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
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

**Lifetime Risk of HIV Diagnosis among MSM by Race/Ethnicity**

- **African American MSM**: 1 in 2
- **Hispanic MSM**: 1 in 4
- **White MSM**: 1 in 11

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

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

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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

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
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)

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”
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

**Guide to the Doctor Hierarchy**

- **Medical Student**: Doctor in the final year of medical school.
- **Resident**: (Physician pursuing 2-7 years of specialized training)
- **Fellow**: (Physician pursuing post-residency training)
- **Attending**: (Trained physician practicing in their specialty)

**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

Schools for medicine, nursing, physician assistant, pharmacy
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
Meet people where they’re at

On the streets

Harm reduction programs

Jails, prisons

Community organizations

Youth programs

Pharmacies

TelePrEP

News.Miami.edu, PPPonline.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)
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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Columbia University Irving Medical Center

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April 18, 2023
Nothing to disclose
New HIV treatment shot given only 'game changer'
The Food and Drug Administration has approved S suppress HIV for patients who suffered drug resista
Dec 30, 2022

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

‘Revolutionary’ HIV prevention jab set to expand choices for consumers
By Andrew Green // 01 March 2023

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?

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:
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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 and Brandon D.L. MARSHALL, PhD1

THE LANCET
HIV

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 • Check for updates
Innovations in HIV treatment lead to disparities


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

PrEP Use

Incident HIV infections

- Black
- Hispanic
- White

CDC, 2022
A New Science of Impact: The Revolution?

- A combination of interventions to address multiple challenges (structural, social, and behavioral)
- The interventions are tested together as a package and are intended to be synergistic.
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.

... And where are we?
Current Landscape of LAI ARVs
Limited Uptake of Injectable PrEP

In September 2022, 186,367 persons were prescribed PrEP

<table>
<thead>
<tr>
<th>PrEP Formulation</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic FTC/TDF</td>
<td>93,808</td>
<td>50.3%</td>
</tr>
<tr>
<td>FTC/TAF</td>
<td>84,141</td>
<td>45.1%</td>
</tr>
<tr>
<td>Brand FTC/TDF</td>
<td>7,065</td>
<td>3.8%</td>
</tr>
<tr>
<td>Cab-LA</td>
<td>1,353</td>
<td>.5%</td>
</tr>
</tbody>
</table>

From January-August 2022:
- 1951 persons had cab-LA prescriptions filled
- 313 (16%) did not receive a second dose one month later

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 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

- **West**: 7 (18%)
- **Mid-West**: 4 (11%)
- **Northeast**: 10 (26%)
- **Southeast**: 8 (21%)
- **Southwest**: 9 (24%)
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.

Number of people on ARV treatment:
- Southeast ASO: 5768
- Northeast AMC: 2729
- Southeast DOH: 1577
- Southeast FQHC: 369
- Northeast DOC: 360
- Southwest ASO: 313
- Midwest Hospital: 207
- Southwest ASO: 74

- Number on LAI ARV 01/2023
- Number on LAI ARV 03/2023
- Number waiting to start LAI ARV 03/2023
- 12-month LAI ARV target
Outer Setting
- Insurance coverage
- Classification of benefit
- Licensing

Inner Setting
- Staffing
- Clinic flow
- Protocols
- Wrap around services

Individual
- Product-specific education
- Modality-specific mistrust
- Experienced stigma
- Life (job, childcare, transport)

Intervention Characteristics
- Narrow indication
- High cost
- Complex
- Painful

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
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

- 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
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?

- 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

ALAI UP Clinical Demonstration Sites
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La Bodega: A Co-Localized Approach to HCV Elimination

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Jacobs School of Medicine
University at Buffalo
Medical Director, Hepatology
Erie County Medical Center
Disclosures

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Consulting: Abbvie, Gilead, Antios, Intercept, Eisai
March 9, 2023

A National Hepatitis C Elimination Program in the United States
A Historic Opportunity

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

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.
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?

Simplified testing, diagnosis and treatment

Non-specialist providers to manage HCV

Decentralized care in the community

Increased rates of screening, linkage and Tx starts

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

- Screening
- Linkage
- Tx Initiation
- Harm Reduction

Mix and match
One Size Doesn’t Fit All

Underserved patients
- People who use drugs
- Justice involved
- Unstably housed
- Migrants/Indigenous

People who use drugs
- Justice involved
- Unstably housed
- Migrants/Indigenous
Mix-and-Match Approach: Settings, Services, Providers

<table>
<thead>
<tr>
<th>Settings</th>
<th>Services</th>
<th>Providers</th>
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</thead>
<tbody>
<tr>
<td>Sexual health clinics</td>
<td>Screening, Confirmed viral load, Treatment, Follow-up</td>
<td>• Other specialists</td>
</tr>
<tr>
<td>NSP services</td>
<td></td>
<td>• Primary care providers</td>
</tr>
<tr>
<td>Substance use clinics</td>
<td></td>
<td>• Addiction medicine providers</td>
</tr>
<tr>
<td>Primary healthcare/GPs</td>
<td></td>
<td>• Nurse Practitioners, Physician Assistants, Pharmacists</td>
</tr>
<tr>
<td>Community health centers</td>
<td></td>
<td>• Peer support workers</td>
</tr>
<tr>
<td>Prisons – State / Federal; Jail</td>
<td></td>
<td>• Others</td>
</tr>
</tbody>
</table>

- Screening
- Confirmed viral load
- Treatment
- Follow-up
Clinical Models to Improve Linkages to HCV/Addiction Care and Treatment Uptake

<table>
<thead>
<tr>
<th>Conventional referral</th>
<th>Telemedicine</th>
<th>Colocalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>• System is difficult to navigate for many</td>
<td>• Useful to deliver services to any setting (prison, rural, substance abuse clinics)</td>
<td>• One-stop shopping</td>
</tr>
<tr>
<td>• Transportation</td>
<td>• Provide specialty care where not otherwise available</td>
<td>• Multiple services offered in one location</td>
</tr>
<tr>
<td>• Need a multidisciplinary approach</td>
<td>• Supportive data in both addiction and HCV settings</td>
<td>• Minimizes loss to follow-up</td>
</tr>
<tr>
<td>• Utilization of case managers</td>
<td>• Slows cascade</td>
<td>• Streamlines care</td>
</tr>
<tr>
<td>• Peer navigators</td>
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</tbody>
</table>
La Bodega

- Conventional Hepatology
- Conventional Addiction Medicine
- Combined Hep/Addiction
La Bodega Buffalo, NY – Modified rapid start/test and treat model

Pre-Hub Sites

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

Hub - La Bodega

- 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

SVR

Minimale monitoring
No on Tx labs
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)

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Full adherence</th>
<th>Variable adherence</th>
<th>Treatment failure</th>
<th>SVR</th>
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</thead>
<tbody>
<tr>
<td><strong>8-weeks</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Glecaprevir/pibrentasvir ($n=403$)</td>
<td>423 (90.4%)</td>
<td>45 (9.6%)</td>
<td>28 (6.0%)</td>
<td>440 (94.0%)</td>
</tr>
<tr>
<td>Sofosbuvir/ledipasvir ($n=65$)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>12-weeks</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elbasvir/grazoprevir ($n=83$)</td>
<td>607 (91.3%)</td>
<td>58 (8.7%)</td>
<td>40 (6.0%)</td>
<td>625 (94.0%)</td>
</tr>
<tr>
<td>Glecaprevir/pibrentasvir ($n=52$)</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Sofosbuvir/ledipasvir ($n=189$)</td>
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<td></td>
</tr>
<tr>
<td>Sofosbuvir/velpatasvir ($n=301$)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Sofosbuvir/velpatasvir/voxilaprevir ($n=40$)</td>
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<td><strong>P=0.75</strong></td>
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<td>63</td>
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<tr>
<td><strong>P=0.90</strong></td>
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- 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


- 748 visits conducted by video call or telephone
- 88% of all visits were conducted by video at the end of Week 2
- 51 patients were seen for an initial HCV evaluation
- 96% initiated HCV treatment (n=49) SVR 100%

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

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

*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
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 harm 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
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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?