

# Enhance HIV Prevention Efforts at your Health Center: Activity Session on PrEP and PEP Prescribing Workflows

Thursday April 10<sup>th</sup>, 2025

3:00 - 4:00pm Eastern / 12:00 - 1:00pm Pacific

*This project is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$550,000 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit [HRSA.gov](https://www.hrsa.gov).*

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IT'S WHO WE  
DO IT FOR.**



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A health program with international reach, focused on the most vulnerable among us.

## Locations & Service Sites



### THREE FOUNDATIONAL PILLARS

1	2	3
Clinical Excellence	Research and Development	Training the Next Generation

### Profile

- Founded: **May 1, 1972**
- Staff: **1,400**
- Active Patients: **150,000**
- Patients CY: **107,225**
- SBHCs across CT: **152**

Year	2021	2022	2023
Patients Seen	99,598	102,275	107,225

# National Training and Technical Assistance Partners (NTTAP) Clinical Workforce Development

Provides free training and technical assistance to health centers across the nation through national webinars, activity sessions, learning collaboratives, trainings, publications, and more!

To learn more, please visit <https://www.weitzmaninstitute.org/nca>.

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# Speakers

- Marwan Haddad, MD, MPH, AAHIVS, Medical Director of the Center for Key Populations, Community Health Center, Inc. (CHCI)
- Jeannie McIntosh, APRN, FNP-C, AAHIVS, Center for Key Populations, Community Health Center, Inc. (CHCI)

# Learning Objectives

At the conclusion of this activity session, participants will be able to:

- Identify who is eligible for PrEP
- What to prescribe and how to monitor people on PrEP
- Understand who is eligible for PEP and what and how to prescribe

# Overview of PrEP

# Assessing Eligibility for PrEP

- Determine eligibility based on a good sexual and substance use history.
- Prescribe PrEP if:
  - Individual has engaged in anal or vaginal sex in past 6 months and
    - Has partner with HIV, especially if unknown or detectable VL or
    - Has one or more sexual partners with no or inconsistent condom use or
    - Had bacterial STI (GC, chlamydia, syphilis) in past 6 months
  - Individual has injected in past 6 months and
    - Has injecting partner with HIV *or*
    - Has shared injection equipment
  - Individual requests PrEP

**Let's talk  
about PrEP!**



# Proactive Identification of Individuals Who Potentially Could Benefit from PrEP

- Identification of individuals at high exposure rates to HIV from electronic health records
  - Through sexual risk assessments
- HIV/STI testing
  - Syphilis, gonorrhea, chlamydia in last 6 months
- Substance use disorder diagnoses
  - ICD-10
  - Buprenorphine/methadone/naltrexone on medication list

# Laboratory Tests Prior To Prescribing PrEP

- HIV Testing
  - Negative within 7 days of PrEP prescription
    - 4th generation test (Ab/Ag test)
      - Rapid test
      - Blood draw (serum)
- No symptoms or signs of acute HIV infection in past 4-6 weeks
  - E.g. fever, fatigue, myalgia, rash, headache, sore throat, cervical adenopathy, arthralgia, night sweats, diarrhea

# Laboratory Tests Prior To Prescribing PrEP

## STI Testing

- Can be done as part of initial work up
  - PrEP prescription should not be delayed if unable to do STI testing initially

## Syphilis

- Syphilis cascade
- RPR

## Gonorrhea and Chlamydia

- Nucleic Acid Amplification Test (NAAT)
- 3- site testing of areas of exposure
  - Pharyngeal
  - Cervical/urethral
  - Rectal
  - Self collection acceptable

# Laboratory Tests Prior To Oral PrEP

## Renal Function

- TDF/FTC if Creatinine Clearance  $\geq 60$  mL/min
- TAF/FTC if Creatinine Clearance  $\geq 30$  mL/min
- NO ORAL PrEP if  $\leq 30$  mL/min

## Hepatitis B Virus (HBV)

- HBVsAg, sAb, cAb
- If chronic HBV, can experience hepatitis flares when TDF/TAF is discontinued
- Can start PrEP prior to having results

## Lipid Profile

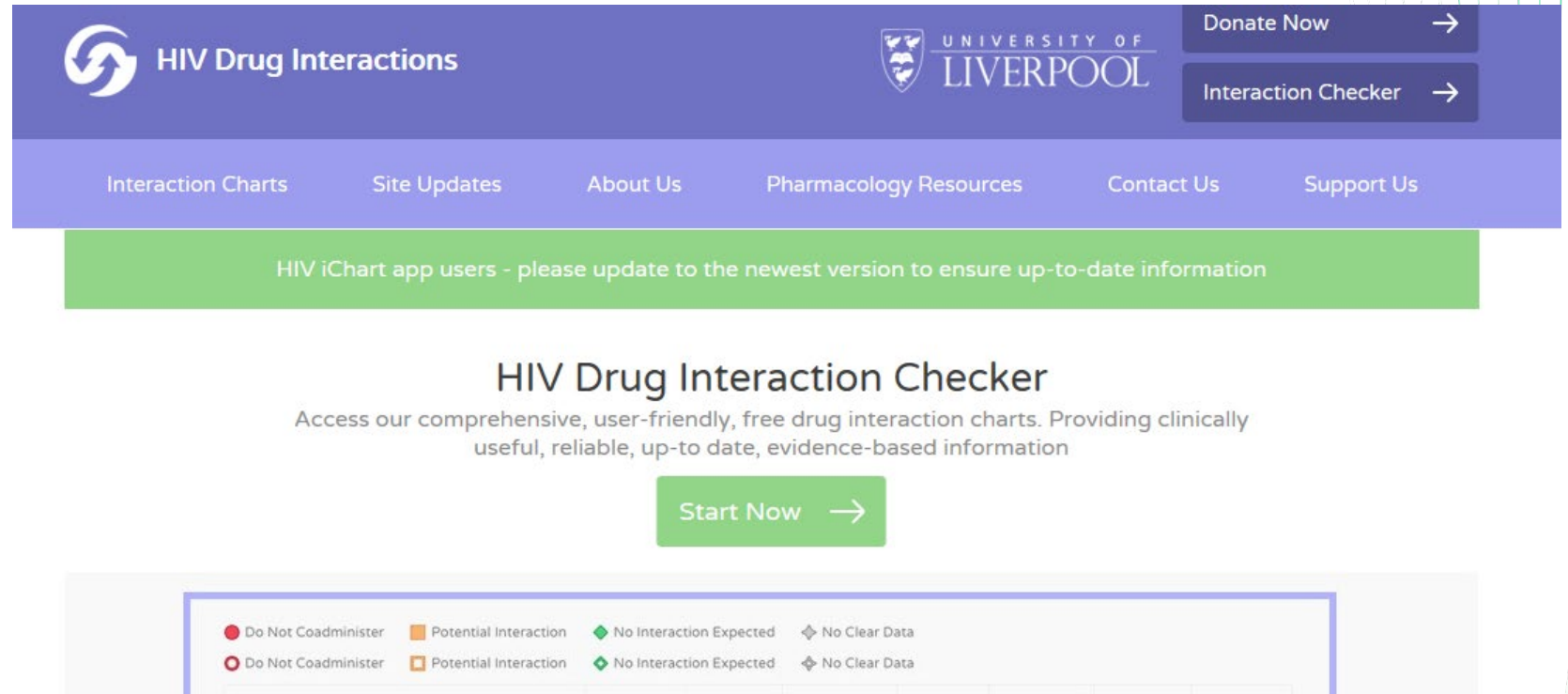
- For TAF/FTC only
- Baseline cholesterol and triglyceride levels

# Laboratory Tests NOT Routinely Indicated

- Bone mineral density DEXA scans
- Liver function tests
- Hematologic assays (CBC)
- Urinalysis



# Check for Medication Interactions



The screenshot shows the homepage of the HIV Drug Interactions website. The header is purple with the 'HIV Drug Interactions' logo on the left and the University of Liverpool logo on the right. Navigation links include 'Interaction Charts', 'Site Updates', 'About Us', 'Pharmacology Resources', 'Contact Us', and 'Support Us'. A green banner below the header reads: 'HIV iChart app users - please update to the newest version to ensure up-to-date information'. The main heading is 'HIV Drug Interaction Checker' with a subtext: 'Access our comprehensive, user-friendly, free drug interaction charts. Providing clinically useful, reliable, up-to date, evidence-based information'. A green 'Start Now' button is centered below the text. At the bottom, a legend shows four categories: 'Do Not Coadminister' (red circle), 'Potential Interaction' (orange square), 'No Interaction Expected' (green diamond), and 'No Clear Data' (grey diamond).

<http://www.hiv-druginteractions.org/>

AND/OR

Free App: Liverpool HIV iChart

# PrEP Regimens

# Oral PrEP Medication

**Table 1a: Summary of Clinician Guidance for Daily Oral PrEP Use**

	Sexually-Active Adults and Adolescents <sup>1</sup>	Persons Who Inject Drug <sup>2</sup>
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: <ul style="list-style-type: none"> <li>HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)</li> <li>Bacterial STI in past 6 months<sup>3</sup></li> <li>History of inconsistent or no condom use with sexual partner(s)</li> </ul>	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	<b><u>ALL OF THE FOLLOWING CONDITIONS ARE MET:</u></b> <ul style="list-style-type: none"> <li>Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP</li> <li>No signs/symptoms of acute HIV infection</li> <li>Estimated creatinine clearance <math>\geq 30</math> ml/min<sup>4</sup></li> <li>No contraindicated medications</li> </ul>	
Dosage	<ul style="list-style-type: none"> <li>Daily, continuing, oral doses of F/TDF (Truvada®), <math>\leq 90</math>-day supply</li> </ul> OR <ul style="list-style-type: none"> <li>For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), <math>\leq 90</math>-day supply</li> </ul>	
Follow-up care	<b><u>Follow-up visits at least every 3 months to provide the following:</u></b> <ul style="list-style-type: none"> <li>HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support</li> <li>Bacterial STI screening for MSM and transgender women who have sex with men<sup>3</sup> – oral, rectal, urine, blood</li> <li>Access to clean needles/syringes and drug treatment services for PWID</li> </ul> <b><u>Follow-up visits every 6 months to provide the following:</u></b> <ul style="list-style-type: none"> <li>Assess renal function for patients aged <math>\geq 50</math> years or who have an eCrCl <math>&lt; 90</math> ml/min at PrEP initiation</li> <li>Bacterial STI screening for all sexually-active patients<sup>3</sup> – [vaginal, oral, rectal, urine- as indicated], blood</li> </ul> <b><u>Follow-up visits every 12 months to provide the following:</u></b> <ul style="list-style-type: none"> <li>Assess renal function for all patients</li> <li>Chlamydia screening for heterosexually active women and men – vaginal, urine</li> <li>For patients on F/TAF, assess weight, triglyceride and cholesterol levels</li> </ul>	

<sup>1</sup> adolescents weighing at least 35 kg (77 lb)

<sup>2</sup> Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

<sup>3</sup> Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs

<sup>4</sup> estimated creatine clearance (eCrCl) by Cockcroft Gault formula  $\geq 60$  ml/min for F/TDF use,  $\geq 30$  ml/min for F/TAF use

# Injectable PrEP Medication

**Table 1b: Summary of Clinician Guidance for Cabotegravir Injection PrEP Use**

	Sexually-Active Adults	Persons Who Inject Drugs <sup>1</sup>
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: <ul style="list-style-type: none"> <li>HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)</li> <li>Bacterial STI in past 6 months<sup>2</sup></li> <li>History of inconsistent or no condom use with sexual partner(s)</li> </ul>	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	<b><u>ALL OF THE FOLLOWING CONDITIONS ARE MET:</u></b> <ul style="list-style-type: none"> <li>Documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection</li> <li>No signs/symptoms of acute HIV infection</li> <li>No contraindicated medications or conditions</li> </ul>	
Dosage	<ul style="list-style-type: none"> <li>600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle               <ul style="list-style-type: none"> <li>Initial dose</li> <li>Second dose 4 weeks after first dose (month 1 follow-up visit)</li> <li>Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)</li> </ul> </li> </ul>	
Follow-up care	<b><u>At follow-up visit 1 month after first injection</u></b> <ul style="list-style-type: none"> <li>HIV Ag/Ab test and HIV-1 RNA assay</li> </ul> <b><u>At follow-up visits every 2 months (beginning with the third injection – month 3) provide the following:</u></b> <ul style="list-style-type: none"> <li>HIV Ag/Ab test and HIV-1 RNA assay</li> <li>Access to clean needles/syringes and drug treatment services for PWID</li> </ul> <b><u>At follow-up visits every 4 months (beginning with the third injection- month 3) provide the following:</u></b> <ul style="list-style-type: none"> <li>Bacterial STI screening<sup>2</sup> for MSM and transgender women who have sex with men<sup>2</sup> – oral, rectal, urine, blood</li> </ul> <b><u>At follow-up visits every 6 months (beginning with the fifth injection – month 7) provide the following:</u></b> <ul style="list-style-type: none"> <li>Bacterial STI screening<sup>1</sup> for all heterosexually-active women and men – [vaginal, rectal, urine - as indicated], blood</li> </ul> <b><u>At follow-up visits at least every 12 months (after the first injection) provide the following:</u></b> <ul style="list-style-type: none"> <li>Assess desire to continue injections for PrEP</li> <li>Chlamydia screening for heterosexually active women and men – vaginal, urine</li> </ul> <b><u>At follow-up visits when discontinuing cabotegravir injections provide the following:</u></b>	

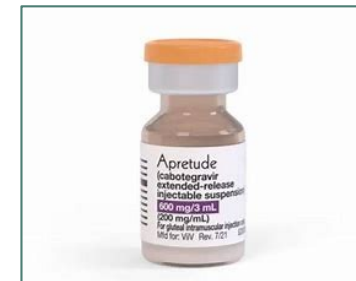
<sup>1</sup> Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

<sup>2</sup> Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs



# Recommended PrEP Regimens

- Fixed-dose TDF/FTC (Truvada or generic) for all individuals with sexual or injection risk
  - Single pill once daily
  - On-Demand 2-1-1 (MSM only)
- Fixed-dose TAF/FTC (Descovy) for sexual prevention in men who have sex with men
  - Single pill once daily
- Injectable cabotegravir (Apretude) for adults and adolescents at least 35 kg for sexual risk
  - Monthly injection for 2 months then every other month.





# Drug Manufacturers Patient Assistance Programs

## Truvada and Descovy

- Copay Coupon Card for commercially insured patients with high copay
- Patient Support Program for patients without prescription drug coverage



## Apretude

- Savings Program for commercially insured patients
  - up to \$7,500 in assistance with out-of-pocket costs per year
- Patient Assistance Program (PAP)
  - Free medication for patients with very limited (or no) prescription drug coverage
  - Household income  $\leq$  500% federal poverty level



# Discounted Generic Emtricitabine/Tenofovir DF

- 30-day supply for less than \$30 per month
- A good option for patients who want to pick up the Rx immediately and do not mind paying out-of-pocket
- **Options:**
  - 340B – at eligible clinics serving low-income communities
  - Pharmacy discount programs
  - GoodRx <https://www.goodrx.com/truvada>

# 2-1-1 Oral PrEP On-Demand

- Taking PrEP before and after sex, instead of daily.
  - 2 pills at least 2-24 hours before sex
  - 1 pill 24 hours after first dose
  - 1 pill 48 hours after first dose
  - If sexual activity continues, take 1 pill every 24 hrs until 48 hrs after last encounter.
- Only studied in MSM and only with TDF/FTC (Truvada).
  - ANRS Ipergay, ANRS Prevenir, AMPrEP studies
- Not FDA approved but is recommended as an option in CDC Guidelines
- For those who experience side effects, they may continue to occur with every use.
- Best to avoid in a person with chronic active Hepatitis B infection.



# Oral PrEP Prescribing

- Limit refills based on recommended intervals for HIV testing
  - Daily PrEP ( $\leq 90$  days)
  - 2-1-1 PrEP ( $\leq 30$  days)

# STI Prevention: DoxyPEP

- Eligibility: Men who have sex with men with STI in the past 12 months
  - Insufficient data in women (consider with shared decision making)
- **Doxycycline 200 mg single dose soon after sexual encounter and within 72 hours**
  - No more than one dose of 200 mg in 24 hrs
- Screen for STIs regularly while using doxyPEP
- Efficacy against
  - Chlamydia (74-86%)
  - Syphilis (77-79%)
  - GC (33-57%) likely due to baseline tetracycline resistance
- Antimicrobial resistance ongoing concern and being studied





# Transitioning from Oral to Injectable PrEP

- Evaluating patient preferences
- Assessing adherence challenges
- Discussing potential benefits
- Considering individual circumstances
- Addressing concerns
- Monitoring and support
- Coverage:
  - Insurance; prior authorization
  - Patient Assistance Program through ViiV Connect (uninsured and underinsured)

# Considerations for Same Day PrEP

- HIV test and serum creatinine
  - Point of care
  - Blood draw
- Assistance for enrolling in health insurance, copayment assistance, medication assistance programs for uninsured or underinsured.
- Rapid follow up contact for patients (e.g. for positive/abnormal results)
- Scheduled follow up visits
- Clinicians available to prescribe oral PrEP or administer IM injection
- STI testing if available/possible

# Considerations for Same Day PrEP

- NOT APPROPRIATE if:
  - Ambivalence about PrEP
  - Cannot draw blood
  - Signs/symptoms of possible acute HIV
  - History of renal disease or associated conditions (DM, HTN) (for Oral PrEP)
  - No insurance or means to pay
  - No confirmed means of contact
- May not be appropriate if:
  - Very recent possible HIV exposure
    - May be eligible for nPEP (started within 72 hours, taken for 28 days, and if ongoing risk, can immediately switch to PrEP with HIV negative screen at end of 28 days of nPEP)
  - Not easily contacted for return visits
  - Mental health conditions present that interfere with understanding of PrEP requirements

# PrEP by Telehealth

- Conduct PrEP screening, initiation, or follow up visits by phone or video-based telehealth.
- Obtain specimens for HIV, STI, renal function and other-related tests
  - Laboratory visits for specimen collection only
  - Order home specimen collection kits for specified tests
    - Fingertick
    - Self collected swabs or urine
    - Mailed to patient and mailed back to lab
- When HIV negative is confirmed, provide prescription for 90 days to minimize trips to pharmacy and to facilitate adherence.

# PrEP Monitoring

- **Oral PrEP Monitoring (F/TDF, F/TAF)**
  - HIV test (Ab/Ag +/- HIV RNA) every 3 months
  - STI screening every 3 months for MSM and every 6 months for all others
  - Renal function every 6 months for 50+ and GFR<90, once a year for all others.
  - If on F/TAF, lipids once a year
- **Injectable PrEP Monitoring (Cabotegravir)**
  - HIV test (Ab/Ag +/- HIV RNA) every 2 months
  - STI screening every 4 months for MSM and every 6 months for all others



# PrEP Protocol and Policy

- Serve as reference for providers and other clinical team members.
- Set clinical expectations.
- Include information that clinical providers/teams would want.
- Evidence-based/Guidelines-based
- CHCI Example – [access here](#)

<b>Policy Name:</b>	<b>Pre-exposure Prophylaxis for HIV</b>
<b>Department:</b>	<b>Medical</b>
<b>Location of Policy:</b>	<b>Provision of Care, Treatment and Services</b>
<b>Date Effective:</b>	
<b>Revision:</b>	<b>December, 2014 (Dr. Huddleston)</b>
	<b>August, 2015 (Dr. Haddad); May 3, 2021, May 12, 2022 (Haddad)</b>
<b>Reviewed:</b>	<b>July 2017</b>

# CHCI PrEP Policy Overview

- Rationale
- PrEP Program Info
- Definition
- Identification of PrEP Candidates
- Eligibility
- PrEP Initiation
  - Choice of PrEP
  - Dosing and Adherence
  - Adverse Effects
  - Protection against HIV after PrEP Start and D/C
- Prescribing and Monitoring Recommendations
- PrEP Medication Switch
- Discontinuation
- Pregnancy
- Risk Reduction Counseling
- Adherence Counseling
- Access and Coverage of PrEP
- Appendices: Useful Websites/ Guidelines, Templates

# PrEP Process Workflow

# Clinician Prescriber Role

- Essential to PrEP Program
  - Sets tone for program and for Clinical Team Members
- Identifying PrEP Champion Provider
- Provider Training and Support
  - Webinars
  - Protocols/Guidelines/Quick References
  - Mentorships
  - ECHOs
- PrEP Templates in Health Records
- Sexual Risk Assessment Template in Health Records



# PrEP Discussion

c/o	Denies	Symptom	Duration	Notes
S		PrEP Discussion		
S		PrEP Initial		
S		Oral PrEP Follow...		
S		Injectable PrEP ...		

PI Notes:PrEP Discu... TESTPATIENT, aeion Jan 1, 1991 (31 yo F) Acc No. 695455 App: (11/11/2021 ...)

Default Default For All Clear Clear All

Name	Value	Notes
<input type="checkbox"/> Risk: Sexually Active Past 6 Months		
<input type="checkbox"/> Risk: Injecting Drugs		
<input type="checkbox"/> Outcome:		

☐ [Select all]  
☐ Sexual Partner with HIV  
☐ Bacterial STI past 6 months  
☐ Inconsistent or no condom use  
☐ NA

HPI Notes:PrEP Discu... TESTPATIENT, aeion Jan 1, 1991 (31 yo F) Acc No. 695455 App: (11/11/2021 ...)

Default Default For All Clear Clear All

Name	Value	Notes
<input type="checkbox"/> Risk: Sexually Active Past 6 Months		
<input type="checkbox"/> Risk: Injecting Drugs		
<input type="checkbox"/> Outcome:		

☐ [Select all]  
☐ Injecting partner with HIV  
☐ Sharing injection equipment  
☐ NA

HPI Notes:PrEP Discu... TESTPATIENT, aeion Jan 1, 1991 (31 yo F) Acc No. 695455 App: (11/11/2021 ...)

Default Default For All Clear Clear All

Name	Value	Notes
<input type="checkbox"/> Risk: Sexually Active Past 6 Months		
<input type="checkbox"/> Risk: Injecting Drugs		
<input type="checkbox"/> Outcome:		

☐ Offered and will consider  
☐ Accepted  
☐ Declined





# Oral PrEP Monitoring Visit

Oral Prep:

HPI ▸ Notes:Oral PrEP ... TESTPATIENT, aeioun Jan 1, 1991 (31 yo F) Acc No. 695455 Appt: (11/11/2021 ...)

Default ▾ Default For All ▾ Clear Clear All

Name	Value	Notes
<input type="checkbox"/> Wanting to continue PrEP?	<input type="text"/>	x
<input type="checkbox"/> Adherence Assessed?	<input type="radio"/> Yes <input type="radio"/> No	x
<input type="checkbox"/> Side Effects	<input type="text"/>	
<input type="checkbox"/> Risk Reduction Counseling	<input type="radio"/> Every 3 months at least, for MSM and transw <input type="radio"/> Every 6 months at least, for all others	
<input type="checkbox"/> HIV Ab/Ag+HIV RNA at Least Every 3 Month ...	<input type="text"/>	
<input type="checkbox"/> STI Screening (syphilis, GC, chlamydia 3 ...	<input type="checkbox"/> [Select all] <input type="checkbox"/> Condom use for STIs <input type="checkbox"/> No sharing of injecting equipment <input type="checkbox"/> Syringe Services Program <input type="checkbox"/> PEP <input type="checkbox"/> U=U <input type="checkbox"/> Medication for substance use disorders <input type="checkbox"/> Regular STI testing	x
<input type="checkbox"/> Renal Function		x
<input type="checkbox"/> Lipid Levels for TAF/FTC		x
<input type="checkbox"/> Pregnant?		
<input type="checkbox"/> Discussion if discontinuing Oral PrEP	<input type="checkbox"/> [Select all] <input type="checkbox"/> Assessed ongoing HIV risks <input type="checkbox"/> If ongoing risk, advised on other prevention s <input type="checkbox"/> Continue follow up with HIV testing regularly	

# Injectable PrEP Monitoring Visit

Name	Value
<input type="checkbox"/> Wanting to continue PrEP?	Yes
<input type="checkbox"/> Adherence Assessed?	Yes
<input type="checkbox"/> Cabotegravir Side Effects Reviewed	Injection site reactions, Poten...
<input type="checkbox"/> Risk Reduction Counseling	Condom use for STIs, No sha...
<input type="checkbox"/> HIV Ab/Ag+HIV RNA at Every Injection Vis ...	Positive
<input checked="" type="checkbox"/> STI Screening (syphilis, GC, chlamydia 3 ...	Every 4 months at least, for ...
<input type="checkbox"/> Ordered:	
<input type="checkbox"/> Pregnant?	
<input type="checkbox"/> Discussion if discontinuing Cabotegravir	

☐ [Select all]  
☐ Reviewed risk of persistent Cabotegravir level  
☐ Assessed ongoing HIV risks  
☐ If ongoing risk, advised to take oral PrEP with  
☐ Continue follow up with HIV testing regularly

☐ [Select all]  
☐ Oral  
☐ Rectal  
☐ Urine  
☐ Blood

# PrEP Order Set

ORDER SET: PrEP

New Copy Update Delete

MEASURE:

QUICK ORDER SET: YES

DIAGNOSES (TRIGGER):

DIAGNOSES (LINKED):

AGE (TRIGGER): All Age

GENDER (TRIGGER): Unknown

Display Labs/DI based on

☒ Show All
 ☐ Show Favorite Lab Companies Only

★

**PRACTICE ADMINISTRATOR**

•	Truvada	200 mg-300 mg	sex, then 1 tab a day for the next 2 days	as directed	30 day(s)	0	Orally	tablet	30			
•	Descovy	200 mg-25 mg	1 tab(s)	once a day	30 day(s)	0	orally	tablet	30			
•	Apretude (cabotegravir)	600mg/3ml	inject 3ml	as directed	60 days	0	IM	injection	1 kit			

Labs

Browse

	Description	Lab Company	Delete
•	COMPREHENSIVE METABOLIC PANEL	QuestQLS	✖
•	LIPID PANEL	QuestQLS	✖
•	Renal Function Panel w/eGFR 10314	QuestQLS	✖
•	Syphilis Antibody Cascading Reflex 90349	QuestQLS	✖
•	Trichomonas Urine Female 19550	QuestQLS	✖
•	Trichomonas Urine Male 90801	QuestQLS	✖
•	Gonorrhea RNA, TMA, RECTAL 16504	QuestQLS	✖
•	Gonorrhea RNA, TMA, THROAT 70049	QuestQLS	✖
•	Hepatitis Panel, Acute incl IGM C2228	QuestQLS	✖
•	Hepatitis Panel, Chronic w reflex C2229	QuestQLS	✖
•	RPR (Monitor) w/rfx Titer 799	QuestQLS	✖
•	RPR (DX) W/REFL TITER AND CONFIRMATORY TESTING 36126	QuestQLS	✖
•	HCV Ab w/ refl to HCV RNA, QN PCR 8472	QuestQLS	✖
•	HBV core Ab, Total 501	QuestQLS	✖
•	HBV s Ag w/reflex conf 498	QuestQLS	✖
•	HBV Surface AB, QL w rfx QN 26526	QuestQLS	✖
•	HIV 1 /HIV-2 Screen 91431	QuestQLS	✖
•	HIV 1 /RNA, quantitative, real-time PCR 40085	QuestQLS	✖
•	HIV 1 /HIV-2 Rapid Test (Alere Determine) IH	QuestQLS	✖
•	Chl/GC aptima urine/endocervical/urethral 11363	QuestQLS	✖
•	Chlamydia trachomatis RNA TMA, Urogenital 15083	QuestQLS	✖
•	Chlamydia trachomatis RNA, TMA, Urogenital 11361	QuestQLS	✖
•	Chlamydia Trachomatis, RNA, TMA, Rectal 16505	QuestQLS	✖
•	Chlamydia Trachomatis, RNA, TMA, Throat 70048	QuestQLS	✖
•	Chlamydia Trachomatis/Neisseria Gonorrhoeae, RNA, TMA, Throat 70051	QuestQLS	✖
•	Chlamydia/N. gonorrhoeae and T. vaginalis RNA, Qualitative, TMA, Pap Vial 91448	QuestQLS	✖
•	Chlamydia/N. gonorrhoeae, T. vaginalis, Qualitative, TMA and HSV-1/2 DNA, Real-Time PCR, Pap Vial 91437	QuestQLS	✖
•	Chlamydia/Neisseria gonorrhoeae RNA, TMA, Rectal 16506	QuestQLS	✖



# Nursing Role

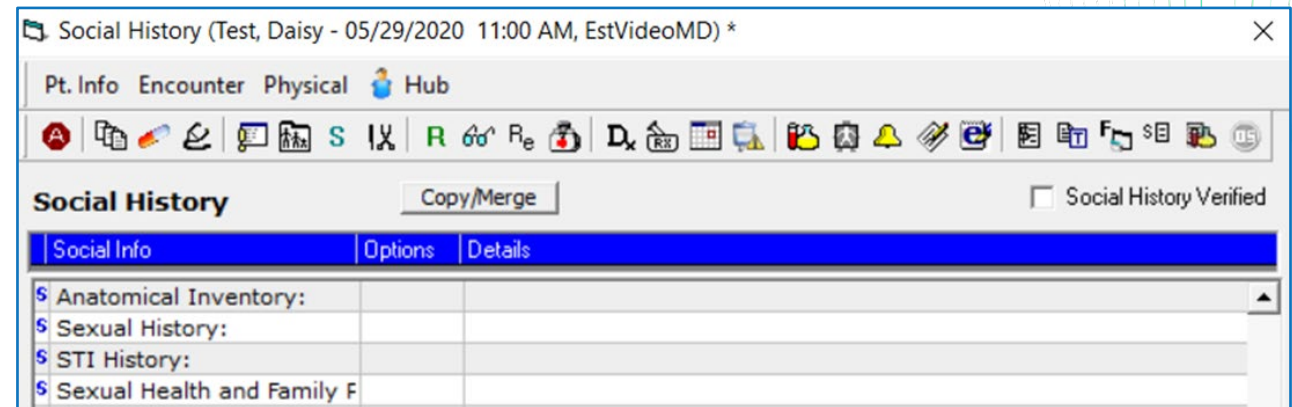
- Provider Support
- Patient Resource and Support
- Patient Counseling/Risk Reduction Counseling
- Self-management Goals
- Planned Care/PrEP Dashboards
- Nursing Visits for PrEP/STI Screening
  - Specimen Collections
  - HIV Rapid Testing





# STI Nursing Visit

- Provider-directed visit currently
- Standing order for patient-directed visit (near future)
- History including 5 P's
  - Anatomical inventory
  - Sexual History
  - STI History
  - Sexual Health and Family Planning
- Testing:
  - Urine and pharyngeal swab collection
  - Self collection of rectal/vaginal swabs
  - HIV rapid test
- Lab orders for blood draw (HIV, syphilis, HCV, HBV)
- Vaccinations (e.g. HAV, HBV, HPV)
- Patient education/counseling (PrEP, condom distribution)



Social History (Test, Daisy - 05/29/2020 11:00 AM, EstVideoMD) \*

Pt. Info Encounter Physical Hub

**Social History** Copy/Merge ☐ Social History Verified

Social Info	Options	Details
5 Anatomical Inventory:		
5 Sexual History:		
5 STI History:		
5 Sexual Health and Family F		

# Medical Assistant Role

- Planned Care Dashboard
- PrEP Dashboard
- Specimen Collections
- HIV Rapid Testing
- Patient Support



## Planned Care Dashboard and Clinical Expectation: Universal HIV Screening

ALERTS	Last Date	Due Date	Value	Notes
Needs Flu Vaccine 2016-2017				
DM Retinopathy	4/14/2015	4/14/2016		
Body Mass Index	5/16/2016		34.41	Needs Education
HIV Screen Needed				Once, 13-64 yrs old

**Policy:** Clinical Expectations for Medical Providers  
**Location:** Provision of Care, Treatment, and Services  
**Department:** Medical

Lung Cancer (USPSTF))	Asymptomatic adults aged 55 to 80 years who have a 30 pack year smoking history and currently smoke or have quit within the past 15 years: Screen annually with low dose Computed Tomography until the patient has not smoked for 15 years.
HIV Screening (CDC)	HIV screening been <u>done/offered</u> to patients ages 13-64 at least once.
HCV Screening (USPSTF)	<ul style="list-style-type: none"> <li>HCV screening for persons at high risk for infection</li> <li>One time screening in individuals born between 1945-1965</li> </ul>
Depression Screening – adolescents (AAP/USPSTF)	<del>Annual depression screening for adolescents ages 12 and above.</del>
Depression Screening – adults (USPSTF)	Annual depression screening for adults ages 18 and above.

# Planned Care Dashboard: STI Screening

- Routine annual STI Screening for specific groups:
  - Women 13-24 (chlamydia)
  - MSM and others at increased exposure risk (3-site testing chlamydia/gonorrhea, syphilis)
  - PrEP Patients (3-site testing chlamydia/gonorrhea, syphilis)

ALERTS	Last Date	Due Date	Value	Notes
Dental Exam				
Needs Flu Vaccine 2017-2018				
Body Mass Index	2/23/2018		58.89	Needs Education if BMI is under 19 OR over 25
HIV Screen Needed				Once, 13-64 yrs old
SBIRT	10/4/2016			Yearly, 18+ yrs old
HTN	2/23/2018		140/87	
STI Screening: Chlamydia. Gonorrhea. Syphilis.				STI screening recommend annually



# Rectal Specimen Patient Self-Collection



## INSTRUCTIONS FOR PATIENTS: How to Swab Your Bottom:

1. Wash your hands.
2. Take out the blue swab from the package.
3. Open your bottom by using one hand to spread your cheek.
4. Put the swab inside your bottom about 1 – 2 inches. That is about the length of your pinkie finger.



5. Turn the swab around 3 times.
6. Make sure the swab touches all sides of the inside of your bottom

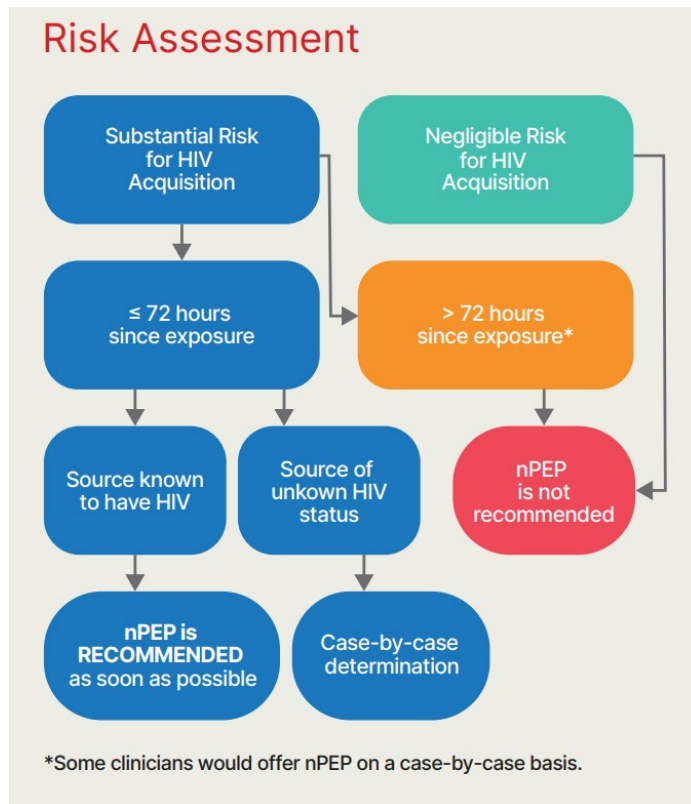


7. Take the swab out of your bottom.
8. Put the cotton tip of the swab inside the tube.
9. Break the swab at the mark that is near the end of the swab handle.
10. Throw away the end of the handle.
11. Close the tube with the cotton end of the swab inside.
12. Give it back to your provider



# Non-Occupational Post Exposure Prophylaxis (nPEP) Prescribing Workflow

# Recommendations for Use of ARVs for nPEP



## Substantial Risk for HIV Acquisition

**Exposure of:** vagina, penis, rectum, eye, mouth or other mucous membrane, non-intact skin, or percutaneous contact

**With:** blood, semen, vaginal secretions, rectal secretions, breast milk, any body fluid that is visibly contaminated with blood

**When:** the source is known to have HIV

## Negligible Risk for HIV Acquisition

**Exposure of:** vagina, penis, rectum, eye, mouth or other mucous membrane, non-intact skin, or percutaneous contact

**With:** urine, nasal secretions, saliva, sweat, tears (if visible blood, see "Substantial Risk for HIV Acquisition")

**When:** regardless of the known or suspected HIV status of the source

# Determinations Prior to nPEP

- **Person seeking nPEP**
  - HIV status
    - Perform HIV baseline testing on persons seeking nPEP, ideally with HIV Ab/Ag test
  - Time and frequency of exposure
    - nPEP is less likely to be effective >72 hours post-exposure
  - Type of exposure
    - Sexual, injection drug use, or other exposure
    - Determine relative risk of exposure
- **Source patient**
  - With HIV
    - Consider nPEP if within 72 hours of exposure
    - When possible, determine source patient's ARV use and viral load
  - HIV Status Unknown
    - Determine if source patient available for testing
    - If from high prevalence group, risk might be increased
- **Do not delay in starting nPEP**

# Special Considerations for:

- Pregnant women and women of childbearing potential
- Children
- Sexual assault survivors
- Inmates
- People who inject drugs

# nPEP Recommended Regimens

**Table 5. Preferred and alternative antiretroviral medication 28-day regimens for nPEP<sup>a,b</sup>**

Age group	Preferred/ alternative	Medication
Adults and adolescents aged $\geq 13$ years, including pregnant women, with normal renal function (creatinine clearance $\geq 60$ mL/min)	Preferred	A 3-drug regimen consisting of tenofovir DF 300 mg <i>and</i> fixed dose combination emtricitabine 200 mg (Truvada <sup>c</sup> ) once daily <i>with</i> raltegravir 400 mg twice daily <i>or</i> dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of tenofovir DF 300 mg <i>and</i> fixed dose combination emtricitabine 200 mg (Truvada) once daily <i>with</i> darunavir 800 mg (as 2, 400-mg tablets) once daily <i>and</i> ritonavir <sup>b</sup> 100 mg once daily





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SCIENCE NEWS

## Biktarvy Can Be a Good Option for Post-Exposure Prophylaxis

Study results showing that Biktarvy is convenient and well tolerated suggest that it should be added to PEP guidelines.

April 3, 2024 • By Liz Highleyman



PREVENTION RESEARCH

## Safety and Tolerability of Once Daily Coformulated Bictegravir, Emtricitabine, and Tenofovir Alafenamide for Postexposure Prophylaxis After Sexual Exposure

Mayer, Kenneth H. MD<sup>a,b,c</sup>; Gelman, Marcy NP<sup>a</sup>; Holmes, Johnathon NP<sup>a</sup>; Kraft, Jessica NP<sup>a</sup>; Melbourne, Kathleen PharmD<sup>d</sup>; Mimiaga, Matthew J. ScD, MPH<sup>a,e</sup>

Author Information 

*JAIDS Journal of Acquired Immune Deficiency Syndromes* 90(1):p 27-32, May 1, 2022. | DOI:  
10.1097/QAI.0000000000002912



### Methods:

Individuals accessing PEP were enrolled in an open-label study of coformulated BIC/FTC/TAF, taken as one pill daily for 28 days. Pearson's  $\chi^2$  and Fisher's exact tests were used to assess whether BIC/FTC/TAF differed with respect to side effects and regimen completion rates compared with historical PEP regimens.

### Results:

Between August, 2018 and March, 2020, 52 individuals enrolled in the study. Most identified as cisgender gay (67.3%) or bisexual (11.5%) men, but 7.7% identified as cisgender heterosexual men and 3.8% cisgender heterosexual women. The most common regimen side effects were nausea or vomiting (15.4%), fatigue (9.6%), and diarrhea/loose stools (7.7%), which were less common than historical controls using other PEP regimens, including those containing other integrase strand transfer inhibitors. Only 1 participant discontinued the regimen because of fatigue, and all other side effects were self-limited. Almost all participants (90.4%) completed the indicated regimen, which was a higher completion rate compared with earlier PEP regimens, and none became HIV-positive.

### Conclusions:

BIC/FTC/TAF coformulated as a single daily pill was found to be safe, well-tolerated, and highly acceptable when used for PEP, and compared more favorably than historical PEP regimens used at an urban health center.

## CONFERENCE DATES AND LOCATION

March 3-6, 2024 | Denver, Colorado

## ABSTRACT NUMBER

1134

## SESSION TITLE

PEP Prevention Toolbox: Do We Know How to Use It?

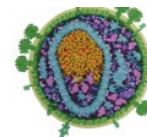
## SESSION NUMBER

Themed Discussion-03

## AUTHORS

Darrell H. Tan, Reva Persaud, Attia Qamar, Isaac I. Bogoch, Arlene Chan, Allison Chris, Karla Fisher, Richard T. Lester, John Maxwell, James Murray, Hong Qian, Hubert Wong

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**CROI**  
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## BIC/FTC/TAF as HIV PEP Was Well-Tolerated With High Adherence and No Seroconversions

### Methods:

Adults initiating a standard PEP regimen within the preceding five days for a confirmed or potential sexual exposure to HIV were randomized to either receive short message service (SMS) check-ins using the WelTel platform, or standard care. All participants underwent baseline HIV testing and were switched from their original PEP regimen (if applicable) to B/F/TAF to complete 28 days. CBC, ALT and creatinine were assessed at week 2; medication adherence at week 4; HIV serology at weeks 6 and 12; and adverse events at all visits.



## Results:

Of 120 individuals screened for participation in the trial, 119 participants were enrolled and are included in this analysis; all were HIV-negative at baseline. Median (interquartile range) age was 29 (25, 34) years and 22% had previously used PEP. Most (86%) were men who have sex with men. Medication adherence was high; among 101 participants with available data, all took all 28 days of PEP except for two who stopped prematurely after 7 and 8 days respectively. B/F/TAF was well-tolerated, with only 11% experiencing adverse events of grade  $\geq 2$  severity; 38% experiencing AEs at least possibly related to study drug (Table), most often gastrointestinal. No HIV seroconversions were observed.

## Conclusions:

B/F/TAF PEP was associated with high tolerability, high adherence and no HIV seroconversion in this cohort. These data support the use of this single tablet regimen as HIV PEP after sexual exposures.

**Table: Adverse events occurring in >3% of participants receiving B/F/TAF PEP**

Adverse event	Overall N (% of participants)	Severity grade $\geq 2$ N (% of participants)	Any grade, at least possibly related to study drug N (% of participants)
Diarrhea	11(8%)	4 (3%)	10 (8%)
Dizziness	5 (4%)	0 (0%)	5 (4%)
Fatigue	21(18%)	2 (2%)	21 (18%)
Headache	9 (8%)	0 (0%)	9 (8%)
Insomnia	4 (3%)	0 (0%)	4 (3%)
Lethargy	3 (3%)	0 (0%)	3 (3%)
Nausea	13 (11%)	0 (0%)	13 (11%)

## Follow-up:

- Check in with patient within first few days of nPEP start.
- At end of nPEP
- Consider additional visits based on clinical circumstances.
- Visits could be in-person or telehealth.
- Other clinical team members could check-in with patient.

**Table 2. Recommended schedule of laboratory evaluations of source and exposed persons for providing nPEP with preferred regimens**

Test	Source	Exposed persons			
	Baseline	Baseline	4–6 weeks after exposure	3 months after exposure	6 months after exposure
		For all persons considered for or prescribed nPEP for any exposure			
HIV Ag/Ab testing <sup>a</sup> (or antibody testing if Ag/Ab test unavailable)	✓	✓	✓	✓	✓ <sup>b</sup>
Hepatitis B serology, including: hepatitis B surface antigen hepatitis B surface antibody hepatitis B core antibody	✓	✓	—	—	✓ <sup>c</sup>
Hepatitis C antibody test	✓	✓	—	—	✓ <sup>d</sup>
		For all persons considered for or prescribed nPEP for sexual exposure			
Syphilis serology <sup>e</sup>	✓	✓	✓	—	✓
Gonorrhea <sup>f</sup>	✓	✓	✓ <sup>g</sup>	—	—
Chlamydia <sup>f</sup>	✓	✓	✓ <sup>g</sup>	—	—
Pregnancy <sup>h</sup>	—	✓	✓	—	—
		For persons prescribed tenofovir DF+ emtricitabine + raltegravir or tenofovir DF+ emtricitabine + dolutegravir			
Serum creatinine (for calculating estimated creatinine clearance <sup>i</sup> )		✓	✓	—	—
Alanine transaminase, aspartate aminotransferase		✓	✓	—	—
		For all persons with HIV infection confirmed at any visit			
HIV viral load	✓			✓ <sup>j</sup>	
HIV genotypic resistance	✓			✓ <sup>j</sup>	



# nPEP Risks and Considerations

- ARV side effects and toxicity
- Selection of resistant HIV virus if HIV infection occurs
- Risk-reduction behaviors and behavioral interventions
- Pregnancy
- Adherence to regimen and follow up testing
- Barriers to receiving nPEP
  - Low levels of awareness
  - Lack of access



## PrEP After nPEP

- Persons who are at ongoing risk of HIV should be offered PrEP immediately after 28 days of nPEP.
- A gap between nPEP and PrEP is NOT necessary
- No proof that taking nPEP delays seroconversion
- nPEP is highly effective
- Test for HIV, ideally with 4th generation Ab/Ag +/- HIV RNA test at end of nPEP

## nPEP in Context of PrEP

- If person is adherent to PrEP and a HIV exposure occurs, no need for nPEP since PrEP is highly effective.
- If person is non-adherent to PrEP and has high risk exposure, 28-day nPEP may be indicated.
  - Continue PrEP after 28 day nPEP if ongoing risk and HIV test is negative.

# Questions?

# Wrap-Up



# Enhance HIV Prevention Efforts at your Health Center

## Upcoming Activity Sessions

Register Here: [link](#)

- **May 1<sup>st</sup>:** Effective Education and Outreach
- **May 22<sup>nd</sup>:** Managing Your HIV Prevention Program

# Explore more resources!

## National Learning Library: Resources for Clinical Workforce Development

National Learning Library



CHC has curated a series of resources, including webinars to support your health center through education, assistance and training.

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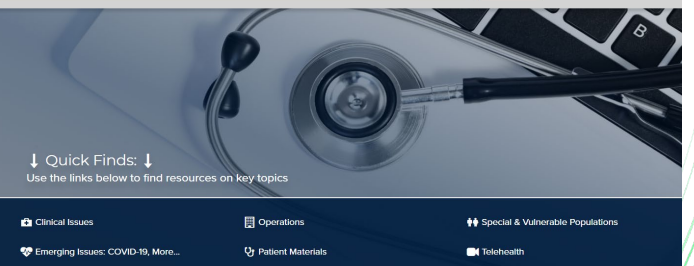
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