AETC AIDS Education & Training Center Program Southeast

KY AETC Kentucky AIDS Education & Training Center

What's  : HIV Clinical Science

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Faculty Disclosure

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Objectives

Upon completion of this educational activity, you will be able to:

- Discuss the latest updates on HIV prevention and treatment.
- Review long acting treatments for HIV prevention and treatment.
- State the latest approaches to managing HIV and co-infections.
- Describe the current context in which scaling up of HIV treatment and prevention is occurring.

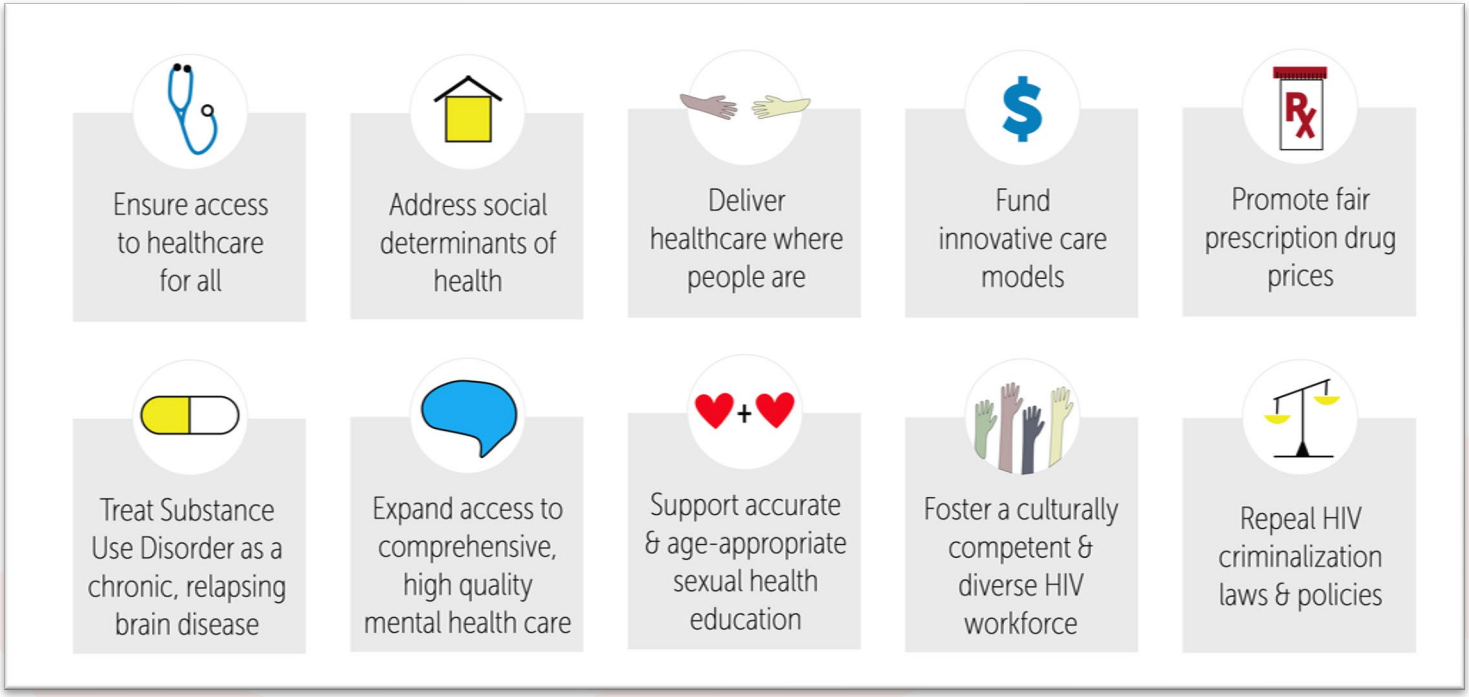
Ending the HIV Epidemic

Treat people with HIV rapidly and effectively to reach sustained viral suppression.

Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

END HIV
AS AN EPIDEMIC

PRINCIPLES FOR EXPANDING & IMPROVING
HEALTHCARE ACCESS & DELIVERY



Person et al. Principles for Ending HIV as an Epidemic in the United States: A Policy Paper of IDSA and HIVMA. Clin Infect Dis. 2022 Aug 15:ciac626. doi: 10.1093/cid/ciac626. Epub ahead of print. PMID: 35965395.

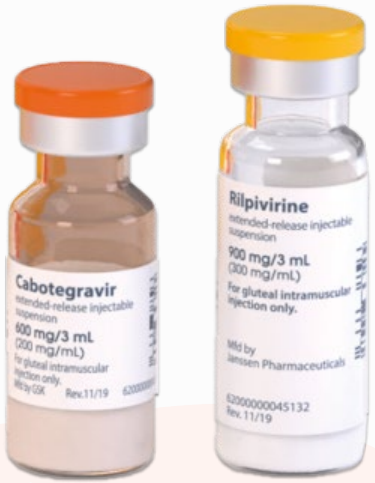
HIV Clinical Workforce Crisis

- Shortage of HIV clinicians not meeting increased patient demand.[1,2]
- Gaps worse in the South.[3]
  - 81% of counties had no HIV-experienced clinicians.
  - Rural counties generally had even fewer HIV-experienced clinicians.

1Gilman et al. HIV Clinician Workforce Study, Mathematica Policy Research, May 2013. Available at: https://www.mathematica.org/our-publications-and-findings/publications/hiv-clinician-workforce-study. Accessed 11 March 2020
2 Weiser et al. Qualifications, demographics, satisfaction, and future capacity of the HIV care provider workforce in the United States, 2013-2014. *Clin Infect Dis* 2016; 63:966–75.
3 Bono et al. HIV-experienced clinician workforce capacity: urban–rural disparities in the US South. *Clin Infect Dis* 2020.
Wendy S Armstrong, The Human Immunodeficiency Virus Workforce in Crisis: An Urgent Need to Build the Foundation Required to End the Epidemic, *Clinical Infectious Diseases*, Volume 72, Issue 9, 1 May 2021, Pages 1627–1630, https://doi.org/10.1093/cid/ciaa302

Long-Acting Injectable HIV Treatment

- Cabotegravir/Rilpivirine (CAB/RPV LA)
  - Complete injectable regimen
  - Administered every 2 months (approved Feb 2022)
    - Q 8 weeks non-inferior to Q 4 weeks[1, 2]
    - BMI ≥30 [3,4], use 2-inch needle



1 Jaeger et al. Long-acting cabotegravir and rilpivirine dosed every 2 months in adults with HIV-1 infection (ATLAS-2M), 96-week results: a randomised, multicentre, open-label, phase 3b, non-inferiority study. Lancet HIV. 2021 Nov;8(11):e679-e689. doi: 10.1016/S2352-3018(21)00185-5. Epub 2021 Oct 11. PMID: 34648734. 2 Overton. CROI 2022. Abstr 479. NCT03299049.3 Cutrell et al. Exploring predictors of HIV-1 virologic failure to long-acting cabotegravir and rilpivirine: a multivariable analysis. AIDS. 2021 Jul 15;35(9):1333-1342. doi: 10.1097/QAD.0000000000002883. PMID: 33730748; PMCID: PMC8270504. 4 Eliot. EACS 2021. Abstr BPD1/8.

Patient-Level Challenges

Ideal Candidate

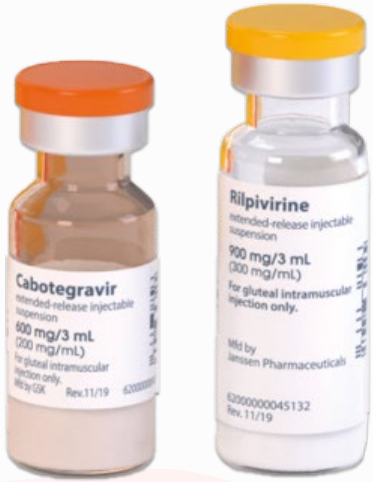
- Virologically suppressed on oral regimen
  - Pill/daily fatigue, convenience, side effects, confidentiality
- Able and willing to come in every 1-2 months to clinic
- No history of INSTI or NNRTI resistance (except 103N)
- No chronic Hepatitis B infection

Challenges

- Adherence challenges
  - Inability to take with meals; must be on PPIs
- Intolerance to any oral regimen
  - Unable to be virally suppressed
- Difficulty coming in to clinic frequently
  - Costs associated with visits
  - Housing insecurity
  - Transportation
  - Child care/ Work
- Unknown or incomplete ARV history and resistance profile
- Coverage of LAI ARV

Long-Acting Injectable HIV Treatment

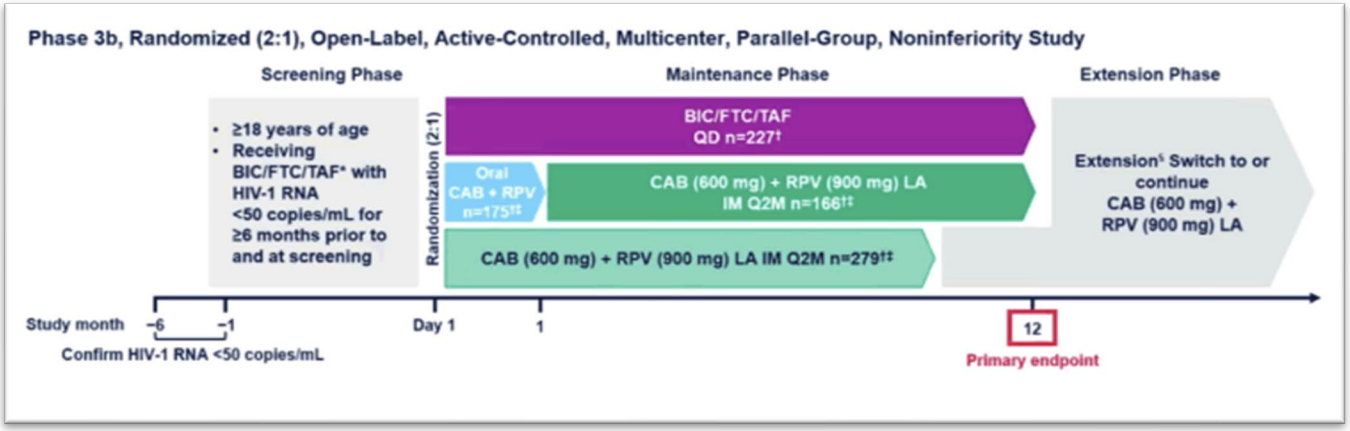
- Can initiate without oral lead-in (direct to injection)[1]
- Initiate without being virally suppressed[2,3]
- Can be self-administered by patient
  - Lateral thigh administration[4,5]; subcutaneous route[6]



1 Orkin et al. Initiation of long-acting cabotegravir plus rilpivirine as direct-to-injection or with an oral lead-in in adults with HIV-1 infection: week 124 results of the open-label phase 3 FLAIR study. Lancet HIV. 2021 Nov;8(11):e668-e678. doi: 10.1016/S2352-3018(21)00184-3. Epub 2021 Oct 14. PMID: 34656207; 2 Christopoulos et al. Demonstration Project of Long-Acting Injectable Antiretroviral Therapy for Persons With and Without Detectable HIV Viremia in an Urban HIV Clinic. Clin Infect Dis. 2022 Aug 1:ciac631. doi: 10.1093/cid/ciac631. Epub ahead of print. PMID: 35913500. 3 Gandhi. CROI 2023. Abstr 518. 4 Han K et al. *Pharmacokinetics (PK) and tolerability of cabotegravir (CAB) and rilpivirine (RPV) long-acting (LA) intramuscular (IM) injections to the vastus lateralis (lateral thigh) muscles of healthy adult participants.* 24th International AIDS Conference, Montreal, abstract EPB176/9906, 2022. 5 Felizarta. CROI 2023. Abstr 519. 6 Benn P et al. *A study evaluating the safety, tolerability, and pharmacokinetics of a high-concentration (CAB 400mg/ml) cabotegravir long-acting injectable formulation following subcutaneous and intramuscular administration in healthy adult participants.* 24th International AIDS Conference, Montreal, abstract PESUB24/6276, 2022.

SOLAR Switch Study from BIC/FTC/TAF to CAB/RPV LA

- Multicenter, randomized, open-label non inferiority phase IIIb study



- 47% of all participants at baseline had psychosocial challenges with daily oral therapy (e.g. unintentional status discovery, worry about forgetting, reminder of their status)
- CAB/RPV LA viral suppression non-inferior to BIC/FTC/TAF
  - Only 2 participants (0.4%) had virologic failure
    - Developed RPV and INSTI resistance
- No difference in safety
- Improvement in treatment satisfaction in CAB/RPV LA arm
- 90% preferred CAB/RPV LA, 5% had no preference

Ramgopal. CROI 2023. Abstr 191.

CAB/RPV LA in San Francisco's Ward 86 Safety Net Clinic

- N=133 patients with HIV
  - Initiated CAB/RPV LA between June 2021 to Nov 2022 with biweekly patient review and significant support services
  - Inclusion criteria:
    - no RPV or INSTI mutations
    - agree to come to clinic q 4 wks, provide contact info and receive outreach
    - **viral suppression (VS) not required**
  - 43% were viremic (mean VL ~4.21 log); mean CD4 215
  - 16% Black, 38% Hispanic, 14% Multiracial, 66% unstable housing/homeless
  - 33% stimulant use; 38% major mental illness
  - RESULTS at 48 weeks:
    - 74% on time injections
    - 100% of 76 patients originally suppressed maintained VS
    - 96% of 57 patients originally not VS achieved suppression by median of 33 days
      - Only 2 patients did not achieve VS <24 weeks
  - 1.5% virologic failure rate similar to 1.4% failure in clinical trials

Gandhi. CROI 2023. Abstr 518.

Lateral Thigh Injections of CAB/RPV LA: ATLAS-2M Thigh PK Substudy

- N=118 (q 4 wks n= 64; q 8 wks n= 54)
  - Switched to lateral thigh (vastus lateralis) injections for 16 weeks
    - Healthcare professionals administered
    - 1.5 inch needles used; one injection in each thigh
- Plasma concentrations of CAB/RPV no difference between gluteal vs. thigh administration
- No serious A/Es; pain most common injection site reaction
- High VS rates maintained (95.3% for q4wks; 94.4% for q8wks)
- 30% preferred thigh administration for ease of access.

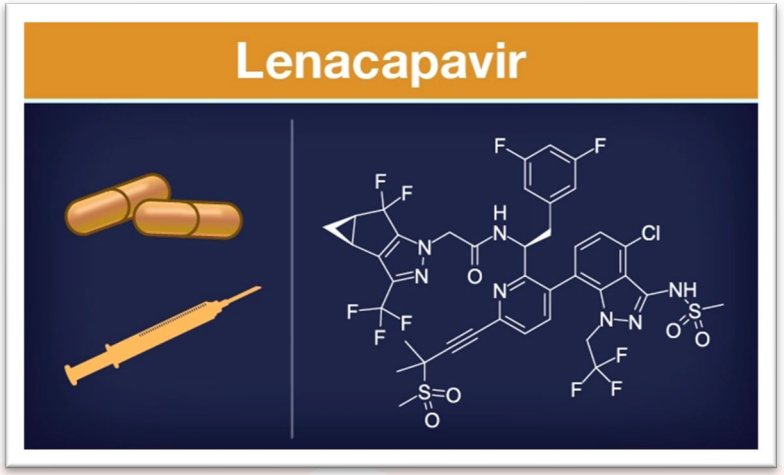
Felizarta. CROI 2023. Abstr 519.

System-Level Challenges

- Team-based approach
  - Prescribing, procuring coverage, receiving and storing med, training and administering injections
- Good communication among team and with patients
- Staff/systems for tracking appointments/reminders
- Managing missed doses/delays
  - Oral bridging
  - Dosing of injections
  - When to order resistance testing
- Innovative methods to increase access
  - Community pharmacists
  - Mobile vans

Future Long-Acting Injectable HIV Treatment

- Lenacapavir
  - Novel first-in-class Capsid Inhibitor
  - CAPELLA[1]: Treatment-experienced
  - CALIBRATE[2]: Treatment-naive
  - Q 6 months subQ (in combination with other ARVs)
  - Can be self-administered



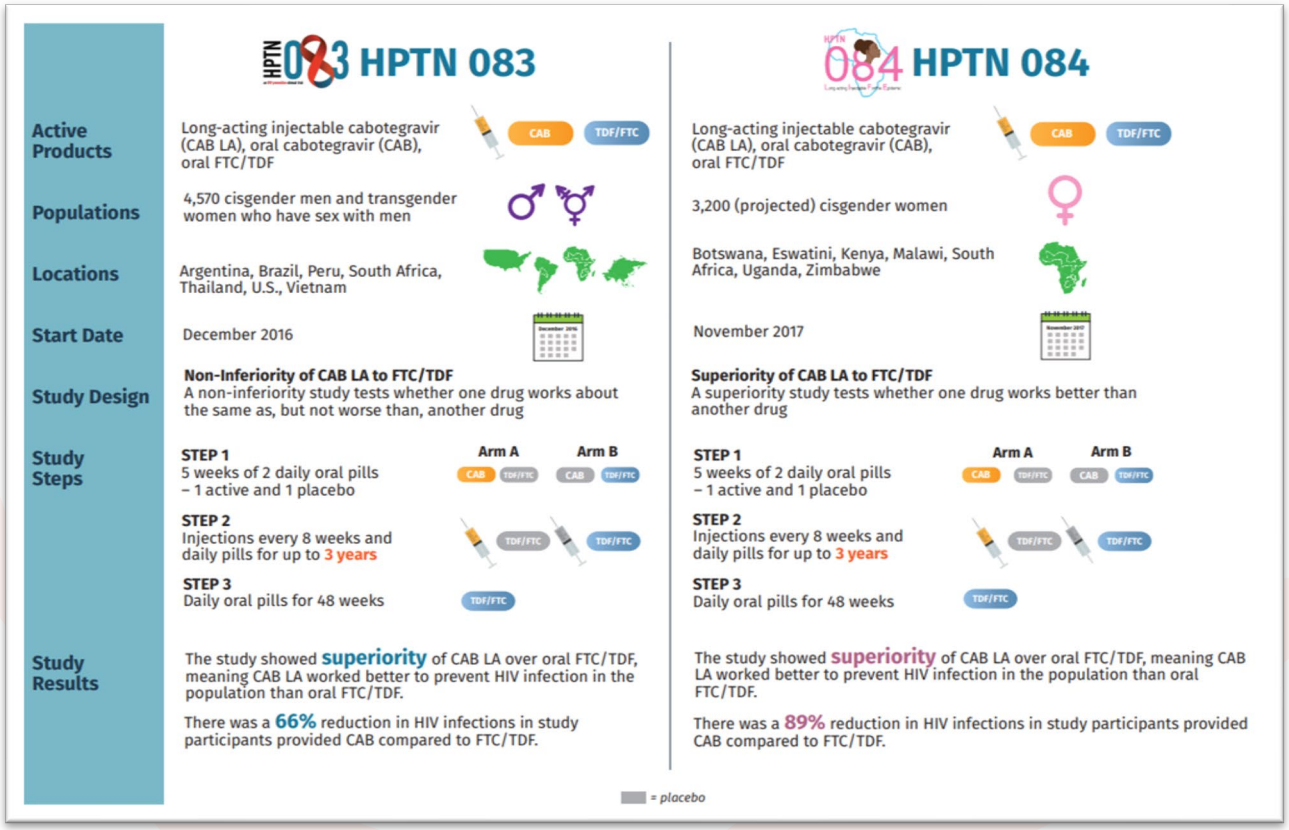
1 Ogbuagu. CROI 2022. Abstr 491;
2 Gupta. CROI 2022. Abstr 138.

Lenacapavir + 2 Broadly Neutralizing Abs

- Multicenter, randomized, blinded phase 1b study
  - Inclusion criteria: VS≥18 mos. on baseline ART, susceptible to bNAbs, CD4≥500
- N=21, majority male, White, ~1/3 Hispanic, BMI 30
- Protocol:
  - Day 1: Lenacapavir 600 mg PO x 2 and 927 mg subcutaneous with infusions of Teropavimab and Zinlirvimab (2 different doses)
  - Day 2: Lenacapavir 600 mg PO x 2
  - Original study to wk 52 but changed to wk 26 because Lenacapavir became unavailable.
  - Wk 26: return to baseline ART
- Results:
  - Data available for 19 patients (1 withdrew, 1 no virologic data)
  - 18 of 19 patients had VS at wk 26
  - 1 of 19 had viral rebound at wk 16 (resuppressed upon return to baseline ART)
  - CD4 counts remained stable.
  - Drug levels remained therapeutic at wk 26
  - Adverse events: injection site reactions

Eron. CROI 2023. Abstr 193

Long-Acting Injectable HIV PrEP: Cabotegravir



- 1 year post unblinding of HPTN 083[2] and 084[4].
- Results persisted.

1. Landovitz et al. Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women. N Engl J Med. 2021 Aug 12;385(7):595-608. doi 10.1056/NEJMoa2101016. PMID: 34379922; PMCID: PMC8448593.
2. Landovitz. CROI 2022. Abstr 96.
3. Delany-Moretlwe. HIVR4P 2021. Abstr HY01.02
4. Delany-Moretlwe. AIDS 2022. Abstr OALBX0107.

Long-Acting Injectable HIV PrEP

- **Cabotegravir**
  - Oral lead in optional
  - Monthly x 2 then every 2 months
  - CDC monitoring recommendations[1]
    - Use of 4th generation HIV Ab/Ag and HIV RNA to decrease delay in HIV diagnoses and resistance development
      - Cost, requires blood draw, time
  - Management of Cabotegravir tail

- **Lenacapavir**
  - Subcutaneous injection every 6 months
  - In trials now

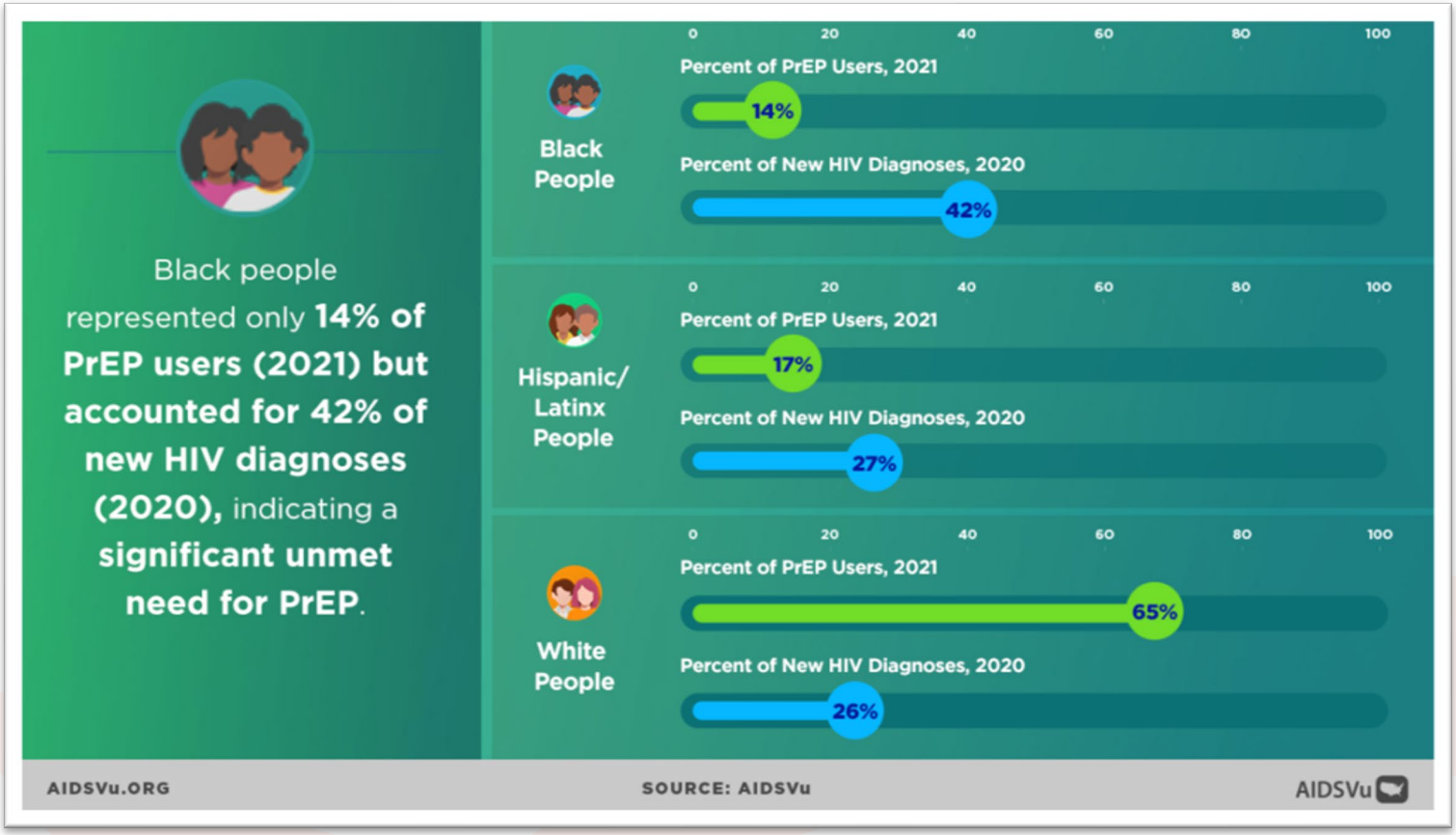
1 US Public Health Service: PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE, A CLINICAL PRACTICE GUIDELINE (cdc.gov)

Long-Acting Early Viral Inhibition (LEVI) with LA CAB PrEP

- HPTN 083 (MSM and TGW) N= 2,282
  - 6 infections despite on-time injections
  - 28 other infections
    - 16 no recent CAB exposure within 6 months
    - 4 HIV at enrollment
    - 3 infected while receiving oral CAB
    - 3 infected after >= 1 delayed injection
    - 2 infected near the time of CAB reinitiation
- INSTI Resistance
  - No INSTI resistance in n=16 with >6 months after last CAB injection
  - INSTI resistance developed in 10/18 with CAB administration within 6 months of HIV positive test
- HIV rapid tests and Ag/Ab tests failed often to detect the infections
- Retrospective testing with HIV RNA detected most infections before INSTI resistance emerged.
  - Guidelines do state that RNA testing should be done as part of HIV screening for patients on LA CAB
- LEVI Syndrome
  - Smoldering viral replication
  - Low/undetectable viral load and delayed/diminished Ab expression lasting months after CAB D/C
  - Minimal seroconversion symptoms
  - Unlikely transmission

Eshleman. CROI 2023. Abstr 160.

Health Equity



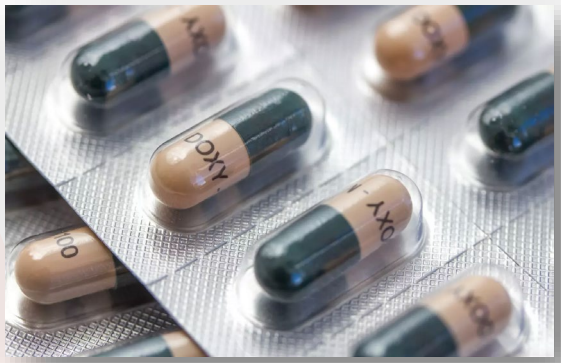
[Deeper Look: PrEP - AIDSVu]

HPTN 083 Substudy of US Black MSM and TGW

- Compared US Black vs. Non-Black MSM and TGW during blinded period through May 14, 2020
  - 49.7% (844/1698) of participants identified as Black or mixed race including Black; ~93% were MSM, ~7% TGW
- HIV prevention overall remained high and LA CAB among Black MSM and TGW did better than oral FTC/TDF
- HIV incidence higher among Black MSM and TGW
  - 19 infections (15 in FTC/TDF arm and 4 in LA CAB arm) occurred in Black MSM and TGW
  - 5 infections (all in FTC/TDF arm) in non-Black MSM and TGW
- Adherence lower among Black than non-Black
  - Oral: TDF dried blood spots (65% vs. 81% ≥4 tablets/week)
  - Injections: on-time LA CAB injections (83.1% vs. 90.2%)
    - Even when rates of injection site reactions lower among Blacks

Scott. CROI 2023. Abstr 161.

STI Prevention: DOXY-PEP



- Randomized (2:1) open-label trial in Seattle and San Francisco of 501 MSM and TGW with STI in past year.
  - 327 people on PrEP; 174 people with HIV
  - 67% White, 7% Black, 11% Asian, 30% Hispanic, 3% TGW/NB
  - Median # sex partners in past 3 months: 9
- Treatment arm: took doxycycline 200 mg within 72 hours post sexual encounter.
- Significantly decreased infections of gonorrhea, chlamydia, and syphilis in both PrEP patients and patients with HIV at quarterly visits
  - In PrEP patients: 10.7% vs. 31.9%
    - Decrease by 55% for gonorrhea, 88% for chlamydia, 87% for syphilis
  - In patients with HIV: 11.8% vs. 30.5%
    - Decrease by 57% for gonorrhea, 74% for chlamydia, 77% for syphilis
- Combined incidence of gonorrhea, chlamydia, and syphilis was lowered by two thirds with doxy-PEP than with standard of care.

AF Leutkemeyer et al. Doxycycline to prevent bacterial sexually transmitted infections. NEJM DOI: 10.1056/NEJMoa2211934 (2023).

DOXY-PEP & Antimicrobial Resistance

- Resistance samples for N. gonorrhoeae, S. aureus, and commensal Neisseria spp collected in both arms over 1 year.
- N. gonorrhoeae:
  - TCN-R present in GC isolates:
    - 4 baseline
    - 6 incident in doxy-PEP arm
    - 2 incident in standard of care arm.
- S. aureus:
  - Compared to baseline, doxy-PEP associated with:
    - 14% absolute reduction in colonization
    - 8% absolute increase in doxycycline resistance
  - MRSA prevalence was low (6%) and doxy-resistant MRSA unchanged with doxy-PEP.
- Non-pathogenic commensal Neisseria species:
  - 2/3 of isolates had preexisting doxy resistance.
  - No significant change associated with doxy-PEP use.

- Limitations:
  - Small number of GC isolates available
  - ≤12 months of follow-up
  - Standard of care participants received doxycycline for incident STIs
- Conclusions:
  - Modest changes in S.aureus resistance unlikely to have clinical significance
  - Suggests doxy-PEP may be less protective against TCN-R GC strains, keeping in mind intervention reduced GC infections by >50%
  - Unable to assess doxy-PEP as driver of TCN-R in GC.
  - Surveillance for the impact of TCN-R GC on doxy-PEP efficacy and doxy-PEP on GC resistance is needed.

Luetkemeyer A et al. *DOXYPEP and antimicrobial resistance in* N. Gonorrhoeae*, commensal* Neisseria *and* S. Aureus. Conference on Retroviruses and Opportunistic Infections, Seattle, abstract 120, 2023.

ANCHOR Study: Should we perform Anal Pap Smears on our patients with HIV?

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Treatment of Anal High-Grade Squamous Intraepithelial Lesions to Prevent Anal Cancer

Joel M. Palefsky, M.D., C.M., Jeannette Y. Lee, Ph.D., Naomi Jay, R.N., Ph.D., Stephen E. Goldstone, M.D., Teresa M. Darragh, M.D., Hillary A. Dunlevy, M.D., Isabella Rosa-Cunha, M.D., Abigail Arons, M.P.H., Julia C. Pugliese, M.P.H., Don Vena, N.D., Joseph A. Sparano, M.D., Timothy J. Wilkin, M.D., et al., for the ANCHOR Investigators Group*

Article Figures/Media Metrics

June 16, 2022
N Engl J Med 2022; 386:2273-2282
DOI: 10.1056/NEJMoa2201048

40 References 7 Citing Articles Letters

- Multi-site RCT, N=4459
  - ~80% Male, ~16% Female, ~3% TG/NB; ~77% MSM, 23% Heterosexual, ~42% Black, ~33% White, 16% Hispanic
- To determine if early treatment of anal dysplasia can prevent progression to anal cancer in people with HIV ≥35 years who had biopsy-confirmed anal HSIL.
  - High-resolution anoscopy (HRA) at least every 6 months
- Rate of progression to anal cancer was 57% lower in the treatment group than in the active monitoring group (9 vs. 21 cases).
- Challenges:
  - Limited access to trained and experienced clinicians who can perform HRA and treat HSIL effectively.
  - Biomarkers needed to help predict who is at greatest risk for HSIL progression.
  - Best treatment choices for HSIL.

Palefsky et al. Treatment of Anal High-Grade Squamous Intraepithelial Lesions to Prevent Anal Cancer. N Engl J Med. 2022 Jun 16;386(24):2273-2282. doi: 10.1056/NEJMoa2201048. PMID: 35704479.

Simplification

- SIMPL'HIV at week 144
  - Randomized, open-label, non-inferiority study; N=187
    - Had to be virologically suppressed for at least 24 weeks; no known INSTI resistance, no Hep B infection
  - Simplifying regimen from 3-drug regimen to DTG-FTC
    - N=94 on 3-drug regimen: 66% INSTI-based; 25.5% NNRTI-based; 6.4% PI-based
    - N=93 in DTG-FTC arm, had similar breakdown of 3-drug regimen prior to switch.
    - DTG was INSTI received at study entry in half of all participants.
  - Viral suppression maintained to wk 144
    - No significant differences in weight gain, adverse events, quality of life.

Marinosci. AIDS 2022. Abstr OAB0302.

NADIA Trial

- Multicenter, 2 x 2 randomized open label non inferiority trial
- N=464 patients, 7 Sub-Saharan African sites
  - 61% female, 51% CD4<200, 28% VL> 100,000.
  - Switch from failing NNRTI-based regimen to DTG vs. DRV and ZDV vs. TDF, all with 3TC
  - 58% baseline intermediate-high level resistance to tenofovir; 92% resistance to lamivudine.
- Week 96 results:
  - VL<400 in 89.9% of DTG group and 86.9% of DRV group, indicating non-inferiority of DTG.
    - Responses were equally good in subgroups with no predicted-active NRTIs in regimen.
  - VL < 400 in 91.8% of TDF group and 84.8% in the ZDV group indicating superiority of TDF.
- 7 DTG resistance– 5 in ZDV arm and 2 in TDF arm; no DRV resistance developed.
  - TDF may protect against DTG resistance.

Paton et al. Dolutegravir or Darunavir in Combination with Zidovudine or Tenofovir to Treat HIV. N Engl J Med. 2021 Jul 22;385(4):330-341. doi: 10.1056/NEJMoa2101609. PMID: 34289276.
Paton. CROI 2022. Abstr 137.

D²EFT Study

- Randomized trial of N=831 participants with post- first line NNRTI regimen failure
  - ~83% EFV, ~11% NVP
  - No previous PI/INSTI exposure
  - No HBV
- Original design:
  - DRV/RTV + 2NRTIs (76% 3TC/ZDV and 19% 3TC or FTC+TDF; no recycled NRTIs, NRTI chosen by GT or WHO algorithm) vs. DRV/RTV + DTG
- Modified design:
  - DRV/RTV + 2NRTIs (n=210) vs.
  - DRV/RTV + DTG (n=216) vs.
  - DTG + (3TC or FTC)TDF (recycled NRTIs, no GT required) (n=296)

Matthews. CROI 2023. Abstr 198.

D^{2}EFT Study: Results at wk 48

- DTG + DRV/RTV superior and DTG + (3TC or FTC)/TDF noninferior to DRV/RTV + 2NRTIs
- Mean CD4 increase better for DTG + DRV/RTV (+ 56 cells/mm3) and DTG + (3TC or FTC)/TDF (+39.9 cells/mm3) compared to DRV/RTV + 2NRTIs
- Weight gain increased more for DTG + DRV/RTV (+ 2.7 kg) and DTG + (3TC or FTC)/TDF (+1.7 kg) compared to DRV/RTV + 2NRTIs

Matthews. CROI 2023. Abstr 198.

Weight and Metabolic Changes

- SOLAR: weight and metabolic changes at 12 months[1]
  - Overweight to Obese: 9% on BIC/FTC/TAF and 8% LA CAB/RPV
  - Normal BMI to Overweight: 13% on BIC/FTC/TAF and 7% LA CAB/RPV
  - No significant changes in metabolic syndrome/insulin resistance at 12 months in either arm.
- ADVANCE at wk 192: randomized, open label phase 3 in South Africa[2]
  - ART-naïve trial with 3 arms (DTG/FTC/TAF, DTG/FTC/TDF, EFV/FTC/TDF)
  - Highest weight increase with DTG/FTC/TAF (8.9 kg), then DTG/FTC/TDF (5.8 kg), then EFV/FTC/TDF (3.3 kg).
- CHARACTERISE at wk 52: N=172 from ADVANCE arms switched to DTG/3TC/TDF[3]
  - Females: -1.6 kg going from DTG/FTC/TAF to DTG/3TC/TDF and +2.9 kg from EFV/FTC/TDF to DTG/3TC/TDF.
  - Males: no significant weight changes in any arm
    - EFV arm weight increased but too few participants

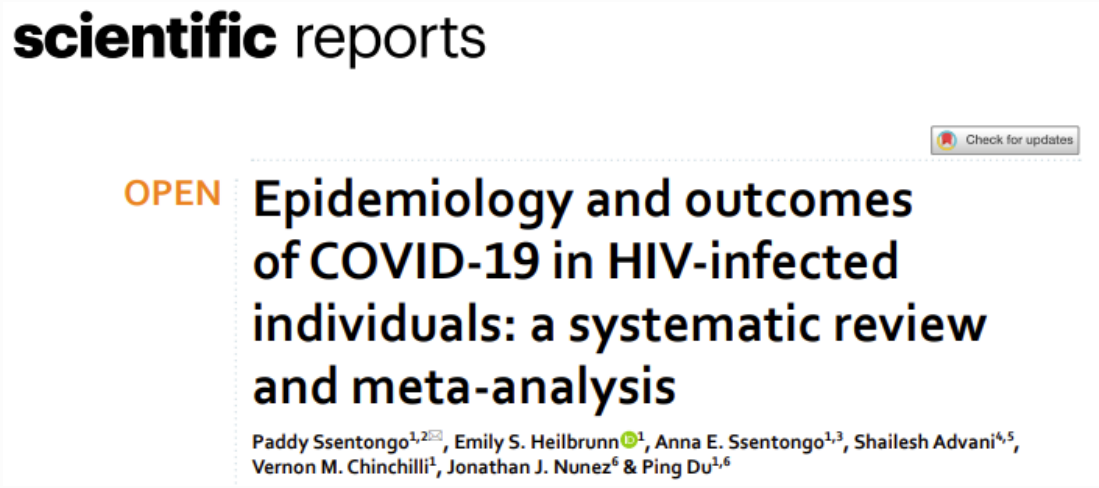
1 Tan. CROI 2023. Abstr 146. 2 Venter. AIDS 2022. Abstr PELBB01. 3 Bosch. CROI 2023. Abstr 167

CV Risk in Swiss HIV Cohort Study

- N=1837 on INSTI, N=3525 on other ART
- Followed until first cardiovascular event (MI, stroke, invasive CV procedure)
- 116 CV events observed over 4.9 years
- No difference observed in adjusted CV event incidence between INSTI-based ART and other ART.

Surial. CROI 2023. Abstr 149.

COVID-19 & HIV



- 22 studies from North America, Africa, Europe, and Asia
  - Sample size totaling ~ 21 million with over 610,000 people with HIV
    - Mean age 56, 66% male.
    - Most common comorbidities in PWH: HTN, DM, COPD, CKD.
    - Mean CD4 538; >96% on ART; >80% virally suppressed
- HIV associated with significant higher risk of COVID infection (RR 1.24) and COVID mortality (RR 1.78)
  - Pooled HIV prevalence among COVID patients was 1.22%, double HIV prevalence in general population in the analyzed cities (0.65%)
  - HIV associated with almost 80% excess risk for COVID mortality.

Ssentongo, P., Heilbrunn, E.S., Ssentongo, A.E. *et al.* Epidemiology and outcomes of COVID-19 in HIV-infected individuals: a systematic review and meta-analysis. *Sci Rep* **11**, 6283 (2021). https://doi.org/10.1038/s41598-021-85359-3

COVID-19 & HIV

HIV Res Clin Pract. 2021 : 1–17.
Published online 2021 Sep 12. doi: 10.1080/25787489.2021.1975608
PMCID: PMC8442751
PMID: 34514963

HIV and COVID-19: review of clinical course and outcomes

Lauren K. Barbera,[1] Kevin F. Kamis,[2] Sarah E. Rowan,[2,3,4] Amelia J. Davis,[1] Soraya Shehata,[1] Jesse J. Carlson,[2] Steven C. Johnson,[4] and Kristine M. Erlandson[4]

- Although many initial case series and cohort studies showed no increased risk of severe COVID outcomes, recent studies have signaled an increased risk for severe progression even in setting of controlled HIV.
  - ?Due to increased prevalence of co-morbidities and other SDOH.
  - ?CD4 <200 may be a major risk factor.
  - CDC recommends three-dose primary vaccine series for people with HIV not on ART or who have advanced HIV. ?Should all people with HIV get the three-dose series.

Barbera et al. HIV and COVID-19: review of clinical course and outcomes. HIV Res Clin Pract. 2021 Aug;22(4):102-118. doi: 10.1080/25787489.2021.1975608. Epub 2021 Sep 12. PMID: 34514963; PMCID: PMC8442751.
COVID-19 and HIV | HIV Basics | HIV/AIDS | CDC

Observational Study > Immun Inflamm Dis. 2021 Sep;9(3):1037-1043. doi: 10.1002/iid3.467. Epub 2021 Jun 2.

Long-coronavirus disease among people living with HIV in western India: An observational study

Sanjay Pujari [1], Sunil Gaikwad [1], Abhishek Chitalikar [1], Digamber Dabhade [1], Kedar Joshi [1], Vivek Bele [1]

- Prospective, observational study examining Long COVID in PWH (N=94), defined as at least one COVID symptom present 30 days after illness onset.
  - Majority had mild/asymptomatic illness (76.6%).
  - Moderate to severe illness significantly associated with Long COVID.
  - Presence of Long COVID 43.6%.
    - Cough and fatigue most common symptoms.
  - 10 individuals (10.6%) had symptoms a median of 109 days post onset.

Pujari et al. Long-coronavirus disease among people living with HIV in western India: An observational study. Immun Inflamm Dis. 2021 Sep;9(3):1037-1043. doi: 10.1002/iid3.467. Epub 2021 Jun 2. PMID: 34078004; PMCID: PMC8239760.

Monkeypox & HIV

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

Morbidity and Mortality Weekly Report (*MMWR*)

CDC

HIV and Sexually Transmitted Infections Among Persons with Monkeypox — Eight U.S. Jurisdictions, May 17–July 22, 2022

Weekly / September 9, 2022 / 71(36);1141–1147

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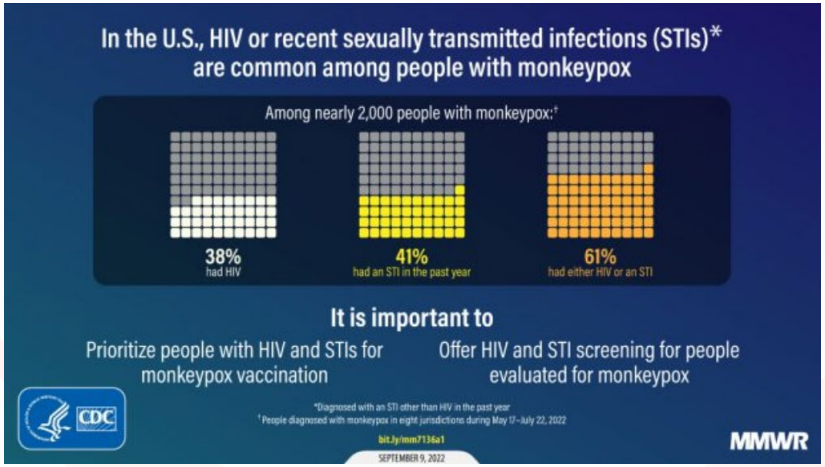
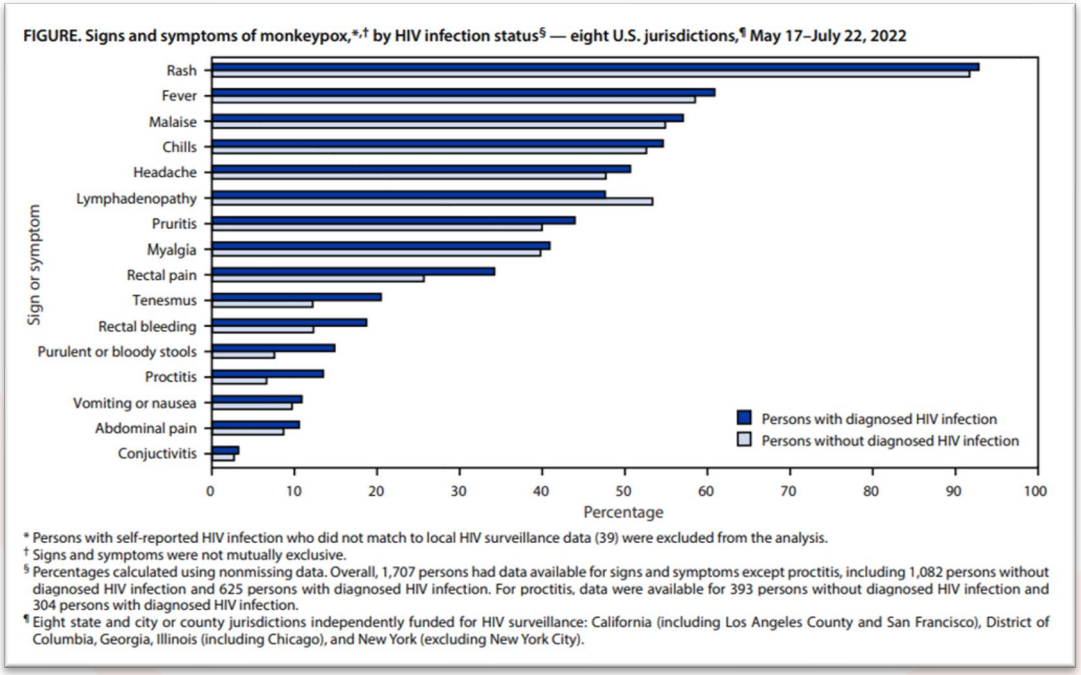


- N=1969
  - 38% (n=755) with HIV
    - 59% ≥ 55 years
    - 63% Black, 41% Hispanic, 28% White, 22% Asian
  - 82% VL<200; 78% CD4 ≥ 350
  - Higher proportion with HIV were hospitalized (8%) vs. without HIV (3%).
    - Of 45 with unsuppressed HIV, 27% hospitalized;
    - Of 61 with CD4 <350, 15% were hospitalized.

Curran et al. HIV and Sexually Transmitted Infections Among Persons with Monkeypox — Eight U.S. Jurisdictions, May 17–July 22, 2022. MMWR Morb Mortal Wkly Rep 2022;71:1141–1147. DOI: http://dx.doi.org/10.15585/mmwr.mm7136a1.

Monkeypox & HIV



- People with HIV more likely to report
  - rectal pain
  - tenesmus
  - rectal bleeding
  - purulent or bloody stools
  - proctitis
- Less likely to report
  - lymphadenopathy (unless unsuppressed)

Curran et al. HIV and Sexually Transmitted Infections Among Persons with Monkeypox — Eight U.S. Jurisdictions, May 17–July 22, 2022. MMWR Morb Mortal Wkly Rep 2022;71:1141–1147. DOI: http://dx.doi.org/10.15585/mmwr.mm7136a1.

MPOX in People with Advanced HIV

- International study
  - 19 countries in Americas (72.5%), Europe (25.9%), Africa (1.6%)
  - N=382 with CD4<350 (22% CD4<100; 25% CD4 100-200), 96% male, 91% known HIV, 60% known HIV on ART, 50% virally suppressed, 4% vaccinated against smallpox prior to 2022, 7% vaccinated in 2022.
  - Clinical manifestations: severe necrotizing, disseminated form involving multiple organs including sepsis
    - Massive necrotizing skin, genital and non genital cutaneous and mucosal lesions
    - Lung involvement with perivascular nodules
    - Severe cutaneous and bloodstream secondary bacterial infections
  - Mortality overall 7.1%, all in people with CD4<200
    - 15% in CD4<200; 27.1% in CD4<100
    - No deaths in those vaccinated
  - Tecovirimat used only in 62 patients (16.2%) because of lack of access
  - 85 patients started or restarted ART: 25% developed MPOX IRIS, with 57% mortality rate.

Orkin. CROI 2023. Abstr 173.

September 30, 2022

Human Monkeypox Virus Infection in the Immediate Period After Receiving Modified Vaccinia Ankara Vaccine

Aniruddha Hazra, MD[1]; Laura Rusie, ScM[1]; Trevor Hedberg, MPH, PA-C[1]; et al

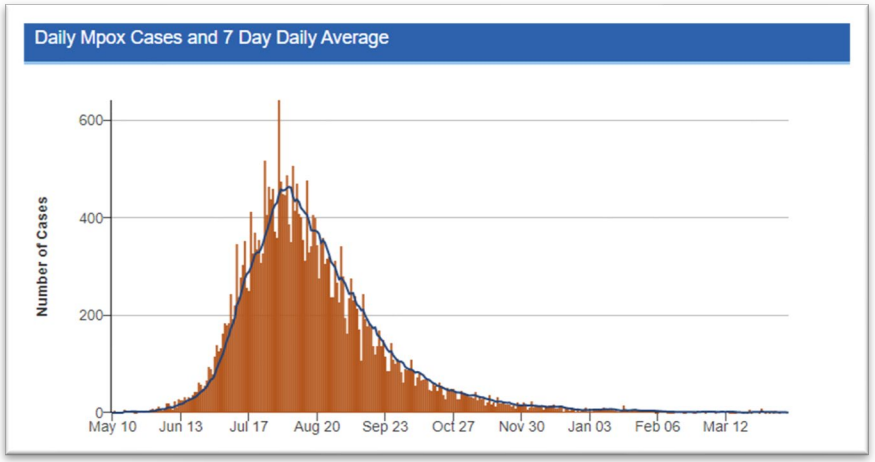
» Author Affiliations | Article Information

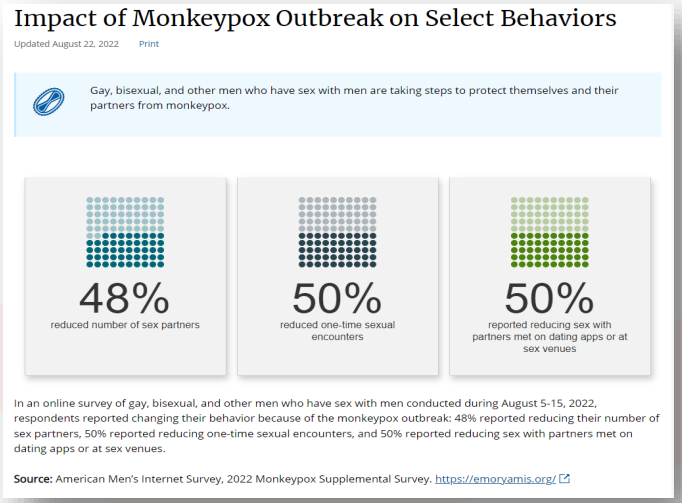
JAMA. Published online September 30, 2022. doi:10.1001/jama.2022.18320

- 90 ‘breakthrough’ infections.
- Only 2 infections were past 14 days post second vaccine.
- Single site (Howard Brown Health, Chicago)

Hazra et al. Human Monkeypox Virus Infection in the Immediate Period After Receiving Modified Vaccinia Ankara Vaccine. *JAMA*. Published online September 30, 2022. doi:10.1001/jama.2022.18320

U.S. Monkeypox Case Trends Reported to CDC as of Oct 12, 2022





- Need to stay vigilant
- LGBT community response
- Need more information:
  - Who should get the treatment?
  - How effective are the treatments, e.g. TPOXX?

Impact of Monkeypox Outbreak on Select Behaviors | Monkeypox | Poxvirus | CDC

Delaney et al. Strategies Adopted by Gay, Bisexual, and Other Men Who Have Sex with Men to Prevent *Monkeypox virus* Transmission — United States, August 2022. MMWR Morb Mortal Wkly Rep 2022;71:1126-1130. DOI: http://dx.doi.org/10.15585/mmwr.mm7135e1


NOTHING
ABOUT US
WITHOUT US

Substance Use and HIV

PUBLIC HEALTH

Amid urban outbreaks, signs point to HIV spread in rural West Virginia

by Quenton King April 19th, 2022

In 2018, Syringe Services Programs were shut down in West Virginia.

HIV cases now found in 29 WV counties including Cabell, Kanawha, Berkley, and Taylor with 8 counties seeing cases for the first time in years.

Predominant mode of HIV transmission is now injection drug use.

Culture Wars: Harming Patients, Clinicians, and Care

The New York Times
NEWSLETTER
Evening Briefing

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By Remy Tumin

Published June 24, 2022 Updated June 26

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Updated April 8, 2023 ·

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Sarah McCammon

POLITICS

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Updated April 11, 2023 · 2:30 PM ET

Heard on Morning Edition

By Rachel Treisman

npr

The NEW ENGLAND JOURNAL of MEDICINE

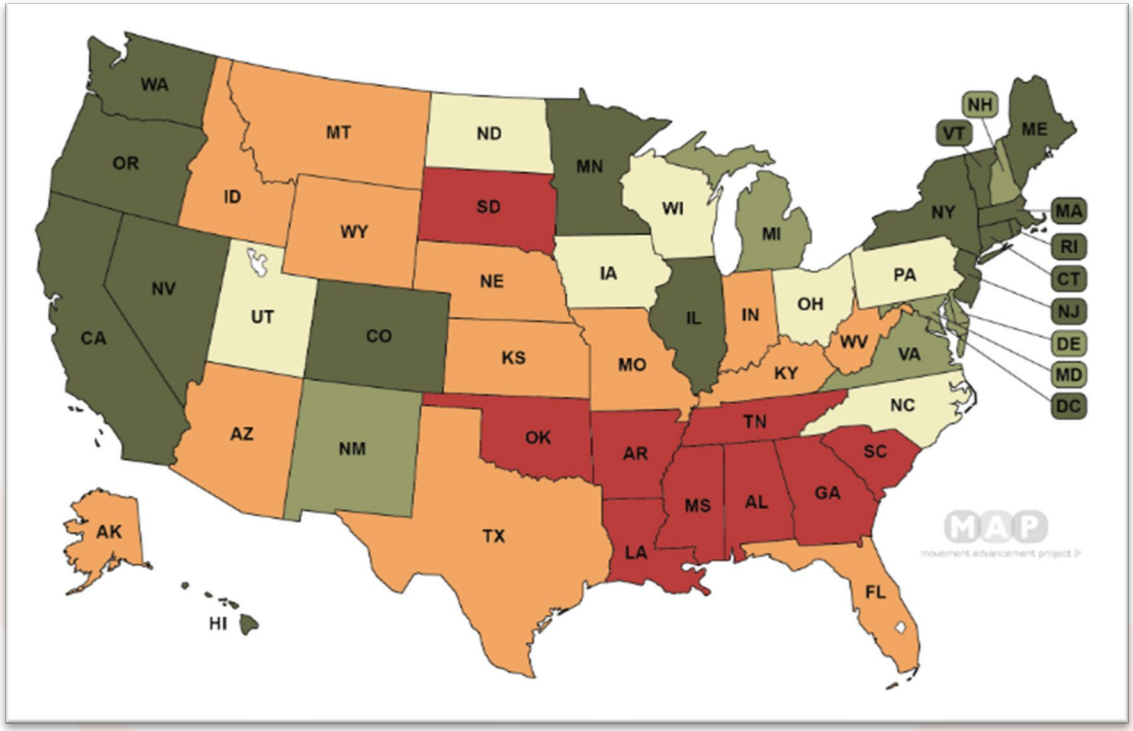
Lawmakers v. The Scientific Realities of Human Reproduction

The Editors

Article Metrics

July 28, 2022
N Engl J Med 2022; 387:367-368

Culture Wars: Harming Patients, Clinicians, and Care

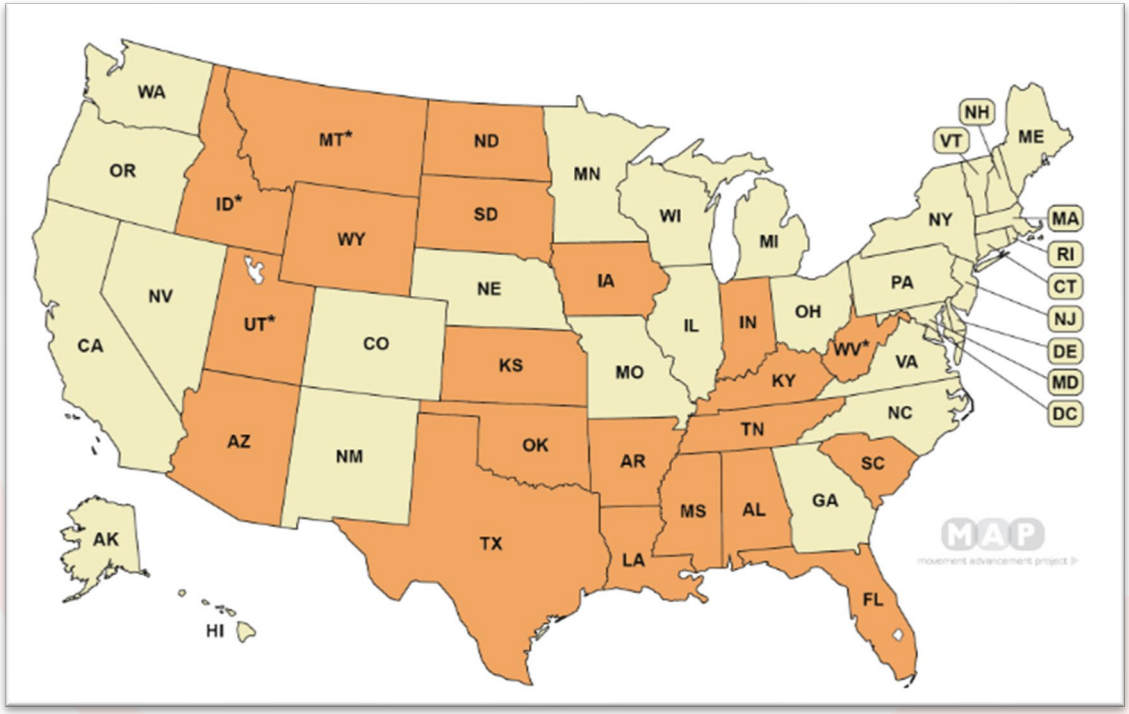


LGBTQ-related Policies

- High Overall Policy Tally *(15 states + D.C.)*
- Medium Overall Policy Tally *(6 states, 1 territory)*
- Fair Overall Policy Tally *(7 states, 1 territory)*
- Low Overall Policy Tally *(13 states, 3 territories)*
- Negative Overall Policy Tally *(9 states)*

Movement Advancement Project | Snapshot: LGBTQ Equality by State (lgbtmap.org)

Culture Wars: Harming Patients, Clinicians, and Care



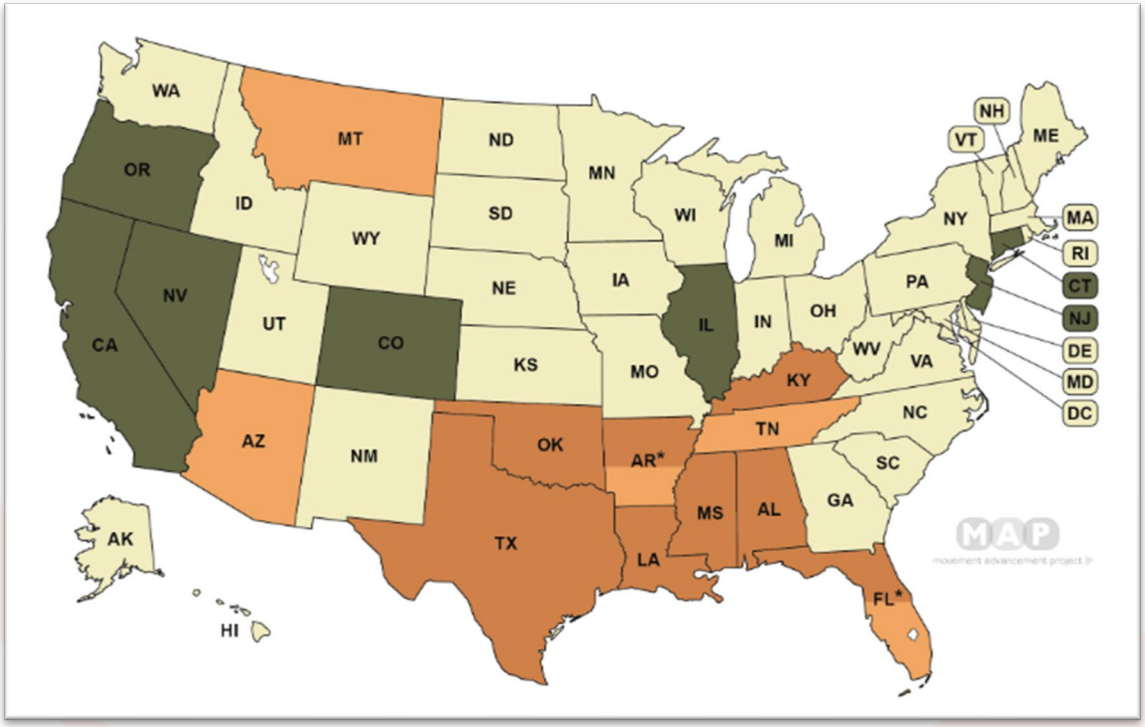
States that Outlaw Transgender Youth Participation in Sports

State law bans transgender students from participating in sports consistent with their gender identity *(21 states)*

State law does not ban transgender students from participating in sports consistent with their gender identity *(29 states, 5 territories + D.C.)*

[Movement Advancement Project | Bans on Transgender Youth Participation in Sports (lgbtmap.org)]

Culture Wars: Harming Patients, Clinicians, and Care

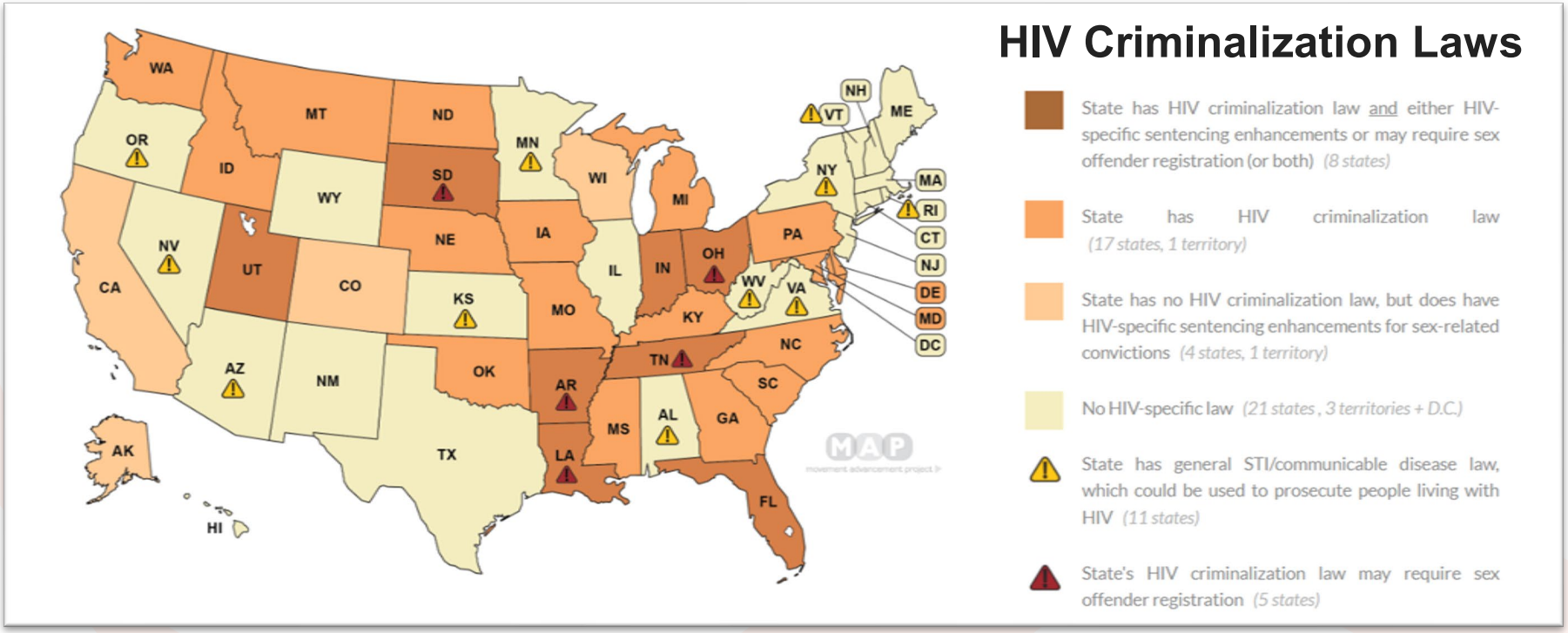


LGBTQ CURRICULAR LAWS

- State law explicitly requires LGBTQ inclusion in state curricular standards *(7 states)*
- State has none of these LGBTQ-specific curricular laws *(32 states, 5 territories + D.C.)*
- State law requires parental notification of LGBTQ-inclusive curricula and allows parents to opt their children out *(5 states)*
- State law censors discussions of LGBTQ people or issues in school (i.e., "Don't Say Gay or Trans") *(8 states)*

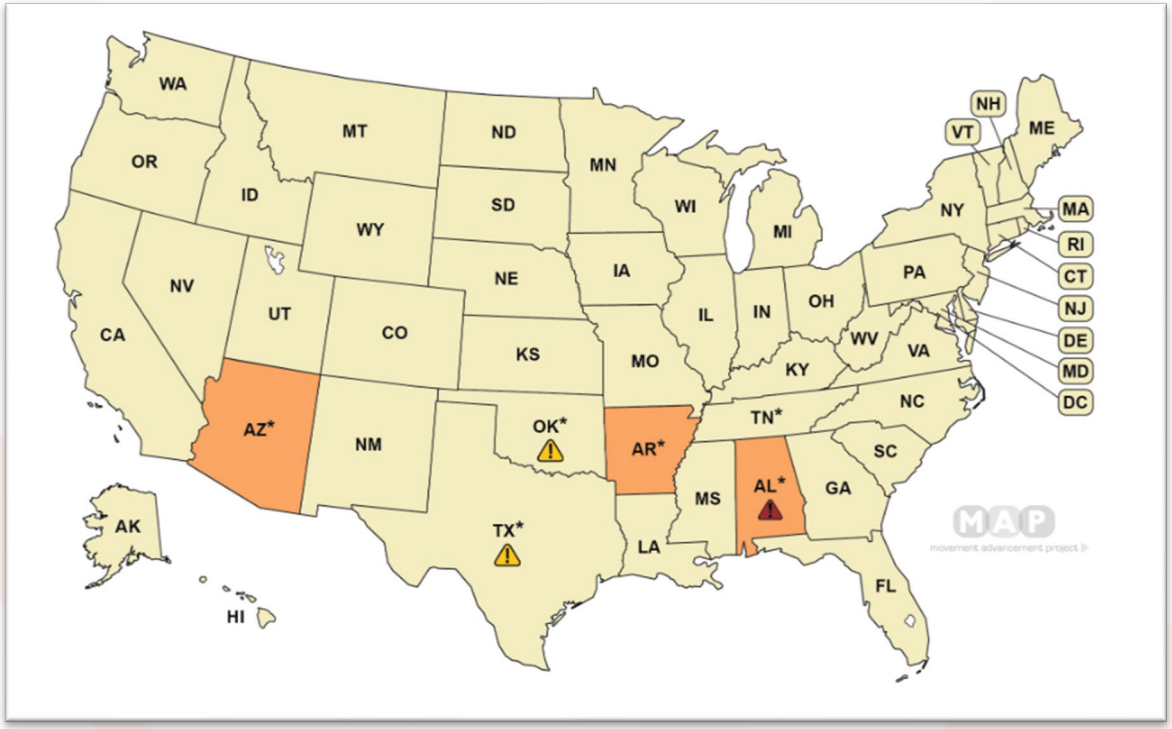
Movement Advancement Project | LGBTQ Curricular Laws (lgbtmap.org)

Culture Wars: Harming Patients, Clinicians, and Care



[Movement Advancement Project | HIV Criminalization Laws (lgbtmap.org)]

Culture Wars: Harming Patients, Clinicians, and Care

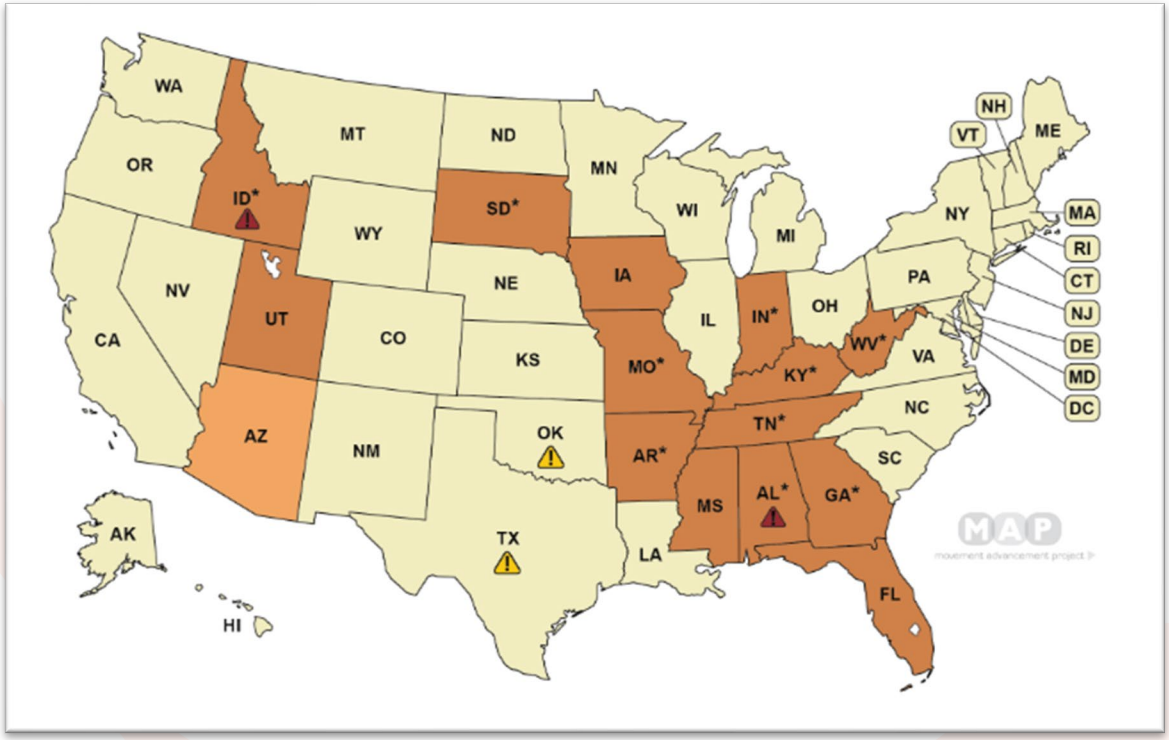


States Restricting Access to Transgender Healthcare

- State law bans or restricts best practice medical care for transgender youth (see note) *(3 states)*
- State does not ban best practice medical care for transgender youth *(47 states, 5 territories + D.C.)*
- State ban makes it a felony crime to provide best practice medical care for transgender youth *(1 state)*
- State executives have attempted to limit or restrict medical care for transgender youth, but state law does not ban this care (see note) *(2 states)*

6 months ago

Culture Wars: Harming Patients, Clinicians, and Care



States Restricting Access to Transgender Healthcare

- State bans best practice medication and surgical care for transgender youth *(14 states)*
- State bans best practice surgical care for transgender youth *(1 state)*
- State does not ban best practice medical care for transgender youth *(35 states, 5 territories + D.C.)*
- State ban makes it a felony crime to provide best practice medical care for transgender youth *(2 states)*
- State has taken steps to ban or restrict best practice medical care for transgender youth, but state law does not ban this care (see note) *(2 states)*

Today

Movement Advancement Project | Health Care / Bans on Best Practice Medical Care for Transgender Youth (lgbtmap.org)

Culture Wars: Harming Patients, Clinicians, and Care

The Washington Post
Democracy Dies in Darkness

A Texas Judge Just Took Religious 'Freedom' Too Far

Analysis by Noah Feldman | Bloomberg
September 19, 2022 at 7:16 a.m. EDT

USA TODAY

NATION

Texas judge rules government can't mandate employers offer HIV prevention drugs in coverage

Cady Stanton
USA TODAY

Published 5:30 p.m. ET Sept. 7, 2022 | **Updated 5:31 p.m. ET Sept. 7, 2022**

HEALTH AFFAIRS FOREFRONT | FOLLOWING THE ACA

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Sweeping Ruling Blocks Preventive Services Coverage Requirements Nationwide

Andrew Twinamatsiko, Zachary Baron

APRIL 7, 2023 10.1377/forefront.20230405.235446

Summary

Exciting and 

- Long acting injectables for HIV treatment and PrEP
- PEP for STIs
- Prevention of anal cancer
- HIV treatment simplification
- Streamlined second line therapies even in the context of little to no predicted NRTI activity

On 

- COVID-19 and Long COVID
- Monkeypox
- Substance use disorder and syringe services programs
- Advocacy
- Government interference
- Stigma and discrimination
- Health equity
- HIV clinical workforce

AETC AIDS Education & Training Center Program Southeast

Q&A

Thank you!

haddadm@chc1.com

AETC AIDS Education & Training Center Program Southeast

AETC Program
National Centers and National HIV Curriculum

- National Coordinating Resource Center serves as the central web based repository for AETC Program training and capacity building resources; its website includes a free virtual library with training and technical assistance materials, a program directory, and a calendar of trainings and other events. Learn more: https ://aidsetc.org

- National Clinician Consultation Center provides free, peer to peer, expert advice for health professionals on HIV prevention, care, and treatment and related topics. Learn more: https ://nccc.ucsf.edu

- National HIV Curriculum provides ongoing, up to date HIV training and information for health professionals through a free, web based curriculum; also provides free CME credits, CNE contact hours, CE contact hours, and maintenance of certification credits. Learn more: www.hiv.uw.edu