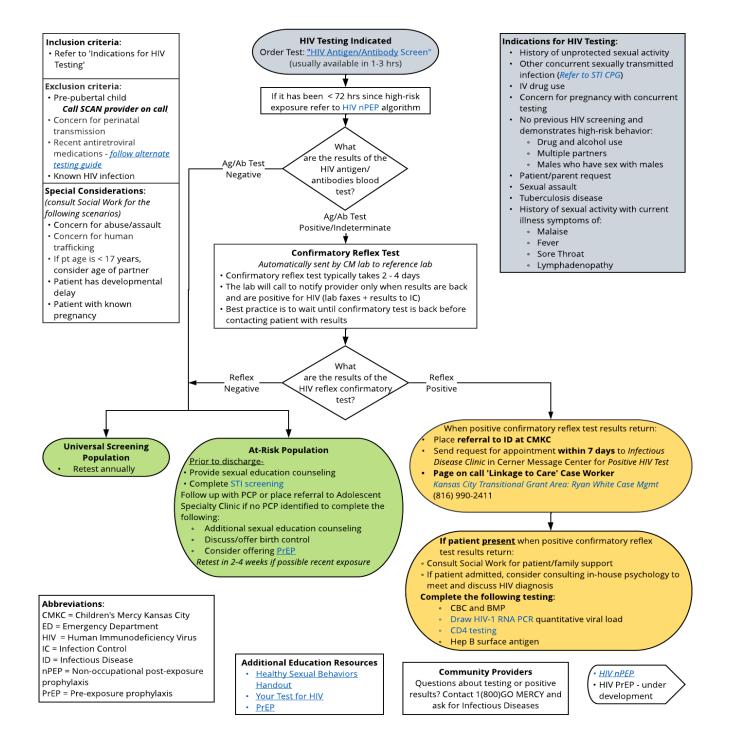


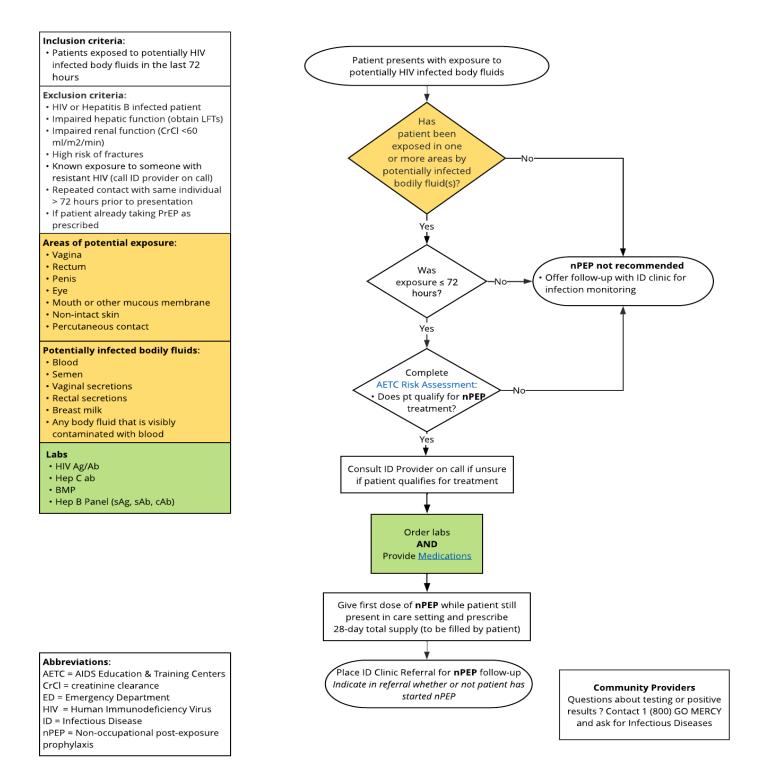
Human Immunodeficiency Virus (HIV) Care Process Model Synopsis

HIV Testing Algorithm



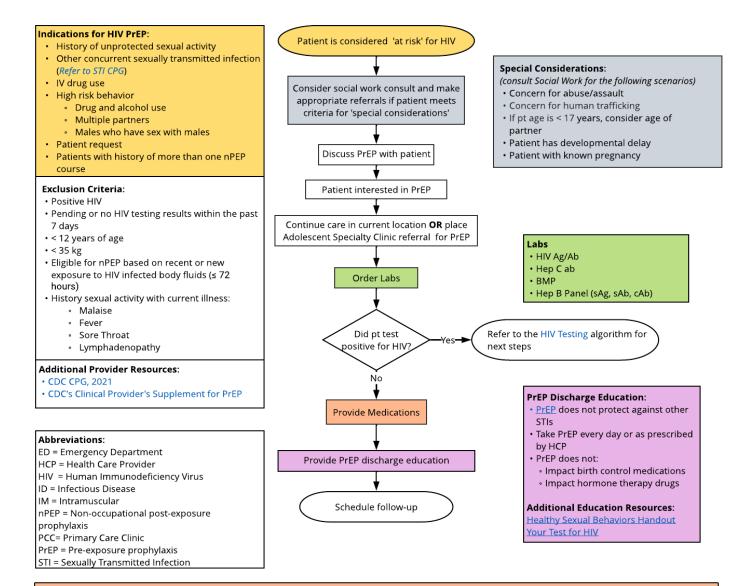


HIV nPEP Algorithm





HIV PrEP Algorithm



Medication Options for HIV Pre-Exposure Prophylaxis (PrEP)				
Medication	Dosage/Formulation/Sig	Indication	Contraindications	
Truvada® (emtricitabine/tenofovir disoproxil fumarate)	1 tablet (200/300mg)* by mouth once daily while at risk for HIV exposure	 For people at risk of HIV exposure from sex or injection drug use Primary choice for accessibility and 	• Existing Renal Disease • CrCl < 60 mL/m2/min • Significant risk of bone	
Descovy® (emtricitabine/tenofovir alafenamide)	1 tablet (200/25mg)* by mouth once daily while at risk for HIV exposure	 For assigned male at birth at risk of HIV exposure from sex Patient has contraindication to Truvada 	 Indicated for patients with pre-existing renal disease or specific medical contraindication 	
Apretude (cabotegravir) *Not currently provided at CMKC - refer to provider locator link	Injectable cabotegravir (600mg/3mL)* IM given once every other month	 For people at risk of HIV exposure from sex Patient unable to comply or tolerate oral meds Some insurance providers require reason why patient failed oral treatment 	Patients who are not able to comply with more frequent clinic visits and blood draws	



Table of Contents

HIV Testing Algorithm
HIV nPEP Algorithm
HIV PrEP Algorithm
Objective of Care Process Model
Background
Target Users
Target Population
Practice Recommendations
Additional Questions Posed by the CPM Committee
Children's Mercy Practice Recommendations and Reasoning
Care Management Recommendations Based on Standards of Care and Expert Opinions
Measures
Value Implications
Organizational Barriers and Facilitators
Diversity/Equity/Inclusion
Power Plans
Care Process Preparation
HIV Testing, nPEP, and PrEP CPM Committee Members and Representation
Care Process Model Development Funding10
Approval Process
Review Requested
Version History
Date for Next Review
Implementation & Follow-Up
Disclaimer
References
Appendix A



Objective of Care Process Model

The objective of this care process model (CPM) is to standardize and improve care for patients at risk for human immunodeficiency virus (HIV). Standardization of care will assist in reducing HIV transmission and complications from untreated disease.

Background

"Most sexually active youth in the United States do not believe that they are at risk for contracting HIV and have never been tested" as reported by the Committee on Pediatric AIDS (Hsu & Rakhmanina, 2022, p. 1). In 2019, there were approximately 36,740 new HIV diagnoses, 7,763 (21%) of which were children, adolescents, or young adults (Centers for Disease Control and Prevention, 2021).

While the number of new diagnoses in these age groups (children, and adolescents/young adults 13-24 years) has remained stable since 2015, the number of teens who are aware of their HIV status is more concerning. It is estimated that 87% of adults with HIV knew their status but only 56% of adolescents or young adults (13 – 24 years of age) were aware of their status (CDC, 2021). The decrease in knowledge of status in the youth/young adult age groups shows a disparity between HIV prevention and testing in this age group compared to the general population. Additionally, among 16–24-year-old people, only 16% who could have benefitted from utilization of pre-exposure prophylaxis (PrEP) for HIV were prescribed it (Hsu & Rkhmanina, 2022).

HIV testing and prevention services are readily available. An increase in provider awareness and confidence regarding testing for and preventing HIV can lead to increased identification and treatment to reach the long-term goal of ending the epidemic. This CPM outlines recommendations for HIV testing, nPEP (non-occupational post-exposure prophylaxis), and PrEP (pre-exposure prophylaxis).

Target Users

- Physicians (Ambulatory, Urgent Care, Emergency Department, Hospital Medicine, Fellows, and Resident Physicians, Infectious Diseases)
- Advanced Practice Providers
- Nurses [including SANE (Sexual Assault Nurse Examiner) Program]
- Pharmacists

Target Population

HIV Testing

Inclusion Criteria

- Concern for pregnancy with concurrent testing
- History of unprotected sexual activity
- Other concurrent sexually transmitted infection (STI)
- IV drug use
- High risk behavior
 - Drug and alcohol use
 - Multiple partners
 - Male who has sex with males
- No previous HIV screening
- Patient/parent request
- Sexual Assault
- Tuberculosis disease
 - History of sexual activity with included current symptoms:
 - Malaise
 - o Fever
 - Sore Throat
 - o Lymphadenopathy



Date Finalized: February 2023 6

Exclusion Criteria

- Pre-pubertal child Call SCAN provider on call
- Concern for perinatal transmission
- Recent antiretroviral medications
- Known HIV infection

HIV nPEP

Inclusion Criteria

• Patients exposed to potentially HIV infected body fluids in the last 72 hours

Exclusion Criteria

- HIV or Hepatitis B infected patient
- Impaired hepatic function
- Impaired renal function (CrCl <60 ml/m2/min)
- High risk of fractures
- Known exposure to someone with resistant HIV
- Repeated contact with same individual > 72 hours prior to presentation
- If patient already taking PrEP as prescribed

HIV PrEP

Inclusion Criteria (Indications for HIV PrEP)

- History of unprotected sexual activity
- Other concurrent STI
- IV drug use
- High risk behavior
- Drug and alcohol use
- Multiple partners
- Males who have sex with males
- Patient request
- Patients with history of more than one nPEP course

Exclusion Criteria

- Positive HIV
- Pending or no HIV testing results within the past 7 days
- < 12 years of age
- < 35 kg
- Eligible for nPEP based on recent or new exposure to HIV infected body fluids (\leq 72 hours)
- History of sexual activity with included current symptoms:
 - Malaise
 - Fever
 - Sore Throat
 - Lymphadenopathy

Practice Recommendations

Please refer to the CDCs Sexually Transmitted Infections and Treatment (Workowski et al., 2021) Clinical Practice Guideline for full practice recommendations, evaluation, and treatment recommendations. No deviations were made from the CDC guideline regarding practice recommendations, but logistical processes specific to Children's Mercy were added.

Additional Questions Posed by the CPM Committee

No clinical questions were posed for this review



Children's Mercy Practice Recommendations and Reasoning

No deviations were made from the CDC guideline regarding practice recommendations, but logistical processes specific to Children's Mercy were added. These processes are specific to the referral processes to speciality clinics such as the SANE program, Infectious Diseases, and/or Adolescent Speciality Clinics. This is outlined in the algorithms and care management descriptions.

Care Management Recommendations Based on Standards of Care and Expert Opinions *HIV Testing*

HIV testing is recommended for all those seeking STI testing and not already known to have HIV. HIV testing is also recommended for those patients with a concern for exposure to HIV, risk factors for HIV, or signs/symptoms of HIV. The following steps are in place to guide the provider at Children's Mercy on recommendations established by the Centers for Disease Control (CDC) STI guideline (2021).

- Complete screening for HIV if patient meets the inclusion criteria above or requests HIV testing
- If patient has completed recent antiretroviral medications, follow the alternate testing guide provided by the CDC
- Order HIV antigen/antibody (Ag/Ab) screen (If patient is unlikely to follow-up, consider a rapid-PCR HIV screen)
- If the screening test is positive or indeterminant, the CM lab will automatically send out a reflex confirmatory test. Test turnaround time is 2 4 days and the lab will notify clinician when results are back to CM.
- The confirmatory test results will verify diagnosis and guide appropriate treatment
- If screening and, if needed, confirmatory tests are negative:
 - If patient is not at high risk for HIV, retest annually or as requested
 - If patient is considered 'at risk', have them follow-up with PCP or place a referral to Adolescent Speciality Clinic. Provide sexual education counseling, offer birth control, complete additional STI screening (see Appendix A), and consider PrEP
- If screening and confirmatory tests are positive and patient is present when results are returned:
 - Page the on-call 'Linkage to Care' Case Worker (<u>Kansas City Transitional Grant Area: Ryan White Case</u> <u>Management</u>) at (816)990-2411
 - Consult Social Work for patient and family support
 - Call Infectious Diseases Community doctor if needed
 - Consult Psychology
 - Complete the following testing:
 - CBC and BMP
 - Draw <u>HIV-1 RNA PCR</u> quantitative viral load
 - <u>CD4 testing</u>
 - Hepatitis B surface antigen
 - If preliminary and confirmatory tests are positive but patient is NOT present when results are returned:
 - Place a referral to Infectious Diseases Clinic AND
 - Send request for appointment within 7 days to Infectious Disease Clinic in Cerner Message Center for Positive HIV Test
- Provide the Healthy Sexual Behavior Handout (see Appendix A)

HIV nPEP

HIV nonoccupational post-exposure prophylaxis (nPEP) is the use of antiretroviral medication in emergency situations (exposure within the last 72 hours) for patients with limited or isolated exposure to blood, genital secretions, or other potentially infectious body fluids that have or may contain HIV. The CDC nPEP Guidelines Update (2016) adopted the use of rapid antigen/antibody (Ag/Ab) combination HIV test and updated preferred and alternative 3-drug antiretroviral nPEP regimens. Children's Mercy has incorporated many of these recommendations and guidance for the provider is included below:

- If patient has tested positive for both the HIV screening and confirmatory tests, the provider will need to review the exclusion criteria and determine appropriateness to begin nPEP medications
- Provider to make appropriate consultations to social work and/or Infectious Diseases
- Provider to complete the AIDS Education and Training Centers Risk Assessment to confirm patient qualifies for nPEP
- Infectious Diseases provider available for consult if questions remain regarding patient qualification for nPEP

Children's Mercy KANSAS CITY

- Order labs
 - HIV Ag/Ab
 - o LFT
 - o BMP
 - Hepatitis B Panel (Surf Ag, Surf Ab, Core Ab)
- Give first doses of nPEP medications while patient still present in the care setting and prescribe a 28-day treatment supply (to be filled by the patient).
- Complete patient education including (refer to Appendix A for education resources):
 - Importance of taking nPEP medication as described
 - \circ What actions patient needs to take to keep themselves and their partners safe while taking nPEP
- Regardless of patient starting on nPEP or not, complete referral to Infectious Diseases Clinic for follow-up (indicate in the referral order if patient has or has not started nPEP)

HIV PrEP

PrEP (pre-exposure prophylaxis) is medicine that reduces a person's chances of contracting HIV from sex or injection drug use. When taken as prescribed, PrEP is highly effective for preventing HIV. The CDC PrEP Guideline Update (2021) makes a conditional recommendation based on pending FDA approval of an intramuscular (IM) medication and a recommendation to inform all sexually active adults and adolescents about PrEP treatment. Children's Mercy has incorporated many of the recommendations as well as the two new recommendations and provides the following guidance for the provider:

- If patient has tested negative for both the HIV screening and confirmatory tests, and is determined to be at 'high risk' for acquiring HIV, the clinician will share information about PrEP with the patient
- If patient chooses to proceed with PrEP , consult social work and make appropriate referrals to Infectious Diseases or Adolescent Specialty.
- Order the following labs:
 - HIV Ag/Ab (if not already completed)
 - o LFT
 - o BMP
 - Hep B Panel (Surf Ag, Surf Ab, Core Ab)
 - Prescribe appropriate medications using medication table for PrEP
- Provide discharge education
- Place Adolescent Specialty Clinic referral for PrEP follow-up (if not already being followed in Adolescent Specialty Clinic).

SANE Program

- HIV Testing and nPEP
 - HIV Testing and nPEP
 - Patients must have genital to mucosal membrane contact within the last 72 hours to be eligible for consideration of HIV nPEP
 - SANE discusses the pros and cons of HIV nPEP as prophylaxis for HIV
 - ID on-call provider is available if questions arise regarding eligibility or medication regimen.
 - Obtain baseline bloodwork before starting a patient on HIV nPEP (refer to nPEP power plan)
 - SANE speaks with Emergency Department (ED) provider about ordering HIV nPEP. If they have questions about dosing, they can talk with the pharmacy or ID
 - Give the first dose of HIV nPEP at the initial visit. Send a prescription for the remaining doses to the Children's Mercy outpatient pharmacy, OR the provider should call the local pharmacy for availability.
 - Educate the patient/family about the need for follow-up with the ID clinic, and complete a referral through Cerner

Measures

Percent of patients \geq 14 years of age who undergo HIV testing (monitored through STI CPG data)



Value Implications

The following potential improvements may reduce costs and resource utilization for healthcare facilities and reduce healthcare costs and non-monetary costs (e.g., missed school/work, loss of wages, stress) for patients and families.

- Decreased risk of under diagnosis
- Decreased risk of under treatment (i.e., correctly identify patients through standardized testing to target appropriate treatment and education)
- Decreased transmission of disease
- Decrease potential inequities in care based on gender, race, ethnicity, or sexual orientation
- Decreased unwarranted variation in care

Organizational Barriers and Facilitators

Potential Barriers

- Variability of screening processes among different care settings
- Variable knowledge of evidence-based recommendations among providers
- Challenges with follow-up faced by some patients
- Challenges related to poor medication adherence by patients

Potential Facilitators

- Collaborative engagement across care continuum settings during CPM development
- Increased awareness and use of CPM
- Standardized order set for Urgent Care, Emergency Department, Inpatient, and Specialty Care Clinics
- Processes to maintain patient confidentiality
- Access to patient education materials

Diversity/Equity/Inclusion

Our aim is to provide equitable care. These issues were discussed with the Committee, reviewed in the literature, and discussed prior to making any practice recommendations.

Power Plans

- EDP SAFE
- HIV PrEP

Associated Policies

• Treatment of Sexually Transmitted Infection

Education Materials

- Healthy Sexual Behaviors
- Your Test for HIV
- CDC Guilde to ARV Medications
- PrEP webpage

Care Process Preparation

This care process was prepared by the Evidence Based Practice Department (EBP) in collaboration with HIV CPM Committee composed of content experts at Children's Mercy Kansas City. Development of this care process supports the Division of Quality Excellence and Safety's initiative to promote care standardization that is evidenced by measured outcomes. If a conflict of interest is identified the conflict will be disclosed next to the committee member's name.

HIV Testing, nPEP, and PrEP CPM Committee Members and Representation

- Diane Petrie, FNP-BC, AAHIVS, CPN | Infectious Diseases | Committee Chair
- Jennifer Hansen, MD | SCAN Clinic, SANE Program | Committee Member
- Andrea Noss, MD | Adolescent Speciality | Committee Member

Children's Mercy KANSAS CITY

Evidence Based Practice

- Alaina Burns, PharmD, BCPPS | Pharmacy | Committee Member
- Miriam Crandall, RN, BSN, SANE-P | Emergency Department, SANE Program | Committee Member
- Kara LaTessa, MSN, RN, SANE-A, SANE-P | SANE Program | Committee Member
- Rachel Neihart, LCSW, LSCSW | Social Work | Committee Member
- Lisa Post-Jones, MSN, RN, CPN, SANE-P | SANE Program | Committee Member

EBP Committee Members

- Kathleen Berg, MD, FAAP | Hospitalist, Evidence Based Practice
- Andrea Melanson, OTD, OTR/L | Evidence Based Practice

Care Process Model Development Funding

The development of this care process model was underwritten by the following departments: EBP, Infectious Diseases, Emergency, and Adolescent Speciality Departments and the SANE program.

Conflict of Interest

The contributors to the HIV CPM have no conflicts of interest to disclose related to the subject matter or materials discussed in this care process.

Approval Process

- This product was reviewed and approved by the HIV Committee, Content Expert Departments/Divisions, and the EBP Department.
- Products are reviewed and updated as necessary every 3 years within the EBP Department at CMKC. Content expert teams are involved with every review and update.

Review Requested

Department/Unit	Date Approved	
Emergency Department	February 2023	
Infectious Diseases	February 2023	
Pharmacy	February 2023	
SANE Clinic	February 2023	
Social Work	February 2023	
Adolescent Specialty Clinic	February 2023	
Evidence Based Practice	February 2023	

Version History

Date	Comments
March 2018	Version one
July 2019	Revised to incorporate recommendations from the CDC
February 2023	Revised to incorporate updates to medications and education from the CDC, 2021 guidelines

Date for Next Review

• February 2026

Implementation & Follow-Up

- Once approved, the care process was presented to appropriate care teams and implemented. Care
 measurements will be assessed and shared with appropriate care teams to determine if changes need to
 occur.
- Education tools reviewed by health literacy, family advisory board, and human factors. Education material underwent usability testing.
- Power plans consistent with recommendations were created or updated for each care setting
- Education was provided to all stakeholders:



Departments of Emergency Medicine, Infectious Diseases, Pharmacy, and Social Work Providers from SANE and Adolesent Speciality Clinics

- Resident physicians
- Additional institution-wide announcements were made via email, hospital website, and relevant huddles.
- Metrics will be assessed and shared with appropriate care teams to determine if changes need to occur.

Disclaimer

When evidence is lacking or inconclusive, options in care are provided in the care process model and the power plans that accompany the CPM.

This model does not establish a standard of care to be followed in every case. It is recognized that each case is different, and those individuals involved in providing health care are expected to use their judgment in determining what is in the best interests of the patient based on the circumstances existing at the time.

It is impossible to anticipate all possible situations that may exist and to prepare processes for each. Accordingly, these processes should guide care with the understanding that departures from them may be required at times.



References

- Centers for Disease Control and Prevention. (2016). Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV United States 2016 update.
- Centers for Disease Control and Prevention. *HIV Surveillance Report, 2019*; vol.32. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2021. Accessed December 19, 2022.
- Center for Disease Control and Prevention. (2021). Pre-exposure prophylaxis for the prevention of HIV infection in the united states 2021 update. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
- Hsu, K. K., Rakhmanina, N. Y., & AIDS, C. o. P. (2021). Adolescents and Young Adults: The Pediatrician's Role in HIV Testing and Pre- and Postexposure HIV Prophylaxis. *Pediatrics*, 149(1). https://doi.org/10.1542/peds.2021-055207
- Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. (October 11, 2022). Guidelines for the use of antiretroviral agents in pediatric HIV infection. *Department of Health and Human Services*. Available at https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv. Accessed December 19, 2022
- Workowski, K. A., Bachmann, L. H., Chan, P. A., Johnston, C. M., Muzny, C. A., Park, I., Reno, H., Zenilman, J. M., & Bolan, G. A. (2021). Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep, 70(4), 1-187. https://doi.org/10.15585/mmwr.rr7004a1



Date Finalized: February 2023 13

Appendix A

STI Screening Questions Healthy Sexual Behaviors Protecting Yourself During Sex