PrEP and the Pharmacist's Role in Ending the HIV Epidemic

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Pharmacy Forward: Advancing Practice for a Healthier Tomorrow!

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OHIO PHARMACISTS ASSOCIATION

Disclosure Statement

- Steve Leonard has no relevant financial relationship(s) with ineligible companies to disclose.
  and
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

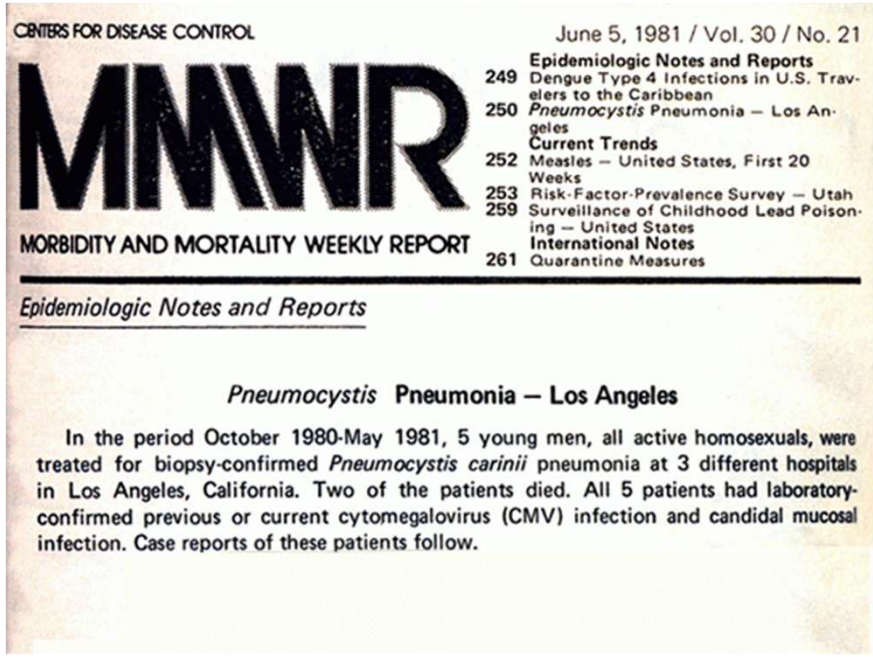
At the completion of this activity, the participant will be able to:

1. Explain why HIV vaccine development remains challenging
2. Describe evidence-based strategies to end the HIV epidemic
3. Define PrEP and identify eligible candidates
4. Discuss new PrEP formulations, including long-acting injectables
5. Evaluate the pharmacist's role and opportunities for expanding PrEP access in Ohio

THE VIRUS AND A UNIQUE CHALLENGE

Why no HIV vaccine after 40+ years?

- First cases of HIV identified in 1981
- Billions invested in vaccine research
- Numerous failed trials (AIDSVAX, HVTN 505, etc.)
- Most “successful” trial (RV144) = only 31% efficacy
- Compare that to COVID vaccines – 90% efficacy in less than 1 year



CENTERS FOR DISEASE CONTROL

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MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

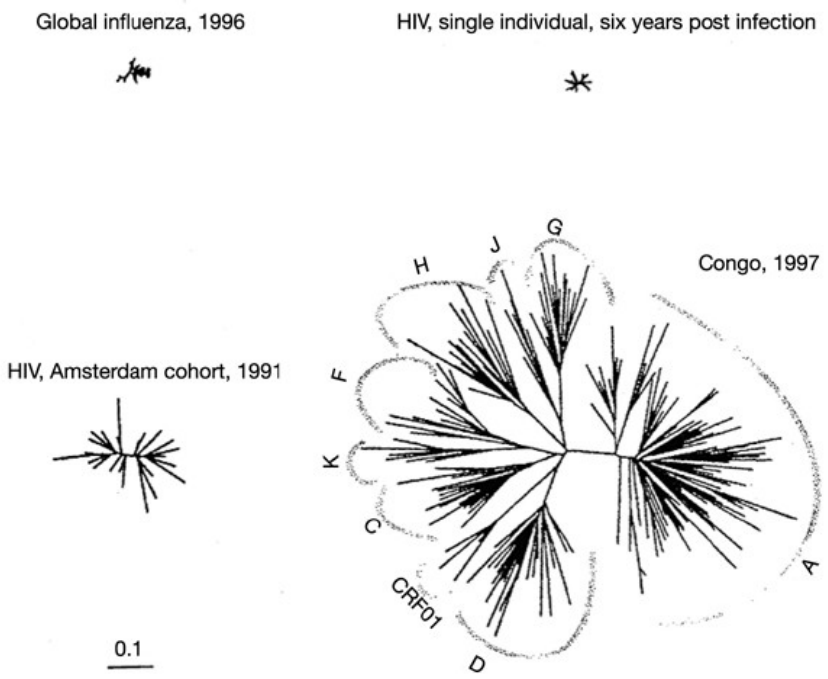
Epidemiologic Notes and Reports

Pneumocystis **Pneumonia – Los Angeles**

In the period October 1980-May 1981, 5 young men, all active homosexuals, were treated for biopsy-confirmed *Pneumocystis carinii* pneumonia at 3 different hospitals in Los Angeles, California. Two of the patients died. All 5 patients had laboratory-confirmed previous or current cytomegalovirus (CMV) infection and candidal mucosal infection. Case reports of these patients follow.

Challenge #1 – extreme genetic diversity

- Globally there are multiple groups, subtypes, and recombinant forms
- Reverse transcription is so error prone it leads to roughly 1 mutation per genome per replication cycle
  - HIV mutates 10,000x faster than influenza
  - HIV mutates ~1,000,000x faster than our DNA
- In one single person, HIV exists as a quasispecies swarm
- Result → Even a strong immune response chases a moving target and any single vaccine immunogen can only cover a tiny fraction of circulating strains



Mansky LM & Temin HM. *J Virol.* 1995;69(8):5087–5094., Cuevas JM et al. *PLoS Biol.* 2015;13(9):e1002251., Sanjuán R et al. *J Virol.* 2010;84(19):9733–9748., Korber B, Gaschen B, Yusim K, Thakallapally R, Kesmir C, Detours V. *Br Med Bull.* 2001;58(1):19–42.

Challenge #2 – glycan shielding

- I can hear you saying…isn't any part of the virus highly conserved and couldn't we target that? I hear "they" are trying to do that with a "universal flu vaccine"!
- Well…
  - HIV is an enveloped virus and the envelope is covered in host derived sugar molecules
  - Those sugars act as a shield hiding viral proteins
  - Host immune system does not recognize host sugar molecules ("self") as foreign
- So, the most conserved regions that we'd want to target, like the CD4 receptor or fusion peptides, are the most heavily shielded by this glycan armor
- Result → Immune system cannot effectively target this virus

Challenge #3 – Integration and Latency

- HIV becomes part of the host
  - Viral DNA must integrate permanently into host cell chromosomes in order to function (replicate)
  - Infected cells can remain dormant (latent) for years, in particular resting memory T cells
  - Latent viruses are invisible to the immune system
  - Even with a perfect immune response, once HIV establishes latency, hidden virus will remain.
- For a virus that can establish latency in this way, an immune response would need to happen **before integration** – entirely preventing infection from establishing in the first place
- HIV can establish integrated infection in lymphoid tissue within 48-72 hours of exposure, long before adaptive immune system could respond
- A protective vaccine would need to induce sterilizing immunity *at the moment of exposure* – an extraordinarily high bar

Haase AT. *Nature Med.* 2010;16(12):1389–1390., Zhang ZQ et al. *Science.* 1999;286(5443):1353–1357., Miller CJ et al. *J Virol.* 2005;79(18):11664–11672.

Additional scientific challenges

- No natural immunity – nobody ever spontaneously clears HIV
  - TWO possible exceptions – in studies of elite controllers, no intact HIV genomes were found in any of billions of cells analyzed
- Broadly neutralizing antibodies are rare and difficult to induce
  - Current studies using mRNA vaccines to induce bnAbs are in Phase 1 trials
- Need both strong B cell and T cell responses simultaneously
- No correlate of protection – we don't know what level of immune response would lead to "protection"
- Limited animal models that can be used
- Virus targets the very cells that coordinate immune responses!

Yu XG et al. Nature. 2020;583:261–265; Jiang C et al. Ann Intern Med. 2021;174:1633–1642.

Elite Controllers – A Glimmer of Hope?

- Elite Controllers: ~0.2-0.5% of people with HIV
  - Spontaneously suppress viral replication to undetectable levels
  - Maintain high CD4+ counts without ARV
  - Still infected (integrated HIV virus) – just extremely well controlled
- Exceptional Elite Controllers (Roughly 10-15 documented cases worldwide)
  - Maintain control for 25+ years without treatment
  - Extremely low viral reservoirs
  - Unique genetic factors (HLA-B57, CCR5-delta32, others)
    - HLA-B*57:01 is the most common allele in the B57 family and is the same gene strongly associated with abacavir hypersensitivity
  - Represent potential “functional cure” model
- This doesn’t change the broader problem:
  - Requires specific genetic factors not present in the general population and which we don’t know how to replicate
  - They are still infected

WHAT ACTUALLY WORKS

Evidence-Based Strategies to End the HIV Epidemic

- **Test and Treat** (Universal testing + immediate linkage to care and ART)
  - It's estimated that ~85% of those who are HIV+ know it
- **Treatment as Prevention** (TasP) – U=U: Undetectable = Untransmittable
- **Pre-Exposure Prophylaxis** (PrEP)
- Post-Exposure Prophylaxis (PEP)
- Addressing structural barriers to care (stigma, access, affordability, discrimination)
- Comprehensive sexual health education
- Harm reduction services (needle exchange, safe injection programs)

CDC. Ending the HIV Epidemic in the U.S. (EHE) Initiative, 2023; UNAIDS Global AIDS Update, 2023

The Holy Trinity

- Test and Treat – Universal HIV testing (home based, community based, facility based)
  - Immediate linkage to care and rapid ART initiation for those who test positive
  - Achieved >90% testing coverage in major community trials
  - Resulted in 20-30% reduction in HIV incidence in intervention communities
- U=U – treatment as prevention
  - People living with HIV on effective ART with an undetectable viral load cannot sexually transmit the virus
  - Numerous studies show anything from a 96% reduction in transmission to zero linked transmissions
- PrEP – Pre-Exposure Prophylaxis
  - Protects HIV negative people at ongoing risk
  - Oral PrEP up to 99% effective with good adherence for preventing sexually transmitted HIV
  - New long acting injectable PrEP (lenacapavir) may be 99.9+% effective

Hayes R et al., NEJM 2019 (PopART/HPTN 071); Havlir DV et al., NEJM 2019 (SEARCH); Makhema J et al., NEJM 2019 (Ya Tsie); Cohen MS et al., NEJM 2011; Rodger AJ et al., JAMA 2016 & 2019; Bavinton BR et al., Lancet HIV 2018; Grant RM et al., NEJM 2010 (iPrEx); Baeten JM et al., NEJM 2012 (Partners PrEP); Bekker LG et al., NEJM 2024 (PURPOSE 1); Mayer KH et al., NEJM 2024 (PURPOSE 2)

The Synergy in the Trinity

- Test everybody → Treat those with HIV (U=U) OR prevent those at risk (PrEP)
- Result → Those with HIV can't transmit + people at risk are protected = epidemic ends (or slows A LOT)
- San Francisco – Getting to Zero
  - Comprehensive test and treat + PrEP scale-up beginning in 2012
  - New HIV diagnoses declined 58% from 2012-2018, 59% from 2014-2023
  - PrEP uptake among MSM increased from ~4,400 (2014) to 16,300-20,000 (2017)
  - Annual diagnoses dropped from 485 (2012) to 133 (2023)
- Australia – Ninth National HIV strategy 2024-2030
  - National combination prevention approach
  - 30% decline in new HIV diagnoses among gay and bisexual men (2013-19)
  - Some jurisdictions reporting near-zero new infections
  - Mathematical model shows that 90-90-90 targets PLUS PrEP can end epidemic
    - 90% of those with HIV know their status, 90% of those diagnosed are on ARV, 90% on ART are undetectable

Buchbinder SP et al., J Int AIDS Soc 2020 (Getting to Zero SF collective impact); San Francisco Department of Public Health, HIV Epidemiology Annual Report 2022; Australian Government Department of Health, Ninth National HIV Strategy 2024-2030; Grulich A et al., IAS 2023 Conference (Inner Sydney 88% reduction); Keen P et al., Lancet Reg Health West Pac 2025 (NSW 56% decline in GBM)

Barriers

- Geographic – rural vs urban care availability
- Economic – insurance, cost of medications
- Stigma – both individual and structural
- Healthcare system navigation
- Cultural and language barriers

- Pharmacists are uniquely positioned to address these!

PRE-EXPOSURE PROPHYLAXIS (PrEP)

PrEP as the entry point…the reason for the focus

- **PrEP services necessarily require the entire prevention cascade (the holy trinity)**
- To provide PrEP ethically and effectively we must:
  1. Test for HIV – every PrEP initiation and every follow up requires HIV testing
     - Cannot prescribe PrEP to someone with undiagnosed HIV
     - This makes us HIV testing providers
  2. Refer HIV-positive individuals
     - Immediate linkage to care for treatment initiation
     - Connects patients to the U=U pathway
  3. Provide ongoing prevention
     - Testing every 3 months or at every follow up = early detection if seroconversion occurs

What is PrEP?

- Medication taken daily by HIV-negative people to prevent HIV infection
- Highly effective when taken consistently
- Two main types: daily oral and long-acting injectable
- Requires regular monitoring and follow-up
- Most effective when combined with other preventions methods
  - Good counseling point – this is not your carte blanche to do whatever risky thing you want!

PrEP Efficacy

Regimen	Population/trial	Overall (ITT) Efficacy	With high adherence	Notes
Daily oral TDF/FTC (Truvada)	MSM & transgender women	44%	92-99%	Adherence strongly correlated with protection
	Heterosexual serodiscordant couples	63-75%	~90%	TDF alone ≈ 63% TDF/FTC ≈ 75%
	People who inject drugs	~49%	70-74%	Higher efficacy in DOT/adherent
Injectable cabotegravir (Apretude, every 2 months)	MSM, transgender women, cisgender women	N/A – active comparator (TDF/FTC).	>99% with on time injections	**Superior to daily oral PrEP** (66-89% fewer infections than oral PrEP)
Injectable lenacapavir (Yeztugo, every 6 months	MSM, transgender women, cisgender women	96% relative reduction	99.9+% (0 infections in purpose 1, 2 infections in purpose 2)	Twice yearly dosing; high certainty of high efficacy and safety from large studies

Grant RM et al., NEJM 2010 (iPrEx); Baeten JM et al., NEJM 2012 (Partners PrEP); Choopanya K et al., Lancet 2013 (Bangkok Tenofovir); Landovitz RJ et al., NEJM 2021 (HPTN 083); Delany-Moretlwe S et al., Lancet 2022 (HPTN 084); NEJM 2024 (PURPOSE 1 & 2 – Lenacapavir)

Who should get PrEP?

- CDC recommendations: two pathways

  1. Prescribe to ANYONE who asks for it

  – Even if they don't disclose any HIV specific risk behaviors

  – Reduces stigma and barriers to access

  2. Proactively offer to those with specific indications:

  – Any adult or adolescent who has had anal or vaginal sex in the past 6 months AND:

    - Has a sexual partner with HIV OR
    - Has not consistently used condoms OR
    - Has been diagnosed with an STI in the past 6 months

    OR

    - Injects drugs and shares injection equipment
    - Has been prescribed PEP and reports continued risk

- Bottom line: all sexually active patients should be informed about PrEP. If someone asks for it, prescribe it

https://www.cdc.gov/hivnexus/hcp/prep/index.html

PrEP medications – oral options

- Mechanism: nucleoside/nucleotide reverse transcriptase inhibitors
- Truvada (TDF/FTC) – approved 2012
  - Dosing: One tablet (300 mg TDF/200 mg FTC) daily
  - Generic available – *this is the workhorse of oral options*
  - Monitoring required:
    - SCr every 3-6 months (do not use with CrCl < 60 mL/min)
    - Consider bone mineral density testing (greater concern in adolescents still building peak bone mass)
- Descovy (TAF/FTC) – approved 2019
  - Dosing: One tablet (25 mg TAF/200 mg FTC) daily
  - NOT approved for people assigned female at birth for receptive vaginal sex (poor PK in vaginal, cervical tissues AND lack of efficacy in clinical trials for females)
  - Improved safety profile (less kidney and bone impact than TDF)
  - Not for use with CrCl < 30 mL/min

Long-acting injectable PrEP – Cabotegravir (Apretude)

- Integrase strand transfer inhibitor (INSTI) – FDA approved 2021
- Intramuscular injection (gluteal muscle) ← has to be gluteal due to large volume/depot effect and need for slow pharmacokinetic release
- 66-89% more effective than oral PrEP in trials
- Requires specialized administration training
- Dosing:
  - Optional oral lead-in: 30 mg daily x 28 days to assess tolerance
  - Initial: 600 mg IM (3 mL) into gluteal muscle
  - Second injection: 600 mg IM (3 mL) into gluteal muscle one month after first injection (alternate side typically)
  - Maintenance: 600 mg IM (3 mL) into gluteal muscle every 2 months (alternating sides)

Game changer – lenacapavir (Yeztugo)

- Capsid inhibitor – FDA approved June 2025
- Subcutaneous depot injection (1.5 mL in abdomen)
  - Elimination half life is 10-12 weeks
  - Also formulated as a sustained release suspension
- PURPOSE 1: zero infections among cisgender women
- PURPOSE 2: 2 infections among 2,179 participants (99.9% efficacy)
- 96% reduction vs background incidence; 89% more effective than daily Truvada
- Dosing:
  - Initial: Two 463.5 mg (2 x 1.5 mL = Total 3 mL and 927 mg) subcutaneous injections on Day 1 PLUS 600 mg orally on day 1 and 600 mg orally on day 2
  - Maintenance: Two 463.5 mg (2 x 1.5 mL = Total 3 mL and 927 mg) subcutaneous injections every 26 weeks ± 2 weeks (6 months)
  - Note – oral doses on days 1 and 2 achieve adequate drug levels quickly due to slow initial release from subcutaneous depot

Bekker LG et al., NEJM 2024 (PURPOSE 1); Kelley CF et al., NEJM 2025 (PURPOSE 2); CDC Clinical Recommendation for Lenacapavir as HIV PrEP, MMWR 2025

PrEP IN PRACTICE

CLIA-waived HIV tests

- OraQuick ADVANCE Rapid HIV-1/2 antibody test
  - Specimen types: Oral fluid (CLIA-waived), fingerstick whole blood (CLIA-waived), venipuncture whole blood
  - Time to result: 20 minutes
  - Performance (oral fluid – professional use) – fingerstick blood similar
    - Sensitivity 99.6%
    - Specificity 99.98%
  - Cost: ~$20-30 per test
- Determine HIV-1/2 Ag/Ab combo (Abbott)
  - Specimen types: fingerstick whole blood (CLIA-waived), venipuncture whole blood, plasma, serum
  - Time to result: 20 minutes
  - Performance
    - Sensitivity 99.9% (detects both antibodies and p24 antigen)
    - Specificity 99.8%
    - Advantage – 4th generation test detects HIV earlier than antibody only test
  - Cost: ~$20-30 per test

CLIA waived HIV tests – critical considerations

- Window period:
  - Antibody-only tests (OraQuick) ~3 months to detect infection reliably from initial exposure
  - 4th generation tests (Determine) ~2-4 weeks shorter window (antigen detection)
  - Note: CDC recommends 90-day window for all rapid tests when counseling patients
- **Negative predictive value – the critical metric for PrEP initiation**
  - NPV >99.9% in all settings – when the test says negative the person is almost certainly HIV negative
  - Still counsel about the window period and recent possible exposures ← this is the most likely time for a false negative
- Positive predictive value
  - PPV varies by prevalence of HIV in the population – can be as low as 30-70% in low prevalence settings
  - Many "positive" tests will be false positives in low-risk populations
  - ALL positive tests must be confirmed

PrEP implementation process – A practical workflow

- In-pharmacy activities (Day 1):
  - HIV rapid testing (CLIA-waived) – pharmacist performs
  - Risk assessment and counseling – pharmacist conducts
  - Laboratory orders placed via CPA authority: Serum creatinine (required for oral options), Hepatitis B serology (HBsAg, anti-HBs, anti-HBc), STI screening (gonorrhea/chlamydia NAAT, syphilis serology), pregnancy test (optional)
    - *Note – a rapid HBsAg test is WHO-prequalified and widely available internationally – CLIA waiver in the US may be on the horizon*
  - IF HIV test negative, pharmacist prescribes PrEP
- Patient completes within 1 week (partner sites):
  - Labs as ordered at a commercial lab or county health department
- Pharmacist follow-up within 1 week
  - Review labs and adjust if needed

How this could work

- Pharmacists are the most accessible healthcare professional ← we love to say this!
- We are perfectly positioned to provide this relatively simple service – entry level HIV testing is CLIA waived (anybody can do it)
- County health departments are there and able to perform the other requisite testing that needs doing but is not critical on day one
- Those who test positive are referred for treatment (more people with U=U)
- Those who test negative get PrEP (incredibly effective)
- Do this in a widespread fashion it works, the data shows it!

PrEP monitoring – Oral PrEP

- Every 3 months
  - HIV testing
    - Standard: CLIA-waived antigen/antibody test
    - Enhanced: Antigen/antibody test PLUS HIV-1 RNA (viral load) ← if recent exposure, symptoms, or high suspicion
  - STI screening (gonorrhea, chlamydia, syphilis) ← order via CPA
  - Pregnancy testing if applicable
  - Adherence assessment and risk reduction counseling
- Every 3-6 months
  - Serum creatinine
- Every 6-12 months
  - Lipid panel for TAF users
  - Hepatitis C screening if ongoing injection drug risk
- **Critical Safety Requirement – only prescribe 90-day supply with no refills**

PrEP monitoring – Injectable PrEP

- Cabotegravir – every 2 months (with each injection)
  - HIV testing – HIV antigen/antibody PLUS HIV-1 RNA (viral load) strongly recommended
  - STI screening
- Lenacapavir – every 6 months (with each injection)
  - HIV testing – HIV antigen/antibody PLUS HIV-1 RNA (viral load) strongly recommended
  - STI screening
- Why dual testing for injectable PrEP?
  - Dual testing strongly recommended by CDC – injectable agents are more potent at suppressing virus
  - Greater risk of delayed diagnosis with long interval (especially lenacapavir)
  - HIV-1 RNA (viral load) should be ordered via CPA
- Advantages: no renal or lipid monitoring, built in adherence due to injections, testing aligns with clinic visits

Special populations

- Adolescents
  - PrEP approved for adolescents weighing at least 35 kg
  - **Ohio consent laws**: minors can consent to STI testing and treatment (ORC 3709.241) *by a physician*
    - PrEP falls under STI prevention – minors may consent without parental involvement
    - Consult with collaborating provider on clinic policy and ensure CPA specifies age and consent procedures
    - Caution is warranted here regarding whether the CPA delegates this aspect of physician authority
  - Bone health monitoring particularly important – TAF (Descovy) less risky for bone health than TDF (Truvada)
- Pregnant and breastfeeding
  - PrEP is not contraindicated in pregnancy – pregnancy increases HIV acquisition risk
  - Extensive safety data for TDF/FTC, less for TAF/FTC but no real concerns
  - Limited data for injectable products
  - Recommendation: continue PrEP during pregnancy if ongoing HIV risk
  - Breastfeeding: compatible with oral PrEP; discuss risks vs benefits for injectable PrEP

Special populations

- Hepatitis B co infection
  - CRITICAL for tenofovir-based PrEP (TDF and TAF) as these drugs also treat hepatitis B
  - If the patient has hepatitis B, and you stop tenofovir-based PrEP → risk of severe hepatitis B flare
  - This is why we must test people at initiation of PrEP
  - If a patient has hepatitis B (HBsAG positive): We treat chronic (>6 months), not acute
    - Option 1: Use TDF or TAF based PrEP as it also treats chronic hepatitis B as a preferred agent at the same time (awesome!)
    - Option 2: Injectable PrEP PLUS separate hepatitis B treatment (cabotegravir and lenacapavir have no activity against hepatitis B)
- Drug interactions
  - Generally minimal
  - Rifampin significantly reduces cabotegravir levels (use different agent)
  - Anticonvulsants (phenytoin, phenobarbital, carbamazepine) may reduce PrEP drug levels
  - Watch out for multiple possible nephrotoxic agents with TDF

Cost and Access

- Insurance coverage (ACA Mandate)
  - PrEP is preventative care and MUST be covered with zero cost sharing
  - Includes: PrEP medication, office visits, monitoring labs (HIV tests, STI screens, creatinine)
  - Note that insurance likely will have formulary preferences – generic TDF/FTC generally is preferred
- Ohio PAPI (Prevention Assistance Program Interventions)
  - Eligibility: HIV-negative Ohio residents with income < 500% federal poverty level ($72,900 for an individual)
  - Covers:
    - Prescription co-pays
    - Office visit copays
    - Laboratory work copays
  - Providers bill PAPI directly; patient pays nothing out of pocket
- Other resources
  - Manufacturer patient assistance programs
  - Generic TDF/FTC dramatically reduces cost for cash-pay patients

https://ohiv.org/free-prep/

Current Authority in Ohio

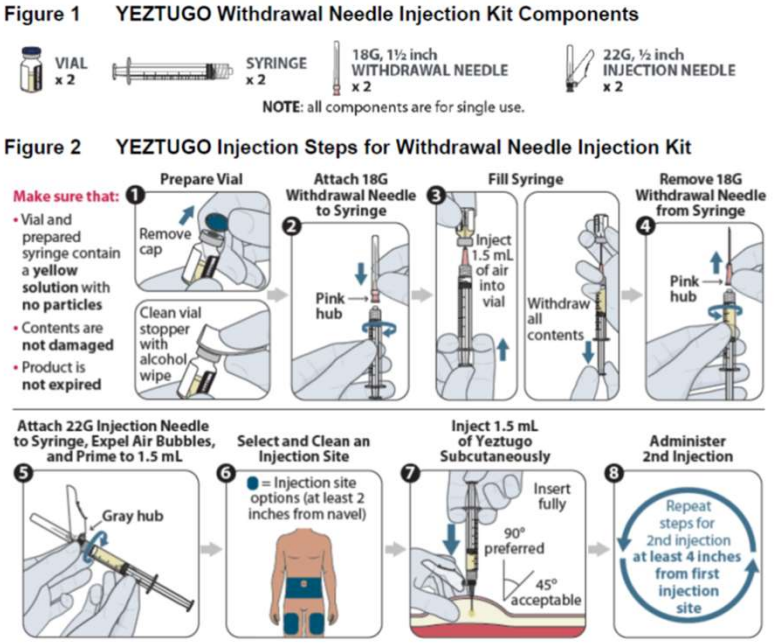
- ~15 other states have independent PrEP authority of some variety…but NOT Ohio
- Collaborative Practice Agreement (CPA) required to prescribe PrEP and order laboratory tests with the following requirements:
  - Training and/or experience in HIV prevention/PrEP (recommended but not required)
    - APhA “Pharmacy-Based HIV Prevention Services” Certificate program
    - CDC PrEP training resources: https://www.cdc.gov/hivnexus/hcp/prep/index.html
  - Ongoing practitioner-patient relationships
  - Written agreement specifying scope of practice
  - Documentation and communication requirements
  - Templates for CPAs are available through OPA website

For Long-Acting Injectable PrEP Administration

- CPA must explicitly authorize pharmacist administration of injectable PrEP
- Pharmacist must be competent in subcutaneous/intramuscular injection technique
- BLS certification must be maintained
- Appropriate injection supplies and sharps disposal
- Follow manufacturer administration guidelines

- Note: In trials pre-numbing with topical anesthetic
- was allowed (at least 30 min contact time)
- 10 minutes ice pack before injection also allowed

- Up to 65% of patients will have a noticeable “bump”



https://www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi.pdf

MOVING FORWARD

Overcoming barriers – making it work

- "I don't have a lab in the pharmacy"
  - Awesome news, you don't need one!
  - You need the CPA, then partner with labs – a county health department might be able to help you
- "Patients won't go somewhere else for testing"
  - Use health department walk in hours, if available, to maximize convenience for patients
  - Consider injectable PrEP to decrease monitoring burden (beware cost burden of drugs)
- "This seems too complicated"
  - Start small – one (friendly) physician, one formulation of PrEP
  - Try to use PAPI ← provides FREE PrEP to many Ohioans

Making it work – consider this progression

- Phase 1: Oral PrEP
  - Familiar dispensing
  - Build workflow with CLIA waived testing and partner lab testing
  - TDF/FTC (Truvada) good for most, generic, least expensive, no concerns about anatomy like with Descovy
- Phase 2: Add lenacapavir (Yeztugo)
  - Subcutaneous injection should be reasonably familiar technique
  - Twice yearly visits great for compliance and decreased lab coordination
  - Superior efficacy
  - Caution – wholesale cost >$10,000 per dose so make sure you will use it
  - Best for: patients struggling with adherence, those wanting fewer visits, whoever you can justify this option in (given superior efficacy)
- You do not have to offer every agent to have good service – for example cabotegravir is an agent that is likely less well suited for pharmacy based PrEP

Making it work – easier

- Other states allow pharmacists full independent authority to initiate PrEP, I think this is a great opportunity to advocate for our profession in this state and nationwide and it would, of course, significantly simplify all of this
- CLIA waived Hepatitis B testing could be on the horizon and would simplify initiation
- Health Information Exchange (HIE), which could allow pharmacies access to patients' electronic medical records would also simplify initiation

Need More Information?

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