

Monkeypox Vaccination, New Types of PrEP, Injectable HIV Care: Emerging Topics in LGBTQ Care

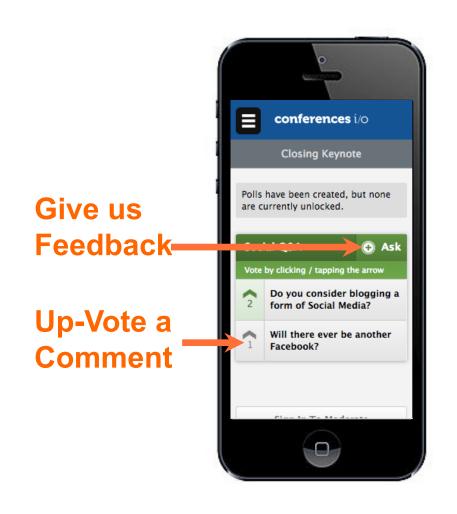
Wednesday, November 16 | 8:15 – 9:45am

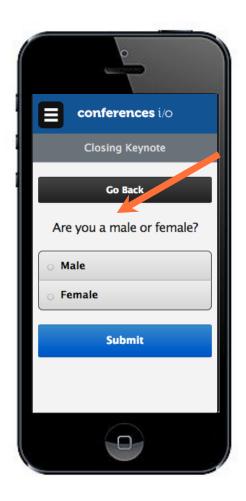
Atlantic 5-6, The Westin Fort Lauderdale Hotel

Fort Lauderdale, FL



Vote / Give Feedback/ Respond to Polls

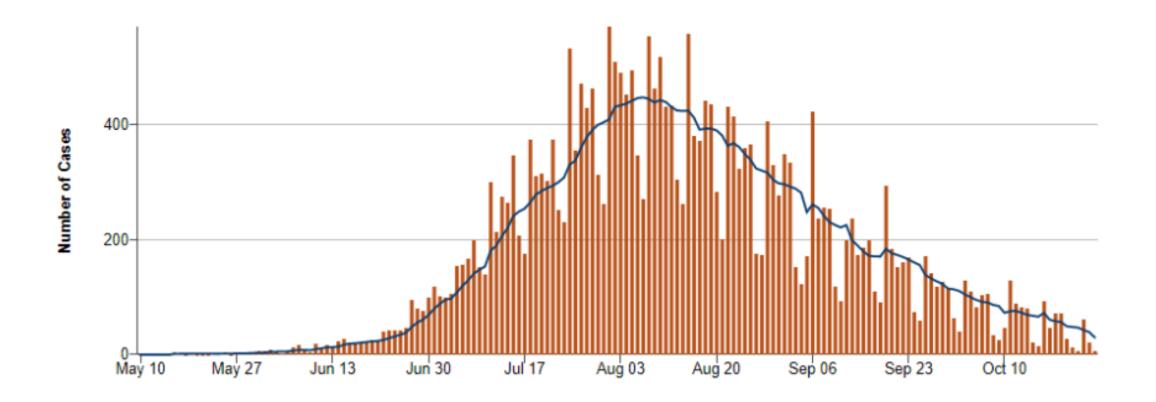




Click on question and then Respond to Polls when they appear

Monkeypox Updates

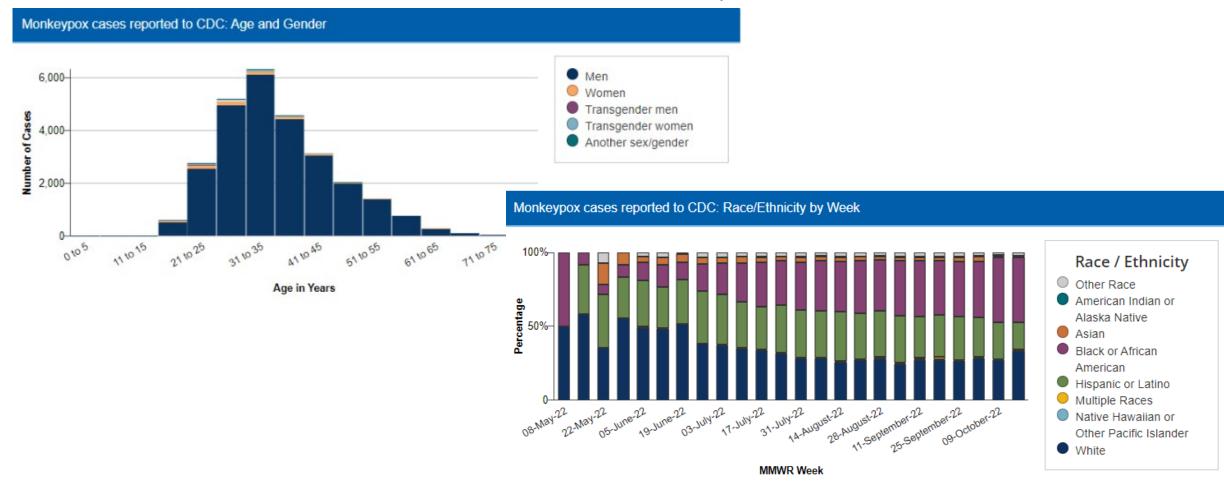
Daily Monkeypox Cases Reported and 7-day daily average





Epidemic Demographics

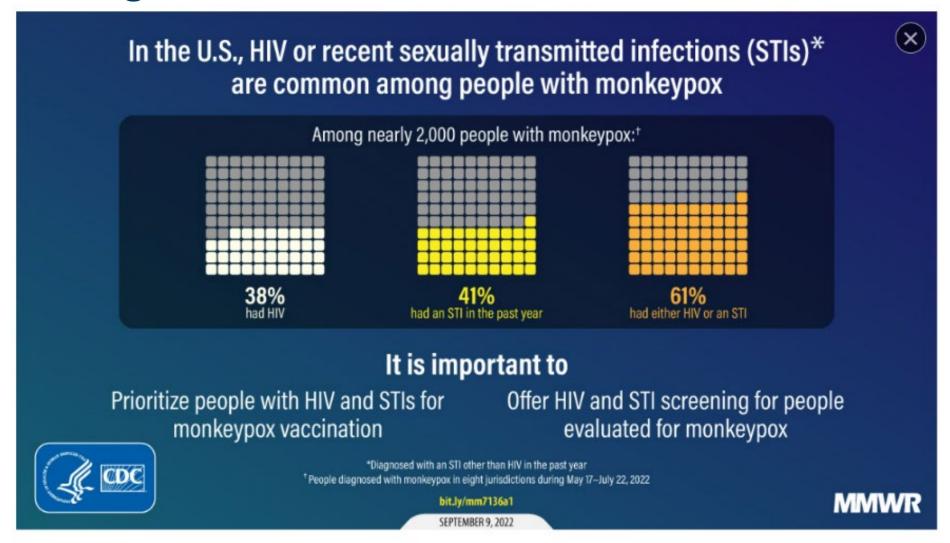
Data as of October 26, 2022







CDC Message

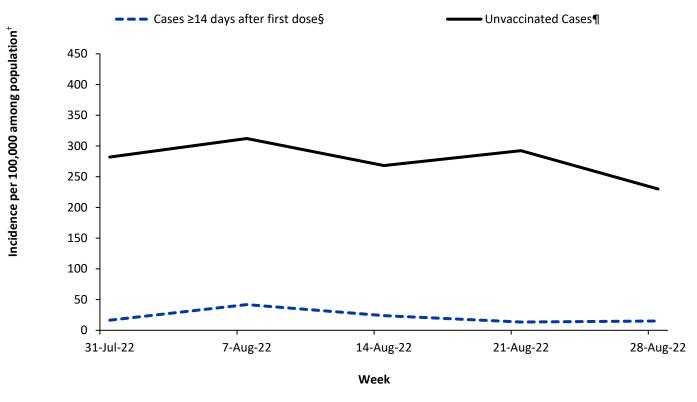


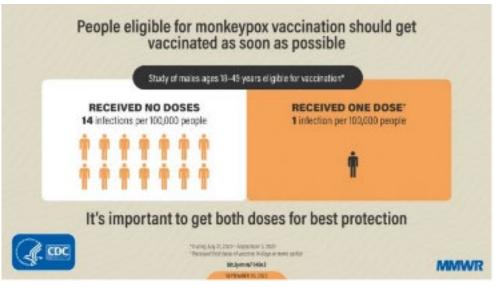




Rates of Monkeypox Cases* by Vaccination Status

July 31, 2022 – September 3, 2022







HIV Prevention

PrEP: Pre-exposure Prophylaxis for HIV Prevention

- The use of anti-retroviral (ARV) medications to reduce the risk of infection in people who are HIV-negative, before exposure
- It can be oral, injectable, intravaginal, rectal...
- Available regimens:
 - Tenofovir disoproxil fumarate (TDF) 300mg/emtricitabine (FTC) 200mg PO daily or on-demand (usually in a fixed-dose combination tablet) (TDF/FTC)
 - Tenofovir alafenamide fumarate (TAF) 25mg/emtricitabine (FTC) 200mg PO daily* (usually in a fixed-dose combination tablet) (TAF/FTC)
 - Cabotegravir 30mg PO daily x 5 weeks, followed by 600mg IM q4wks x 2, followed by 600mg IM q8wks





Old Guidance

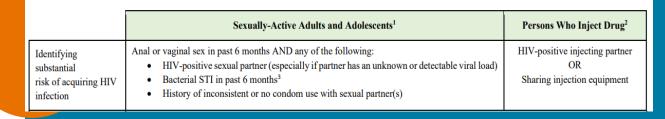
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New Guidance

Table 1: Summary of Guidance for PrEP Use

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

STI: sexually transmitted infection





PrEP 2-1-1

- CDC currently only recommends daily PrEP
- Event-driven PrEP (ED-PrEP) is an option for some patients (off-label)
 - MSM
 - Sexual transmission
- Also called PrEP On-demand, intermittent PrEP, or 2 1 1 PrEP

For whom is ED-PrEP appropriate?	For whom is ED-PrEP NOT appropriate?		
a man who has sex with another man:	cisgender women or transgender women		
 who would find ED-PrEP more effective and convenient 	• transgender men having vaginal/frontal sex		
 who has infrequent sex (for example, sex less than 2 times per week on average) 	 men having vaginal or anal sex with women 		
2 times per week on average)	 people with chronic hepatitis B infection. 		
 who is able to plan for sex at least 2 hours in advance, or who can delay sex for at least 2 hours 			

Injectable PrEP Apretude (Cabotegravir)

PROS, although not many, are really important

NO PILLS, increased adherence and protection

from HIV

Decreased disclosure concerns

Decreased oral medication toxicities including bone, renal and certain metabolic concerns

***MOST IMPORTANT, increases access, if we can get it to people who need it





Injectable PrEP Apretude (Cabotegravir)

- Expensive (compared to TDF/FTC)
- Injection Site Reactions
- More Frequent Clinic Visits
- Medication "tail" after discontinuation
- Cannot administer if history of silicone or fillers in buttocks
- No protection against Hepatitis B
- Delayed HIV Ag/Ab conversion
- Requires 4th gen and viral load every 2 months
- Access issues at every level





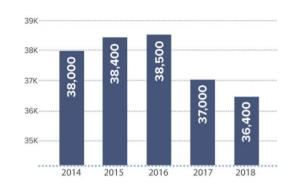
PrEP in the US

Challenges with Uptake and Persistence

A little about HIV in the US*...

~37,000 annual new cases 2014 - 2018

> 60% among Black and Latinx





1 in 2 lifetime HIV risk Black MSM

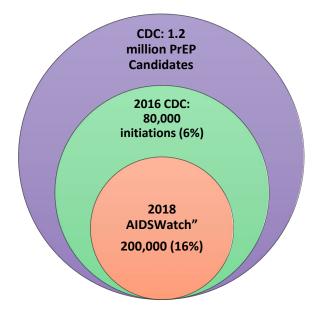


1 in 4 lifetime HIV risk Latinx MSM



50% of New HIV infections are transmitted by individuals who are unaware of their HIV status

PrEP uptake in US



- 1% and 3% of Black and Latinx candidates
- Additional challenges with persistence



1 in 7 individuals living with HIV are not aware of their Serostatus









PrEP uptake in US

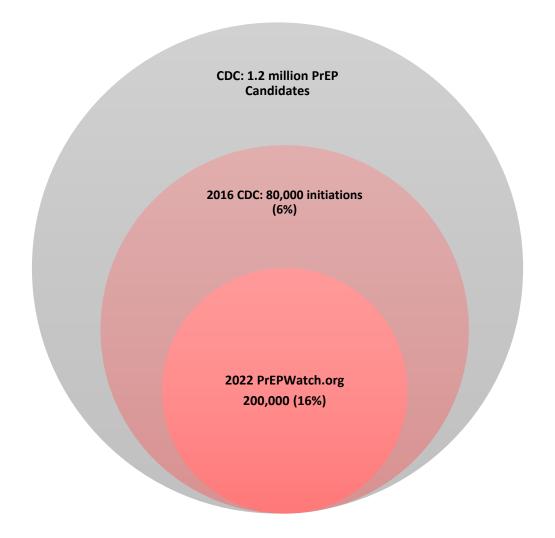


TABLE 2. Estimated percentages and numbers of adults with indications for preexposure prophylaxis (PrEP), by transmission risk group —
United States, 2015

Transmission risk group	% with PrEP indications*	Estimated no.	(95% CI)
Men who have sex with men, aged 18–59 yrs^{\dagger}	24.7	492,000	(212,000-772,000)
Adults who inject drugs, aged ≥18 yrs§	18.5	115,000	(45,000-185,000)
Heterosexually active adults, aged 18–59 yrs¶	0.4	624,000	(404,000-846,000)
Men**	0.2	157,000	(62,000-252,000)
Women	0.6	468,000	(274,000-662,000)
Total	_	1,232,000	(661,000-1,803,000)

TABLE 1. Annual number of persons aged ≥16 years prescribed HIV preexposure prophylaxis, by selected characteristics — IQVIA* Longitudinal Prescription Database, United States, 2014–2016

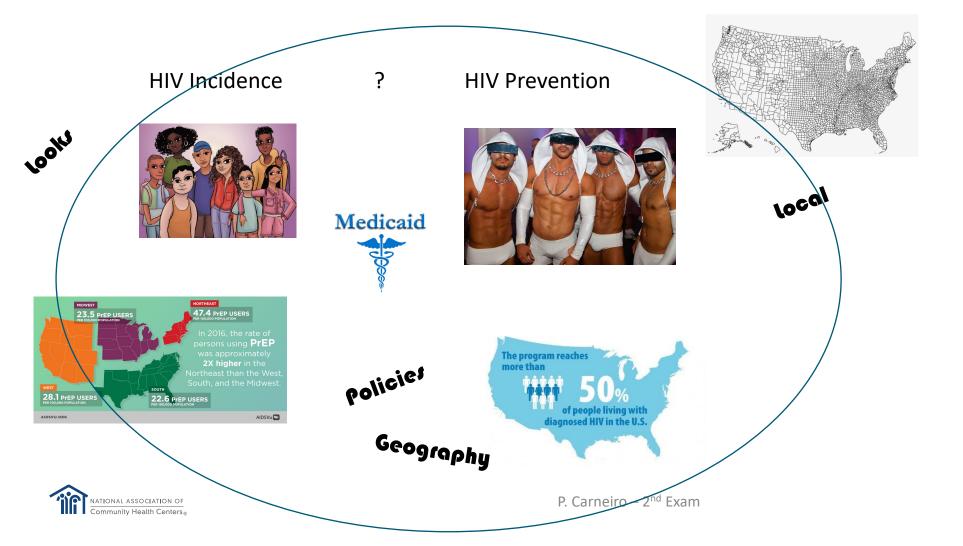
	no (%)			
Characteristic	2014	2015	2016	
Total	13,748 (100)	38,879 (100)	78,360 (100)	
Sex				
Male	12,624 (91.8)	36,845 (94.8)	74,639 (95.3)	
Female	1,110 (8.1)	2,012 (5.2)	3,678 (4.7)	
Unknown/Missing	14 (0.1)	22 (0.1)	43 (0.1)	
Age group (yrs)				
16-17	22 (0.2)	29 (0.1)	64 (0.1)	
18-24	953 (6.9)	3,223 (8.3)	7,382 (9.4)	
25-34	4,687 (34.1)	14,766 (38.0)	30,959 (39.5)	
35-44	3,825 (27.8)	10,156 (26.1)	19,989 (25.5)	
45-54	2,845 (20.7)	7,564 (19.5)	13,913 (17.8)	
55-64	1,080 (7.9)	2,543 (6.5)	5,046 (6.4)	
≥65	336 (2.4)	598 (1.5)	1,007 (1.3)	
Census region				
Northeast	3,411 (24.8)	10,110 (26.0)	20,909 (26.7)	
Midwest	2,330 (17.0)	6,350 (16.3)	12,748 (16.3)	
South	3,562 (25.9)	10,223 (26.3)	21,335 (27.2)	
West	4,420 (32.2)	12,169 (31.3)	23,306 (29.7)	
Other [†]	22 (0.2)	22 (0.1)	55 (0.1)	
Unknown/Missing	3 (0.0)	5 (0.0)	7 (0.0)	
Payer type§				
Medicaid/CHIP	1,430 (10.4)	4,547 (11.7)	9,542 (12.2)	
Medicare	488 (3.6)	968 (2.5)	1,832 (2.3)	
Commercial	9,980 (72.6)	31,993 (82.3)	63,430 (81.0)	
Cash	163 (1.2)	262 (0.7)	732 (0.9)	
Other [¶]	356 (2.6)	1,080 (2.8)	2,705 (3.5)	
Unknown/Missing	1,331 (9.7)	29 (0.1)	119 (0.2)	







HIV Prevention individuals and Structural Issues





Challenges with PrEP uptake

Initiation

Who is a good candidate? How to talk to them? Getting the medication at pharmacy



How well are patients doing? What modality of PrEP is best? Side effects concerns Misconceptions

Persistence

How to stay engaged? Long term care plan 3-month f/u forever?

- Psychosocial factors
 - Initiative
 - Stigma
 - Shame
- Primary Care factors
 - Lack of time
 - Provider discomfort
 - Unawareness
 - Lack of competency
 - "purview paradox"





How is PrEP prescribed?

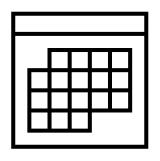
Only Medical Providers can prescribe daily oral PrEP

New PrEP guidelines add more options.... And more are coming





Long Acting injectable



Monthly PrEP







Together 5,000

- Internet-based national cohort of cisgender men and transgender people who have sex with men
 - All participants met clinical guideline criteria for PrEP
 - Recently diagnosed with an STI
 - Recently used PEP
 - Had condomless anal sex with a man
 - Share needles or used Crystal meth recently
 - Our analysis sample *n*=6264

Who spoke to the provider about PrEP

Communication with a medical provider about PrEP

- Have you ever spoken to a medical provider about starting PrEP?
 - No, I have not ever spoken to a provider about starting PrEP
 - Yes, and we both decided it was a good option for me and I should start PrEP
 - Yes, and we both decided it might be a good option but to wait before beginning PrEP
 - Yes, and we both decided it was not a good option for me
 - Yes, and the provider was not comfortable prescribing PrEP for me
 - Yes, and the provider thought it was a good option, but I chose not to do it

Who answered each of the potential answers





Who spoke to the provider about PrEP?

• Only **31%**

Moral of the story:

Less than half of one third (~12%) of respondents may go into taking PrEP soon

How were their answers?

- Yes, and we both decided it was a good option for me and I should start PrEP (45%)
- Yes, and we both decided it might be a good option but to wait before beginning PrEP (16%)
- Yes, and we both decided it was not a goof option for me (7%)
- Yes, and the provider was not comfortable prescribing PrEP for me (15%)
- Yes, and the provider thought it was a good option, but I chose not to do it (17%)





Structural Barriers to HIV Prevention and (Some) Solutions

Challenges implementing PrEP services

- Low PrEP awareness by prescriber and potential PrEP users
- Misperceptions about and around PrEP use
- Systems/programs/work-flows that identify people at risk for HIV are lacking
- Prescribing PrEP may seem complicated
- (Cost)
- HIV/PrEP Stigma





Low PrEP awareness

- Medical provider gaps (Petroll, 2017):
 - 76% of PCPs had heard about it
 - 28% felt familiar with prescribing it
 - 17% had prescribed it
- Community awareness
 - 64% of MSM had heard about it (Iniesta, 2018)
 - <10% of women at risk for HIV knew about it (Auerbach, 2015)
 - 96% of MSM and TGW C.M. users heard about, 3.3% had ever used PrEP (McMahan, 2017)
 - 28% of urban AYA knew about it (Caves, 2019)
 - 3-65% of TGW had knowledge of PrEP (Sevelius, 2015. Wood, 2018)
 - 68% of 13-18y.o. YMSM had heard of PrEP (Gordian-Arroyo, 2020)





Misperceptions about PrEP

- Among medical providers (Petroll, 2017)
 - It results in risk compensation
 - People should use condoms instead of PrEP
 - It will increase resistance
 - PrEP users are not likely to adhere
- Among patients
 - It is not effective
 - Interferes with hormones (GA-HT)
 - Bad side effects





Identifying those at risk for HIV – Reframing it

WE NEED TO TALK ABOUT SEX AND DRUGS!

- Validating and encouraging, not judgmental
- Less about eligibility criteria and more about the desire to remain healthy and not worry about HIV
- Less about number of partners and more about sexual health ideals
- Less about "high-risk behaviors" and more about community-level prevalence and social contexts





Not all HIV prevention is created equal

SOCIALLY ACCEPTABLE AND CONVENTIONAL HIV PREVENTION:

- Limiting sexual activity
- Limiting number of sexual partners
- Consistent condom use

LESS SOCIALLY ACCEPTABLE (albeit probably more effective) HIV PREVENTION:

PrEP

There is a perception that PrEP (a highly-effective HIV prevention strategy) is an "excuse" from adherence to other HIV prevention strategies (which may be less effective)





Institutional PrEP stigma

- Language suggesting that PrEP is only for those at "very high risk" of infection
- PrEP eligibility assessments that provide mixed messages about the definition of "high-risk" behavior
 - > The man who had condomless sex once with a regular well-known male partner

Is as good a candidate for PrEP as

The man who had condomless encounters with multiple casual/anonymous partners while intoxicated with CM and sharing needles



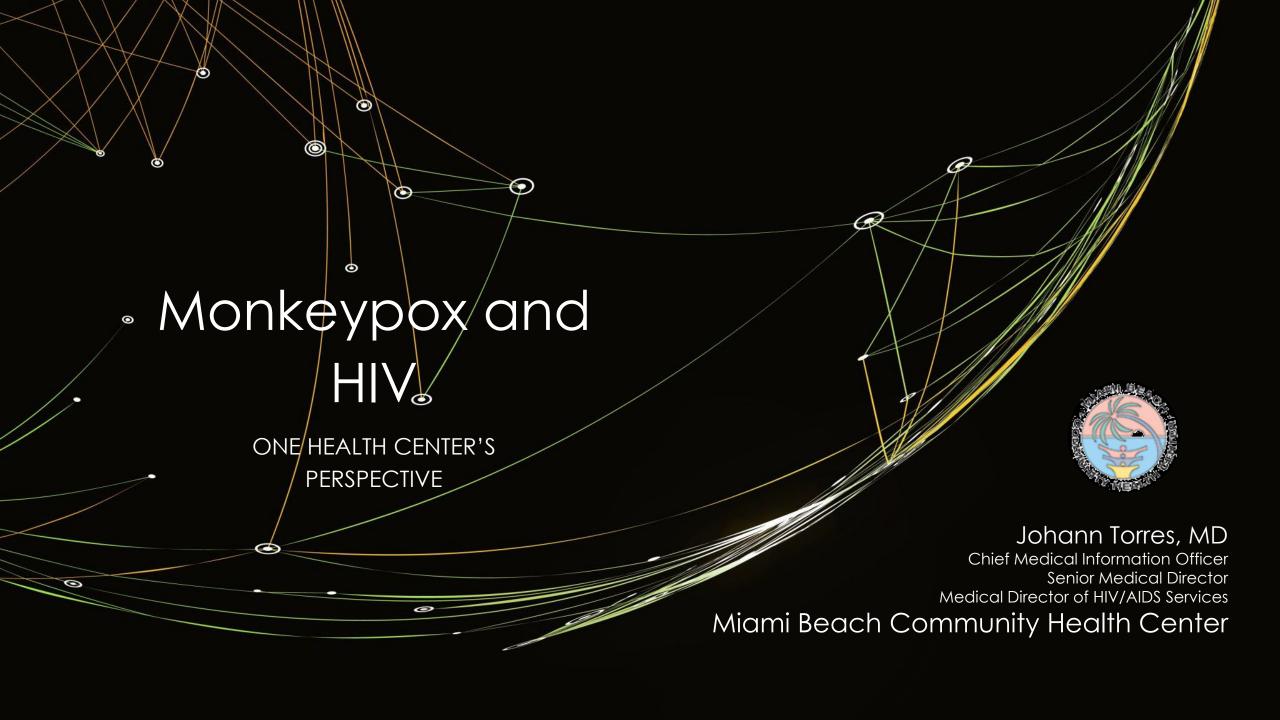


Revisit messaging

- Instead of relying on traditional risk assessments
- Ask patients about their own HIV and STI concerns: "What are your concerns about your sexual health? How much do you worry about HIV and other STIs and why?"
 - Providers will learn more about patients' true behavior, attitudes, and risk perception
 - Asking patients about their sexual goals ("What's your ideal for your own sexual health? What would you need to improve your sexual health?") helps patients feel that providers are trying to give them what they need rather than judge
 - This would also identify PrEP candidates because of future or anticipated behavior



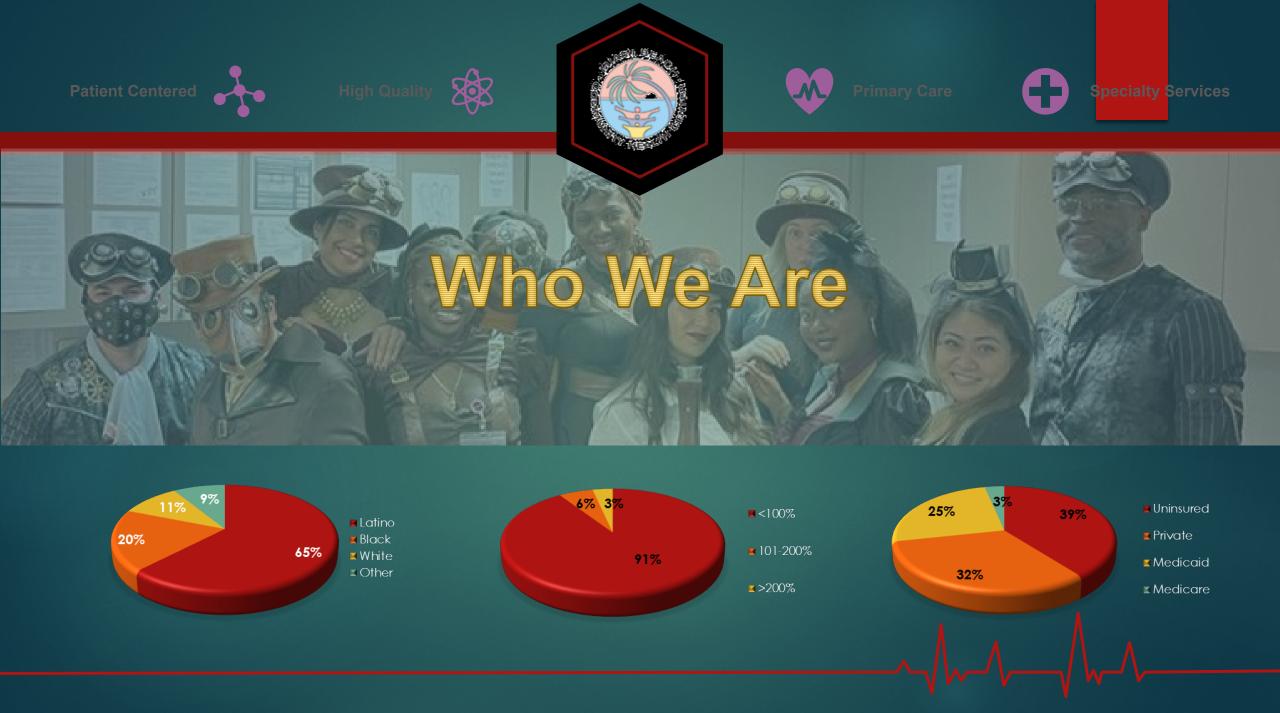


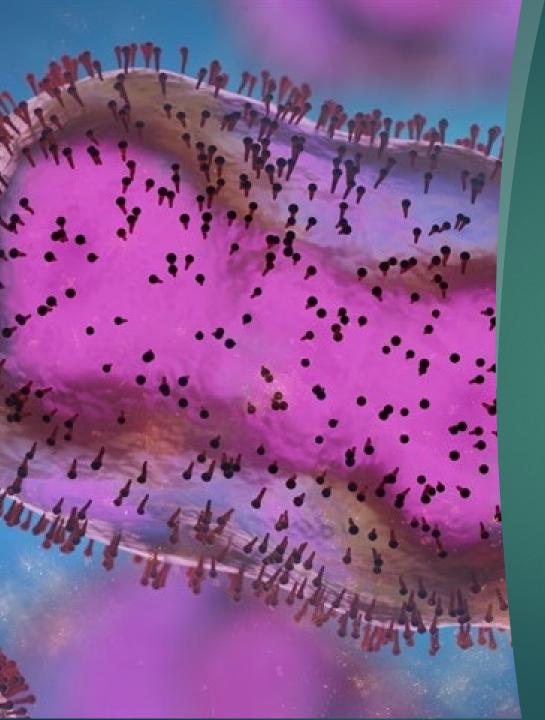


Miami Beach Community Health Center



- Serving Southeast Florida area since 1977
- 3 Physical locations (South Beach, North Beach and North Miami)
- Served 58,506 Patients in 2021 (1023 Persons with HIV)
- > 50+ Medical providers across about a dozen specialties
 - 8 HIV Providers with more in training
 - 4 Dentists, 2 Dental Hygienists
 - 1 Registered Dietitian, 1 Ryan White Nutritionist
 - 2 Clinical Psychologists
 - 2 Endocrinology Providers and 1 in training
 - 2 Optometrists
- > 400+ Employees
 - 8 Ryan White Case Managers, 3 Peer Educators
 - 10 Population Health Specialists
 - > 3 Health Promotion Navigators
 - > 1 Clinical Pharmacist, 5 Medical Preauthorization Assistants
- Joint Commission, PCMH and URAC Specialty Pharmacy Certified
- > 340B Pharmacy
- On-site laboratory (specimen collection and POC testing)
 - Dental Imaging, Retine Vue, Fibro Scan®





Monkeypox Diagnosis and Treatment Response Plan



- July 2022 First Case of Monkeypox referred to MBCHC
- Identified Treating Medical Providers at least 2 at each site
- Set aside "Isolation Rooms" where patients can be treated
- Set up a Fast Track process
- Provider and Staff Education
 - Monkeypox Education at Bimonthly Provider Meeting
 - CDC and FDOH Treatment Protocols reviewed with treating staff
- Total of 28 Confirmed Cases since July (4 cases in November)
 - Tecovirmat antiviral therapy
 - ► EA-IND Exapanded Acccess of an Investigational New Drug ("Compassionate Use")
 - Strategic National Stockpile
 - Coordinated via FDOH (Miami Dade County ADAP pharmacy)

Monkeypox Vaccine

- ► Late July 200 doses distributed from FDOH in coordination with MDC Ryan White Program
- August 400 vials from HRSA and 200 more vials from FDOH
- ▶ 431 1st Doses and 333 2nd Doses (764 total)
- Initially Campaigned using our Population Health Team to our patients at risk (HIV positive, MSM, Staff)
- Currently open to public
- Lessons and processes from COVID vaccine roll out



State of Florida's EHE (Ending the HIV Epidemic Plan) MBCHC's Implementation

Implement Routine Screening

Provide Rapid Access Ensure Retention-In-Care

Improve and Promote Medical Prevention

Increase HIV Awareness

Screening Policy

- •Create a Culture of Routine Screening
- Opt-Out
- Standing Order
- •POC Rapid Testing via RW Test Counsellors
- Mail Out OraQuick kits

Data-Driven

UDS Data to Create Registry

- •EHR Reminders
- Provider Report Cards
- •Frequent and Targeted Re-Education
- •Population Health Team to Close Gaps

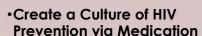
Rapid Access

- Monitor HIV Test Results Through Reporting
- •Increase HIV Provider Base
- Provide Immediate Access to HIV Care via Telemedicine or Warm Handoff
- Pharmacy Maintains Ready-To-Go 30-Day Supplies of Common RA Medications (e.g. Biktarvy)
- Ryan White Case Managers
 On-Site for Expedited
 Registration

Retention-In-Care

- Maintain a Registry
- Weekly Meetings to Monitor and Troubleshoot Progress
- Use both RW Case
 Management and
 Population Health Team

PrEP



- Provider Education (and Re-Education
- Multidisciplinary Approach (e.g. Behavioral Health, OB-Gyn)
- •Data-Driven **Proactive** Approach
- •PrEP Protocol
- •Same-Day PrEP
- •POC Rapid HIV
- Pharmacy Maintains Readyto-Go 7-Day Supplies
- •Health Promotion Navigators

nPEP

- •Referred to Health Promotion Navigators
- Same Day or Next Day Appointments with HIV Providers
- •nPEP Protocol

UNDER CONSTRUCTION

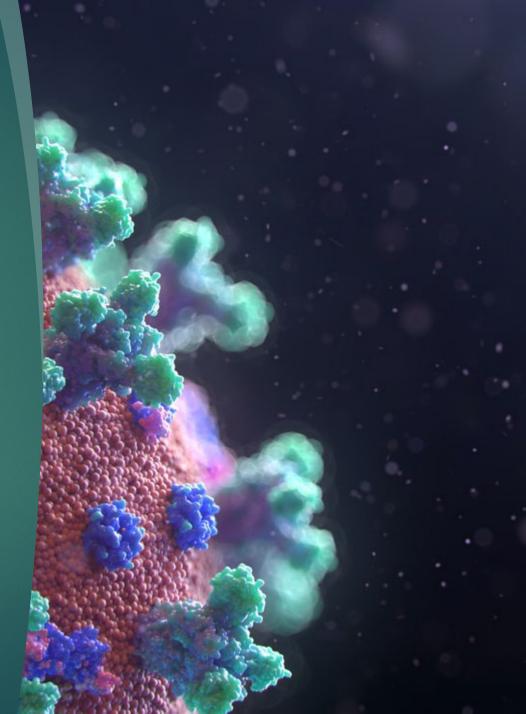




PrEP: Lemonade from Lemons A Story of Telehealth

- ► The MBCHC Telehealth Story: Origins
- ▶ 2020 Pandemic Shut Down Lessons
- Health Promotion Navigators as Care Coordinators
- Leverage Telehealth for to minimize barriers to care
- Utilize Commercial Lab Patient Service Centers
- Delivery Service for Medications
- (Future: Home Self-Testing Kits)







PrEP: Importance of 340B

- 340 Savings could be redirected towards:
 - Cost of lab work and follow up visits
 - ► Health Navigator and Population Health Teams
 - ► Clinical Analytics Time to find new patients
- Challenges
 - Truvada (tenofovir disproxil fumarate) went generic in March 2021
 - Descovy (tenofovir alafenamide)
 - ▶ Not approved on all plans without prior authorization
 - ▶ Occasionally managed by PBM's
 - Apreture (cabotegravir)
 - ▶ Early (just became avaible Feb 14, 2022)
 - Special issues with an injectible

PrEP: Apretude Revolutionary New Tool

- Bi-monthly injection
 - ▶ Pro: Convenience, Discretion, No Pills
 - Cons: Must come to office, Injection, Cost (staff, supplies, medication)
- Superior Efficacy compared to TDF
 - ► HPTN 083: MSM/TGW 66% Risk Reduction
 - ► HPTN 084: CGW 90% Risk Reduction
- Why is this revolutionary
 - PrEP is like birth control/family planning
 - Discretion
 - Reduces barriers to care



PARTING GIFTS

- ▶ No HIV Specialists, No Problem!
 - ► THE POWER OF THE HEALTH CENTER CONTROLLED NETWORK
 - ▶ HIV "Specialty" Care is the Realm of the PCP
 - ► AAHIVM Mentor Program, National HIV Curriculum
 - Take advantage of Telehealth, ECHO
- ▶ Identify a Champion(s) AND Do not be afraid to change
- Patient-Centered Care: Minimizing Barriers
- ▶ The Value of the Pilot Convincing the C-Suite
- ▶ Repetition Nurtures the Mission: "Turning the Tanker"
- Inspiration vs. Emulation

Thank You





QUESTIONS?



THANK YOU!

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