Creatinine
+/- Pregnancy Test

Molecular Testing Labs

Basic PrEP Continuation Panel

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Molecular Testing Labs

Full PrEP Continuation Panel

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Full PrEP
HIV
Hep C
syphilis
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Triple Site Chlamydia
Triple Site Gonorrhea
Creatinine
+/- Pregnancy Test

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