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Clinical Workforce Development
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Health System

Developing a PrEP Framework for Your Health Center

Thursday, December 14, 2023
3:00-4:00pm Eastern / 12:00-1:00pm Pacific

At the Weitzman Institute, we value a culture of equity, inclusiveness, diversity, and mutually respectful dialogue. We want to ensure that all feel welcome. If there is anything said in our program that makes you feel uncomfortable, please let us know via email at nca@chc1.com

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National Training and Technical Assistance Partners

Clinical Workforce Development

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

Team-Based Care

- Fundamentals of Comprehensive Care
- Advancing Team-Based Care

Training the Next Generation

- Postgraduate Residency and Fellowship Training
- Health Professions Training

Emerging Issue

- HIV Prevention

Advancing Health Equity

Preparedness for Emergencies and Environmental Impacts on Health

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Speakers

- **Marwan Haddad**, MD, MPH, AAHIVS
  - Medical Director, Center for Key Populations, Community Health Center, Inc.
- **Jeannie McIntosh**, APRN, FNP-C, AAHIVS
  - Family Nurse Practitioner, Center for Key Populations, Community Health Center, Inc.

Objectives

By the end of this session, you'll be able to:

- Write or revise your own protocols and templates for PrEP using CHCI best practices as a framework
- Discuss clinical team members' roles in the process
  - Provider, Nurse, Medical Assistant, PrEP Navigator
  - QI team project

Protocols and Templates

- 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

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PrEP Protocol: Based on CDC Guideline 2021

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE

A CLINICAL PRACTICE GUIDELINE

CENTER FOR KEY POPULATIONS

Oral PrEP Medication

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

	Sexually-Active Adults and Adolescents[1]	Persons Who Inject Drug[2]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[3] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min[4] • No contraindicated medications	
Dosage	• Daily, continuing, oral doses of F/TDF (Truvada®), ≤90-day supply OR • For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), ≤90-day supply	
Follow-up care	**Follow-up visits at least every 3 months to provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support • Bacterial STI screening for MSM and transgender women who have sex with men[3] – oral, rectal, urine, blood • Access to clean needles/syringes and drug treatment services for PWID **Follow-up visits every 6 months to provide the following:** • Assess renal function for patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation • Bacterial STI screening for all sexually-active patients[3] – [vaginal, oral, rectal, urine- as indicated], blood **Follow-up visits every 12 months to provide the following:** • Assess renal function for all patients • Chlamydia screening for heterosexually active women and men – vaginal, urine • For patients on F/TAF, assess weight, triglyceride and cholesterol levels	

[1] adolescents weighing at least 35 kg (77 lb)

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

[3] 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

[4] estimated creatine clearance (eCrCl) by Cockcroft Gault formula ≥60 ml/min for F/TDF use, ≥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[1]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[2] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection • No signs/symptoms of acute HIV infection • No contraindicated medications or conditions	
Dosage	• 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle o Initial dose o Second dose 4 weeks after first dose (month 1 follow-up visit) o Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)	
Follow-up care	**At follow-up visit 1 month after first injection** • HIV Ag/Ab test and HIV-1 RNA assay **At follow-up visits every 2 months (beginning with the third injection – month 3) provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay • Access to clean needles/syringes and drug treatment services for PWID **At follow-up visits every 4 months (beginning with the third injection- month 3) provide the following:** • Bacterial STI screening[2] for MSM and transgender women who have sex with men[2] – oral, rectal, urine, blood **At follow-up visits every 6 months (beginning with the fifth injection – month 7) provide the following:** • Bacterial STI screening[1] for all heterosexually-active women and men – [vaginal, rectal, urine - as indicated], blood **At follow-up visits at least every 12 months (after the first injection) provide the following:** • Assess desire to continue injections for PrEP • Chlamydia screening for heterosexually active women and men – vaginal, urine **At follow-up visits when discontinuing cabotegravir injections provide the following:**	

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

[2] 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

- ✓ 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

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

A. Rationale:

The National HIV/AIDS Strategy and the Ending the HIV Epidemic Initiative have at their foundation the Status Neutral Approach, a strategy consisting of two arms: identifying 1) all individuals with HIV living in the U.S. and engaging them in care and antiretroviral (ARV) treatment and 2) all individuals at risk for HIV and connecting them to prevention care and in particular, with HIV pre-exposure prophylaxis (PrEP). Though increasingly treatable, HIV remains without cure. Prevention strategies

B. Definition:

HIV PrEP is treating individuals without HIV who are at risk of acquiring HIV with medication before exposure to prevent transmission. Individuals at risk include those who are at risk through sexual exposure and those at risk through injection drug use exposure. Current available PrEP medication include oral 200 mg emtricitabine/300 mg tenofovir disoproxil fumarate (brand name Truvada), oral 200 mg emtricitabine/25 mg tenofovir alafenamide (brand name Descovy), or injectable 600 mg cabotegravir (brand name Apretude).

C. Identification of PrEP Candidates:

a. Discuss HIV PrEP with every sexually active adult and adolescent (weighing at least 35 kg) and every individual who injects drugs.
b. Identify through sexual risk assessment and through drug-using behavior assessment who may be eligible for PrEP and offer PrEP to them. This includes:
    a. Any individual who has had anal or vaginal sex in the last 6 months AND either has inconsistent use or no use of condoms OR had a bacterial STI (gonorrhea, chlamydia, or syphilis in men and transgender women who have sex with men including those

E. Eligibility:

a. Documented negative HIV Ag/Ab (4th generation) test result within 1 week before PrEP initiation.
b. No signs or symptoms of acute HIV infection (e.g. febrile flu-like illness in the last 4-6 weeks, e.g. fever, fatigue, myalgia, rash, headache, sore throat, cervical adenopathy, arthralgia, night sweats, diarrhea)
c. Estimated creatinine clearance ≥60 mL/min. for Tr
d. No contraindicated medications.
e. If considering use of Truvada or Descovy, screen f components are treatment for active HBV.

F. PrEP Initiation:

1. Delaying start of PrEP for those at-risk could resul prescription.

2. PrEP can be started as soon as possible once patient eligibility is determined as per Section D and patient meets the following criteria:
   a. Fits into at-risk category as per Section D.
   b. HIV negative by testing (within 1 week of start of PrEP), and no symptoms of acute HIV (febrile flu-like illness in the last 6 weeks).
   c. Creatinine clearance ≥60 mL/min for Truvada or ≥30mL/min if eligible for Descovy. No renal restrictions for IM cabotegravir.
   d. Willing to adhere to medication regimen.
   e. Pregnancy test negative and not attempting to become pregnant.
      i. Discuss and consider birth control methods.
      ii. If attempting to become pregnant or pregnancy test positive, discuss risk v. benefit of PrEP.
   f. HBV status determined when considering use of Truvada/Descovy.
   g. If person inquiring after PrEP is not a CHC patient, person can be registered and enrolled as patient prior to treatment or advised to discuss PrEP and treatment with their own PCP.
3. If PrEP would not be delayed, the following can be done prior to prescribing; otherwise the following could be collected after PrEP start:
   a. Screen for other STI's and treat as needed
      i. Gonorrhea and chlamydia—3 site testing if needed (oral, cervical/urethral, rectal).

4. Choice of PrEP medication
    a. Truvada:
        i. Can be used for all men, women, transgender women and men, and people who inject drugs.
        ii. Can be dosed one pill orally once a day.
        iii. Can be dosed as needed with 2-1-1 protocol ONLY for men who have sex with men and transgender women (see Section d ii below). May be appropriate for individuals who are not engaging in at-risk sexual encounters regularly, e.g. less than once a week; once a month.
    b. Descovy:
        i. Can be used ONLY for men and transgender women who have sex with men for sexual risk.
        ii. CANNOT be dosed with 2-1-1 protocol.

        iii. CANNOT be used for injection drug use risk.
        iv. Appropriate to use for individuals with creatinine clearance under 60 ml/min but above 30 ml/min and/or with osteopenia/osteoporosis.
        v. Dosed as one pill orally once a day.
    c. Cabotegravir
        i. Can be used for all men, women, and transgender individuals for sexual risk.
        ii. CANNOT be used for injection drug use only.
        iii. Assess people who inject drugs for sexual risk and if eligible for PrEP for sexual risk, can use cabotegravir.
        iv. Dosed as 600 mg/3 ml IM gluteal injection. First two shots one month apart. Then subsequent shots are every 60 days.

d. Dosing and Adherence for Oral PrEP
    i. For Truvada and Descovy, one pill once a day.
        1. Recommended and FDA approved.
        2. The iPrex OLE study **for Truvada only** demonstrated that
            a. 4-6 daily doses a week similar efficacy as 7 daily doses a week.
            b. 2-3 daily doses a week still has significant risk reduction but higher rates of resistance if HIV infection develops.
            c. ≤2 daily doses a week, not effective.
    ii. 2-1-1 or On-Demand PrEP
        1. Only studied for Truvada for sexual risk and only in MSM/transgender women.
        2. NOT FDA approved dosing.
        3. Best to avoid 2-1-1 dosing in people with chronic HBV since being on and off Truvada can trigger hepatitis flare-ups.
        4. Take 2 tablets 2-24 hours prior to sex, then 1 tablet 24 hours after first 2 pills and then 1 tablet 48 hours after first 2 pills.
            a. If ongoing exposure is occurring, continue with 1 tablet a day until 48 hours after last sexual activity.

e. Potential Adverse Effects
    i. Side effects resolve usually within 1-2 months of starting meds.
        1. May not be the case with 2-1-1 approach
    ii. Treat side effects if need be, e.g. anti-nausea medication, anti-diarrheal, non-opioid pain meds
    iii. TDF/FTC
        1. Nausea, fatigue, headache, weight loss, abdominal pain
        2. Renal toxicity (creatinine increase, proteinuria), bone toxicity
        3. Rare hepatotoxicity, lactic acidosis
        4. Potential for HIV resistance
    iv. TAF/FTC
        1. Nausea, fatigue, headache, abdominal pain, diarrhea, weight gain
        2. Rare hepatotoxicity, lactic acidosis
        3. Potential for HIV resistance
    v. Cabotegravir
        1. Injection site reactions
            a. Pain, tenderness, induration at site of injection
            b. Generally mild to moderate, lasting only a few days
            c. Occurs most frequently after the first 2-3 injections
                i. Can use over the counter pain medication within a couple of hours before or soon after injection and continue as needed for 1-2 days.
                ii. Apply a warm compress or heating pad to the injection site for 15-20 minutes after the injection, e.g. after arriving back at home.
        2. Potential for HIV resistance
    vi. Potential for HIV drug resistance to emerge if medication not taken regularly and HIV infection ensues.
        1. Poor adherence to Truvada or Descovy.
        2. Cabotegravir injection can result in ongoing levels for many months after last injection and can last past a year. For those who stop cabotegravir and are at ongoing risk for HIV should be put on oral PrEP (Truvada/Descovy) within 8 weeks of last injection.

HIV Protection after PrEP Initiation and Discontinuation

f. Protection against HIV after PrEP Initiation
   i. Truvada: adequate levels of Truvada has been measured in anal tissue after 7 days of medication and in cervicovaginal tissue after 20 days of medication. No studies have been done in penile tissue.
   ii. Descovy: unknown since no studies have been done.
   iii. Cabotegravir: unknown since no studies have been done.

g. Protection against HIV after PrEP Discontinuation
   i. Truvada and Descovy:
      1. Protection will likely wane over 7-10 days.
      2. If ongoing risk, discuss immediate alternative protections against HIV like condom use and ensure patient aware of non-occupational Post Exposure Prophylaxis.
   ii. Cabotegravir:
      1. Levels persist for many months after last injection.
      2. Protection will eventually wane and it is unclear when that would be.
      3. If ongoing risk, ensure alternative protections are considered such as oral PrEP, condom use within 8 weeks of last injection.
      4. Ensure patient aware of non-occupational Post Exposure Prophylaxis.

d. **What if the partner with HIV is on treatment with an undetectable viral load?**
    a. Multiple studies (HPTN 052, PARTNER1, PARTNER2, and Opposites Attract) showed definitively that when the person with HIV is durably virologically suppressed, they do not transmit HIV to their sexual partners. This was demonstrated in heterosexual men and women and in MSM and transwomen.
        i. Bottom line:
            1. If the partner with HIV is stable on treatment with a viral load less than 200 copies/ml there is no chance of sexual transmission to their partners. Document in the chart the discussion and that the partner with HIV is durably undetectable (for at least 6 months).
            2. Condoms are reasonable to prevent other STIs.
            3. If the partner with HIV is starting HIV medication and is not yet undetectable, consideration of PrEP for the negative partner during the first 3-6 months until the partner reaches undetectable viral load and another 6 months to demonstrate durability of viral load suppression is warranted.
            4. Otherwise, any further protective benefit of PrEP for the negative partner is minimal to the point of absence and will rarely be merited given the known burdens of this treatment.
            5. If the patient is unaware of partner's HIV treatment, adherence to ARVs, and response to treatment or the patient requests PrEP for any other reason (e.g. outside partners, peace of mind, etc.), PrEP should be prescribed.

G: Prescribing and Monitoring Recommendations:

1. Oral PrEP:
    a. For the first prescription for oral PrEP, write prescription length based on recommended HIV testing intervals (usually ≤ 90 day supply for daily PrEP and ≤ 30 day supply for 2-1-1 PrEP).
        i. Though not FDA approved, discussing on-demand 2-1-1 PrEP with Truvada for MSM/transgender women who do not have chronic HBV and who would prefer this regimen dosing based on frequency of exposure may be a reasonable strategy.
    b. Follow up often with patient within 2 weeks of initiation and on an ongoing basis to check adherence and potential side effects. Follow up could be done by PrEP navigator, nurse, or any other member of the clinical team.
    c. Follow up visits at least every 3 months.
    d. Order HIV testing (HIV Ag/Ab test and HIV-1 RNA) every 3 months for everyone.
    e. Order STI screening (gonorrhea, chlamydia 3 site testing where indicated and syphilis) every 3 months for MSM/transwomen and every 6 months for all others.
    f. Order renal function every 6 months for those ages 50+ and for those with GFR<90, otherwise once a year for all others.
    g. If on Descovy, order lipids and check weight once a year.
    h. The following lab tests are NOT routinely indicated: bone mineral density, urinalysis, LFTs, CBC.
2. Injectable Cabotegravir:
    a. At follow up visit for second injection at 1 month, HIV Ag/Ab test and HIV-1 RNA assay on everyone.
    b. At follow up visits every 2 months after that, HIV Ag/Ab test and HIV-1 RNA assay on everyone.
    c. STI screening (gonorrhea, chlamydia 3 site testing where indicated and syphilis) every 4 months for MSM/transwomen and every 6 months for all others.
3. At all visits, discuss desire to continue PrEP, ongoing risk, risk reduction, side effects, adherence and options for ongoing prevention. (See Sections J and K)
4. Consider pregnancy tests every 2-3 months during follow up visits for individuals who could become pregnant.

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H. PrEP Medication Switch

1. Oral PrEP to Oral PrEP
   a. If you are switching the patient between Truvada
   made without any overlap. The day of the switch, th
   (e.g. Truvada) medication and can start the new Ora
   b. Since there are data indicating Truvada takes abo
   in the anal mucosa and about 21 days to reach appro
   when switching from Descovy to Truvada, the patie
   methods of protection against HIV during that perio
   sexual activity.
   c. Since there are no data about how long Descovy t
   through shared decision making, patients can be adv
   of protection against HIV for about 1-4 weeks if the
   switching from Truvada to Descovy.
2. Oral PrEP to Injectable PrEP
   a. If you are switching the patient from Truvada or I
   can be made.
   b. Since there are no data about how long Apretude
   through shared decision making, the following appr
      i. Oral PrEP (Truvada or Descovy) can be st
      injection of Apretude and the patient uses ba
      HIV for about 1-4 weeks if they engage in s
      ii. Oral PrEP (Truvada or Descovy) can be continued after the first injection of Apretude for 1-4 weeks, if tolerated, and if they plan on engaging in sexual activity. Descovy would need to be continued as daily oral PrEP. Truvada could be continued as daily oral PrEP or if they are MSM, could continue 2-1-1 PrEP if that is how they were taking oral PrEP or start using Truvada as 2-1-1 PrEP during the period of transition.
3. Injectable PrEP to Oral PrEP
   a. If you are switching the patient from Apretude to Oral PrEP Truvada:
      i. If Truvada is to be used as 2-1-1 PrEP (e.g. for MSM), then on the day when they would have been due for the next injection of Apretude, the patient can start using Truvada as per 2-1-1 protocol.
      ii. If Truvada is to be used as daily PrEP, then on the day when the next injection of Apretude would have been due, Truvada can be started. Barrier methods of protection against HIV can be used for 7 days for anal mucosal protection and for 21 days for vaginal mucosal protection.
      iii. Truvada can also be started 7 days (anal mucosa protection) or 21 days (vaginal mucosa protection) prior to when the next injection of Apretude would have been due if medications are well tolerated and the patient wants to engage in sexual activity and does not want to use barrier methods during this period of transition.
      iv. The approach should be chosen through shared decision making with the patient given there are limited data on how long before Truvada reaches appropriate levels in anal and vaginal mucosa and no or very minimal data on how long Descovy and Apretude reach appropriate levels. There are no definitive data either on how long after stopping one medication does a patient remain protected.
   b. If you are switching the patient from Apretude to Oral PrEP Descovy:
      i. On the day when the next injection of Apretude would have been due, Descovy can be started. Barrier methods of protection against HIV can be used for 1-4

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I. Discontinuation:

1. If the patient is no longer willing (or able) to continue the medication.
2. If on Truvada, presentation of renal disease (creatinine clearance decreases by more than 20% or GFR goes below 60 mL/min.) and ineligible for Descovy and cabotegravir.

3. If pregnancy and benefits of stopping outweigh the benefits of continuing.
4. If HIV infection.
5. If on Truvada/Descovy and the patient also has HBV, consult with ECHO clinician prior to discontinuation. Discontinuation may cause hepatitis flare-ups and monitoring of liver is warranted if medication stopped.
6. See Section F.(g) for guidance on discussion and treatment when discontinuing Oral or IM PrEP when patient is still at risk for HIV.

J. Pregnancy:

1. Patients with HIV often take Truvada during pregnancy.
2. Descovy/cabotegravir have limited information in pregnancy (other integrase inhibitors have been taken during pregnancy but data are limited).
3. In HIV negative women who are at risk for HIV transmission, the risk must be weighed against the benefit. Shared decision making is essential. Risk of transmission to the fetus during acute HIV infection during pregnancy is high and consideration of PrEP for those women who are at high risk is important to weigh against the use of Truvada/Descovy/cabotegravir during pregnancy.

K. Risk Reduction Counseling Points to Review

1. Condom use for other STI prevention.
2. Regular STI testing.
3. U=U (undetectable = untransmittable)
4. No sharing of injecting equipment
5. Syringe Services Program
6. Overdose prevention (Narcan)
7. Medication for substance use disorders (e.g. buprenorphine, methadone)
8. Post exposure prophylaxis (PEP)

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L. Adherence Counseling (from CDC Guidelines 2021)

Box B: Key Components of Oral Medication Adherence Counseling

Establish trust and bidirectional communication

Provide simple explanations and education

- Medication dosage and schedule
- Management of common side effects
- Relationship of adherence to the efficacy of PrEP
- Signs and symptoms of acute HIV infection and recommended actions

Support adherence

- Tailor daily dose to patient's daily routine
- Identify reminders and devices to minimize forgetting doses
- Identify and address barriers to adherence
- Reinforce benefit relative to uncommon harms

Monitor medication adherence in a non-judgmental manner

- Normalize occasional missed doses, while ensuring patient understands importance of daily dosing for optimal protection
- Reinforce success
- Identify factors interfering with adherence and plan with patient to address them
- Assess side effects and plan how to manage them

M. Access and Coverage of PrEP

1. Majority of Medicaid/Medicare/third party payers will cover some form of PrEP for those with insurance.
2. The pharmaceutical manufacturers have assistance for those with co-pays.
3. Pharmaceutical manufacturers also provide Patient Assistance Programs for those uninsured and will provide the medications for free.
4. Generic tenofovir/emtricitabine may be more affordable for some.
5. Looking into other programs like 340B may also be helpful.
6. Ready, Set, PrEP program also is available for those who do not have insurance or cannot afford costs associated with the prescriptions. https://readysetprep.hiv.govexternal icon
7. Please reach out to the PrEP Team in the Center for Key Populations at CHC for help:

CENTER FOR KEY POPULATIONS

Appendix A: Useful Websites/Guidelines/Resources

CDC websites

Learn About PrEP | Preventing New HIV Infections | Clinicians | HIV

Pre-Exposure Prophylaxis (PrEP) | HIV Risk and Prevention | HIV/A

https://www.cdc.gov/hiv/basics/prep.html

HIV Prevention | Materials for Your Practice and Patients | Clinicians

2021 CDC Guidelines

US Public Health Service: PREEXPOSURE PROPHYLAXIS FOR T
INFECTION IN THE UNITED STATES – 2021 UPDATE, A CLIN
(cdc.gov)

Preexposure prophylaxis (cdc.gov) Supplemental Guide with Clinical

Clinicians' Quick Guide: Preexposure Prophylaxis for the Prevention
States—2021 Update—A Clinical Practice Guideline (cdc.gov)

Patient Fact Sheets

PrEP Patient Fact Sheet English.pdf

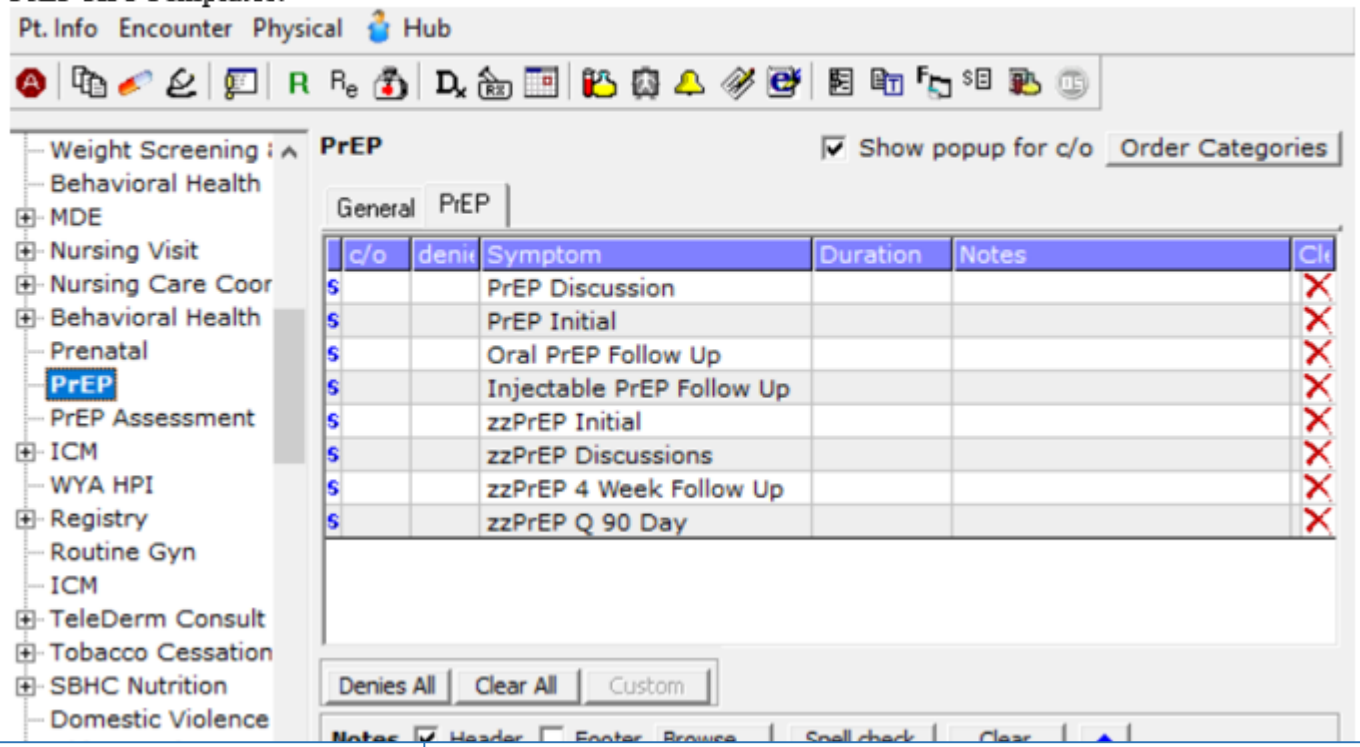
PrEP Patient Fact Sheet Spanish.pdf

PrEP Truvada Fact Sheet English.pdf

PrEP Truvada Fact Sheet Spanish.pdf

Appendix B: PrEP Support Tools/Templates

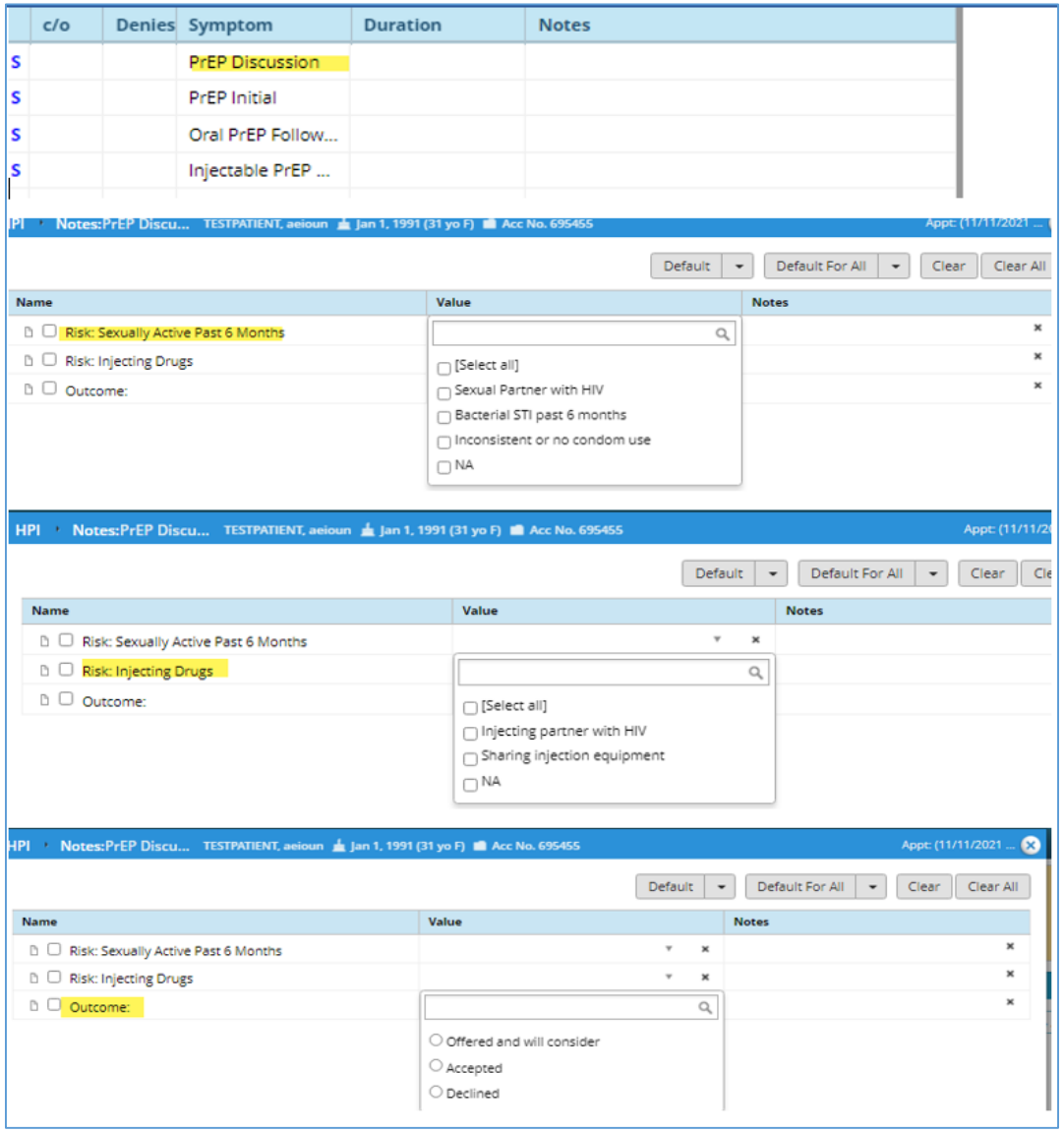
PrEP HPI Templates:



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



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PrEP Initial Visit

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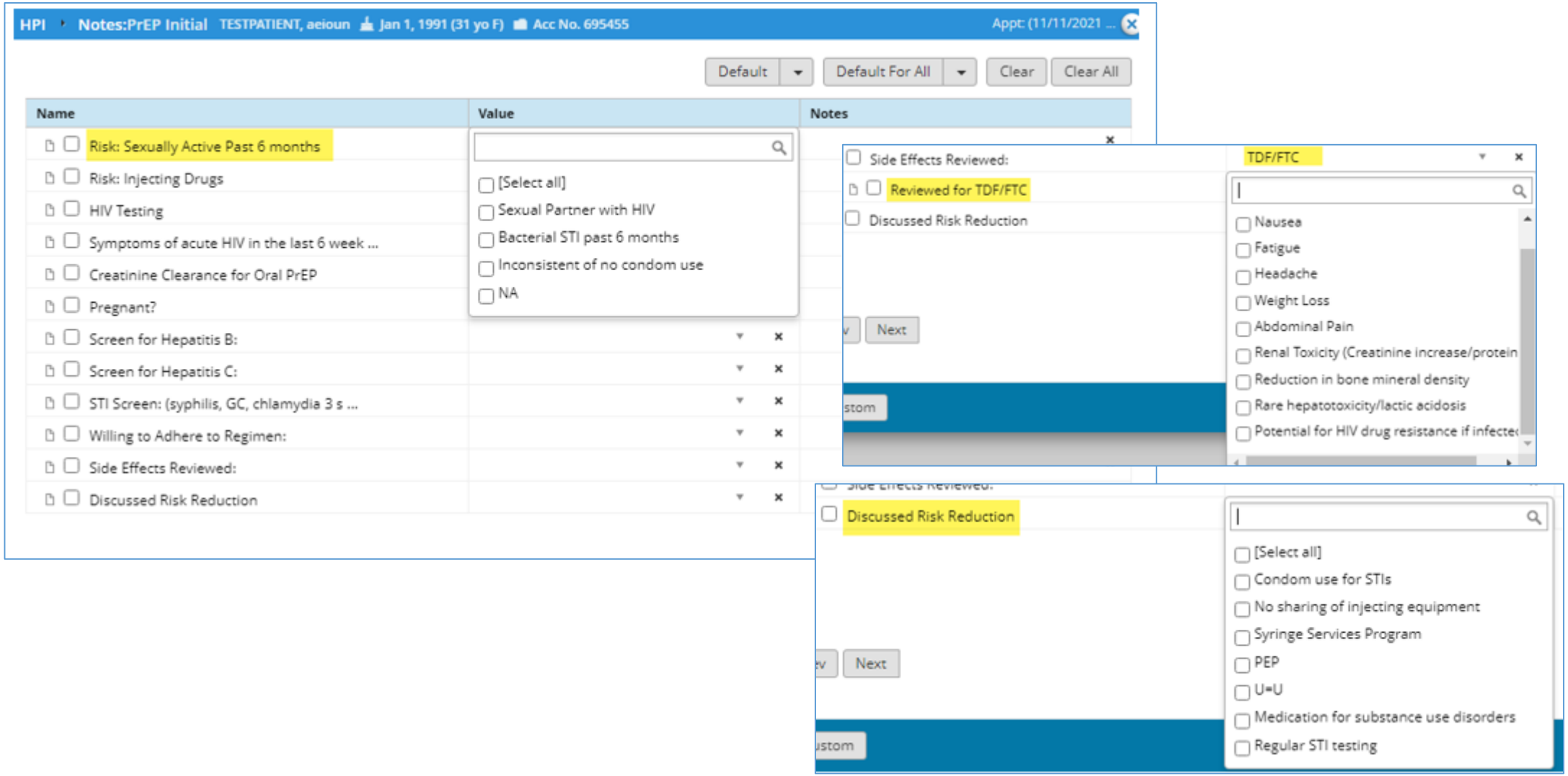

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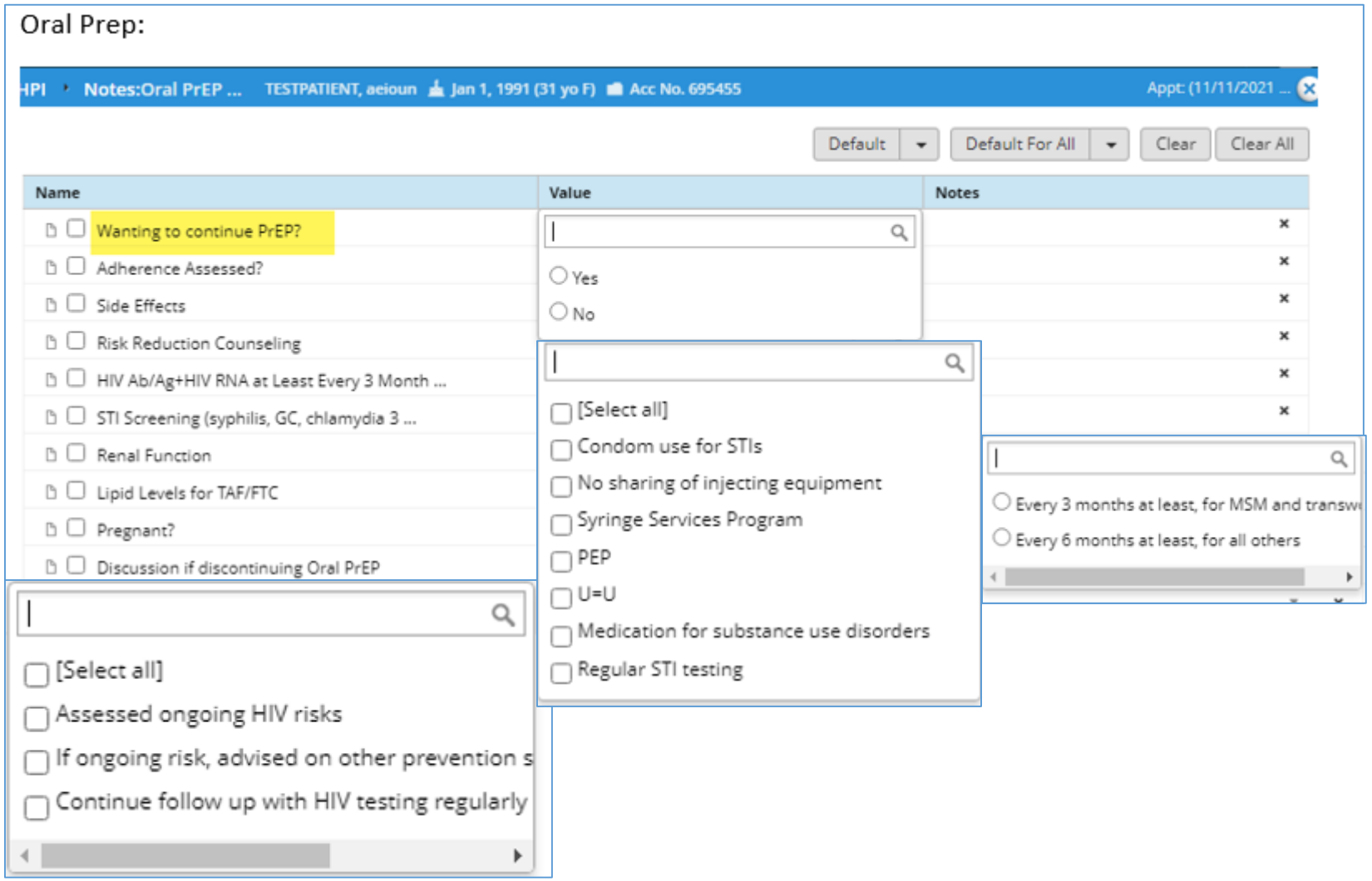
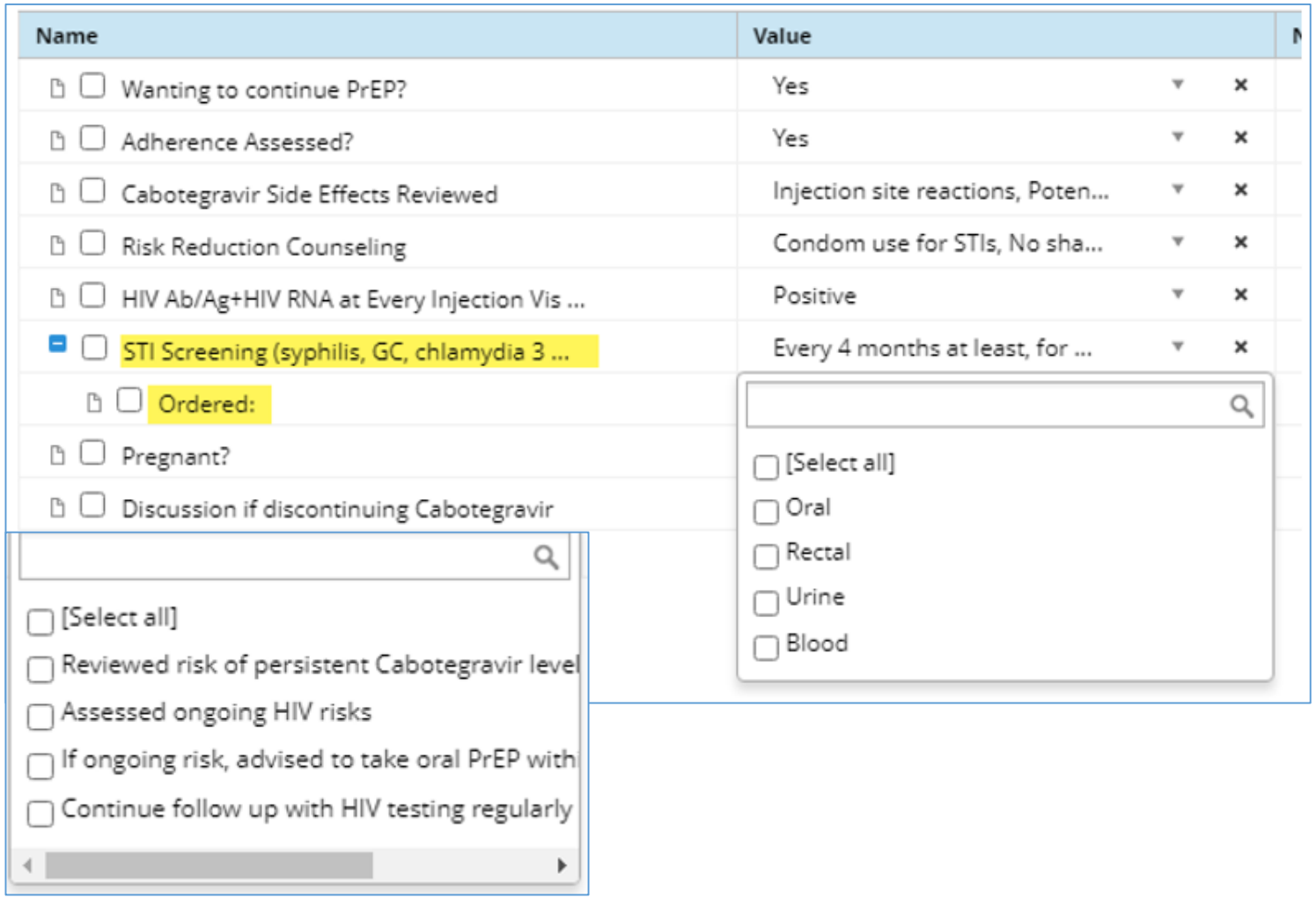
Oral PrEP Monitoring Visit

Oral Prep:



Injectable PrEP Monitoring Visit



PrEP Order Set

ORDER SET: PrEP | New | Copy | Update | Delete | MEASURE: | QUICK ORDER SET: YES

DIAGNOSES (TRIGGER):

DIAGNOSES (LINKED): (SAME AS TRIGGER)

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		

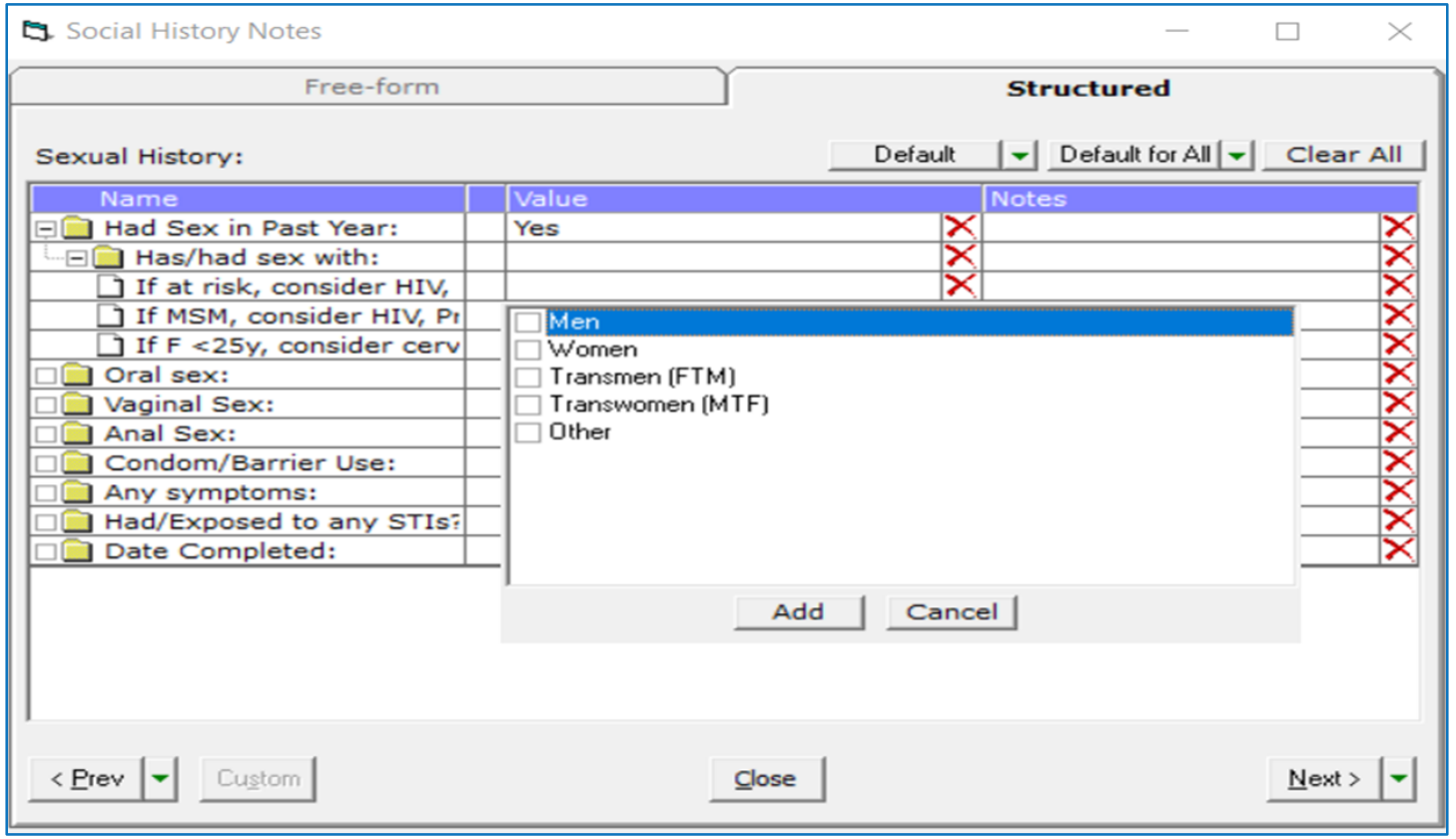
Labs — Browse

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/urethal 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 Gonorrheae, 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	

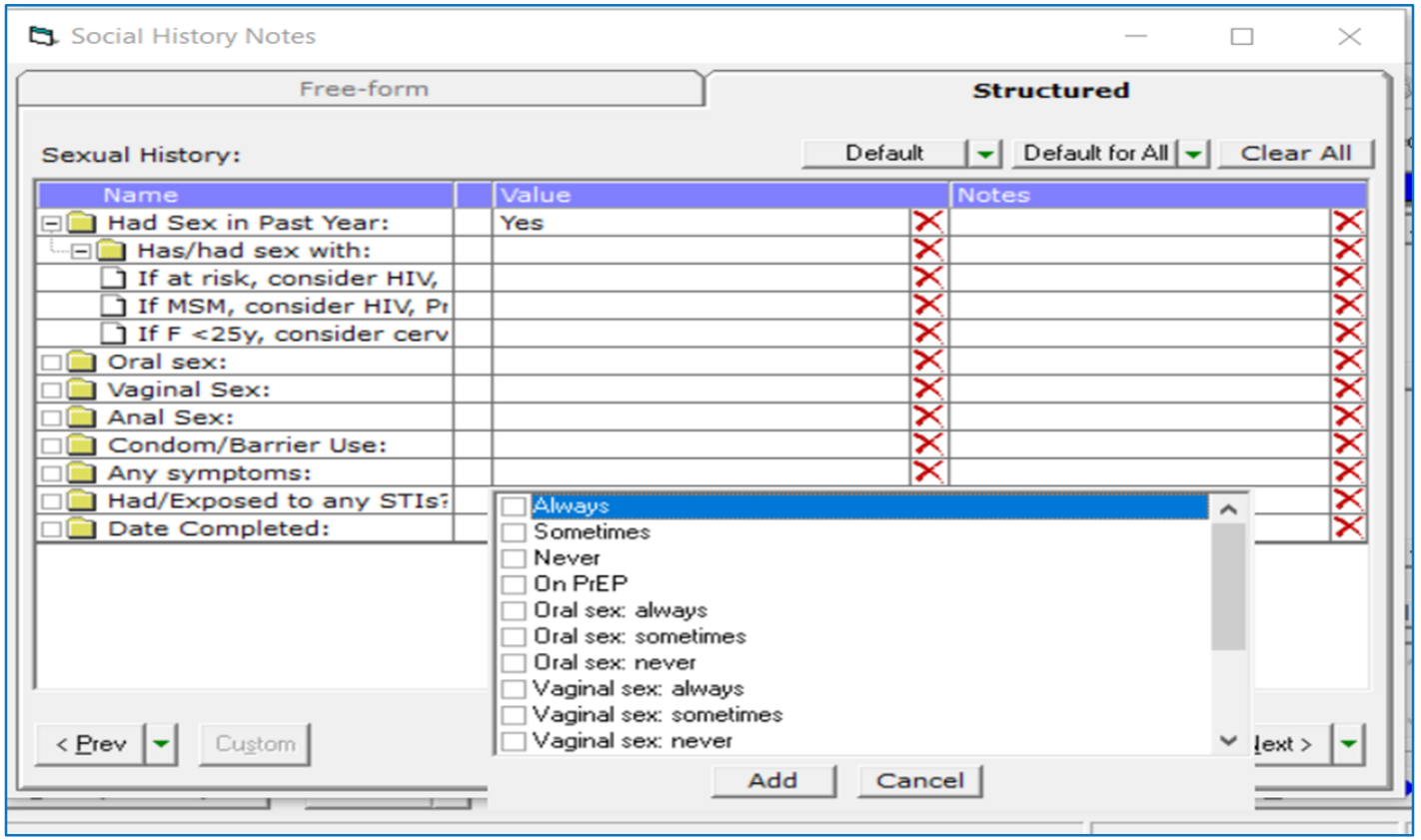
6 Essential Sexual Health Questions:
To Determine STD Screening/Treatment

- Have you ever had any type of sex ?
  - Oral, Vaginal, Anal?
- When was the last time?
- Are partners men, women, transmen, transwomen? How many (1 or more than 1)?
- Do you use condoms/on PrEP? Always, sometimes, never?
- Any symptoms?
- Were you exposed to any STDs that you know?

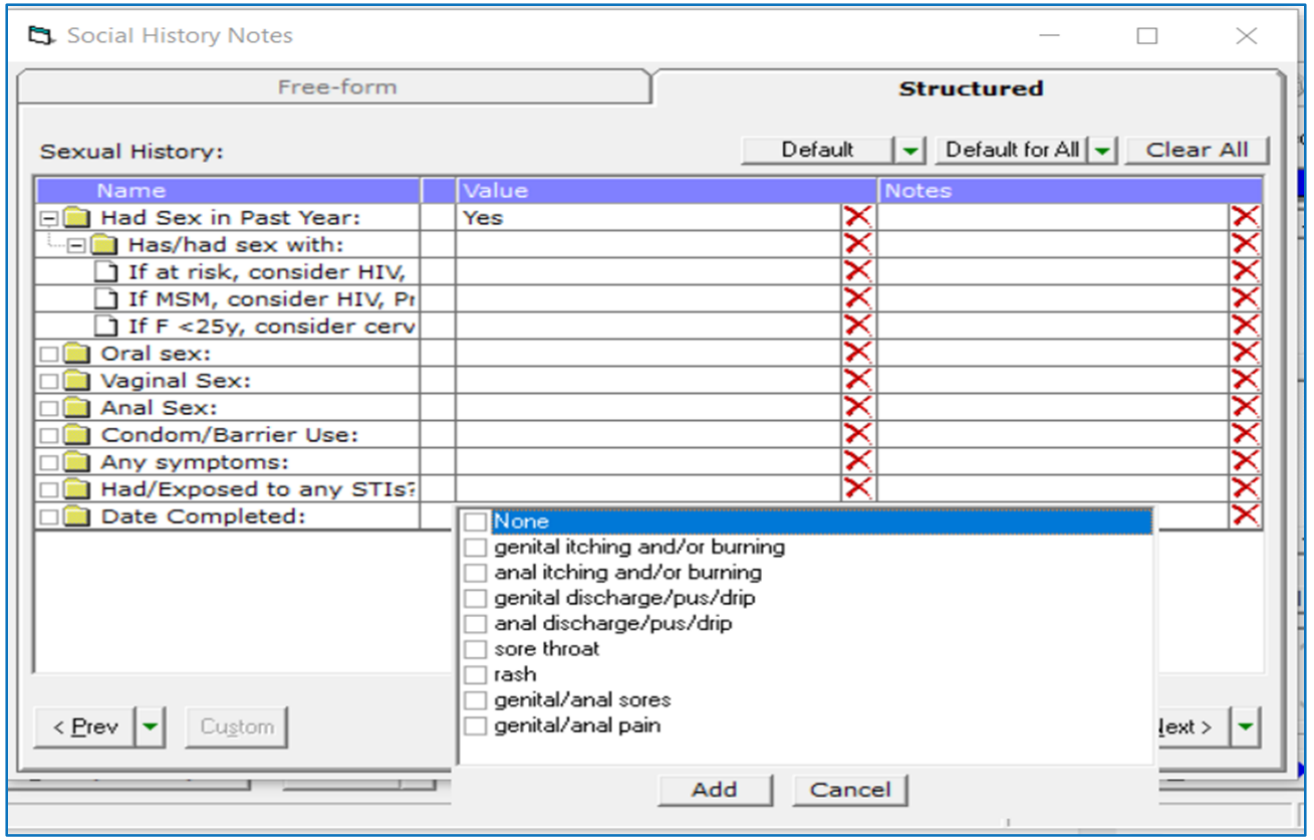
Sexual Risk Assessment: EHR Template



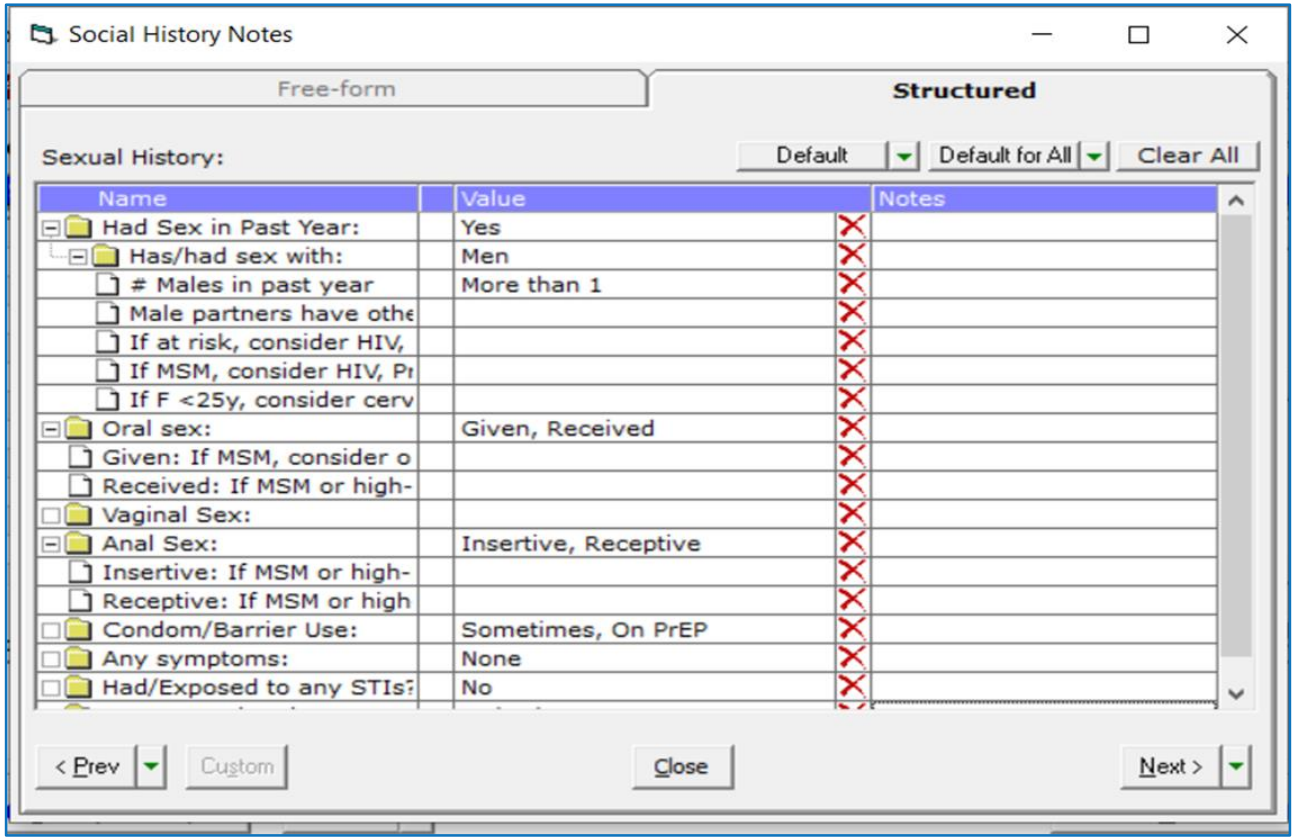
Sexual Risk Assessment: EHR Template



Sexual Risk Assessment: EHR Template



Sexual Risk Assessment: EHR Template

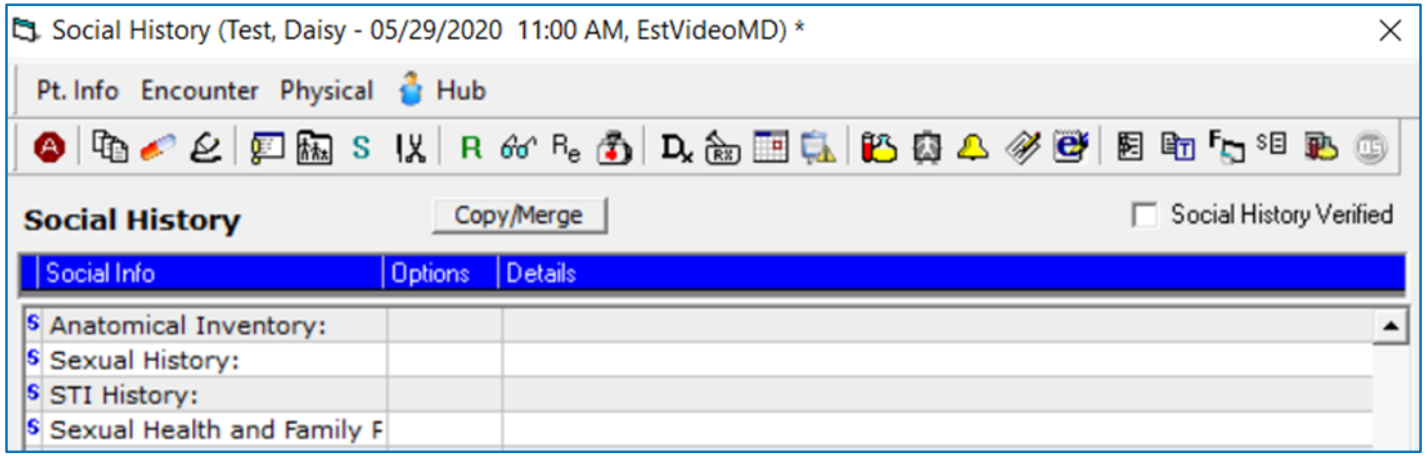


Nursing Role

- 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)



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 with in 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 done/offered to patients ages 13-64 at least once.
HCV Screening (USPSTF)	• HCV screening for persons at high risk for infection • One time screening in individuals born between 1945-1965
Depression Screening – adolescents (AAP/USPSTF)	~~Annual depression screening for adolescents ages 12 and above.~~
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/Transgender individuals (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.				MSM and Trans - STI screening recommended annually.

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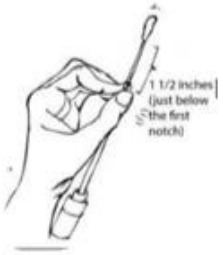
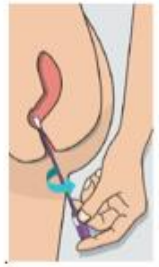
Rectal Specimen Patient Self-Collection

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

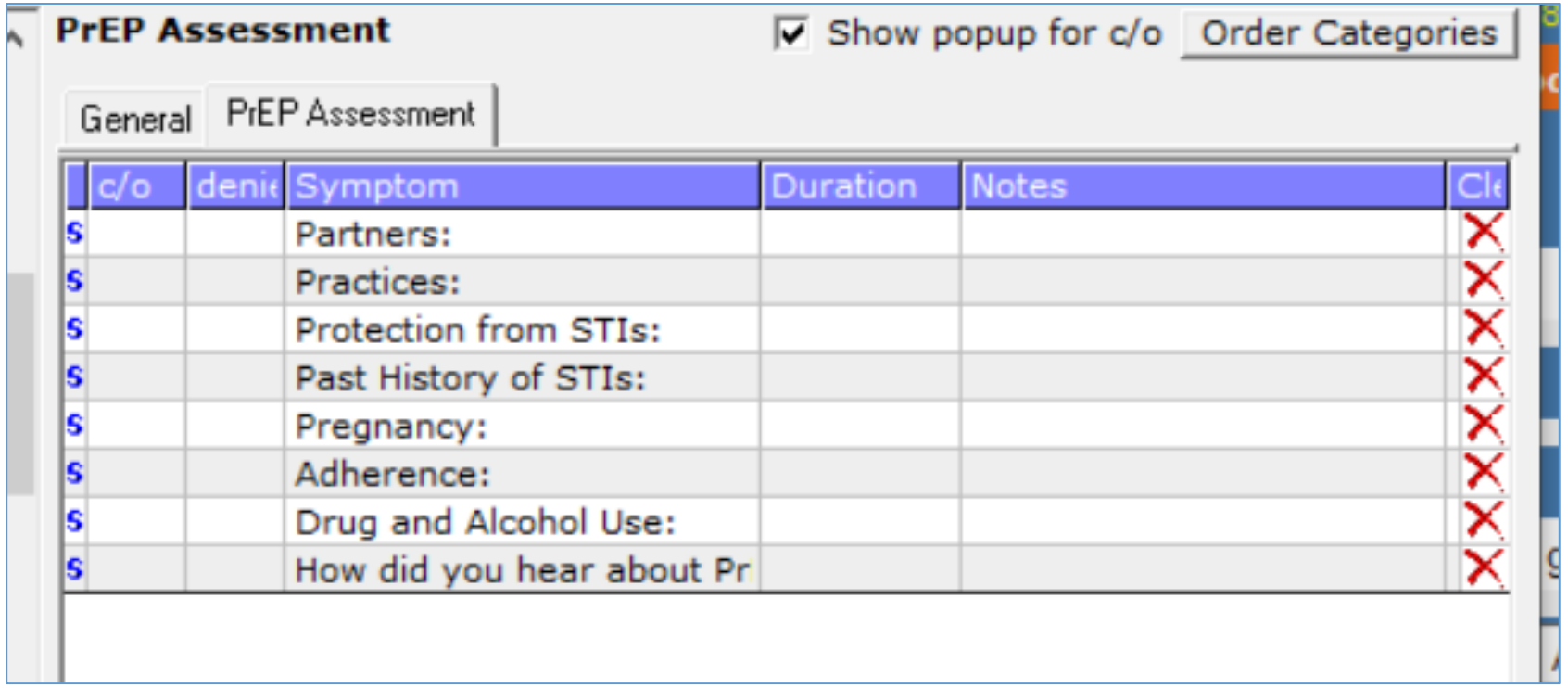
CENTER FOR KEY POPULATIONS

PrEP Navigator

- Supports patients and providers.
- Assists PrEP patients with:
  - ❑ Education on the benefits of PrEP
  - ❑ PrEP Eligibility
  - ❑ PrEP provider identification
  - ❑ Appointment scheduling
  - ❑ Partner notification services support
  - ❑ Health insurance enrollment
  - ❑ Screenings for other STIs
  - ❑ Ongoing maintenance

PrEP Assessment

- Used by PrEP Navigator, other clinical team members



PrEP Dashboard

- Used by PrEP Navigator, Medical Assistant, Nurse, Provider
- Helps with PrEP Follow up and Monitoring
- Can be searched by Medical Provider and by PrEP Medication
- Includes:

- ❑ Age
- ❑ Gender Identity
- ❑ Sexual Orientation
- ❑ Prescriber
- ❑ Last Visit
- ❑ Next Visit
- ❑ Last Rx Name and Date
- ❑ Last Sexual Risk Assessment Date
- ❑ Last HIV Screen
- ❑ Last STI Screens
- ❑ Renal Function and Date
- ❑ Hep B screen
- ❑ Hep A and B vaccination

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PrEP Dashboard

Age	Gender	Gender Identity	Sexual Orientation	PCP	Prescribing Provider	Last Visit with Prescribing Provider	Next Visit with Prescribing Provider	Last Visit with PCP	Next Visit with PCP	Last Rx Name and Date	SH Sexual Hist Date	Last H
			heterosexual							Date: 7/3/2019		Date:
37	M	Transgender Female/Trans Woman	Lesbian or gay or homosexual	McIntosh, Jeannie	McIntosh, Jeannie	4/12/2022	4/26/2022	4/12/2022	4/26/2022	Descovy Date: 3/6/2022	8/22/2013	Valu Re Date:
51	U	Transgender Female/Trans Woman	Straight or heterosexual	McIntosh, Jeannie	McIntosh, Jeannie	4/1/2022	5/6/2022	4/1/2022	5/6/2022	Truvada Date: 11/27/2018	4/1/2022	Val Date:
17	F	Female	Bisexual	Smith, Tonya	McIntosh, Jeannie	6/10/2021		2/18/2022		Truvada Date: 6/12/2021	3/31/2022	Val Date:
49	M	Male	Straight or heterosexual	McIntosh, Jeannie	McIntosh, Jeannie	9/5/2018		9/5/2018		Truvada Date: 9/5/2018	9/5/2018	Val Date:
34	F	Female	Straight or heterosexual	Piekarz Dyjak, Elzbieta	McIntosh, Jeannie	5/5/2020		12/21/2020		Truvada Date: 3/31/2020		Val Date:
33	M	Transgender Female/Trans Woman	Bisexual	McIntosh, Jeannie	McIntosh, Jeannie	2/18/2022	4/18/2022	2/18/2022	4/18/2022	Truvada Date: 11/13/2021	2/18/2022	Val Date:
28	F	Female	Straight or heterosexual	McIntosh, Jeannie	McIntosh, Jeannie	12/17/2021		12/17/2021		Truvada Date: 10/6/2020		Value Date:
31	M	Male	Lesbian or gay or homosexual	Silva, Meaghan	McIntosh, Jeannie	12/15/2020		3/1/2022		Descovy Date: 12/15/2020	3/1/2022	Val Date:
51	M	Male	Lesbian, gay, or homosexual	Borgonos, Ovanes	McIntosh, Jeannie	3/25/2022		3/22/2022		Truvada Date: 4/21/2020	3/25/2022	Val Date:

Parameters

Prescribing Provider: McIntosh, Jeannie

Last Prescription Name: Descovy,Descovy Blister Pack,Truvada

CENTER FOR KEY POPULATIONS

PrEP Dashboard

Last HIV Screen	Last Syphilis Screen	Last Gonorrhea Urethal Cervical Screen	Last Gonorrhea Throat Screen	Last Gonorrhea Rectal Screen	Chlamydia Urethral Cervical Screen	Chlamydia Throat Screen	Chlamydia Rectal Screen	Renal Function (Creatinine) Screen	Hep B s Ag Screen	Hep A
Value: Non-Reactive Date: 4/11/2022	Value: Reactive Date: 4/11/2022	Value: Not Detected Date: 4/11/2022	Value: oral GC neg Date: 4/12/2022	Value: Not Detected Date: 4/12/2022	Value: Not Detected Date: 4/11/2022	Value: oral GC/CT neg Date: 1/22/2022	Value: Not Detected Date: 4/12/2022	Value: 0.77 Date: 4/11/2022	Value: NON-REACTIVE Date: 9/12/2017	Not V

PrEP Global Aim Statement

We aim to improve PrEP services at CHC in CHC service areas.

The process begins with identifying eligible individuals.

The process ends with engaging interested patients to start PrEP.

By working on the process, we expect to:

- Increase the access of care
- Increase the number on patients who are on PrEP
- Increase the number of patients who are aware of PrEP
- Increase the number of providers who prescribe Prep
- Improve the level of care for patients who are a

It is important to work on this now because:

- We are helping to identify the patients that are a
- Prep is a crucial tool in ending the HIV epidemic
- CKP has a responsibility to promote Prep as outli

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Specific Aim Statement

1. We will increase the number/amount of documented conversations during visits about PrEP from 0 to 25 patients (combined) starting February 6th, 2023 for 8 weeks at the Meriden site.

Quality Improvement Projects

PDSA Worksheet for Testing Change

Date:	2/6/2023
Team Members:	Maria Lorenzo, Nathan Parilla, Michael Judd, Jeannie McIntosh, Marlene Edelstein, Dr. Haddad, Kasey Harding, Lizbeth Vazquez, Doug Janssen, Lenon Adam, Bernie Delgado, Lucy Ehrenheld, Deborah Ward, and Briana Reaves

Aim:

Every goal will require multiple smaller tests of change

Describe your first (or next) test of change:	Person Responsible	When to be Done	Where to be Done
PrEP Navigators will conduct outreach to providers to identify patients who are candidates for PrEP.	PrEP Navigators		

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PrEP Microsystem Project: Documenting PrEP Discussions

PDSA Cycles (rapid cycle tests of change) at 4 practice sites over 6 months

Inclusion Criteria:

- HIV-negative, 13+, medical visit in past 6mo AND
- Self-identified as MSM or Transgender Female on SOGI OR
- Anyone with + STI result in past 6mo

	Patients (SOGI, STI, Both)	PrEP Discussion Documented (PRE-PDSA)	Outreach Eligible for PrEP (CDC guidelines, 18+)	PrEP Discussion Documented (POST-PDSA)
CKP Hub 1	147	11	71	30
CKP Hub 2	129	0	97	33
Small Site 1	20	4	17	17
Small Site 2	34	1	25	25

1 PrEP Coordinator

105 PrEP Discussions at 2 CKP hubs and 2 small sites far from hubs!

CENTER FOR KEY POPULATIONS

What did this project achieve?

- Brought PrEP to PCPs' attention
- Provided PCPs with support from PrEP Coordinators & CKP provider experts
- Collected baseline data on PrEP-eligible patients at 2 large CHC sites with "CKP hubs" and 2 smaller CHC sites further from "CKP hubs"
- Developed:
  - Standard PrEP Navigation telephone encounter (TE) language for (a) Adults and (b) Adolescents
  - Convention for PrEP Navigators to support PCPs and patients during PrEP discussions
  - Data collection forms/process in electronic health record

Plan

List the tasks needed to set up this test of change	Person Responsible	When to be Done (Dates & Timeframe)	Where to be Done (Site Location, Where at the site, Pod, etc.)
• PrEP navigators will review charts and identify patients that may be eligible for PrEP (positive STIs in the last 6 months, patients who identify as MSM and trans women from SOGI) • Prompt for PrEP discussion **-Patients that already have an appointment** • Write "Discuss PrEP" in the chief complaint • Merge in PrEP template • Send a TE to advise the provider that the patient may be a good candidate for PrEP. Include the reason why the patient may be a good candidate	PrEP Navigators		

and the appointment date. Also include that assistance can be offered from the PrEP navigator if there are any questions (Copy & Paste TE Script)

- Set Action Item to check on TEs that were sent
- Document outcome on excel sheet

-Was outreach made to the patient

-Was appt scheduled

-Did PrEP discussion occur

-Was the patient offered PrEP (declined or agreed)

-Was prescription sent

-Patients that don't have an appointment

- Send a TE to advise the provider that the patient may be a good candidate for PrEP. If appropriate, TE can be sent back to PrEP navigator to schedule visit. Also include that assistance can be offered from the PrEP navigator if there are any questions (Copy & Paste TE script)

- Set Action Item to check on TEs that were sent
- Document outcome on excel sheet

-Was outreach made to the patient

-Was appt scheduled

-Did PrEP discussion occur

-Was the patient offered PrEP (declined or agreed)

-Was prescription sent

-

Data Review

- PrEP navigators will review the visit notes to see if PrEP was discussed

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• PrEP navigators will review TE that was sent • Data pull for PrEP template Data pull for patients that have tested positive for STIs in the last 6 months, patients who identify as MSM, and trans women from SOGI Next Provider Meeting Date (to announce the PDSA)			

Predict what will happen when the test is carried out	**Measures to determine if prediction succeeds**	**Person (s) Responsible for Collection of Data**
At least half of providers will respond well. Providers will appreciate the focus on vulnerable populations. 70% of providers may share this is too much work. 10% of identified patients will start PrEP. Number of PrEP discussions will increase to 25%	Responses to TEs Number of documented PrEP discussions Total number of identified patients receiving intervention.	

Questions?

Wrap-Up

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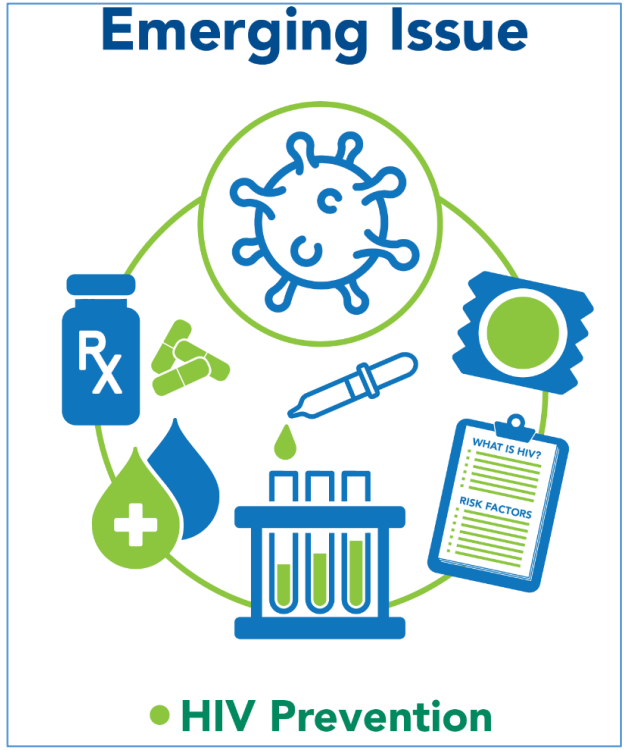
HIV Prevention Learning Collaborative

- Free six-month participatory experience designed to support health centers in enhancing their HIV prevention strategies, including discussion on communication and education, sexual risk assessments, and pre-exposure prophylaxis (PrEP).
- Outcomes of the learning collaborative:
  - Identified at-risk patients & created workflows that will best meet their patient population needs.
  - Launched outreach events & campaigns to increase PrEP education among the patient population.
  - Implemented staff training on stigma, pre and post-exposure prophylaxis options, & screening, testing, & treatment protocols.
- For more information/questions, please reach out to Meaghan Angers (angersm@mwhs1.com) or click here!



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Comprehensive and Team-Based Care Learning Collaborative

- Free eight-month participatory experience designed to provide knowledge, tools, and coaching support to help health centers and look-alikes implement advanced models of team-based care.
- In this Collaborative, teams will learn how to:
  - Use quality improvement concepts and skills to facilitate their implementation of a model of high-performing team-based care
  - Conduct self-assessments of their current team-based care model to identify areas for process improvement and role optimization
- Outcomes of the learning collaborative:
  - Identified a clinical team to work on a quality improvement project
  - Implemented pre-visit planning and morning huddles
  - Integrated behavioral health with warm welcomes/handoffs
  - Increase UDS measures, such as hyptertension, cancer screenings, etc.
- Apply Here! For more information/questions, please reach out to Meaghan Angers (angersm@mwhs1.com)

Team-Based Care

- **Fundamentals of Comprehensive Care**
- **Advancing Team-Based Care**

Our NTTAP also offers learning collaborative opportunities in Postgraduate NP Residency Programs, Health Professions Student Training, and HIV Prevention!

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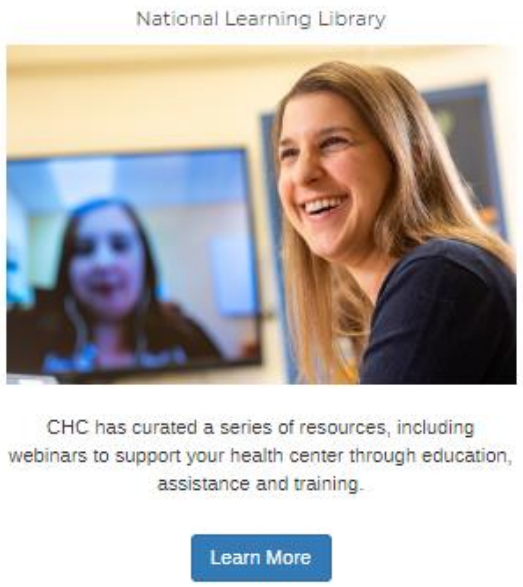
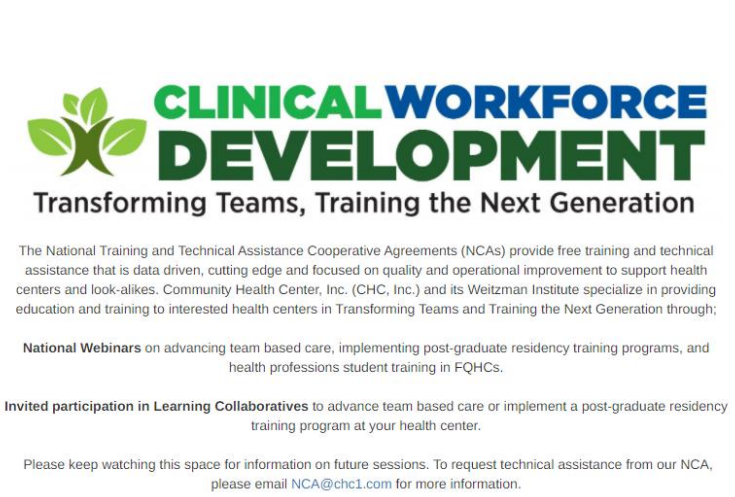
Explore more resources!

National Learning Library:
Resources for Clinical Workforce Development

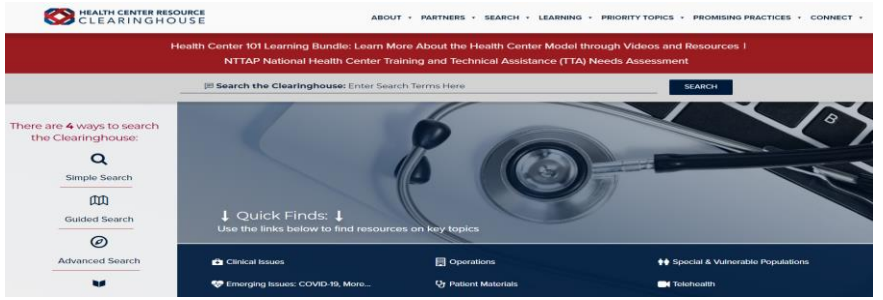




https://www.weitzmaninstitute.org/ncaresources

Health Center Resource Clearinghouse

HEALTH CENTER RESOURCE CLEARINGHOUSE



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Contact Information

For information on future webinars, activity sessions, and learning collaboratives: please reach out to nca@chc1.com or visit https://www.chc1.com/nca