Improving PrEP impact and equity: What we need to do

Douglas Krakower, MD

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC)

April 18, 2023

FENWAY HEALTH

CFAR HARVARD UNIVERSITY CENTER FOR AIDS RESEARCH

Beth Israel Lahey Health

DEPARTMENT OF POPULATION MEDICINE

HARVARD MEDICAL SCHOOL

Harvard Pilgrim Health Care Institute

Beth Israel Deaconess Medical Center

HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Disclosures

- Research support from Merck, Gilead to study HIV pre-exposure prophylaxis (PrEP)
- Funds to develop medical education content on PrEP from Virology Education and UpToDate, Inc.
- Consultant to Loma Linda U. and UAB on research studies on PrEP

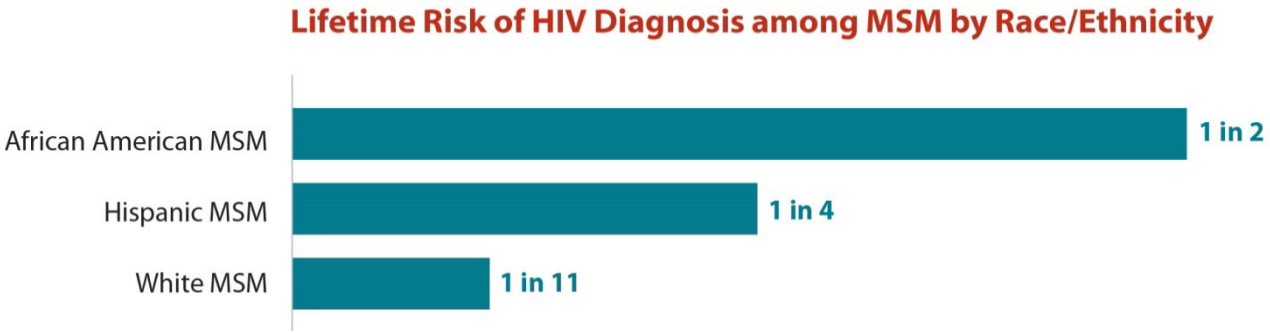
What we need to do to improve PrEP impact and equity

Generate trust and demand for PrEP among priority populations

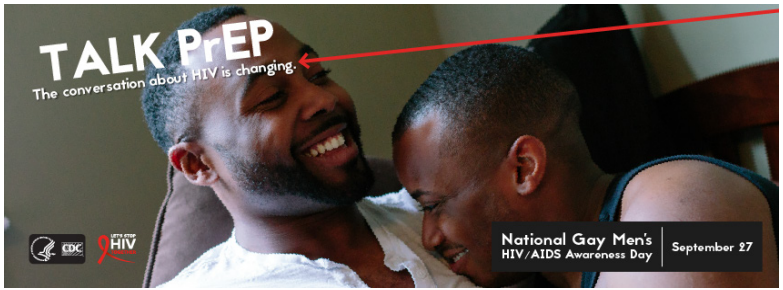
Train and engage health care providers in PrEP

Make PrEP easy to access and use

PrEP is used least by those who could benefit most



PrEP coverage
Black: 8%
Hispanic: 14%
White: 63%



Additional populations
Youth 16-24y: 16%
Cisgender women: 10%
Transgender people: ?
People who inject drugs: ?

Hess et al., *Annals Epi* 2017; Harris et al., *MMWR* 2019; Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2019. HIV Surveillance Supplemental Report 2021;26(No. 2). Centers for Disease Control and Prevention. Core indicators for monitoring the Ending the HIV Epidemic initiative (preliminary data): National HIV Surveillance System data reported through June 2021; and preexposure prophylaxis (PrEP) data reported through March 2021. HIV Surveillance Data Tables 2021;2(No. 4). http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published October 2021. Downing AIDS Beh 2022.

Major barriers to PrEP use and equity

Consumers

- Unaware of PrEP
- Stigma
- Insurance and cost
- Concerns about side effects
- HIV risk assessment
- Worry about being judged by providers
- Competing priorities in life
- Intensive monitoring on PrEP

Health care providers

- Lack of training
- Purview paradox
- Competing demands
- Workforce limitations
- HIV risk assessment
- Stigma
- Structural racism

Centers for Disease Control and Prevention. Core indicators for monitoring the Ending the HIV Epidemic initiative (preliminary data): National HIV Surveillance System data reported through June 2021; and preexposure prophylaxis (PrEP) data reported through March 2021. HIV Surveillance Data Tables 2021;2(No. 4). http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published October 2021. Downing AIDS Beh 2022.

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Strategic demand creation for PrEP

Coordinated strategies

- Partner with communities
- Positive messaging that motivates people
- General audience to create supportive environment, plus tailored campaigns
- Address concerns (e.g. side effects)
- Multiple channels (e.g. social media, TV, in-person, peer ambassadors)

Coombs, Alexandra and Elizabeth Gold. 2019. Generating Demand for PrEP: A Desk Review. Arlington, VA: Strengthening High Impact Interventions for an AIDS-free Generation (AIDSFree) Project.. NYC.gov. ViiVhealthcare.com.

What we need to do to improve PrEP impact and equity

Generate trust and demand for PrEP among priority populations

Train and engage health care providers in PrEP

Make PrEP easy to access and use

PrEP discussions are not routine in primary care

Discuss PrEP with people at substantial risk of HIV (2017)

↓

Discuss PrEP with *all* sexually active people (2021)

- Long way to go: **94%** of PrEP discussions initiated by patients

"I think, in the perfect world, we have more time to be in a room and really, kind of, get into discussions with patients. But in the real world where your boss is telling you [that] you have 15 minutes to see a person… **it's just not practical.**"

– NP, age 40 (Wilson et al.)

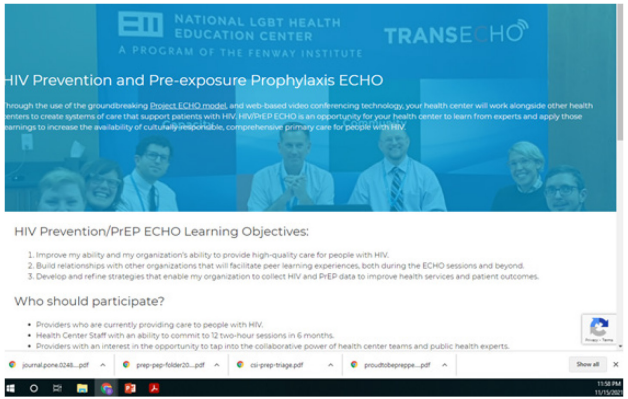
Humphries et al, International AIDS Conference, 2022; Skolnik et al., *J Gen Intern Med* 2020; Zhang et al., *JAIDS* 2018; Blumenthal et al., *AIDS Behav* 2015; Hoffman et al., *JIPAC* 2016; Maloney et al., *LGBT Health* 2017; Calabrese et al., *JIAS* 2018; Calabrese et al., *AIDS Behav* 2014; Hull et al., *JAIDS* 2021; Wilson et al., *Health Comm* 2021

Deploy evidence-supported strategies to engage busy clinicians

Academic Detailing for PrEP

- 1-on-1
- Social marketing
- NYC DOH Campaign
  - 1,348 providers, 860 sites
  - 12% increase in first-ever PrEP Rx

Telementoring – PrEP ECHO



- Improve knowledge
- Address concerns
- Increase prescribing intentions

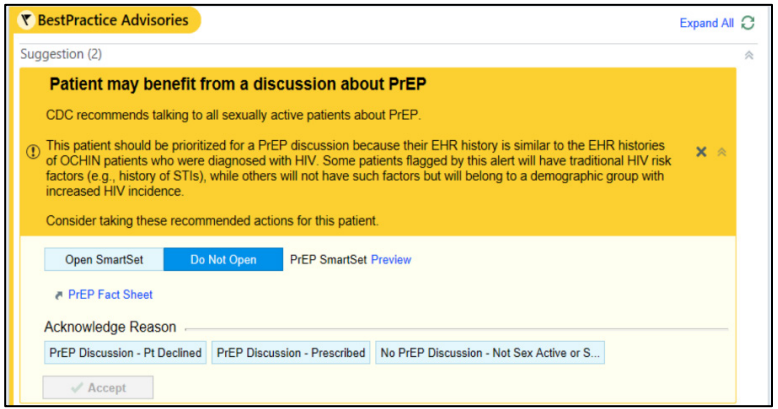
www1.NYC.gov; Wahnich Am J Prev Med 2021, lgbtqiahealtheducation.org; Wood Sex Health 2018

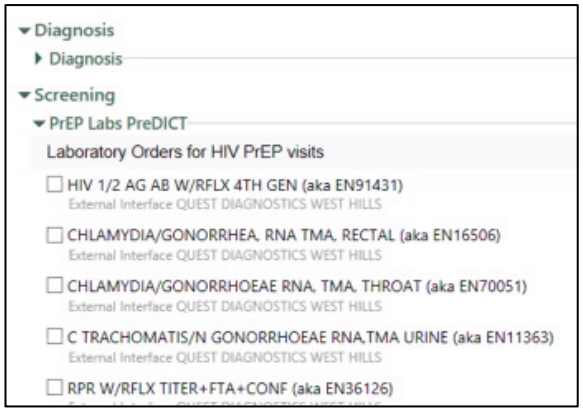
USPSTF cites need to study impact of prediction models for PrEP

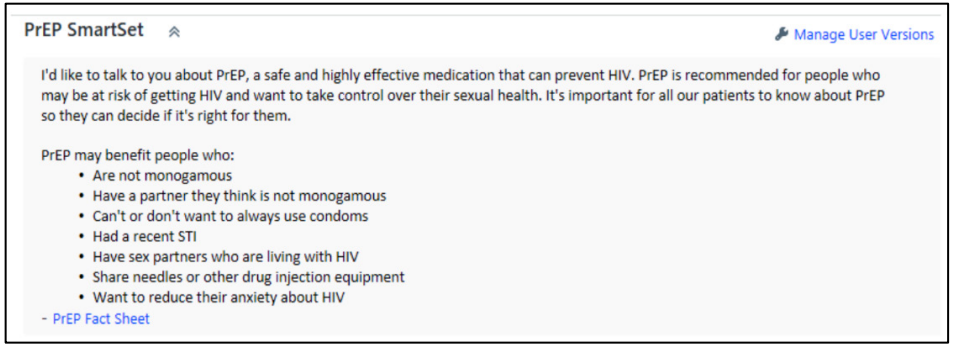
- "Instruments that are accurate for predicting risk of incident HIV infection could help inform decisions regarding eligibility for PrEP"
- "In general populations…two new instruments had moderate to high discrimination (AUROC 0.77 and 0.84) for predicting incident HIV"
  - Marcus *Lancet HIV* 2019, Krakower *Lancet HIV* 2019
- "Studies are needed to verify the accuracy and impact of automated computerized algorithms using EMR data"

Pre-Exposure Prophylaxis for the Prevention of HIV Infection: A Systematic Review for the U.S. Preventive Services Task Force (2022 Draft)

Integration into clinical workflow



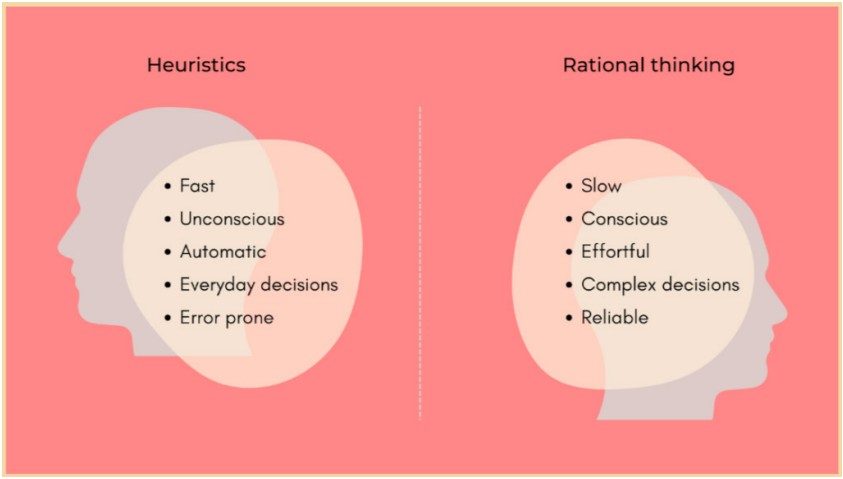




Expand clinical decisions about PrEP beyond traditional heuristics

- 46y cisgender female is flagged for PrEP discussion.
  - Married to male partner
  - Drinks alcohol
  - Lives in LA, identifies as Latina
  - HSV-2 diagnosis years ago

- **Should clinicians prioritize PrEP?**



- Clinicians may not think of PrEP without seeing bacterial STIs or other “obvious” risk factors

  - Safety-net FQHCs (OCHIN): Of 6,182 new HIV diagnoses, only 134 (2.2%) had prior bacterial STI

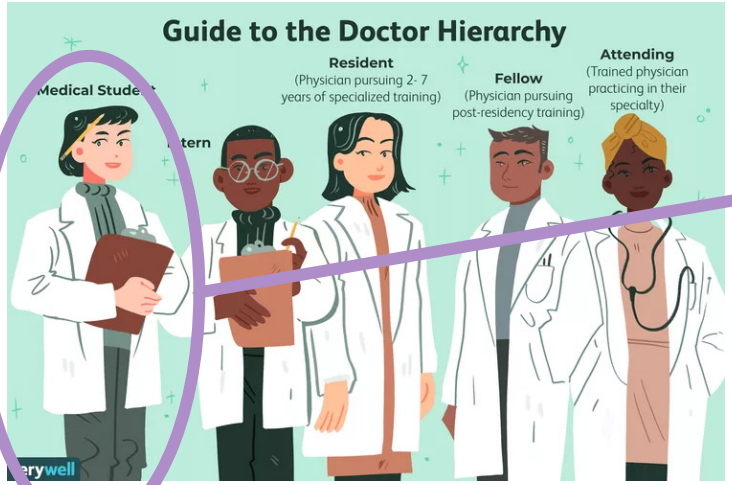
Engage health care providers across specialties

Specialties

- Sexual health
- Addiction medicine, psychiatry
- Family medicine
- Internal medicine
- OB/Gyn
- Pediatric and adolescent health
- Criminal justice
- Infectious disease
- Nursing
- Advanced nurse practitioners
- Physician assistants
- Pharmacists

"Because I talk about my sexual life in detail with her or him. Her most of the time. I feel more comfortable doing that. I'm on birth control, I am on top of my testing, I am on top of my visits. I feel like it would be appropriate for the GYN to administer PrEP services."
(31-year-old, Latinx, Family Planning clinic)

Engage providers at all stages of training



Schools for medicine, nursing, physician assistant, pharmacy

Medical Students for Choice (Howard University):

- To inform students about the different ways to incorporate abortion care into their future medical practice
- To start a conversation about addressing elective abortion on the 3rd year OB/GYN rotation

What we need to do to improve PrEP impact and equity

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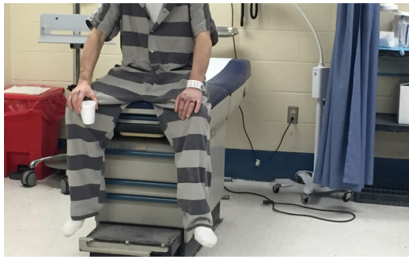
Make PrEP easy to access and use

Meet people where they're at

On the streets

Harm reduction programs



Jails, prisons

Community organizations

Youth programs

Pharmacies

TelePrEP

News.Miami.edu, PPPonlone.org, AboundingProsperity.org, Bagly.org, PrEPIowa.org

Implement a national PrEP program

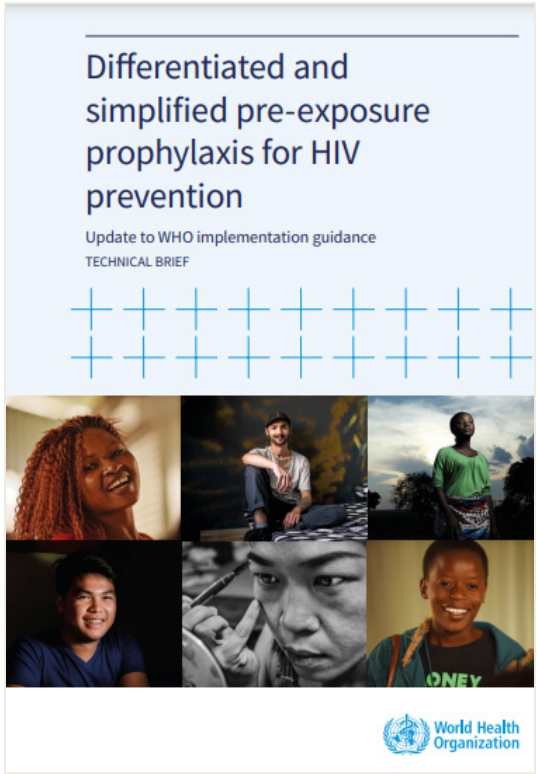
- Expand access to PrEP meds and labs for uninsured / Medicaid
- Federal government to negotiate fair public health prices
- Scale up access to generic PrEP meds for majority of PrEP users
- Expansive network of community-based providers supported by telehealth
- Seamless access at pharmacies for consumers

"Many people are afraid to even ask for the services they need because they are afraid that it will cost them, so it will be important for them to be made aware that it won't."

-Consumer

Killelea et al. Journal of Law, Medicine & Ethics 2022; Johnson NEJM 2023

WHO endorses simplified service delivery for PrEP



- Hep B testing encouraged but not required before PrEP
- Kidney function testing optional age <49y
- HIV self-testing complements existing strategies
- Person- and community-centered approaches

Could an over-the-counter PrEP Package complement traditional implementation strategies in the future?

HIV self-test

(Creatinine, hepatitis B where feasible)

Let's Get Checked.com

Final thoughts

- PrEP is underused and inequities exist
- More effective demand generation in partnership with communities
- Engage providers of many specialties at all stages of training, using innovative trainings and decision support tools
- Must make PrEP easy to access and use by meeting people where they are at and removing financial barriers
- Implement a national PrEP program to decrease costs and improve access
- Explore over-the-counter access to open the floodgates







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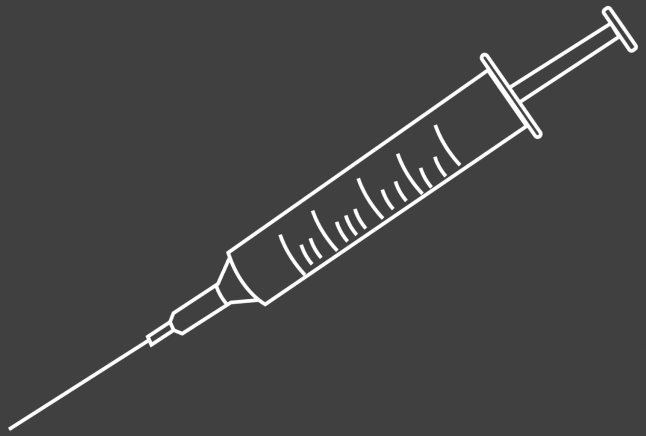
Advancing long-acting injectables for underserved populations



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CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC)
April 18, 2023

Disclosures

Nothing to disclose

Long-Acting Injectables: “Gamechangers” & “Revolutionary”

Medical Xpress

New HIV treatment shot given only f
'game changer'

The Food and Drug Administration has approved S
suppress HIV for patients who suffered drug resista

Dec 30, 2022

INSIDE DEVELOPMENT | GLOBAL HEALTH

‘Revolutionary’ HIV prevention jab set to expand choices for consumers

By *Andrew Green* // *01 March 2023*

Pharmacy Times

Long-Acting HIV Regimen May Prove Revolutionary

FDA approval of 2-drug injectable Cabenuva is a game changer in maintaining viral suppression in patients.

May 24, 2021

BE IN THE

Understanding the HIV epidemic | HIV programming | News and blogs

Sex and relationships | HIV an

blogs

Long-acting injectable PrEP: is it a game changer for HIV prevention?

Oliver Meth
03 August 2022

There are some new developments for PrEP that might change the way you take it in the future

nature › news › article

NEWS | 05 August 2022 | Correction 16 August 2022

Long-lasting HIV prevention drug could be game changer – but who will pay?

Can these interventions be implemented in ways that decrease disparities in health outcomes?

HIV TREATMENT AND MEDICAL CARE › FEATURES

Can Long-Acting ART Be an Equitable Care Option for Black Women?

Dali Adekunle
May 31, 2021

Not a Panacea for Inequities in Access

Alongside the excitement for LA-ART lingers the disquieting inequities that appeared during the early days of AZT through the evolution of NRTIs and the expansion of NNRTIs. Black Americans have been disproportionately affected by HIV/AIDS since the epidemic's beginning, and that disparity has deepened over time. While ART has helped millions of people living with HIV lead healthier lives, Black people living with HIV are more likely than other racial groups to postpone or discontinue medical care and become hospitalized. Add to that that in the U.S., Black people living with HIV have higher rates of virologic failure on ART and of death when compared to white individuals. As for Black women, we represent the majority—nearly 60%—of new HIV infections among U.S. women.

AIDS. Author manuscript; available in PMC 2020 Nov 1.
Published in final edited form as:
AIDS. 2019 Nov 1; 33(13): 2110–2112.
doi: 10.1097/QAD.0000000000002341

PMCID: PMC6777857
NIHMSID: NIHMS1536842
PMID: 31577579

A shot at equity? Addressing disparities among Black men who have sex with men in the coming era of long-acting injectable pre-exposure prophylaxis

William C. GOEDEL, BA,[1] Amy S. NUNN, ScD,[2] Philip A. CHAN, MD, MS,[3] Dustin T. DUNCAN, ScD,[4] Katie B. BIELLO, PhD,[2,5] Steven A. SAFREN, PhD,[5,6] and Brandon D.L. MARSHALL, PhD[1]

THE LANCET
HIV

Submit A

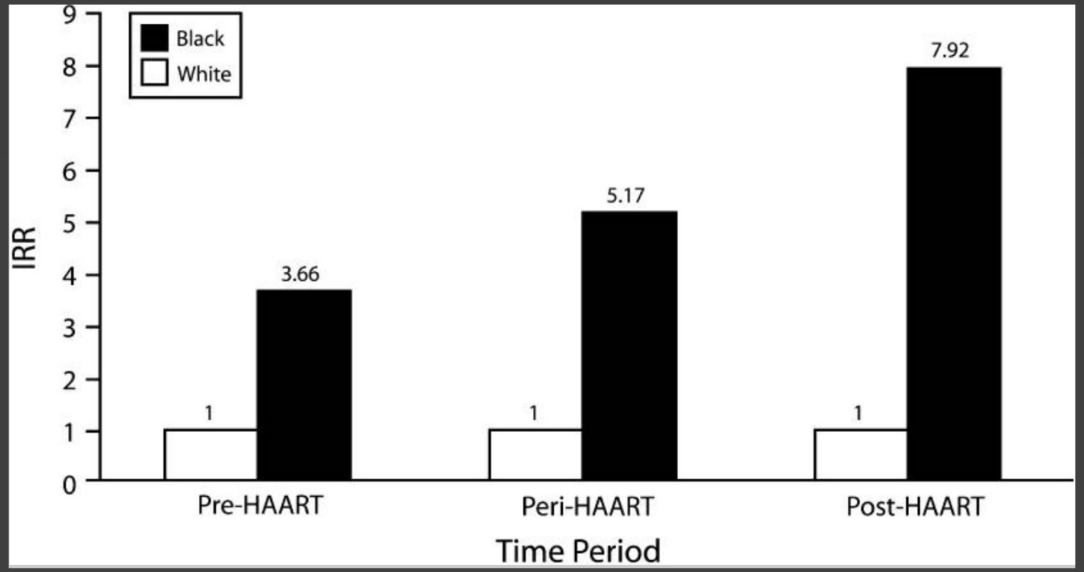
EDITORIAL | VOLUME 9, ISSUE 7, E449, JULY 2022

Equitable access to long-acting PrEP on the way?

The Lancet HIV

Published: July, 2022 • DOI: https://doi.org/10.1016/S2352-3018(22)00167-9 •

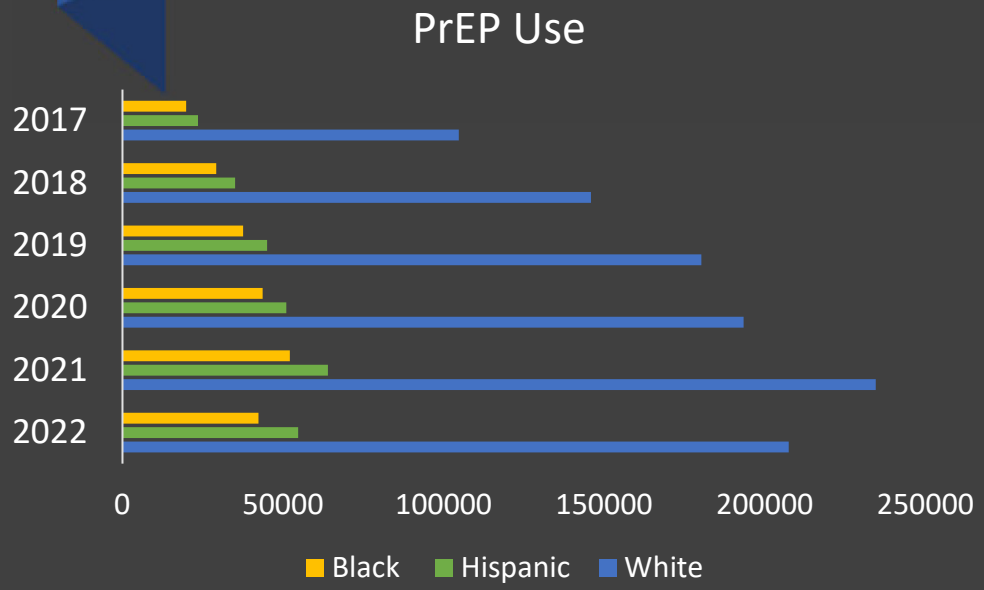
Innovations in HIV treatment lead to disparities

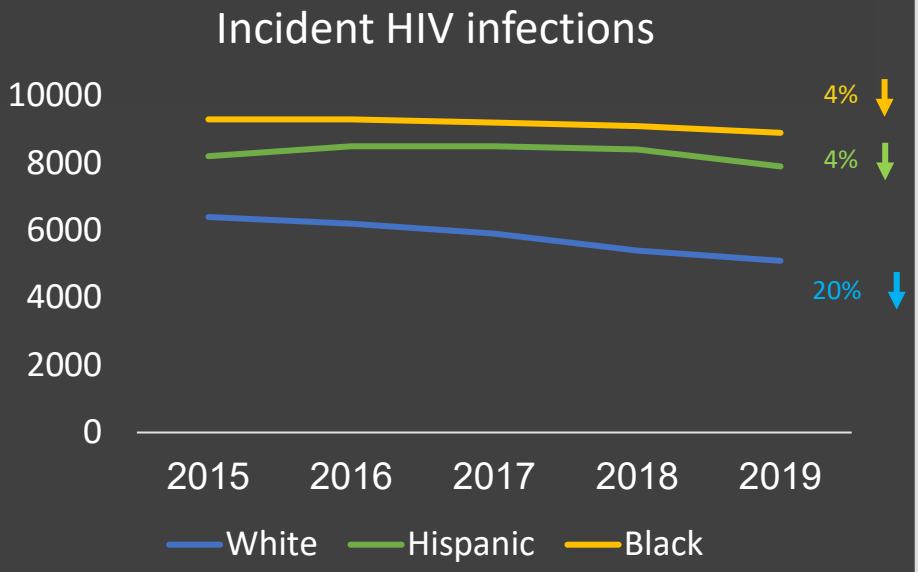


HIV/AIDS mortality among Blacks and Whites during the pre-, peri-, and post-HAART periods: US, 1987–2005.

Rubin, 2010, AJPH, Examination of inequalities in HIV/AIDS mortality in the United States from a fundamental cause perspective

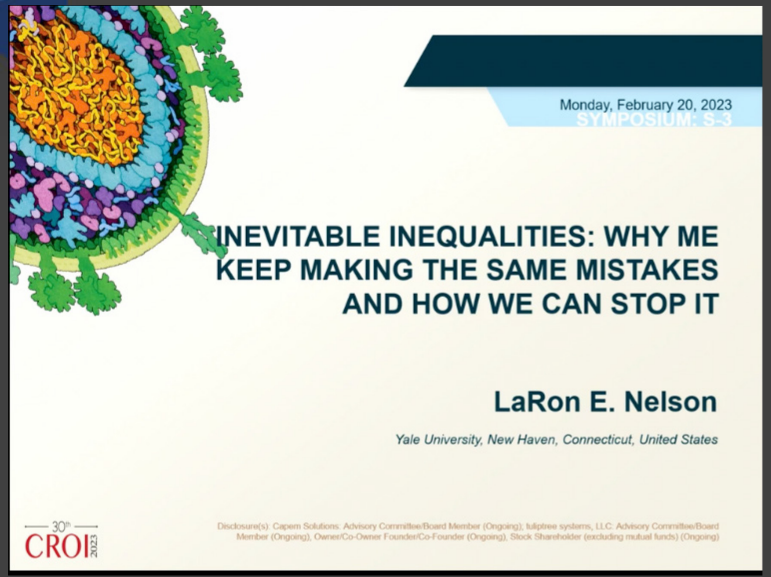
Oral PrEP increases disparities in HIV

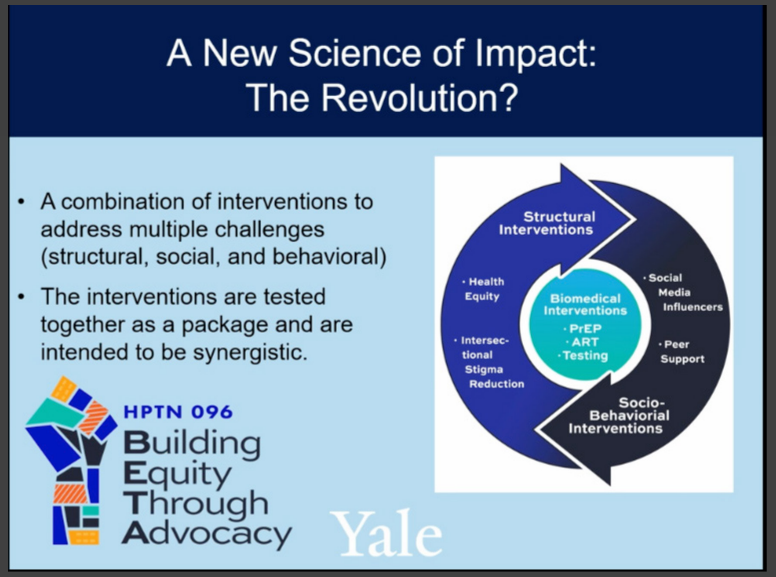




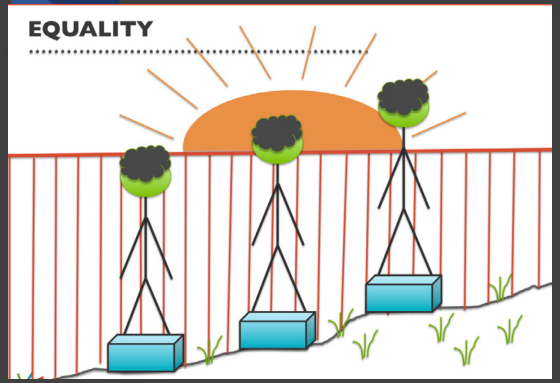
CDC, 2022

Revolutionary: "New Science of Impact"

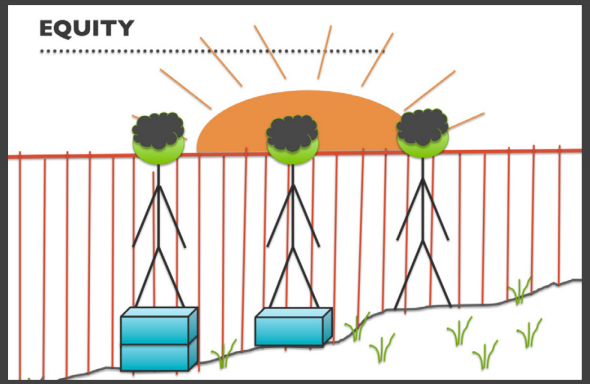




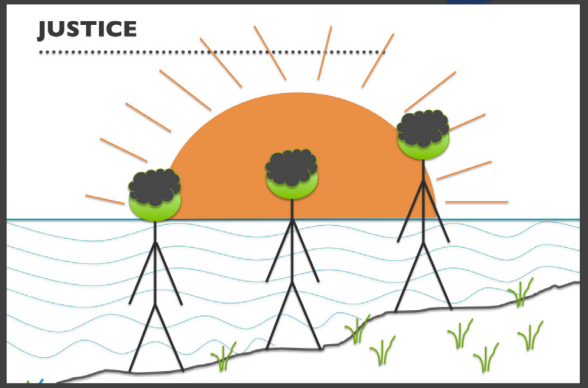
What should we be striving for….



The assumption that everyone benefits from the same supports, leading to equal uptake, sustainment, and benefits of LAI ARVs across all groups.



Everyone gets the support they need to access LAI ARVs, producing equity in uptake, sustainment, and benefits.



Everyone can access LAI ARVs because the causes of the inequity has been addressed; the systemic barriers to access, sustainment, and benefits have been removed.

https://theavarnagroup.com/and-heres-yet-another-equity-v-equality-v-justice-image-series/

… And where are we?
Current Landscape of LAI ARVs

Limited Uptake of Injectable PrEP

In September 2022, 186,367 persons were prescribed PrEP		
Generic FTC/TDF	93,808	50.3%
FTC/TAF	84,141	45.1%
Brand FTC/TDF	7,065	3.8%
Cab-LA	1,353	.5%

From January-August 2022:

- 1951 persons had cab-LA prescriptions filled
- 313 (16%) did not receive a second dose one month later

Zhu, CROI, 2023, "Oral and injectable PrEP use in the United States"

Limited Uptake of Injectable Treatment

A Tale of 2 clinics

California Clinic

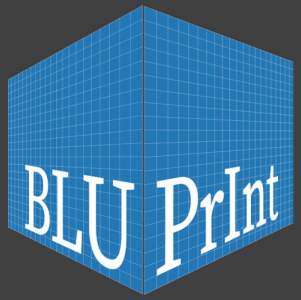
- UC San Diego Owen Clinic
- Ryan White-funded HIV primary care clinic
- Implementing LAI CAB/RPV April 2021-June 2022 (14 mo)
- **~Half of those who expressed interest in cab/ril initiated**

Georgia Clinic

- Ryan White-funded clinic serving >6000 PWH in metropolitan Atlanta, Georgia
- Implementing LAI CAB/RPV April 2021-December 2021 (9 mo)
- **~A quarter of those who expressed interest in cab/ril initiated within 12 months**

Hill et al, 2023, AIDS, Single-Center Experience Single-Center Experience Evaluating and Initiating People with HIV on Long-Acting Cabotegravir/Rilpivirine; Collins et al, 2022, OFID, Early Experience Implementing Long-acting Injectable Cabotegravir/Rilpivirine for HIV-1 Treatment at a Ryan White-funded Clinic in the US South

Reflections from Two Projects



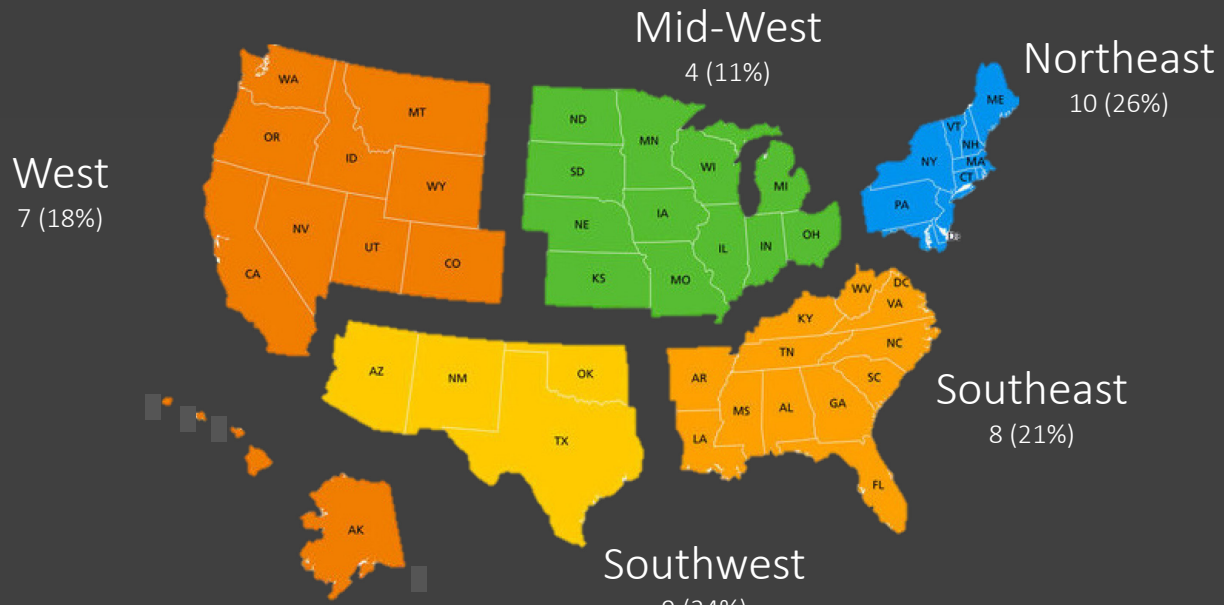
To support clinics create and strengthen HIV prevention programs by synthesizing key research findings, best practices, and implementation resources that promote equity-driven delivery of next generation PrEP products.

R01MH123262 (MPI Golub/Meyers)

To support clinics across the United States develop injectable HIV treatment programs that prioritize the needs of underserved populations by providing ongoing technical assistance with the explicit goal of addressing inequity in health outcomes.

U1SHA46532-01-00 Special Project of National Significance – Minority HIV/AIDS Fund (PD Meyers)

Widespread interest from geographically diverse sites



Widespread interest from range of clinic types

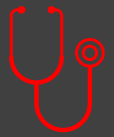
AIDS Service Organizations
8 (21%)

Hospitals
5 (13%)

Academic Medical Centers
8 (21%)

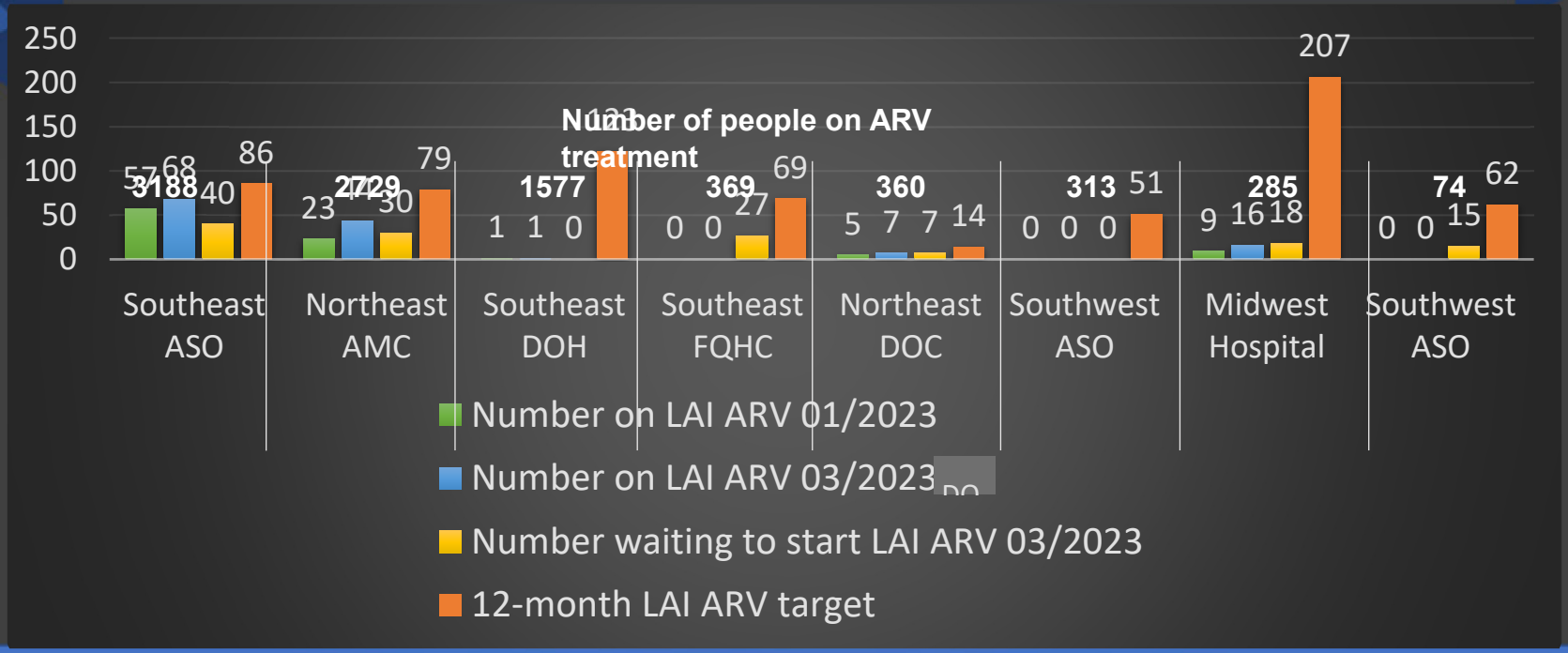
Federally Qualified Health Centers
6 (16%)

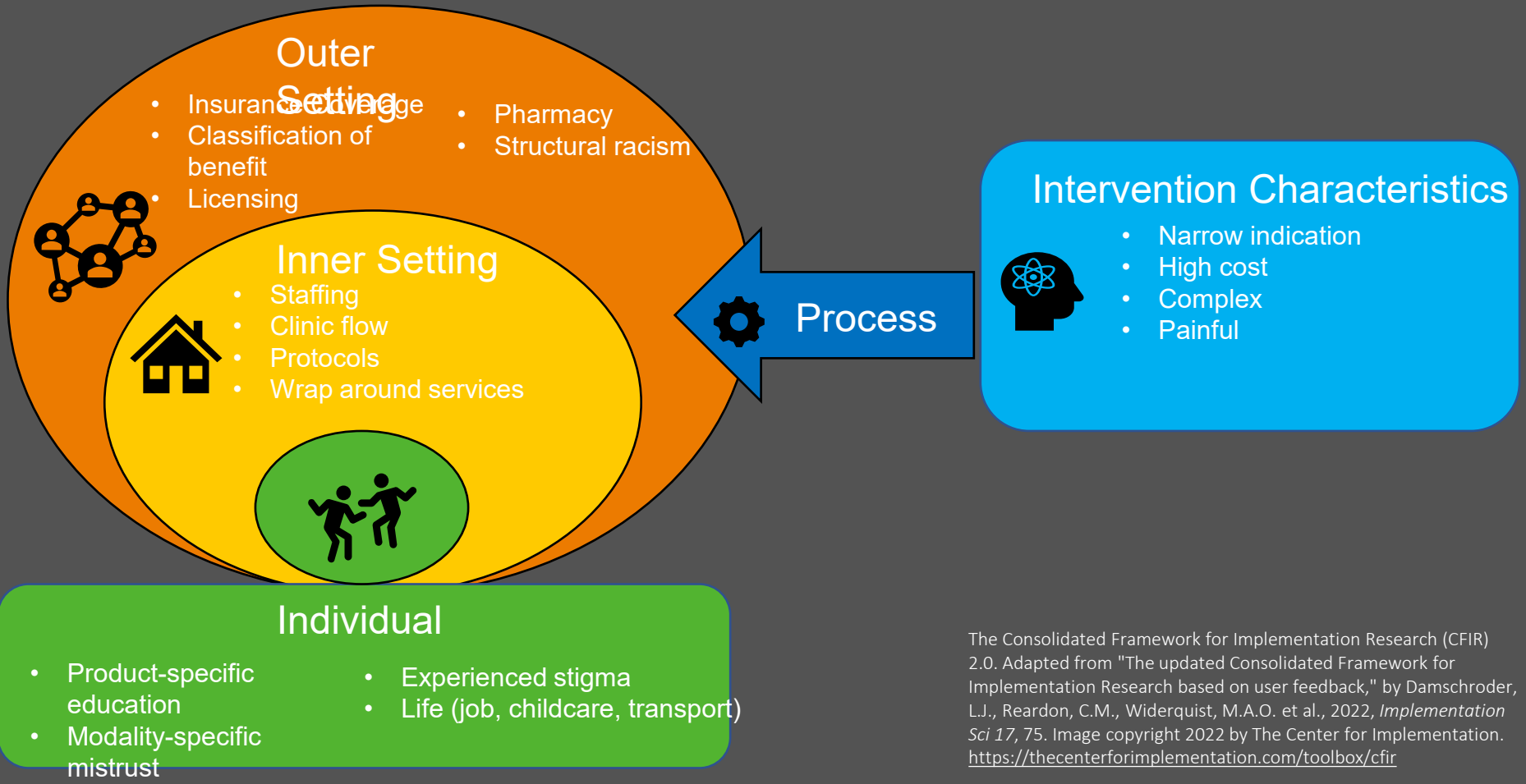
Department of Health
3 (8%)



Primary Care
8 (21%)

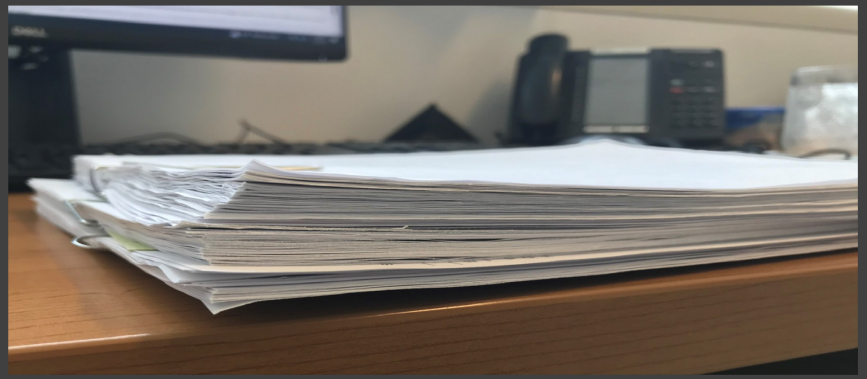
Implementation is slow





The Consolidated Framework for Implementation Research (CFIR) 2.0. Adapted from "The updated Consolidated Framework for Implementation Research based on user feedback," by Damschroder, L.J., Reardon, C.M., Widerquist, M.A.O. et al., 2022, *Implementation Sci 17*, 75. Image copyright 2022 by The Center for Implementation. https://thecenterforimplementation.com/toolbox/cfir

Barrier 1: Insurance-related issues



Denial of Coverage

"This is a picture of the stack of paperwork for three of the patients I have prescribed for. Two were approved and one was denied twice after appeals. This takes hours of work and doesn't represent the phone calls and emails also related to the follow up after a prescription is sent."

-City DOH Sexual Health Clinic Medical Director

Barrier 1: Insurance-related issues

Prior Authorization

Each insurance plan has various administrative rules which are complex to navigate. Almost all require prior-authorization and again as a resource limited provider the increased administrative burden increases our operational cost which ultimately limits the care we can provide. Moreover, the prior authorization process is not well understood at the insurer level as many plans are still asking for inappropriate information, e.g., request for coverage denied because patient has not failed other therapies. Providers are spending a great deal of time doing peer to peer reviews to educate insurers that they are not following FDA prescribing guidance.

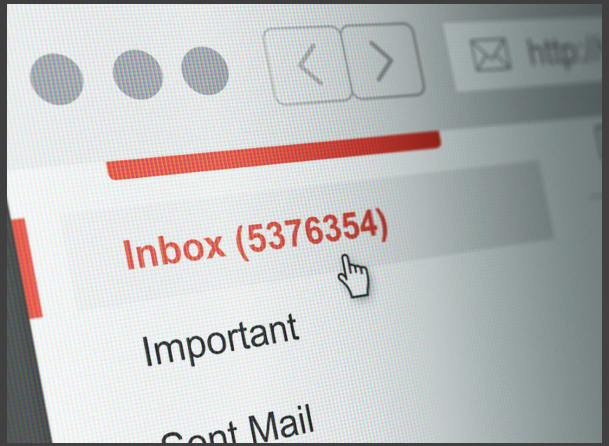
- RN, Southeast AIDS Service Organization

Barrier 1: Insurance-related issues

Continued coverage

"I also worry about the fact that Medicaid is no longer automatically re-enrolling people this year. If patients miss mail or an email about reenrollment they could lose coverage unexpectedly, also interrupting timely injections."

-City DOH Sexual Health Clinic Medical Director



Images: The Atlantic, 2019, https://www.theatlantic.com/technology/archive/2019/01/case-inbox-infinity/579673/; Salon, 2017, https://www.salon.com/2017/12/07/twitter-users-reveal-their-insane-

Proposed Solutions: Simplification through national program & funding

Federal Policy

We need legislative change that requires insurers to act in the interest of public health, e.g., to cover any therapeutic option as deemed appropriate by prescribing provider without prior authorization or cost sharing… [We need] a federal policy that supports treatment as prevention.

-RN, PrEP Champion, SE ASO

Federal Funding

Federal funding to support the necessary infrastructure and administration for these programs, as was provided for the rollout of Patient Centered Medical Homes during the Affordable Care Act.

- Clinic Director, NE Hospital System

Barrier 2: Procurement

ADAP Pharmacy

The State of XXX has limited ADAP access for CABENUVA to only select ADAP pharmacy, e.g., not all ADAP pharmacies can receive the medication. Although we are an ADAP pharmacy, we cannot currently obtain the medication. As a resource limited provider, we do not have the administrative capability to coordinate logistics necessary to obtain medication that requires cold chain from an external pharmacy.

- RN, Southeast AIDS Service Organization

Specialty Pharmacy

Medication for uninsured clients must come from Walgreens Specialty Pharmacy and it's unclear if we will be able to work with it because of our procurement rules. Because of these difficulties, it's unclear if our Department of Health will ever offer the injectable at all of its sites or even whether it will continue to offer it at all.

-State Department of Health HIV Prevention Program Manager

Medical vs Pharmacy

Finding out if the medication is covered under pharmacy or medical benefit is key. Many Ryan White providers lack infrastructure required to medically bill for specialty injectables. While we are working on building this capability; we currently are unable to access for patients whose insurers designates as medical benefit"

-Medical Director, NE Hospital System

Potential Solutions: Consistency & Simplification

adap
AIDS Drug Assistance Program Branch

Specialty pharmacy is...the new pharmacy.

- Lower drug costs
- Add LAI ARV to all state's ADAP formularies
- Ensure every ADAP pharmacy has unrestricted access
- Consistency: Advocate for commercial insurers to cover
- Consistency: Advocate for insurers to cover as pharmacy benefit
- Support accreditation of specialty pharmacies in neighborhoods where clinics that prioritize the underserved are located
- Increase flexibility in DOHMH procurement rules
- Centrally-funded pharmacy liaisons to support clinics that don't have within-system specialty pharmacies

Barrier 3: Narrow Label

Q: What would allow injectable cab/ril to have a real-world impact in your clinic?

A: Extending cab/ril injections to virally unsuppressed patients

A: More prescriber discretion in identifying patients who could benefit.

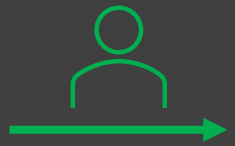
Patients who have difficulty with taking pills daily

Patients who have difficulty swallowing

Patients who have trouble with adherence

Patients who have demonstrated they can show up for appointments

Proposed Solution: Extending the label



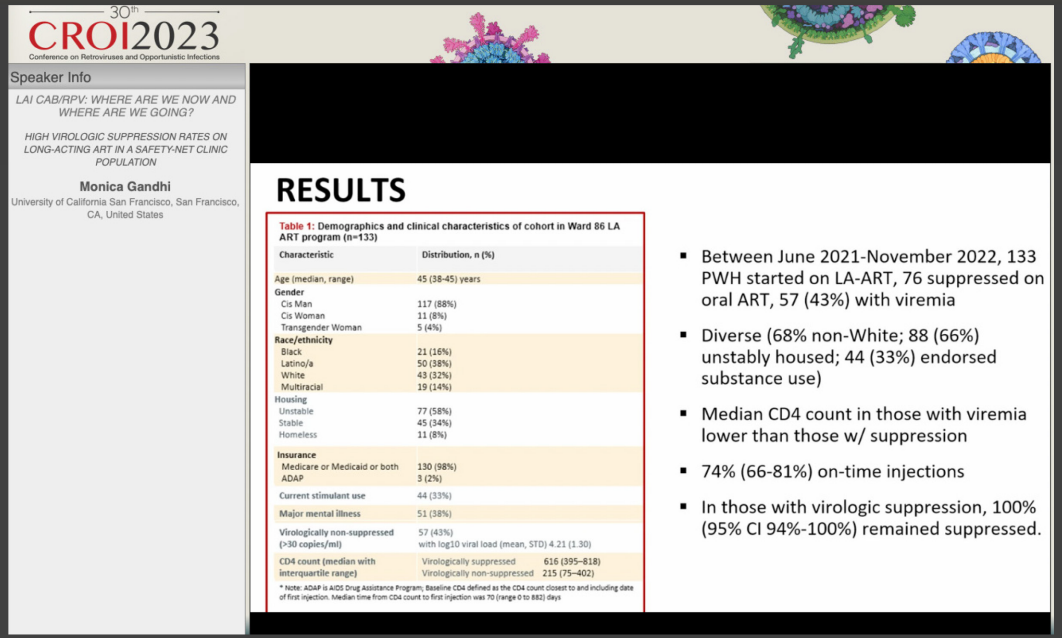
Stably virally suppressed

Inconsistent viral suppression

Not virally suppressed due to adherence challenges

To contribute to progress towards End the HIV Epidemic targets, injectable cab/ril (or other injectable regimens) will need to be an option for people in all three groups

What evidence is needed to support this?



30th CROI2023
Conference on Retroviruses and Opportunistic Infections

Speaker Info

LAI CAB/RPV: WHERE ARE WE NOW AND WHERE ARE WE GOING?

HIGH VIROLOGIC SUPPRESSION RATES ON LONG-ACTING ART IN A SAFETY-NET CLINIC POPULATION

Monica Gandhi
University of California San Francisco, San Francisco, CA, United States

RESULTS

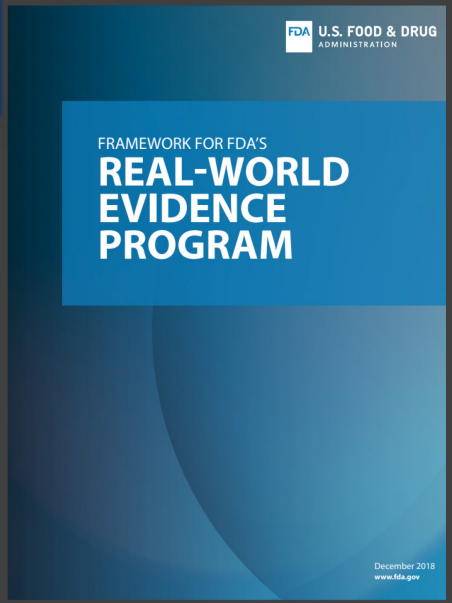
Table 1: Demographics and clinical characteristics of cohort in Ward 86 LA ART program (n=133)

Characteristic	Distribution, n (%)
Age (median, range)	45 (38-45) years
Gender	
Cis Man	117 (88%)
Cis Woman	11 (8%)
Transgender Woman	5 (4%)
Race/ethnicity	
Black	21 (16%)
Latino/a	50 (38%)
White	43 (32%)
Multiracial	19 (14%)
Housing	
Unstable	77 (58%)
Stable	45 (34%)
Homeless	11 (8%)
Insurance	
Medicare or Medicaid or both	130 (98%)
ADAP	3 (2%)
Current stimulant use	44 (33%)
Major mental illness	51 (38%)
Virologically non-suppressed (>30 copies/ml)	57 (43%) with log10 viral load (mean, STD) 4.21 (1.30)
CD4 count (median with interquartile range)	Virologically suppressed 616 (395–818); Virologically non-suppressed 215 (75–402)

* Note: ADAP is AIDS Drug Assistance Program; Baseline CD4 defined as the CD4 count closest to and including date of first injection. Median time from CD4 count to first injection was 70 (range 0 to 882) days

- Between June 2021-November 2022, 133 PWH started on LA-ART, 76 suppressed on oral ART, 57 (43%) with viremia
- Diverse (68% non-White; 88 (66%) unstably housed; 44 (33%) endorsed substance use)
- Median CD4 count in those with viremia lower than those w/ suppression
- 74% (66-81%) on-time injections
- In those with virologic suppression, 100% (95% CI 94%-100%) remained suppressed.

What evidence would be needed to extend the label?



Framework to evaluate the potential use of real-world evidence to help support the approval of a new indication for a drug already approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act

Potential options

- Randomized Controlled Trial
- Single arm prospective observational cohort
- Registry of real-world LAI ARV users

Acknowledgements

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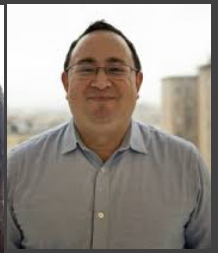
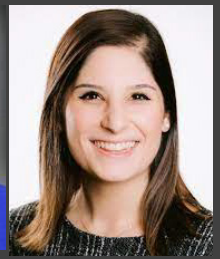
Delivette Castor


Kerri Carnevale


Jason Zucker


Jenn Burdge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Albert Einstein College of Medicine


Bryan **Kutner**

New York City Department of Mental Health and Hygiene


Katey King

City University Of New York Hunter College


Sarit Golub

ALAI UP Clinical Demonstration Sites

R01MH123262 (MPI Golub/Meyers)

ALAI UP is an SPNS Project supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $7,000,000 with 0% financed with non-governmental sources. The contents of this presentation are my own and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.

La Bodega: A Co-Localized Approach to HCV Elimination

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Jacobs School of Medicine
University at Buffalo
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Erie County Medical Center

Disclosures

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Research: Abbvie, Gilead, Allergan, Intercept

Consulting: Abbvie, Gilead, Antios, Intercept, Eisai

US National HCV Elimination Plan

March 9, 2023

A National Hepatitis C Elimination Program in the United States

A Historic Opportunity

Rachael L. Fleurence, MSc, PhD[1]; Francis S. Collins, MD, PhD[1]

Author Affiliations | Article Information

JAMA. Published online March 9, 2023. doi:10.1001/jama.2023.3692

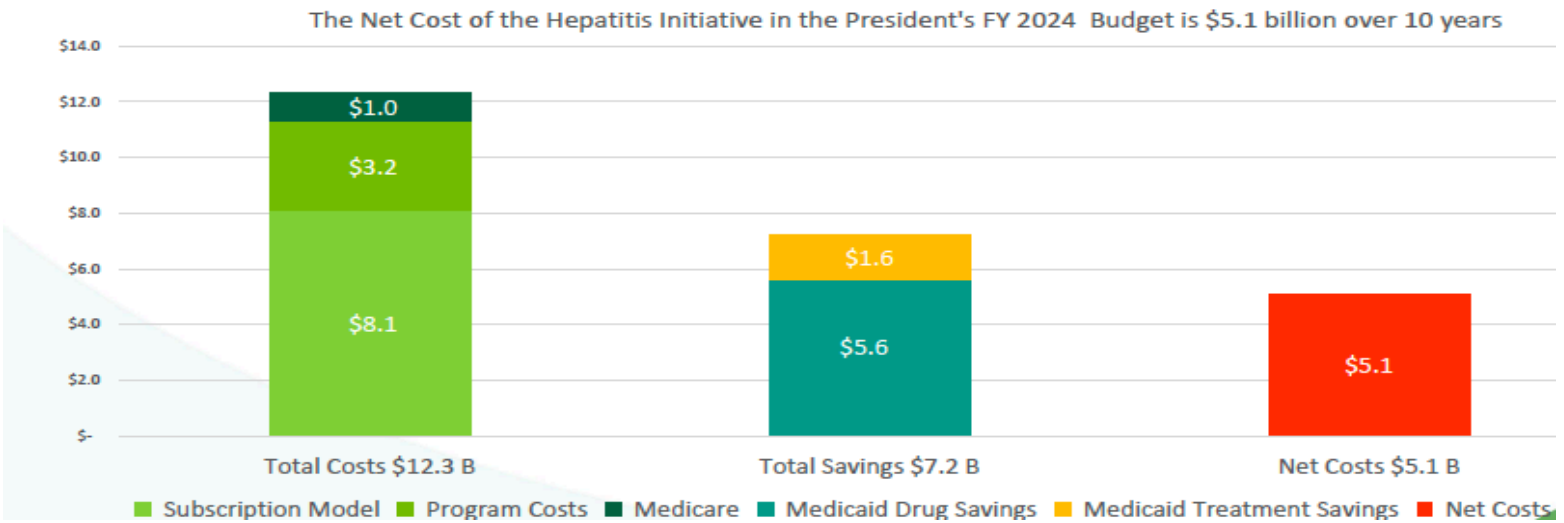
Highlights of the White House Plan

Proposed a plan to eliminate hepatitis C in five years in the United States through a mandatory authorization:

1. Supporting the development of point-of-care diagnostic tests to enable a test-to-treat model;
2. Broadening access to curative hepatitis C medications, primarily through a national subscription model; and
3. Expanding infrastructure needed to reach, test, and treat all affected individuals.

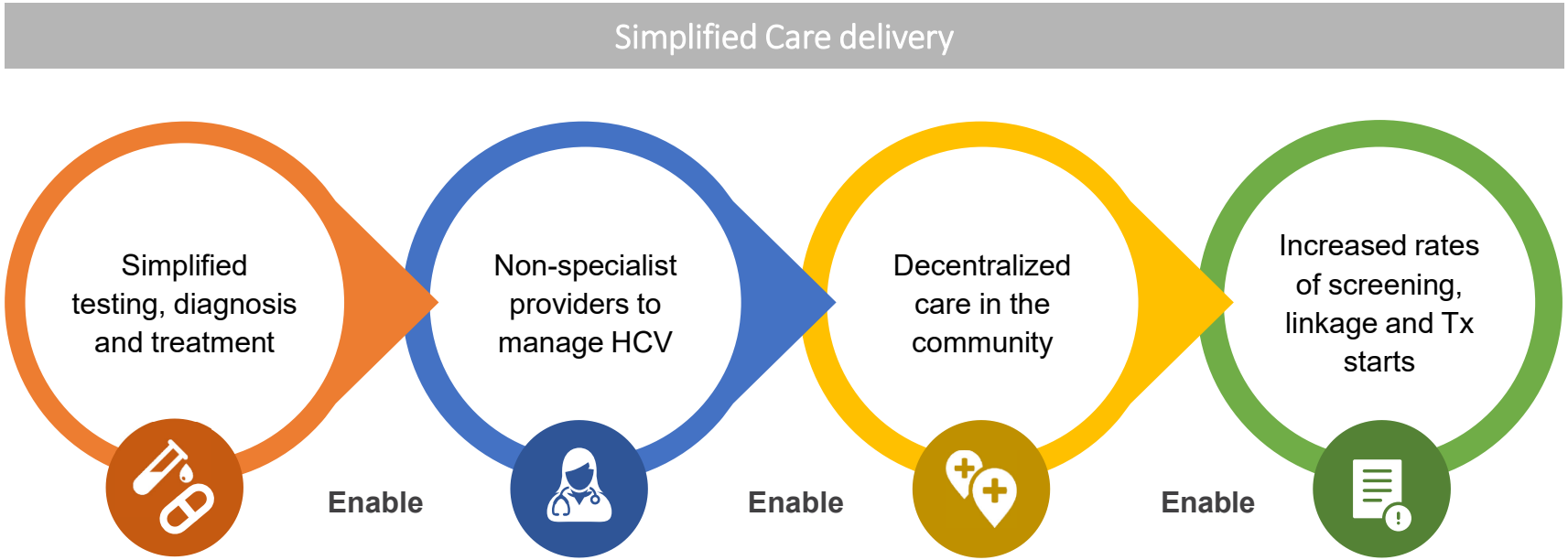
.

White House Plan Cost Estimate



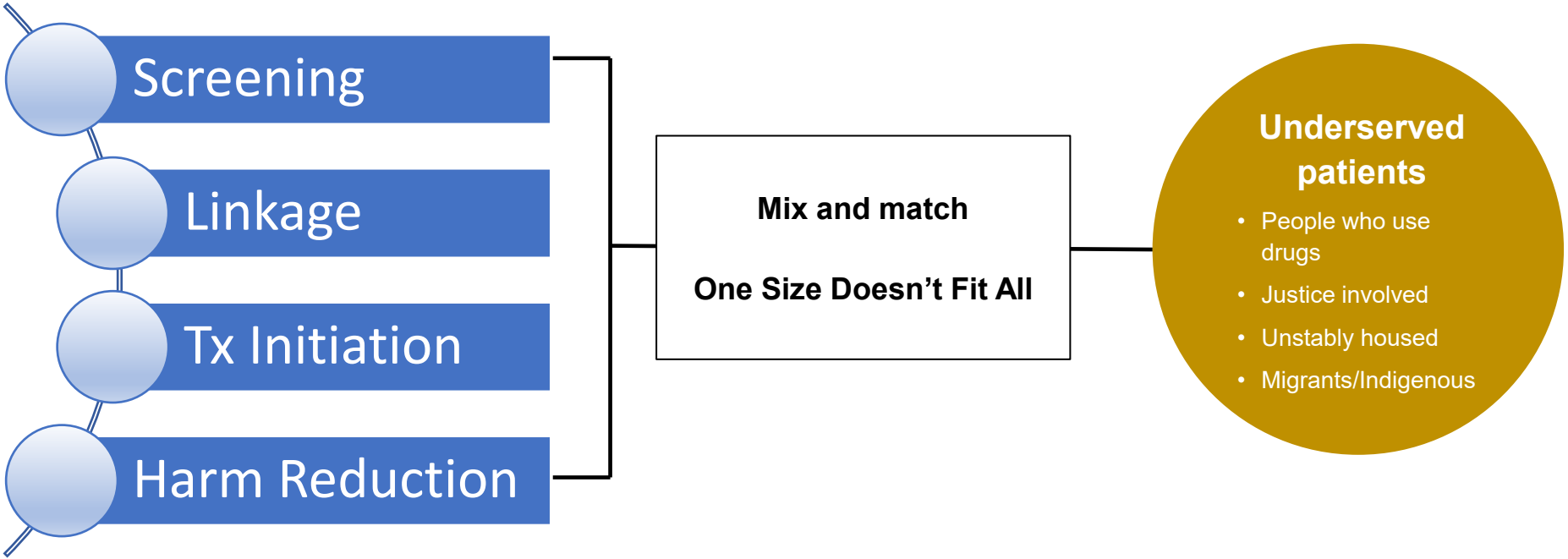
In order to achieve the $7 billion dollar cost savings, need to treat >300,000 patients annually x 5 years
What will an effective program look like?

What does Simplified Care Delivery Entail?



Adapted from World Health Organization. *Updated recommendations on simplified service delivery and diagnostics for hepatitis C infection*, 2022.

Pillars For HCV Elimination



Mix-and-Match Approach: Settings, Services, Providers

Settings

- Sexual health clinics
- NSP services
- Substance use clinics
- Primary healthcare/GPs
- Community health centers
- Prisons – State / Federal; Jail

Services

Screening

Confirmed viral load

Treatment

Follow-up

Providers

- Other specialists
- Primary care providers
- Addiction medicine providers
- Nurse Practitioners, Physician Assistants, Pharmacists
- Peer support workers
- Others

Clinical Models to Improve Linkages to HCV/Addiction Care and Treatment Uptake

Conventional referral

- System is difficult to navigate for many
- Transportation
- Need a multidisciplinary approach
- Utilization of case managers
- Peer navigators

Telemedicine

- Useful to deliver services to any setting (prison, rural, substance abuse clinics)
- Provide specialty care where not otherwise available
- Supportive data in both addiction and HCV settings
- Slows cascade

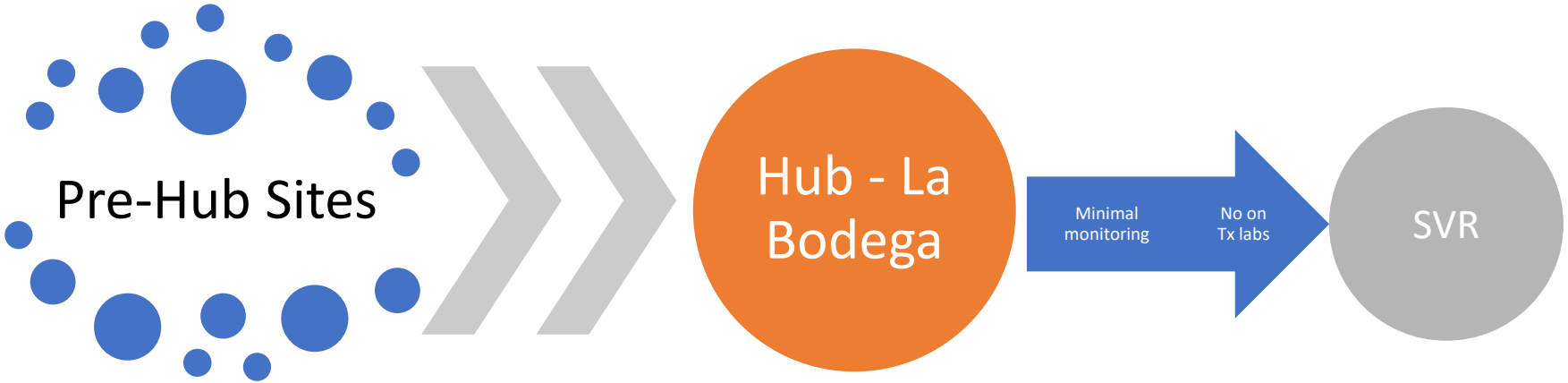
Colocalization

- One-stop shopping
- Multiple services offered in one location
- Minimizes loss to follow-up
- Streamlines care

La Bodega

- Conventional Hepatology
- Conventional Addiction Medicine
- Combined Hep/Addiction

La Bodega Buffalo, NY – Modified rapid start/test and treat model



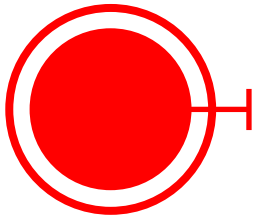
- Community addiction clinics SEPs
- High Risk OB / Peds (foster care system)
- Prison / Jail
- STI clinics
- ER
- Primary care
- Street Medicine

- Individualized screening protocol: POC AB test; conventional Ab w/PCR reflex
- Single number and email for referral
- Bodega staff schedules / navigates system

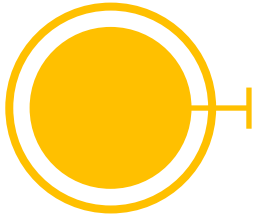
- On-site lab draw
- Colocalized MAT – rapid start
- Immediate HCV Tx
- On-site pharmacy
- Counseling services
- PrEP, HIV, Primary Care

- Staff assists with refills based on triage system – red, yellow, green

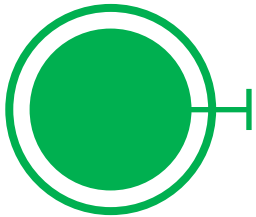
La Bodega Triage System



Full support required – meds delivered to clinic or held at clinic; frequent check-ins and reminders via phone, text, social media



Intermediate support – meds delivered to the patient; Bodega staff tracks refills, deliveries; less frequent check in



Minimal support required – script written, see you in 5-6 months!

La Bodega Buffalo

A hybrid model of outreach, referral, colocalization, and telemedicine, implemented state-wide and nationally

Key success factors of the model
Meets the patients AND the providers where they are.

Facilitating linkage

- Low threshold – no wait time
- Flexible and forgiving schedule
- Eases burden on referring provider
- “Show up and we will see you”

Transportation

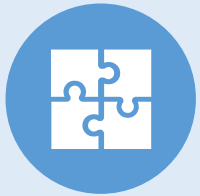
- Arranged immediately if needed
- Public transportation vouchers provided
- Telemed if needed
- Medicaid cabs
- “We go get you”

System navigation

- Appointments and follow-ups made for patients within days
- No formal referral process or labs needed from providers
- “Call this number”

Handpicked, dedicated team

- Multidisciplinary team
- Case manager, counselor, social worker, nurses, PA and secretaries
- No titles / hierarchy



Mix-and-match approach

- Multiple micro-models in place within a global structure, based on local resource availability
- “One size does not fit all”

La Bodega Outcomes (Active PWUD)

Colocalized model, 2014–2020 n = 1133 (Total PWUD 1600)

Regimen	Full adherence	Variable adherence	Treatment failure	SVR
8-weeks Glecaprevir/pibrentasvir (n=403) Sofosbuvir/ledipasvir (n=65)	423 (90.4%)	45 (9.6%)	28 (6.0%)	440 (94.0%)
12-weeks Elbasvir/grazoprevir (n=83) Glecaprevir/pibrentasvir (n=52) Sofosbuvir/ledipasvir (n=189) Sofosbuvir/velpatasvir (n=301) Sofosbuvir/velpatasvir/voxilaprevir (n=40)	607 (91.3%)	58 (8.7%)	40 (6.0%)	625 (94.0%)
		P=0.75		P=0.90

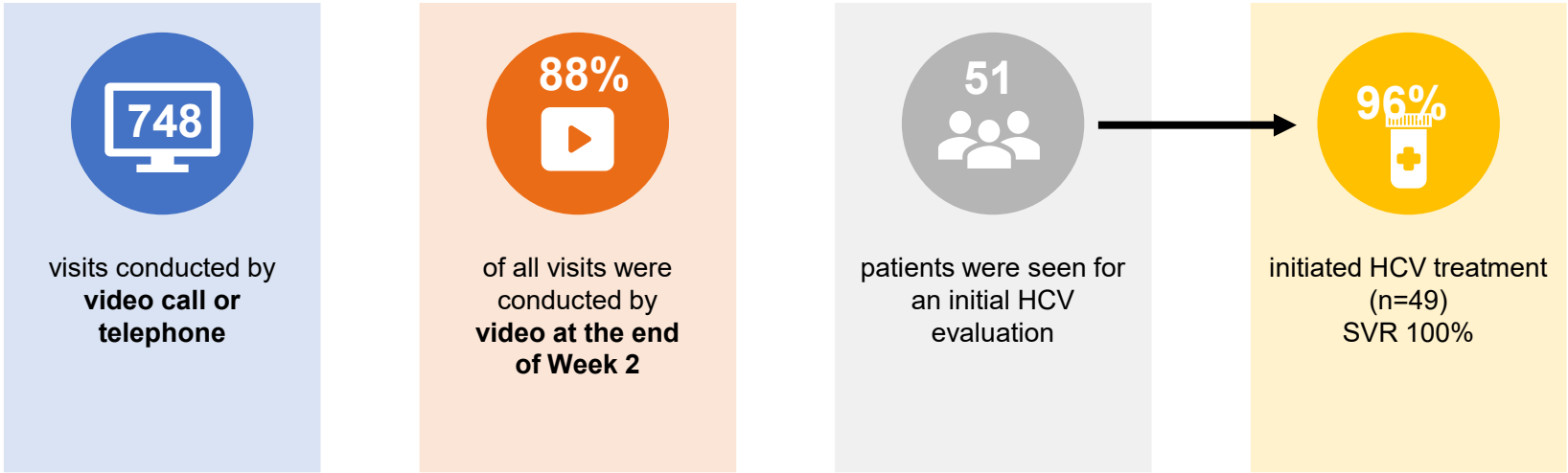
- PWUD had high rates of SVR (94%), high rates of adherence (91%) to HCV treatment, low rates of reinfection (2/1000 PY = 1.4%)
- Adherence and SVR rates were similar with 8- and 12-week therapies
- 8000 visits annually, 80% show rate and 85% rate of retention in care, 100% uptake in OAT initiation

A colocalised, hybrid model of care is an effective and flexible strategy, helping to increase HCV screening and treatment uptake among people with addiction disorders

VARIABLE ADHERENCE TO HCV TREATMENT AMONG PEOPLE WHO INJECT DRUGS TREATED WITH 8 VERSUS 12 WEEKS OF ANTIVIRAL THERAPY RESULTED IN HIGH RATES OF SVR12 AND REINFECTION RATE WAS LOW, The Liver Meeting American Association For The Study Of Liver Disease, Washington, DC, 2022. Abstract # 38479

La Bodega Telemedicine Outcomes

Telemedicine among PWUD in response to COVID-19, March 2020 – June 2020



Benefits

Facilitates linkage to care; flexibility; good for no-shows

Limitations

Telemedicine can slow down the HCV management cascade from linkage to treatment initiation due to **delays in obtaining lab data**

La Bodega Harm Reduction Measures

Safe Injection tool kit

- Sharps container
- Clean syringes x 10
- Sterile cookers x 3
- Clean water source
- Sterile tie downs
- BandAids
- Alcohol Prep Pad
- Safe Filter material

Harm Reduction kit

- Case Fentanyl Test Strips x 100
- Case worker / Never Use Alone contact info
- FTS x 3 & Instructions
- Safe Injection Tool Kit
- Case Narcan Nasal Spray 4mg x 12
- Sterile tie downs x 5
- Alcohol Prep Pad
- Condoms / lip balm / sanitizer
- Discreet hold all bag

- Uninterrupted MAT/MOUD/OAT
- Ongoing harm reduction education
- Overall retention in care = 90%

La Bodega – Outreach, Education and Advocacy

- HCV mini residency for Addiction Medicine Providers
- Bodega rotation part of GME curriculum for GI, ID, Addiction med fellows; IM and FM residents; med students
- Implementation of screening (and Tx in collab with family med) for all children of HCV+ moms
- Implementation of universal screening in the foster care system
- Local, state and federal advocacy efforts

Summary

- Efforts at elimination MUST address 4 pillars: screening, linkage to care, treatment initiation and harm reduction (reinfection prevention)
- Goal to hit 100% in each step of the cascade and to minimize reinfection
- HCV RNA POC approval is not enough – need plans for deployment, resource allocation, reimbursement. Still need eval for underlying liver disease.
- Screening can be improved by elimination of stand-alone antibody testing; use of mandatory reflex testing; provider incentives/disincentives; changes to reimbursement (removal of bundled billing)
- One size will not fit all for Linkage/Tx initiation; mix and match approach
- Widespread access to ham reduction measures is essential

Thank You!

- Angela
- Crystal
- Irish Phil
- Joe B
- Emily
- Scott
- Kath
- Amy
- Cellina
- Stan
- Steve-O
- Steve 2
- Andrea

Equitable Scale-up of New Interventions: Opportunities for Doxycycline as PEP Implementation

Laura Hinkle Bachmann, MD, MPH, FIDSA, FACP
Chief Medical Officer
Division of STD Prevention
National Center for HIV, Viral Hepatitis, STD and TB Prevention

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

April 18, 2023

Doxycycline as PEP – Similarity and differences to HIV PrEP roll-out

Similarities

- Populations
- Overlap in provider population prescribing intervention
- Concerns among providers and consumers related to potential harms (i.e. AMR) that could impede implementation
- Infrastructure to provide continuity care needed
- Can be offered in context of a comprehensive sexual health approach

Differences

- Doxycycline is well established antimicrobial with long history of use for multiple purposes
- Doxycycline relatively inexpensive
- Safety labs not needed or at least not as frequently
- Medication administration dependent on sexual behavior (i.e. not necessarily daily)

Barriers – Individual Level

- **Knowledge/awareness of intervention**
  - How to disseminate information to populations that would benefit most
- **Psychosocial**
  - Stigma
  - Non-disclosure of sexual orientation/same-sex behavior to providers
  - Medical mistrust – Of health care system, providers, public health officials, pharmaceutical industry, etc
  - Perceived racism
- **Concern about side effects**
  - AMR
- **Access**
  - Structural – clinic location, hours available
  - Financial – co-pay/out-of-pocket costs

Solutions – Individual Level

- **Knowledge/awareness of intervention**
  - Engage community to advise in developing materials about doxycycline as PEP, dissemination strategy
- **Psychosocial**
  - Explore non-traditional settings for doxycycline as PEP implementation
  - Work with communities to identify “safe” spaces for sexual health care
  - Leave determination of appropriateness of doxycycline as PEP to providers (i.e. don’t try to force disclosure of sexual behavior if patient not comfortable)
  - Examine ways to understand and address/reduce medical mistrust
- **Concern about side effects**
  - Provide balanced counseling of benefits/risks
- **Access**
  - Structural – Implement evening and weekend hours when possible; Explore mobile clinics, telehealth, etc
  - Financial – Employ peer navigators

Barrier and Solutions – Provider Level

Barriers

- **Lack of knowledge**
  - About doxycycline as PEP intervention
  - Culturally competent care
- **Bias**
  - Focus on “high-risk” persons
  - Concern about unintended consequences of doxycycline as PEP
- **Stigma**
  - Lack of comfort with sexual history taking
  - Stereotyping

Solutions

- Provide balanced training on doxycycline as PEP intervention – what is known, what is unknown
- Flip the conversation from one about “high-risk” behaviors to one about sexual health concerns and sexual health goals = sexual health promotion
- Train providers to ask ALL patients about sexual orientation and care, routinize sexual health and make sexual health approach standard of care
- Involvement of consumers in development of provider training materials

Barrier and Solutions – Systems Level

Barriers

- Lack of clinics fluent in culturally competent care
- Need for clinical spaces appealing to MSM who are not openly gay or bisexual
- Anti-gay policies
- Lack of Medicaid expansion

Solutions**

- Expand numbers of clinics providing culturally competent sexual health services
- Support creative approaches to sexual health care delivery
- Broaden conceptual framework of space as a modifiable driver of intersectional stigma
- Educate the public and policy makers

**Solutions will vary depending on local resources (ie. Rural/frontier locations may require different approaches)

Application of lessons learned from HIV PrEP implementation to doxycycline as PEP roll-out:

- **Community engagement**
  - Identify leaders and influencers to help develop outreach strategy and content
- **Provider outreach**
  - National Network of STD Clinical Prevention Training Centers
  - AIDS Education and Training Centers
  - Sexual Health Coalition
  - Professional medical organizations
  - Medical and other health professions schools
  - Other partners (NCSD, NACCHO, NASTAD, etc)
- **Establish health equity measures PRIOR TO intervention roll-out**
  - Provide technical assistance to jurisdictions to enhance monitoring of equitable roll-out at local level

Questions?