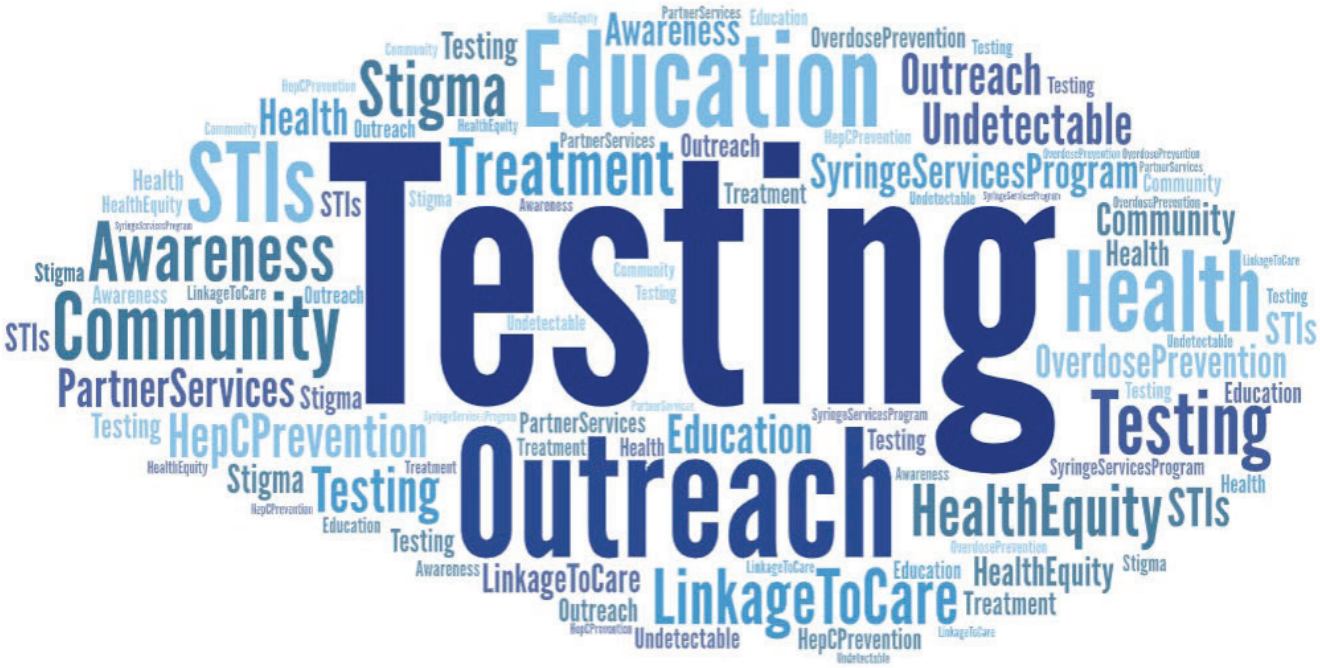
Implementing HIV Testing in Nonclinical Settings

Policies & Procedures Manual for CT DPH Funded HIV Testing Providers



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Program guidance intended for use by CDC-funded HIV testing providers in nonclinical settings.
HIV testing providers not funded by CDC may also find this information useful.

HIV Prevention & Care Programs

TB, HIV, STD & Viral Hepatitis Programs

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Acknowledgments

The *Implementing HIV Testing in Non-Clinical Settings: A Guide for CT HIV Testing Providers* (herein after referred to as Implementation Guide) was created to support the implementation of HIV testing services in nonclinical settings throughout the state of Connecticut. The Implementation Guide was developed by the Connecticut Department of Public Health (CT DPH), Public Health Initiatives Branch TB, HIV, STD & Viral Hepatitis Programs, HIV Prevention Program. This Implementation Guide is a collaboration of previous versions created by both the CT DPH and CDC. Many people supported the creation of this Implementation Guide and contributed to its development.

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Introduction

This protocol describes prevention interventions funded by the State of Connecticut Department of Public Health (CTDPH), TB, HIV, STD, & Viral Hepatitis Program, HIV Prevention Program The content of this manual is based on guidelines from the Centers for Disease Control and Prevention (CDC) and was modified by the CTDPH to address prevention service standards, requirements, and prevention programming in Connecticut. This document is consistent with the Requests for Proposals (RFPs) that HIV Testing in Non-Clinical and Clinical settings, and Harm Reduction Services that offer HIV Testing.

Purpose

The purpose of the protocol is to assist agencies in designing and implementing effective programs, to ensure that clients receive high-quality and appropriate services and to enable the CTDPH, HIV Prevention Program to monitor contracts in a consistent manner. Additionally, the protocol guidance and definitions are provided so that all funded program sites and Contract Managers will be able to describe, discuss, and evaluate their work using a common language. Adherence to the protocol will be assessed in each funded sites' performance.

Effective HIV Prevention Policies

Effective HIV prevention services are based on the following policies:

- Client confidentiality must be strictly protected.
- Informed consent must be obtained prior to services such as HIV and HCV testing Written informed consent is required for HIV testing in non-clinical settings.
- Confidential testing is the preferred method of testing by DPH funded sites.
- Information about the HIV test must be provided to all who request or accept HIV testing,
- HIV prevention services must be provided in a manner consistent with applicable local, state, and federal guidelines, policies, and statutes.
- HIV prevention services must be provided in a manner that is responsive to community needs and priorities (e.g. is available and accessible).
- HIV prevention services must be appropriate to clients' culture, language, sex, sexual orientation, age, and developmental level.
- Providers of HIV prevention services must develop and implement written protocols for OTL services.
- Providers of HIV prevention services must develop and implement written quality improvement and evaluation protocol and procedures.

Goals and Objectives

The CTDPH HIV Prevention Services Goals & Objectives are in alignment with the National HIV AIDS Strategy (NHAS) and the Centers for Disease Control and Prevention (CDC).

Goals:

- To reduce the number of new HIV infections in Connecticut.
- To reduce HIV risk behaviors in focus populations identified by the Connecticut epidemiological data.
- To ensure access to HIV prevention services such as: education, counseling and testing, partner notification, medical case management, and referral services.
- To improve integration of services across health and human service programs serving focus populations.
- To incorporate evaluation and behavioral science into HIV program planning, development, and implementation.

Objectives:

- Ensure that people living with HIV and persons at increased risk for contracting HIV have access to HIV testing to promote early knowledge of their HIV status.
- Receive high-quality HIV prevention counseling to reduce their risk of transmitting or acquiring HIV.
- Have access to appropriate medical, preventive, and psychosocial support services.
- Receive information regarding HIV transmission, prevention, and the meaning of HIV test results upon testing.

Acronyms

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
CADAP	Connecticut AIDS Drug Assistance Program
CBA	Capacity Building Assistance
CBO	Community-Based Organization
CDC	U.S. Centers for Disease Control and Prevention
CHPC	Connecticut HIV Planning Consortium
CLIA	Clinical Laboratory Improvement Amendments
CPP	Comprehensive Prevention for Positives
CT DPH	Connecticut Department of Public Health
D2C	Data to Care
DIS	Disease Intervention Specialist
FDA	Food and Drug Administration
HAART	Highly Active Antiretroviral Therapy
HCO	Health Care Organization
HCV	Hepatitis C Virus
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HNS	HIV Navigation Services
IPV	Intimate Partner Violence
M&E	Monitoring and Evaluations
MOA	Memorandum of Agreement
MSM	Men/Man Who Have Sex with Men
NAT	Nucleic Acid Test
NIC	Never in Care
NHAS	National HIV/AIDS Strategy
NHM&E	National HIV Prevention Monitoring and Evaluation
nPEP	Non-Occupational Post-Exposure Prophylaxis
OSHA	Occupational Safety and Health Administration
OOC	Out of Care
OTL	Outreach, Testing and Linkage to Care
PEP	Post-Exposure Prophylaxis
PII	Personally Identifiable Information
PLWH	Person Living With HIV

PrEP	Pre-Exposure Prophylaxis
PS	Partner Services
PWUD	Persons Who Use Drugs
QA	Quality Assurance
QC	Quality Control
RFP	Request for Proposal
RNA	Ribonucleic Acid
SNS	Social Networking Strategy
STD/STI	Sexually Transmitted Disease/ Sexually Transmitted Infection
TA	Technical Assistance
TB	Tuberculosis

Program Principles and Overview

The following are guidelines the CT DPH should see implemented in funded agencies' own Policies and Procedures pertaining to HIV Testing in non-clinical settings. HIV testing programs must strive to provide high-quality services to best meet the needs of their clients and achieve their program objectives. There are certain principles and standards that should be met by all HIV testing programs to provide high-quality services. This chapter reviews these principles and standards and provides links for accessing more information.

Defining Nonclinical Settings

CDC supports two primary models of HIV testing: (1) routine testing in clinical settings, and (2) focused testing in nonclinical settings. Although more HIV tests are conducted in clinical settings than in nonclinical settings, persons at high risk for HIV infection may not access healthcare services, and so it is important to utilize both strategies. This manual is intended for focused testing in nonclinical settings but may also be useful for HIV testing providers in clinical settings.

For the purposes of this manual, nonclinical settings are sites where medical, diagnostic, and/or treatment services are not *routinely* provided, but where select diagnostic services, such as HIV testing, are offered. Increasingly, agencies are beginning to offer clinical services within nonclinical settings, making this distinction a bit blurred. Still, a key feature of nonclinical settings is their location *within* the community—whether at fixed venues, outreach sites, or in a person's home, nonclinical settings are easily accessible and comfortable for populations who might not access medical services regularly. They typically provide same-day rapid HIV testing, they might offer other HIV prevention services such as structural or behavioral interventions and social services, and they conduct recruitment services to get high-risk populations in for focused HIV testing.

Examples of nonclinical settings where HIV testing may be offered include but are not limited to; community-based organizations (CBOs), mobile testing units, churches, bathhouses, parks, shelters, syringe services programs, health-related storefronts, homes, and other social service organizations. Agencies may choose to provide HIV testing services at multiple venue types to offer a diverse range of options, to better identify high-risk clients, and to meet the needs of the populations they serve.

Some health departments might be considered nonclinical settings and offer focused HIV testing, while others offer clinical services and routine HIV testing. Furthermore, some health care organizations (HCOs) might provide a blend of routine and focused HIV testing, even though they are considered clinical settings. This demonstrates the complexity of distinguishing between clinical and nonclinical settings.

[1] ICF Macro, Inc. Planning and implementing HIV testing and linkage programs in non-clinical settings: a guide for program managers. http://effectiveinterventions.cdc.gov/docs/default-source/public-health-strategies-docs/HIVTestingImplementationGuide_Final.pdf. Published 2012. Accessed May 11, 2015.

HIV Testing in Non-clinical Settings

HIV Outreach, Testing and Linkage to Care is a client-based HIV Prevention methodology centered on meeting the client where they are at and are the core components of non-clinical testing. Several outreach approaches such as social network outreach, routine offering of HIV counseling and testing in clinical and non-clinical settings, social marketing, partner services, etc., are used to find and engage PLWHA out of care or episodically in care and connect them to care, including medical and other clinical care, support services, peer support and sexual assault and domestic violence survivor services.

Funding for HIV testing in non-clinical settings provided by DPH is reserved for individuals at high risk for HIV infection and for those who have no other resources to pay for testing. **Therefore, those requesting HIV testing through DPH contracted sites should be screened to determine that there is a sufficient risk for HIV or lack of health insurance or other means to pay for testing.** Those who are not eligible to receive testing through a DPH contracted OTL site due to low risk should be referred to another resource such as Planned Parenthood, private physician, or an over-the-counter HIV Test Collection Kit. Ultimately, no one should be turned away without exploring other testing options. Contracted programs may actually wish to purchase Home Collection Kits for low-risk individuals who request testing. HIV testing performed through a DPH contracted OTL site is based on focused behavioral risk and not on medical diagnostic criteria. Therefore, those who present with symptoms should also be referred and linked to a healthcare provider.

Once the testing stage has been completed, the result will determine the client's linkage to services. Clients who have a reactive preliminary HIV test (rapid test) will be required to submit a blood sample to a lab for a supplemental test for confirmation and linked to a HIV provider, should the supplemental test result be positive. Clients who receive a negative preliminary HIV test result will be evaluated for PrEP, mental health and other social services and linked to the appropriate support provider.

Comprehensive Prevention for Positives (CPP)

CPP is a set of strategies that integrates HIV prevention and the care and support of people living with HIV/AIDS (PLWHA). These strategies use health promotion and harm reduction approaches to support PLWHA and their partners in their efforts to practice risk reduction and to avoid HIV, STI, and viral hepatitis infection and/or transmission.

Through individual interventions and routine encounters with care and support service providers, PLWHA and their partners are routinely offered opportunities to assess the risks associated with personal behaviors and life circumstances. Group interventions and peer support are offered to help develop communication and other risk-reduction skills and address factors that can influence risk behaviors and overall physical and mental health. Community-level interventions that utilize print media, the Internet and other public health social marketing campaigns are used to promote the adoption of community norms that: (1) motivate individuals to learn their HIV status and access clinical care and support services; (2) support disclosure of HIV status between

sex and drug-using partner; and (3) encourage individuals to take responsibility for and control of their health and the health of their partners.

Comprehensive Prevention for Positives services are a policy shift in the way services are provided to PLWHA. At times for people who are positive, prevention is not a distinct category of service but represents an integral part of their care. Simply put, prevention for HIV positive individuals complements and completes the standard of care for PLWHA.

CPP is composed of the following components:

- Finding and engaging PLWHA never or episodically in care. DPH supports activities such as Data to Care (D2C) that emphasize engaging people who are out of care (OOC) and never in care (NIC)
- Linking PWLHA to medical and other clinical care, peer support, and support services
- Offering risk assessment and prevention counseling
- Providing partner services
- Assisting in the maintenance of care and risk reduction consistently over time.

These components connect the entire HIV/AIDS service delivery system and multiple interventions must be utilized within prevention and education, support services, and clinical care in order to implement them.

Focused Recruitment

This section provides information on focused recruitment for HIV testing and PrEP services. Focused recruitment is the process by which persons from focused populations are located, engaged, and motivated to access HIV prevention services. Regardless of whether HIV testing providers are directly involved in focused recruitment, they should be aware of how their HIV testing services are messaged in the community and how clients reach them for services.

Defining 'Focused'

The term '*Focused'*, in Focused Recruitment, is the process for defining how you will direct your HIV prevention services to identify persons who are unaware of their HIV status and who are at greatest risk for HIV infection. Appropriately focusing your HIV prevention services to these highest-risk populations is necessary for maximizing resources, and for identifying undiagnosed HIV-positive persons in need of HIV medical care, treatment, and prevention services. Focusing on the populations currently impacted the most will help you identify high-risk HIV-negative persons needing important HIV prevention services, such as PrEP, non-occupational post exposure prophylaxis (nPEP), and other social and behavioral interventions.

In nonclinical settings, it is important to focus your services to identify high-risk individuals who do not access health care services or who may not otherwise have access to HIV testing in clinical settings— these are the persons who may benefit most from HIV testing services in nonclinical settings, and so these are the persons you should attempt to recruit into your program. Additionally, in defining your focus population and how to reach them, your program should consult multiple data sources, including local epidemiologic and surveillance data, recent programmatic monitoring and evaluation data. Members of your focus population, agency staff, and other service providers can also be important sources of information for identifying high-risk populations, where they congregate in the community and the best ways of reaching them. Key informant interviews, which are brief interviews to obtain feedback from these groups, can be used for this purpose.

Each agency will need to define or segment their focus populations, which should include both the primary focus population and the secondary focus population (or subpopulation). In order to narrow the overall focus population to reach persons most at risk for HIV infection, agencies will need to know what high-risk behaviors and other factors are related to increased risk in the community, engaging in these behaviors or affected by these factors, and where to identify the populations. This will help agencies tailor messages and services in a way that resonates with the identified focus population and plan for how to best reach them.

To learn who the highest populations at risk for HIV infection are, please visit https://www.cdc.gov/hiv/group/index.html.

Defining Recruitment

Recruitment begins once an agency has defined the focus population and identified where and how to reach them (i.e., phone apps, social media, etc.). Community assessment or formative evaluation can provide valuable information on recruitment, given the dynamics of different communities, and the potential for certain strategies to work better than others with high-risk groups.

Your agency will need to develop a recruitment plan that outlines **when**, **where**, and **how** recruitment of the focus population will be done. The plan should include ideas about where to reach the focus population, as well as the specific recruitment strategies and messages that will be used for reaching them and engaging them in HIV testing and linkage to PrEP. Agencies might find that a particular focus population is accessible at a physical location (e.g., a particular neighborhood, bar, or weekly meeting) or in a virtual space (e.g., Internet chat group, social media).

Once your agency has defined the recruitment strategies to be used to engage the focus population and outlined these in the agency plan, agency staff should pilot these strategies and make refinements based on the results. Even after implementing recruitment strategies, agency staff should routinely monitor HIV prevention services to determine if they are meeting goals and make adjustments to the recruitment strategies as needed. For example, if it is found over the course of 1 month that the staff have not tested anyone who is HIV-positive, the agency might need to revise the recruitment strategies to better reach persons with undiagnosed HIV infection or at high-risk for acquiring HIV infection.

Recruitment Strategies

Agencies should aim to deliver strategic, culturally competent, community-based recruitment strategies that engage the focus population and motivate them to access HIV testing services. Organizations should collaborate with other organizations that have a history of working with and recruiting the focus populations. They should seek input from community stakeholders, such as Community Advisory Boards, to select the most appropriate program promotion and recruitment strategies. Community stakeholders can also be useful for crafting recruitment messages, which may focus on increasing public awareness of the agency's services, destigmatizing HIV and HIV testing, and providing key information about HIV and HIV testing.

The 6 primary categories of recruitment strategies are the following:

1. Street-based and venue-based outreach
2. Internet outreach
3. Internal referrals
4. External referrals
5. Social networking
6. Social marketing

Street-Based and Venue-Based Outreach

Street-based and **venue-based** outreach are done by engaging the focus population in their own environment, such as a particular street, neighborhood, hot spot, or venue (e.g., a bar, hotel, or community center). Outreach workers, who may include HIV testing providers, aim to reach the focus population with key messages about HIV and HIV testing. HIV testing services may also be offered in conjunction with street- and venue-based outreach, if appropriate, and some agencies will bring a mobile testing unit, such as a van or tent, to provide HIV testing for the focus population.

Internet Outreach

Internet outreach involves reaching the focus population through online venues, such as chat rooms, social networking sites, hook-up sites, and mobile applications. Agencies can promote HIV testing services including couples or partner testing through these approaches; provide information about HIV prevention, care, and treatment; or schedule appointments for clients seeking HIV testing. Internet- based outreach may be especially useful for reaching young people and MSM who do not identify as gay or who cannot be found in traditional outreach settings.

Internal Referrals

Internal referrals mean accessing the focus population through other services offered at the HIV testing agency, such as syringe services programs, substance abuse programs, mental health services, evidence-based HIV prevention interventions, sexually transmitted disease (STD) testing and treatment programs, and HIV medical care (for partners of people already in care). This approach can be successful, but persons with high-risk behaviors may not access these services independently, so additional recruitment strategies should also be used.

External Referrals

External referrals means that persons from the focus population are referred to HIV testing services by agencies outside the HIV testing program. External agencies may include syringe services programs, substance disorder programs, mental health services, evidence-based HIV prevention interventions, STD testing and treatment programs, HIV medical care, and homeless shelters. These offsite programs identify high-risk clients who are accessing their services and send them to your agency for HIV testing. Building strong partnerships with external agencies that tend to serve high-risk clients is important, as is sharing information with them about how to make appropriate referrals to your program.

Social Networking Strategy

Social Networking Strategy (SNS) is a peer-driven approach to recruitment that involves identifying HIV- positive or high-risk HIV-negative persons from the community to serve as "recruiters" for your agency. Recruiters deliver key messages and encourage HIV testing among high-risk persons in their social, sexual, or drug-using networks. They may use coupons or invitations as a way of documenting that they have delivered these messages to potential clients. The recruiters are trained or "coached" on the best approaches to reach their peers, including who should be reached through this approach and what messages can motivate their peers to be tested for HIV. Partner referral is a type of social networking that involves recruiters referring their sexual partners to an HIV testing program. Recruiters may refer their sexual partners to be tested alone, or recruiters may accompany their partners and be tested together, as outlined in Chapter 6 on Couples HIV Testing and Counseling.

Social Marketing

Social marketing is the use of media (e.g., flyers and brochures, posters, print advertisements, radio and television advertisements, or Internet advertisements) to recruit clients into HIV testing programs.

Organizations can develop their own social marketing campaigns but are encouraged to use existing resources, such as those available from Positive Prevention (www.PositivePreventionCT.org) and the CDC, and tailor them to their jurisdiction's specific requirements. Materials are available through the Community Distribution Center at https://harmreduction-ct.org/ccdcp.html . CDC's Act Against AIDS campaign materials can be accessed at http://www.cdc.gov/actagainstaids/. Additional materials are available at http://effectiveinterventions.cdc.gov/.

Implementing Recruitment

In order to achieve the best results, agencies should employ multiple recruitment strategies to reach the focus populations. Agencies may even choose to use all 6 recruitment strategies because they each have their own benefits and potential for reaching different subgroups of the focus population. When selecting recruitment strategies your agency should consider staff safety, agency capacity, and availability of resources.

Recruitment of the focus population is essential to the success of a high-impact HIV testing program. In order to have an effective and innovative program, resources should be dedicated to carrying out the recruitment plan. Your program may have the most success if you:

- Hire and train specific recruitment staff who are separate from HIV testing staff.
- Build partnerships in the community to ensure multidirectional referrals and expand your reach.

- Use innovative approaches for reaching the focus population through Internet and social media.
- Offer incentives to reach previously unreached focus populations, generate interest in new services, or obtain buy-in for testing at, or around, high-risk venues (e.g., bars, clubs) where clients might need extra motivation to access HIV testing.

Incentives

Incentives should not be utilized as a means of recruiting participants to be tested for HIV. Any agency wishing to use incentives for other means besides HIV testing must develop an incentive policy for DPH review that aligns with the DPH Incentive Policy. (https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/aids_and_chronic/prevention/pdf/IncentivePolicypdf.pdf?la=en).

Agencies using SNS approaches may deliver incentives to recruiters when the clients they recruit show up for HIV testing. Recruiters should be encouraged to refer clients from the focus population and may wish to specifically focus on referring first-time testers, couples or partners, and high-risk persons in the social networks of HIV-positive clients.

Challenges to using incentives include the potential to attract repeat testers who are more interested in the incentive than the HIV test, interagency competition, and sustainability. In developing an incentive plan, agencies should identify an appropriate incentive rate for reaching the focus population. It may be useful to consult with community advisory boards or clients to elicit feedback on appropriate incentives for HIV testing.

Agencies should regularly revisit and refine their recruitment strategies. If, through monitoring and evaluation (M&E), you discover that your testing program is not reaching the focus population or you are not on track to meet your goals, you will need to try different recruitment strategies.

Boundaries

Maintaining professional boundaries is a basic necessity pertaining to HIV prevention services, especially recruitment. Please refer to your agency's policy and procedure protocol. **The act of promising or enticing potential clients with sexual or monetary incentives in return for getting a HIV test or PrEP referral are not allowed by agencies funded by CT DPH.** Understanding the difference between client and friend relationships is crucial for establishing a smooth-flowing program. When friends are recruited to participate in your agency's services, it is strongly recommended that a coworker or colleague work with that participant, if available. Friends and family members may obstruct the truth when asked about high-risk activities (e.g., sexual health intake, drug use, etc.) in an effort to maintain the reputation or image they want you to have of them, rather than confidentially disclosing the truth to someone they do not know.

Peer workers who utilize MSM geo-location social applications on their own time for recreational purposes must establish professional boundaries while utilizing the same applications for work

purposes. Using an account created by the funded agency is an example of keeping personal and professional boundaries in place. While on the agency's account, anyone who is being engaged for HIV Prevention services is off limits for recreational/non-professional relations. Please speak with your supervisor if clarification is needed on this topic.

Documentation

Documentation of Focused Recruitment efforts is necessary for an effective program as it serves two primary functions. Agencies are encouraged to create their own tracking forms to document their efforts.

1. **Track Efforts:** Keeping track of the number of individuals having been reached is required by the CT DPH for every Tri-Annual report.

2. **Review Efforts:** Referring to previous efforts can provide a clear picture of what is working and not working when evaluating goal achievement and if any changes need to be made. If there is a location, time of year, event, or other variable that helps or inhibits your agency completing goals, this information is very valuable.

HIV Testing Policies

Guiding Principles

Staff conducting HIV testing should be trained in accordance with state and local requirements before providing services to clients.
The following principles guide the provision of HIV testing in nonclinical settings, and HIV testing providers should ensure that these are met:

1. HIV testing is **voluntary**; clients have elected to be tested of their own accord, and they are not coerced or forced to be tested. Clients have the right to decline services.
2. Clients give their expressed written **informed consent** to be tested; they clearly understand basic information about HIV and HIV testing, and they provide written agreement to be tested for HIV.
3. HIV testing is done confidentially to facilitat linkage to care for newly diagnosed HIV-positive clients. Clients should understand the benefits of confidential testing , including what measures are in place to protect their confidentiality, how their personally identifiable information will be protected, and who will know their test results (e.g., the local health department if the results are HIV-positive).
4. HIV testing services should be **client-centered**; that is, services should be focused on the client's concerns and circumstances. Services should also be **culturally competent** with respect to race, ethnicity, gender, sexual orientation, age, language, literacy, relationship status, and other relevant factors.
5. All clients testing HIV-positive should be referred and **linked to Partner Services and HIV Medical Care**, and these linkages should be tracked to ensure timely linkage and successful enrollment in care.

Special Circumstances for Consent

Agencies should establish policies about testing people who are under the influence of alcohol and or drugs. Policies should include information to help counselors understand what to do if clients are under the influence and whether or not to test. In order to get an HIV test CDC requires that people being tested are able to give consent. If testing staff have reason to believe that a client is intoxicated or not of sound mind to give consent, staff should ask a supervisor or other colleague for assistance.

Persons who have a mental health disorder may not be able to give their own consent for HIV testing. Agencies will need to evaluate who to test based on their policies .

Ethical Standards

Agencies should establish an ethical code of conduct for their HIV testing services, which should be read and understood by all testing providers. This code of conduct should clarify that HIV testing providers must protect client confidentiality, should not use or be under the influence of alcohol or drugs while on duty; should not have sex with clients; should not exchange money

with clients; or engage in other inappropriate behavior with clients. Agencies should establish and enforce these boundaries to protect their staff and their clients, and to ensure clients receive high-quality HIV testing services.

Policies and Legal Considerations

HIV testing providers should understand and provide services in accordance with their agency policies and state and local policies and laws. The policies and laws providers should be familiar with include, but are not limited to:

- Authorization for agencies to provide HIV testing
- Provider training and certification to perform HIV testing
- Who can consent to and receive HIV testing (e.g., teenagers or intoxicated persons)
- Provision of confidential testing
- Record keeping and ensuring confidentiality
- Reporting HIV testing results
- Provision of partner services (elicitation, notification services, etc.)
- Laboratory certifications or licensure
- Quality assurance procedures for HIV testing

Laboratory Certificate Requirements

Nonclinical HIV testing sites using waived rapid HIV tests must either obtain their own certificate of waiver under CLIA (the Clinical Laboratory Improvement Amendments of 1988), or establish an agreement to work under the CLIA certificate of an existing laboratory. CLIA outlines quality standards for laboratory testing—including rapid HIV testing—to ensure the accuracy, reliability, and timeliness of patient test results. More information about CLIA certification and CLIA-waived tests can be found on CDC's HIV/AIDS website (https://www.cdc.gov/clia/index.html).

All sites planning to offer waived rapid HIV testing not already CLIA-certified, must obtain a Certificate of Waiver or be included under a multiple site exception, such as limited public health testing or mobile testing. The CLIA form must be completed by completing information on the facility type (select from a list), hours of operation, estimated annual number of waived tests to be performed, the type of control (nonprofit, for profit or government control) and the total number of individuals involved in performing testing (*See Appendixes*).

The facility owner or laboratory director must sign the form. CLIA waiver applications can be obtained by contacting DPH.FLISlab@ct.gov State Department of Public Health. Email the completed form to DPH.FLISlab@ct.gov S For more information on obtaining a CLIA certificate, click on the website at http://www.cms.hhs.gov/CLIA. After the completed form is processed by the State agency, a fee of $150 will be assessed for a Certificate of Waiver. The certificate is valid for two years.

Health Information Compliance

All health care providers—including HIV testing providers—must comply with federal and state laws that protect patients' health information, such as those set out in the Health Information Portability and Accountability Act of 1996 (HIPAA). HIPAA provides clients and patients access to their medical records and gives them control over how their health information is used and

disclosed. Clients and patients can give permission to share their health information with anyone, including friends, family members, and organizations that provide referral services. This means that couples who wish to be tested and receive their results together may do so under HIPAA if both partners are in agreement.

Data Security and Confidentiality

All data collected by nonclinical HIV testing sites should adhere to the standards outlined in Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs. These guidelines provide recommendations related to record keeping, data collection, data management, and data security.

Universal Precautions for Employee and Consumer Safety

The Occupational Safety and Health Administration (OSHA) has established basic precautions designed to keep employees and consumers safe when they might come into contact with blood or other body fluids (e.g., saliva, urine). These precautions are known as "universal precautions" and should be observed by all HIV testing providers. They include the following:

- Wash hands or other skin surfaces immediately before and after handling blood or other body fluids. If soap and water is not available, alcohol-based hand sanitizer may be used.
- Use disposable gloves (preferably nitrile); change gloves between clients.
- Do not eat, drink, apply makeup, or handle contact lenses in the testing area.
- Do not keep food or drink in refrigerators, containers, shelves, cabinets, or countertops where potentially infectious materials are present.
- Dispose of lancets, needles, or other fluid-touched items (e.g., gauze) in proper biohazard containers.
- Disinfect all work surfaces and items before and after testing with 10% bleach solution or Environmental Protection Agency-approved disinfectant.

In the context of HIV testing, the most likely occupational exposure will be through blood collected via fingerstick or blood draw, needlestick injuries while collecting specimens, or through sharp injuries. Other staff, such as janitorial staff who clean up the areas where testing is conducted, may also be occupationally exposed. Agencies must protect workers who may come into contact with blood or other body fluids, and make arrangements for safe and proper disposal of all HIV testing waste.

If you come into contact with body fluids, report this exposure to your supervisor immediately and seek medical guidance to initiate post exposure prophylaxis (PEP).

Provider safety

Agencies should establish policies and procedures to keep staff and volunteers safe in HIV testing settings. These policies may include language about the number of staff required to be onsite; service provision hours; emergency preparedness; and staff conduct in outreach sites, mobile testing units, and HIV testing events.

Quality Assurance

Establishing and implementing Quality Assurance (QA) activities can help ensure that agencies are delivering accurate test results, meeting program objectives, and delivering services according to established procedures. Each agency should develop a QA plan outlining their agency's QA activities,

which might include:

- Running test kit controls according to the manufacturer's protocols
- Keeping both room and refrigerator temperature logs
- Conducting HIV testing data reviews, including medical charts and client data forms
- Conducting role plays with peers, or between supervisors and peers
- Holding team meetings to review activities, discuss problems and concerns, and identify solutions
- Case conferencing to discuss challenging client cases and identify solutions
- Eliciting client feedback through surveys or interviews
- Conducting refresher trainings
- Performing direct observation of HIV testing sessions (with client permission)
- Receiving implementation support from CBA partners
- Reviewing client informational materials to ensure cultural appropriateness and accuracy
- Reviewing community referral and linkage resources, and establishing partnerships

QA activities are most effective when conducted on a regular basis, and when a combination of approaches is used. QA will be coordinated with state health department staff.

To ensure the accuracy of HIV test results, it is important that tests be performed correctly and consistently in accordance with written procedures and the manufacturer's protocols. Agencies should have HIV testing procedures that describe the following:

- Safety precautions to protect clients and testing personnel.
- Quality control (QC) procedures, including frequency of running external quality controls, documentation of QC results, and protocols for follow-up testing for clients with initial HIV-positive results.
- Materials and equipment required to support specimen collection, test performance, and documentation of test results.
- Specific steps required to perform the test correctly, as outlined in the product insert. There can be no deviations from what is in the product insert, or results may be invalid.
- Issues that may affect the accuracy of test results. These are listed in the product insert.
- Plans for addressing QC results that are not within acceptable limits. If there are issues that cannot be addressed, call the manufacturer's customer service line.

Monitoring and Evaluation

Monitoring and Evaluation (M&E) activities assess the resources that go into a program (e.g., staff, funding), the services provided (e.g., tests provided, referrals provided), and the results of the program (e.g., new HIV diagnoses, successful linkage to care) to determine whether the program is meeting its

objectives. Every HIV testing program should conduct M&E activities to assess and track program performance, to identify areas in need of improvement, and to ensure accountability to stakeholders. HIV testing providers play a critical role in M&E activities because they are responsible for the accuracy of client-level data and reporting.

M&E begins with establishing HIV testing program targets based on formative work, your agency's capacity for client flow, and requirements established by your funders. Agencies should establish goals for the total number of clients tested per month, the proportion of testing clients who represent focus populations, the proportion of clients who are tested as couples, and/or the total number of new HIV diagnoses per month. Much of this work will be established in advance by your agency's program manager.

Once your agency has established program goals agencies will need to collect data on each client in order to assess whether goals are being met. This might include demographics, HIV risk behavior, HIV test results, and linkage to HIV medical care. Again, the type of data agencies are required to collect will be established in advance by your testing agency, health department, CDC, or other funding agencies. Standard data collection tools (e.g., forms, logbooks) should be used.

Once client-level data are collected, they should be reviewed for completeness and accuracy, and stored in a secure location. These data should be compiled on a regular basis (e.g., monthly), and trends should be tracked over time. Reports should be produced and shared with stakeholders, including HIV testing program staff, board of directors, health department, CDC, and other funding agencies. Personally identifiable information (PII) such as client names and locating information should not be disclosed in these aggregate reports.

HIV testing programs should establish a process for reviewing these data on a regular basis to determine whether the agency is meeting established goals and objectives and make adjustments to program strategies accordingly. For example, if your agency's monthly report illustrates that only 40% of HIV testing clients are from the focus population, your staff may wish to implement new recruitment approaches the following month to increase that number to 60%. Including all stakeholders in the process of data sharing and review ensures that everyone has the same understanding of program targets and achievements and gets everyone involved in identifying solutions for program improvement. Some agencies may wish to appoint a data monitor to be in charge of data quality and reporting, but all staff have a role in ensuring successful M&E.

State of Connecticut Testing Laws

Testing of Minors

In 1996, Section 19a-952 of the AIDS Confidentiality Law was amended to include the testing and treatment of minors for HIV or AIDS. The section is summarized as follows:

Counseling, testing and treatment of a minor for HIV requires the consent of a parent or guardian, except:

a) If notification would result in denial of treatment

b) If fear of the result of notification would lead the minor not to seek or continue treatment

To treat the minor without notification, the minor must make such a request, and the counselor must fully document his/her reasons for the request. The minor must sign the documentation and it must be included in the client record.

Once confidential treatment is promised:

a) No relevant information can be divulged unless the minor consents

b) Bills should not be sent to the parents' or guardian residence unless the minor agrees in advance

c) The minor is responsible for all costs and expenses

All HIV prevention funds for publicly funded counseling and testing sites should be focused to the voluntary HIV testing of adults and adolescents whose personal behavior puts them at risk for HIV.. Especially for those who are uninsured, under-insured and low-income individuals who cannot pay for HIV testing.

Under no circumstances should HIV testing be provided to individuals under the age of 13 years. Youth 12 years and under should be referred to their pediatrician or comprehensive health care facility.

Deaf and Hard of Hearing

As part of a culturally competent risk assessment, counselors should evaluate the appropriate interpretation needs of the deaf or hearing-impaired such as American Sign Language (ASL) or TTY equipment. Currently TTY equipment is located in the following health departments: Hartford, Bridgeport, New Britain, and New Haven. Appropriate arrangements should be made by the agency to accommodate the needs of deaf and hearing-impaired clients.

Sexual Assault Survivors

HIV is a concern for rape and sexual assault survivors. This violence needs to be considered a risk factor for contracting HIV/AIDS. Although the risk for one-time sexual assault is considered to be low, the benefit of effective HIV Prevention Counseling and Testing can greatly help sexual assault victims in the long run. The State of Connecticut collaborates with CT Alliance to End Sexual Violence http://endsexualviolencect.org/ to ensure that support and services for sexual assault victims is readily accessible and culturally appropriate. Legislation allows for HIV testing of the alleged perpetrator upon request of the victim of sexual assault.

The following information will provide counselors and program supervisors with the current state statute and policy on disclosing offender HIV test results to the victim.

More information on this can be found at https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/aids_and_chronic/prevention/pdf/SABrochurepdf.pdf?la=en

Disclosures

Individuals that come for testing may or may not disclose a history of sexual abuse even if they have been sexually assaulted and referred to a testing site by a sexual assault counselor/advocate.

In certain cases, sexual assault survivors may seek the services of the HIV counseling/testing site to have the testing results of the person charged with assaulting them disclosed. (Please see special consideration).

If in the course of testing, someone does disclose that they were raped or assaulted, the HIV testers supportive and non-judgmental response can have a positive impact in the healing of the client and empowers clients' to understand that information and support are available to them if needed.

HIV Testers must not attempt to counsel on sexual assault but should aid victims and make referrals to a trained Sexual Assault Crisis Counselor, as appropriate. In addition, counselors are encouraged to build connections with the local SACS programs in order to provide these services more effectively. SACS programs provide the following free and confidential services:

- 24-hour hotline (English and Spanish) with immediate access to certified counselor/advocates
- Individual Counseling
- Accompaniment and advocacy throughout the medical and police system
- Preparation, accompaniment, and advocacy throughout the court system
- Information and referral for other needs
- Support groups
- SACC do not release names or information about a client without the expressed consent of the individual. *

Overview of State Ordered Testing

The CT AIDS Confidentiality Law Section 19a-582e8 was amended to allow for the HIV testing of individuals' accused of a Sexual Assault. A summary of the law is as follows:

A defendant accused of a sexual assault may be tested for HIV without consent if a:

1. Sexual assault victim requests that the Connecticut criminal court or juvenile court order such tests or;
2. Judge orders such testing at his/her discretion before final sentencing.

The results will be disclosed to the victim (by the court or their designee) if the test was at the victim's request and only after the offender has received the result. All other aspects of the AIDS confidentiality Law must be followed. The testing of victims of sexual assault should be done as a standard of practice.

Offender Testing

When an offender is accused of a violation of section 53a-70 (Sexual Assault, 1st degree), the rape victim may request that the offender test for HIV. The victim will then complete the Request by Victim of Sexual Act to Test Defendant for AIDS/HIV Form, REQUEST BY VICTIM OF SEXUAL ACT TO TEST DEFENDANT FOR AIDS/HIV 5. Offenders will be tested and the results will be disseminated at a location selected by the victim.

Gives Information to Victims

When a court orders an HIV test at the request of a person charged with a sexual assault crime, the court shall provide the victim with the Notice to and Information for Victim Re: Court ordered REQUEST BY VICTIM OF SEXUAL ACT TO TEST DEFENDANT FOR AIDS/HIV https://www.jud.ct.gov/webforms/forms/cr105.pdf includes the following:

1. Educational materials about human immunodeficiency virus and acquired immune deficiency syndrome developed by the Department of Public Health.
2. Information about and referral to HIV testing and counseling for victims of sexual assault.
3. Referrals and information regarding SACS programs.

Victim Retrieval of Court Ordered HIV Test Results

A victim of sexual assault has two options to retrieve court ordered HIV Test Results. The victim may designate a health care provider chosen by the victim or an HIV testing and counseling site funded by the DPH to receive the results of such test on behalf of the victim. At that the time, the victim will complete the Victim's Designation of Receiver for Defendant's HIV/AIDS Test Results Form, JD-CR 140.

1. Health Care Provider- If the victim has designated a Health Care Provider not currently funded by the State of CT Department of Public Health, the designated health care provider shall disclose the test results to the victim.
2. DPH funded HIV Counseling and Testing Provider Discloses Test Results- If the victim has designated a DPH funded HIV Counseling and Testing Provider for the retrieval of their court ordered HIV test results, they must complete Notice to Victim's Designee to Receive Defendant's HIV/AIDS Test Results Form, JD-CR-141. The court will send a copy of the offender result to the funded DPH Counseling and Testing Provider. The victim will then be instructed to by the court to contact the site for the retrieval of their results and will make arrangements with the site for an appointment.

At that time, a professionally trained counselor will provide counseling about HIV, risk reduction, , and offer referrals if appropriate.

Protocol for Court Ordered HIV Testing:

The DPH in cooperation with the Judicial Department will test individuals sent with a court order for HIV testing under this law. The policy for HIV testing individuals accused of sexual assault are as follows:

If the offender has been charged with a sexual assault crime, the sexual assault victim can ask the court to order the offender be tested for HIV. Forms for making the request are available through the court clerk's office. As of October 1, 2004, the law allows the sexual assault victim to choose a health care provider or DPH funded HIV testing site to receive the offender's test results and disclose them to the sexual victim.

1. **Ask the client for the court order:** If a client comes to your site and states that they have been sent by the court, by their attorney, by a judge or other legal entity **DO NOT TEST WITHOUT THE PAPER WORK**.
2. **Court orders should site the Connecticut general statutes for sexual assault HIV Testing**: See attached Law. Courts may use a generic court order, or one specifically developed for HIV Testing of defendants' accused of sexual assault.
3. **Court orders must be signed by a judge:** The request may have been initiated by someone other than the judge, e.g. an attorney, probation officer, victim advocate, etc. However, a judge must sign it.
4. **Fill out the required DPH Data forms:** Provide Pre-Test Counseling and HIV Testing just as you would for any other client.
5. **Schedule client for posttest counseling:** Client will return to you for their post test result and follow-up.
6. **Send court order in a sealed envelope with blood specimen to the lab:** Write "Court Order" on the envelope. Do not keep a copy of the court order. You have DPH assessment information about the client**.**
7. **It is the court's responsibility to notify the victim or others regarding the result:** The Counseling & Testing site responsibility is as usual to the client being tested.
8. **The lab will send the HIV result and the court order back to the judge:** The site has no responsibility to the court. The laboratory is responsible to get the result back to the judge and keep a copy for their files.
9. **If STD screening is also ordered, the STD clinic needs the original:** Make a copy and forward to the lab as mentioned above. Write on the envelope where you sent client for STD Testing (i.e., Hill Health Center).
10. **Make it easy for the client:** All Planned Parenthood sites can do both HIV Testing and STD court ordered cultures for screening. (STD Clinics in the Health Departments do not do cultures). Other federally funded HIV programs that can do both HIV testing and STD screening are the local hospitals and community health centers (see attached lists).
11. Counselors should consider sending the client to one of these locations if both tests are ordered.

Resource Information:

Connecticut Alliance to End Sexual Violence
http://endsexualviolencect.org/
96 Pitkin Street
East Hartford, CT 06108 860.282.9881
Toll Free Hotline: 1.888.999.5545 English 1.888.568.8332 Spanish

Domestic Violence and Intimate Partner Violence (IPV)

Domestic/intimate partner violence can happen to anyone. Tragically, one in four women will be abused during her lifetime. While most domestic violence involves men assaulting women, it can also involve men assaulting their male partners, or women assaulting their male or female partners.
Domestic violence is more common in the lesbian community than formerly believed (Trisdale,

2005). What constitutes domestic/intimate partner violence?

Violence perpetrated by an intimate partner is widespread globally. It includes:

- Physical violence (e.g. slaps, punches, kicks, assaults with a weapon, homicide);
- Sexual violence (e.g. rape, coercion and abuse include use of physical force, verbal threats, and harassment to have sex, unwanted touching or physical advances, forced participation in pornography or other degrading acts that often persist over time and are accompanied by threats on part of the perpetrator);
- Psychological violence (e.g. belittling the woman, preventing her from seeing family and friends, intimidation, withholding resources, preventing her from working or confiscating her earnings).

Screening for Domestic/Intimate Partner Violence

If a person is a victim of abuse, he or she may be reluctant to share that information therefore screening must take place during the initial risk assessment. The core of the domestic violence screening is a simple straightforward question: "What response would you anticipate from your partner if he or she were notified of possible exposure to HIV?" If the patient identifies concerns about the partner's reaction, a series of follow-up questions should be asked, such as:

Have you ever felt afraid of your partner? Has your partner ever pushed, grabbed, slapped, choked, or kicked you?

Based on what you have told me, do you think that notification of a positive HIV result to this partner will have a severe negative effect on your physical health and safety or that of your children or someone close to you?

Communication is necessary to ensure that the client's safety continues to be the priority in decisions about proceeding with HIV testing and partner notification. If there is a risk of any form of domestic violence, the counselor should refer the client for domestic violence services and partner notification should be deferred.

HIV Incidence Surveillance Program

Newly diagnosed cases of HIV infection are required to be reported to the Department of Public Health HIV Surveillance Program (ct.gov) HIV cases are reported using the *Instructions for HIV Counselors and the Adult HIV Confidential Case report Form (CRF) (See Appendixes)* – designed specifically for use by HIV Testers. HIV/AIDS Surveillance Program staff will mail a CRF to the counselor based on results received by the DPH laboratory but you can report a case at any time. Instructions on how to complete the form can be found at the following: https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/aids_and_chronic/prevention/pdf/OTLCRFinstructionspdf.pdf?la=en

Important! **The HIV Testing History (Section 10 of the CRF) needs to be completed for all clients who test positive for HIV.** For more information, please call the Department of Public Health, HIV/AIDS Surveillance Program at 860-509-7900

HIV Testing Practices

Use Best Possible Technologies and Approaches

Because one of the goals of HIV testing programs is to identify HIV infection as early as possible after exposure, programs should use testing technologies and specimens that allow for early detection. If possible, persons at highest risk should be tested for acute infection. In general, the tests used for this will be antigen/antibody combination tests used with blood specimens collected from the vein. However, it is not always feasible to have someone trained in collecting blood from a vein at nonclinical HIV testing sites, and so blood collected from a fingerstick is often used. Blood (whole blood, serum, or plasma) is the preferred specimen for HIV testing because tests conducted with blood are more sensitive for early infection than tests conducted with oral fluid. If an organization must use oral fluid for testing, it is important that clients and HIV testing providers understand the limitations.

Testing Basics

Your agency should have already selected the types of test kits that you will use to perform HIV testing, and if you will be performing HIV testing, you should receive training on how to conduct these tests. This chapter includes important information you should know about the different types of HIV test kits that are available, so that you are able to answer questions that your clients might have.

Agencies are encouraged to use the best possible testing technologies and specimens that allow them to detect HIV infection as early as possible after exposure. Immediately after infection, during what is referred to as the *eclipse* period, **no HIV test** can detect infection. Following this period is the *acute infection* period, the interval between when HIV ribonucleic acid (RNA) can first be detected using a nucleic acid test and when antibodies can first be detected. Most antibody tests cannot detect acute HIV infection, and persons with acute HIV infection can be highly infectious.

Every test has a *window period* during which the test cannot detect HIV infection. That period depends on the type of test being used, as well as the individual being tested. The window period includes the eclipse period (when no test can detect infection) up through the time when the particular test becomes reactive.

There are 3 types of HIV diagnostic tests: nucleic acid tests (NATs), antigen/antibody tests, and antibody tests. NATs detect HIV RNA directly and have the shortest window period, followed by antigen/antibody tests, and then antibody tests.

Nucleic Acid Tests

Before antibody tests are able to detect the body's response to HIV infection, NATs can detect the presence of the virus in blood. NATs can detect very early infection, as early as 10 days after infection. NATs are used for HIV testing in many laboratory settings. Additional information is available at CDC's website for U.S. HIV tests (http://www.cdc.gov/hiv/testing/).

Combination Antigen/Antibody Tests

Combination antigen/antibody tests detect both the antibody to HIV and the antigen "p24"—a protein that is part of the virus itself. Because the p24 antigen can be detected before antibodies appear, combination tests can identify very early infections. These tests—used with blood specimens collected from the vein—are recommended by CDC as the first test in the laboratory testing algorithm. Combination antigen/antibody *rapid* tests can be used for point-of-care testing but detect infection several days later than the laboratory-based combination tests. The evidence is inconclusive about the ability of combination antigen/antibody rapid tests to accurately detect the p24 antigen on whole blood specimens, and CDC has not provided recommendations about the use of these tests.

Antibody Tests

HIV antibody tests detect the presence of antibodies against HIV, which typically develop within 2 to 8 weeks after exposure to the virus. An antibody test can be conducted on a sample of blood or oral fluid. Many antibody tests are rapid tests, which means results can be returned on the same day, or within the same hour, or even within minutes. Rapid HIV antibody tests can be attractive for use in outreach settings because these settings may not be equipped to conduct venipuncture, and clients can get the results from their screening test quickly. Oral fluid antibody tests have been shown to detect infection a month or more later than blood-based tests because there is a lower concentration of HIV antibodies in oral fluid than in blood. Oral fluid is not ideal for identifying early HIV infection but may also be appealing in outreach settings because collecting oral fluid does not involve a fingerstick or venipuncture to perform the test. No antigen/antibody or nucleic acid tests are available for use with oral fluid. Blood-based rapid HIV antibody tests are widely available in most nonclinical HIV testing sites, and blood (whole blood, serum, or plasma) is the preferred specimen for HIV testing because tests conducted with blood are more likely to detect early infection than those conducted with oral fluid. If your organization must use oral fluid for testing, then you should inform HIV testing clients and patients of the limitations of this type of specimen for testing.

Preparing the HIV Testing Environment

HIV testing should be conducted in a private location where client confidentiality can be ensured and where a specimen can be collected safely and without risk of contamination. Some recommendations for establishing an ideal HIV testing environment include:

1. Room/testing space: Providers should ensure that the testing space has enough room and seating for all clients to feel comfortable and confident in their HIV testing experience.
2. Lighting: There should be enough light to allow providers to perform the test and read results accurately.

3. Temperature: Rapid HIV tests should be stored, transported, and conducted within specific temperature ranges specified by the manufacturer. HIV testing providers should check the package inserts to ensure they are adhering to these temperature specifications.

4. Surface area: Rapid HIV tests must be performed on a clean and level surface. HIV testing supplies and controls should be well organized, and no food or drink should be consumed near the testing area.

5. Storage and disposal: Most rapid HIV tests can be stored at room temperature below30°C/86°F. However, most controls used for quality assurance and quality control procedures must be stored in a refrigerator with temperature controls. HIV testing providers should maintain an inventory of testing supplies, including lot numbers, date of receipt, storage temperatures, expiration dates, and dates of use. Discard opened reagents after the manufacturer's expiration date, and do not use reagents from kits with different lot numbers interchangeably.

6. Equipment: Laboratory-based tests may require refrigeration of specimens. Refrigerators should have temperature controls, should only be used for the storage of samples and/or testing supplies, and should be labeled as such. A centrifuge will also be needed to prepare laboratory samples for testing.

7. Prevention Materials: Condoms, lubricants, and educational materials should be made available to clients in the HIV testing room as well as in the waiting area (or on display if at an outreach or community venue).

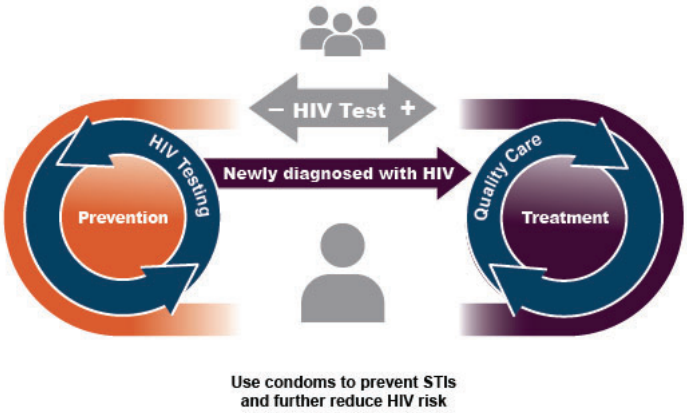
8. Supplies: Staff should have all the supplies, materials, and reference information necessary to provide HIV testing and linkage to care services, including data forms and testing logs; testing supplies and equipment; prevention and educational materials; referral and resource information; and client satisfaction or feedback questionnaires.

Testing Approaches

Status-Neutral Model

The Status-Neutral Model began in New York City in 2016, examining the ideation of a treatment model proposing the same approach to engagement in care, regardless of HIV status. The goals of this model are:

- To remove the clinical and social HIV divide between PrEP and ART
- Normalize HIV prevention and treatment
- Maintain ongoing engagement in care between patients and providers.



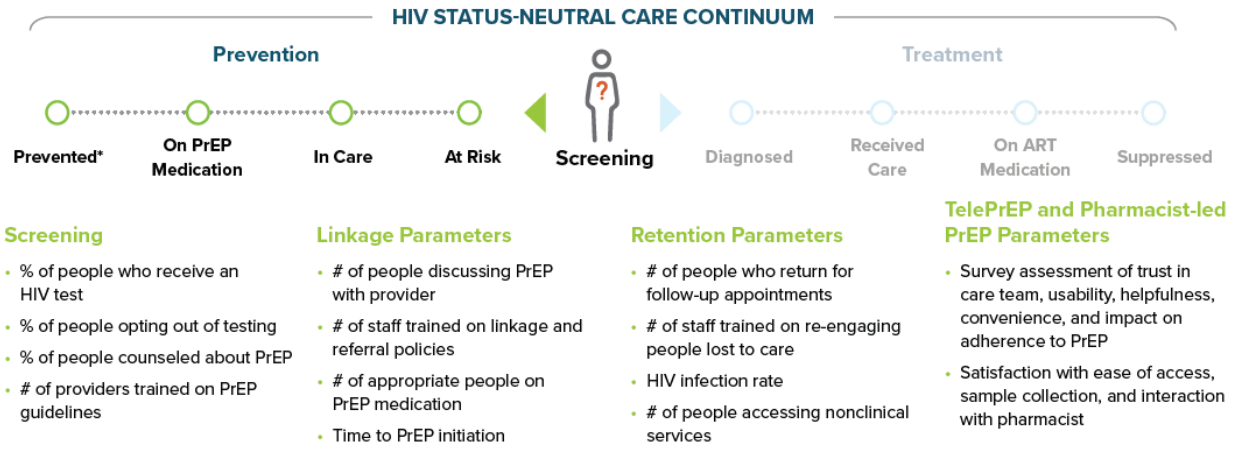
The execution of this model begins with HIV testing and offers two paths, depending on the outcome of the test. Depending on if the rapid test was reactive or non-reactive, the client would either be engaged for ART for people living with HIV or preventative strategies for people at risk for HIV, such as PrEP. After the initial engagement with the HIV Prevention Specialist, the paths become dynamic. Though efforts for preventative and quality-care services is ongoing, the end point is not a final state but a dynamic one requiring attention from both healthcare providers and patients/clients. Those without HIV consistently return for HIV testing, while those with HIV consistently return for treatment.

The CT DPH HIV Prevention Program expects funded HIV Prevention sites adopt this model into their practices.

As long as the client self-identifies as being a candidate for PrEP, regardless of their test result, they will be encouraged to get into treatment, whether it is PrEP if they are non-reactive, or ART if they are reactive.

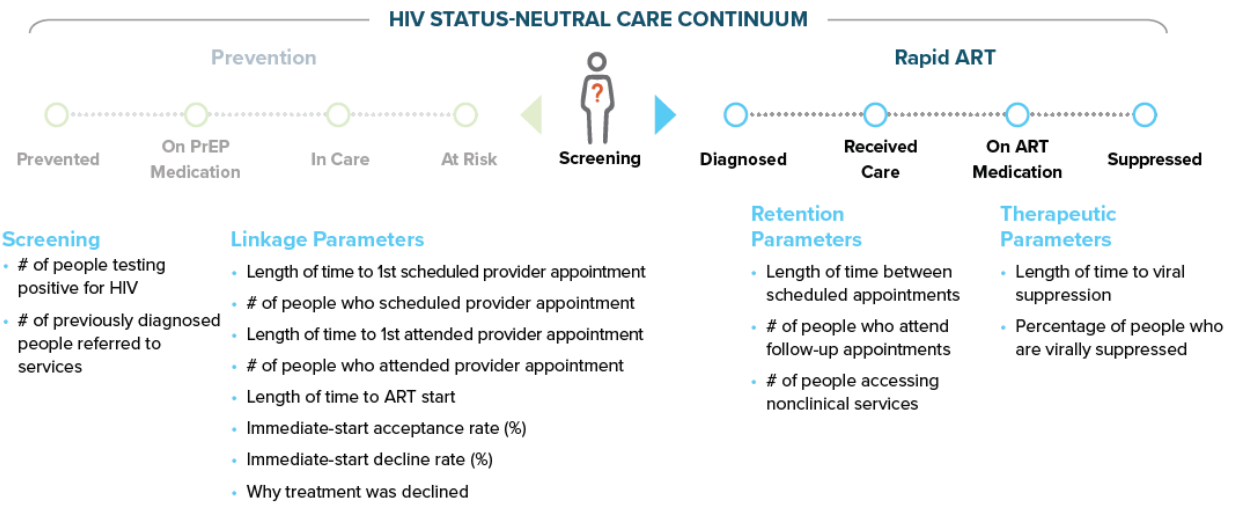
The following diagrams demonstrate the execution of the Status-Neutral Care Continuum based on the result of the HIV rapid test. Below each diagram are objectives to remain mindful of as you provide services to your clients.

NON-REACTIVE HIV TEST



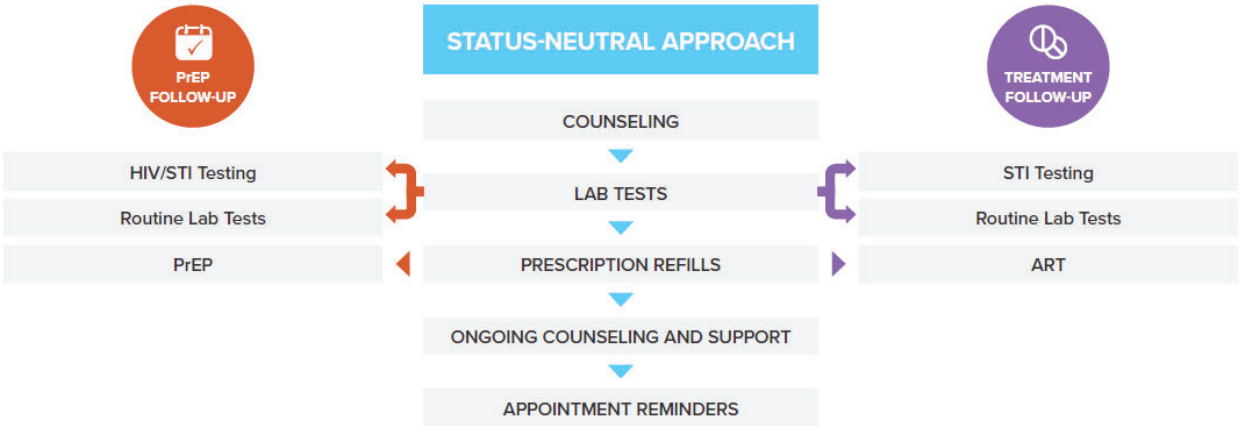
As you can see, once the client was determined non-reactive, they were determined to be a candidate for PrEP, linked into care, retained their treatment regiment, and became fully protected from infection of the HIV virus.

REACTIVE HIV TEST



Shown in this example, once the client was determined to have a reactive test, they were automatically linked into care, retained their treatment regiment, and fully suppressed the HIV virus.

Once the client is engaged into care, the same Status-Neutral approach is able to be continued. The below provides a model explaining the on-going, follow-up treatment the client should receive.



Point-of-Care Testing

Most rapid HIV testing performed in nonclinical settings is considered "point-of-care" or "point-of-contact" because the test is processed onsite where the client is receiving services. Results of rapid tests are provided same day often within minutes. The testing may be called "rapid HIV testing" or "CLIA-waived rapid HIV testing."

CLIA establishes criteria for rapid HIV tests based on 3 different levels of complexity: **waived**, **moderate complexity**, and **high complexity**. CLIA-waived rapid HIV antibody tests are the most common type of tests used in nonclinical HIV testing settings, although some nonclinical settings are also starting to incorporate CLIA-waived combination antigen/antibody rapid tests. CLIA-waived rapid HIV tests can be used in many different settings and are typically used in nonclinical settings because of their ease of use and fast test results. A list of CLIA-waived rapid HIV tests is available at http://www.cdc.gov/hiv/testing/nonclinical/.

Instructions for specimen collection, preparation, and performance of rapid HIV tests are provided by the manufacturer in the test kits. Additionally, many public health laboratories have job aids that can be adapted and used by HIV testing providers. You should always follow the manufacturer's instructions and have them available in the testing area for easy reference. If there are any questions about the test kits or how to perform the test, you should call the manufacturer's customer service number, which is provided on the product insert.

All HIV testing providers should be trained in how to perform rapid HIV tests, including the specimen collection approach that is used at their testing site (i.e., venipuncture, fingerstick, or oral fluid). Many health departments offer this training, and CDC also has a Rapid HIV Testing Online Course that provides some information on how to conduct various types of rapid HIV tests. Instructions for accessing CDC's online course are available at http://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/CTR.aspx.

Self-Tests

Self-testing is an emerging area of interest among consumers and HIV-testing providers because it can be an effective method for reaching people who are not otherwise getting tested as well continuing to test clients post-COVID-19. This approach may also be helpful in reaching couples and persons in sexual relationships. Some nonclinical HIV testing sites are finding opportunities to engage with self-testing clients by being available for follow-up counseling or by actually distributing the tests and serving as a resource for clients who have completed testing and interpreted their results. Strategies for engaging persons who test positive with a self-test should be explored so they can be linked to medical care quickly.

As of November 2021, there are two HIV self-tests available on the market: the Home Access HIV-1 Test System (where a self-collected sample is mailed to a lab for testing) and the OraQuick In-home HIV test. These tests can be found for purchase online and in stores. CT DPH can provide OraQuick In-home HIV tests for HIV testing sites. Contact your Contract Manager for more information. Consumers should ensure that any HIV test advertised for home use is FDA approved before purchasing.

In-Home Testing Initiative

In March 2020, CT DPH launched the In-Home HIV Test initiative, #RequestFreeHIVTestCT, as a pilot to enhance access to free HIV self-testing for hard-to-reach populations, such as LGBTQ+, and people of color. The In-Home HIV Test Kit is an oral-swab rapid HIV test, that is self-administered in the privacy of one's home. In the spirit of true harm reduction philosophy, the initiative aims to meet people where they are. CT DPH HIV Prevention Program is committed to working with our community providers to continue to provide access to the prevention services during challenging times.

CT DPH developed a policy is to assist participating organizations/agencies in developing their own In-Home HIV Self-Test program. This policy provides information on how to request the In-Home HIV Self-Test Kits, how to market the program using the CT DPH social media/marketing materials, how to collect data to report to CT DPH, and how to access additional resources and materials. The policy can be found in the Appendixes. For more information on self-testing visit: https://www.cdc.gov/hiv/basics/hiv-testing/hiv-self-tests.html.

INSTI Tests

INSTI test is another brand of HIV test that frontline can use when conducting rapid testing in their office or out in the field. INSTI is the fastest HIV test which delivers accurate results in as little as one minute. As most clients may be pressed for time, this option will help alleviate the 20-minute processing time, allowing for more time to provide resources to your client and link them into care. The INSTI test detect the IgM antibodies which are produced by the body in response to exposure to HIV and become detectable about 21 days post-infection. The INSTI test requires a fingerstick and a drop of blood.

Agencies are encouraged to discuss the option to use INSTI tests with their Contract Manager. For more information on INSTI tests, use this link: https://www.insti.com/

Testing Algorithms

Most HIV testing conducted in nonclinical settings will include an initial HIV test and, if the initial HIV test is reactive, a follow-up HIV test. If follow-up testing is required, both the initial and follow-up tests are considered part of the same testing event for reporting purposes for CDC-funded programs.

An initial HIV test will either be an antibody test or combination antigen/antibody test. It may involve sending blood to a laboratory or obtaining blood or oral fluid for a rapid test.

Follow-up testing (sometimes referred to as "supplemental testing" or "confirmatory testing") is performed if the initial test result is positive. HIV tests are generally very accurate, but follow-up testing is important to be sure of the diagnosis of HIV infection.

Laboratory Testing Algorithm

In 2014, CDC published new recommendations for the HIV testing algorithm in laboratory https://www.cdc.gov/hiv/pdf/guidelines_testing_recommendedlabtestingalgorithm.pdf The updated recommendations outline a new testing algorithm that begins with a combination antigen/antibody test that detects both HIV-1 and HIV-2 antibodies. This algorithm has many advantages over previous ones:

- follow-up testing does not rely on the Western blot, which does not detect early infections
- accurate diagnosis of HIV-2
- potential for earlier diagnosis of HIV-1

Note: The recommended HIV testing algorithm cannot be used with oral fluid specimens.

Point-of-Care Testing Algorithm

Unlike laboratory testing, CDC has not published guidelines for point-of-care testing algorithms. However, the CT DPH has determined a point-of-care algorithm believed to be the most effective.

Point-of-care rapid HIV testing should follow one of the two testing algorithms determining if staff is trained and able to draw a blood sample:

1. Single rapid test with immediate linkage to clinical provider if initial test is reactive; if initial test is nonreactive, client is presumed to be HIV-negative and linked into PrEP Services.
2. Single rapid test followed by laboratory-based follow-up testing if initial test is reactive and a blood sample can be collected; if initial test is nonreactive, client is presumed to be HIV-negative and linked to PrEP Services.

Agencies should refer to their Contract Manager should they have any questions or concerns.

Specimen Collection and Preparation

Regardless of the HIV testing method you are using, you should perform specimen collection and preparation correctly and consistently to ensure the accuracy of your clients' test results. All HIV testing providers should be trained in the specimen collection procedure that is used at their agency—whether venipuncture, fingerstick, or oral fluid. However, CT DPH does not support collecting oral fluid specimens. Practical hands-on training should be available through your local health department. CDC's Rapid HIV Testing Online Course also provides some of this information, and can be accessed at http://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/CTR.aspx.

Every test kit also has a product insert, which should be readily available to all persons conducting the HIV test. This insert should be consulted to ensure accurate procedures. However, although job aids such as the test kit insert are helpful, they should not be relied on as the sole source of information for conducting tests. All agencies should have HIV testing policies and procedures that describe instructions for accurate specimen collection and preparation, as well as safety precautions and a biohazard disposal protocol to protect clients and testing personnel.

Interpreting Results

In order to deliver an accurate message about the meaning of HIV test results, you should be familiar with the testing algorithm used by your agency. Remember to use simple and clear language to explain test results to clients. We provide examples of this language for each type of result below.

Laboratory-Based Testing

Reactive Results: If the results from the CDC-recommended laboratory algorithm indicate HIV infection, clients should be linked to HIV medical care and referred to partner services (PS) and/or other prevention services. If the laboratory algorithm results indicate an acute infection, linkage to care should be expedited, if possible, due to the increased risk of transmission to partners. In addition, it is beneficial for clients to be counseled to assist them in adopting risk-reduction strategies.

Nonreactive Results: A nonreactive test result indicates no evidence of HIV infection and can be interpreted as HIV negative. Depending on the window period associated with the test that you are using, clients that report recent known or possible exposure to HIV can be advised that, because of their recent exposure, it is possible the test did not detect HIV antibodies at this time. You should recommend retesting at an appropriate interval based on the client's risk and the type of test used. Testing is usually recommended three months after an exposure. Chapter 5 elaborates on retesting recommendations.

Indeterminate Results: On occasion, antibody tests will yield indeterminate results. These test results may be related to recent infection, infection with HIV-2, concurrent infection with other viruses or diseases, vaccination (e.g., HIV vaccine trial participants), or problems with the sample or testing procedure. In this case, laboratories should conduct a NAT to rule out the possibility of

acute HIV-1 infection. Sometimes, the laboratory may request an additional specimen to conduct the NAT. If the laboratory used by your agency cannot perform a NAT, the client must be referred for follow-up testing that includes a NAT.

CLIA-Waived Rapid HIV Testing

Reactive Initial Results: If the initial rapid HIV test is reactive, this indicates that HIV antibodies or antigen have been detected. The result is interpreted as a *preliminary positive* test result and follow-up testing is required to confirm the diagnosis. In most cases, clients who are reactive on their initial rapid HIV test are *true positives*; that is, they are likely to be reactive on a follow-up test as well and should be prepared to receive a confirmed positive result. For this reason, it may be beneficial to immediately link clients who have *preliminary positive* test results to HIV medical care and to PS if follow-up testing cannot be conducted onsite. It is also important to counsel clients and to assist them with risk-reduction strategies while they wait for their follow-up test results.

Follow-up testing should be arranged according to the algorithm your agency uses for rapid testing, which might include 1 of 2 possible options:

1. Make a referral to a clinical provider that can perform follow-up testing and immediate linkage with HIV medical care. The client may also return back to you to be linked with other services, as appropriate.

2. Collect a sample and send it to a laboratory for follow-up testing,and ask the client to return to you to receive their results and get linked with HIV medical care or other services, as appropriate.

Once you have the results of the follow-up test (whether received from a laboratory or from your second rapid HIV test conducted onsite), you should deliver these as confirmed results. In most cases the results of the follow-up test will match the results of the initial test; that is, they will also be reactive, and you will confirm the client's HIV-positive status.

In rare cases, an initial rapid HIV test will be reactive, and a follow-up test will be nonreactive. If this happens when follow-up testing is done at a clinical provider or laboratory, it will either be resolved before your agency receives the follow-up test results, or your agency should receive guidance about how to deliver these results and the next steps. However, if this happens when you are conducting a second rapid HIV test onsite, you may need to incorporate language about what this means and what the next steps are.

Nonreactive Results: If the result of a rapid test is nonreactive, the test result is interpreted as HIV-negative. Depending on the window period associated with the test that you are using, clients that report recent known or possible exposure to HIV can be advised that, because of their recent exposure, it is possible the test did not detect HIV antibodies at this time. You should recommend retesting at an appropriate interval based on the client's risk and the type of test used. Chapter 5 elaborates on retesting recommendations.

Invalid Results: If a rapid test produces an invalid result, it cannot be interpreted. Invalid results are often the result of user error, which means you may have conducted the test incorrectly. You

should repeat the HIV test on a new sample obtained from the client and may wish to call in a supervisor or other experienced HIV testing provider to assist with the test. For additional information on invalid rapid test results, refer to the package insert provided with the test kit by the manufacturer.

Cautions Regarding the Window Period and Acute Infection

In an attempt to address the window period, many agencies recommend that HIV-negative clients return for retesting 3 months after a potential exposure to HIV in order to feel more confident with their results. However, if this message is given to all clients regardless of their specific risk, this message can be diluted, and clients may not fully understand the importance of identifying acute HIV infection. Furthermore, many clients may interpret this message as "3 months from their last HIV negative test," prolonging the time until they are retested and potentially missing opportunities for identifying acute infection.

If someone has acute HIV infection, they can be highly infectious and may be likely to transmit the virus to others. Clients should understand the importance of identifying HIV infection as early as possible. If a client is concerned about a recent exposure or they report symptoms of acute HIV infection such as persistent fever, swollen throat or lymph nodes, or other severe flu-like symptoms, they should be referred immediately to their doctor or other local clinic for acute infection testing. You should emphasize the need for using protection until acute infection can be ruled out. If testing immediately for acute infection is not an option, then the client should be tested at your site and then retested 3 months after their potential exposure.

False-Negative Test Results

False-negative test results occur when someone who is infected with HIV receives an HIV-negative test result. This scenario has been documented in persons on ART43 and in some persons receiving PrEP. However, additional data are needed to determine the extent to which test performance is affected by these factors. HIV testing providers may wish to ask clients if they are currently using ART, nPEP/PEP, or PrEP, in order to determine if additional testing is necessary to rule out a false negative result. False-negative results may occur for other reasons as well, such as test design, improper test procedures, or mislabeling of the specimen.

False-Positive Test Results

False-positive test results occur when someone who is not infected with HIV receives an HIV-positive test result. This scenario is not frequent but can occur in clients who are participating in HIV vaccine trials. HIV vaccine-induced antibodies can cause a rapid HIV antibody test to give a positive result, even though the person does not have HIV. All clients who receive an HIV-positive test result and who are also HIV vaccine trial participants should contact the vaccine trial site for evaluation or to receive a referral to HIV medical care for further evaluation and/or testing.

False-positive test results also occur in people who have not received the HIV vaccine in the study trial. The number of clients who received false positive test results will vary based on the type of tests you use and the HIV prevalence in your setting.

False-positive results may also occur for other reasons such as those mentioned under false-negative results.

Delivering Test Results

Your agency should have clearly defined protocols for delivery of HIV test results. These protocols can be described in your agency's HIV testing policies and procedures. Although there are pros and cons to the different approaches for delivering HIV test results, (e.g., face-to-face, telephone, or Internet), it is most important that clients do receive their results, as well as referrals to and linkage with appropriate follow-up services.

If you use laboratory testing as either the initial HIV test or for follow-up testing after a reactive rapid HIV test result, you will need to schedule a second encounter with the client in order to deliver their confirmed results. However, if rapid HIV testing is performed, the vast majority of clients will receive their test results on the same day during the testing encounter.

Face-to-Face Delivery

Delivering results face-to-face allows you to have some engagement with the client, to assess their reaction to their test results, and to link them with HIV medical care or prevention services, if indicated, or to other appropriate follow-up services. For most nonclinical sites conducting rapid HIV testing, results can be delivered face-to-face during the same visit at which the client was tested. If laboratory testing was conducted, you may still wish to schedule a return visit for the client to deliver their results face-to-face at your site. When possible, it is recommended that HIV-positive results be delivered face-to-face.

Telephone or Internet Delivery

At times, agencies use telephone or Internet (email, video chat, or other secure messaging service) to deliver a client's HIV test results. This approach may be beneficial for clients who are not likely to return to the testing site for their results. Although this approach is not ideal for delivering HIV-positive test results, if it is the only way a client will receive their results, then it should be supported. Agencies who deliver results by telephone or Internet should make a concerted effort to ensure clients have all the information and support they need to access HIV medical care or prevention services, as indicated, and other appropriate follow-up services. Some agencies have had success with video chat for returning results, since it allows for some personal engagement of the client. This can be particularly useful for agencies supporting home-based HIV testing, for following up with clients and supporting linkage to care, as appropriate.

Written Results

Clients sometimes request written copies of their test results. If you are delivering written HIV-negative test results, the results should be accompanied by a clear statement about the meaning of the test results, relative to the window period of the test used. It may also be useful to indicate when the client should return for retesting. If your agency is providing written test results they should be provided on your agency letterhead or a similar form and should clearly state the following:

- The name of your agency and the date the test was conducted
- The test result (positive or negative)

- Explanation of the result relative to the window period and/or date for retesting

It is important to address provision of written test results in your agency's policies and procedures.

Integration of Hepatitis Services

Due to the fact that Hepatitis C (HCV) can be transmitted in the same way as HIV and the high prevalence of HCV among injecting drug users, DPH has established protocol for incorporating HCV prevention counseling into the HIV prevention counseling session. In order to integrate Hepatitis C (HCV) counseling into the pretest counseling session questions should also be asked regarding transfusions, blood product receipt and organ transplant prior to 1992 as well as receipt of clotting factor concentrates prior to 1987.

Agencies funded to conduct HIV testing will also have access to HCV test kits. The counselor should ask if the client has ever been tested for HCV and if they would like to be.

Since the HIV and HCV rapid tests are both conducted using fingerstick blood, gathering the necessary sample can be done at the same time. Be sure to prepare the testing site for both tests prior to gathering the blood sample, as you would normally for the HIV rapid test.

Should the client have a reactive HCV test, the same referral protocol needs to take place by linking the client to the proper support services to have a confirmatory test done and follow-up treatment if needed.

Hepatitis A and B Vaccinations

The State Department of Public Health (CT DPH) is committed to increase Viral Hepatitis education, prevention, testing, linkage to care and treatment, and increase vaccination for Hepatitis A and B. CT DPH aim is to continue to build and sustain relationship with partners in high-impact settings for the expansion of integrated services to address one or more of the intersecting epidemics.

As of April 2020, the Centers for Disease Control and Prevention (CDC) recommends that primary care providers conducts universal screening for all adults 18 years and older at least once in their lifetime for hepatitis C; hepatitis C screening for all pregnant women during each pregnancy; and one-time hepatitis C screening regardless of age or setting prevalence among people with recognized conditions or exposures; routine periodic testing for people with ongoing risk factors such as people with HIV and among People Who Use Drugs (PWUDs); and, screen any person who requests hepatitis C testing. Since Hepatitis C (HCV) can be transmitted in the same way as HIV and with the high prevalence of HCV among PWUDs, DPH has established protocol for incorporating HCV prevention counseling, and education, and referral for vaccination for Hepatitis A and B, into the HIV prevention counseling session. To integrate Hepatitis C (HCV) counseling into the pretest counseling session questions should also be asked regarding HIV status, pregnancy status, blood transfusions, blood product receipt and organ transplant prior to 1992 as well as receipt of clotting factor concentrates prior to 1987.

Around 62-80% of injection drug users with HIV also have Hep C. Having both HIV and Hepatitis C more than triples the odds for liver disease, liver failure, and liver-related death. This means testing is even more important for those at risk for both HIV and Hep C – and testing is easy! There are no vaccines for HCV but there are vaccines for HAV and HAB. Hepatitis C can be treated

and can be cured. Over 90% of people with Hep C are cured with just 8-12weeks of treatment. Hep C cures are covered by most Medicaid and Medicare policies, and major private insurers.

Agencies funded to conduct HIV testing will also have access to HCV test kits. To increase routine HCV and HBV testing in funded health systems and Routine Testing Sites (RTS), the counselor should ask if the client has ever been tested for HCV and HBV, or if they have ever been vaccinated for HAV and HAB and if they would like to be. Since the HIV and HCV rapid tests are both conducted using fingerstick blood samples, gathering the necessary sample can be done at the same time. Be sure to prepare the testing site for both tests prior to gathering the blood sample, as you would normally for the HIV rapid test. Should the client have a reactive HCV test, the same referral protocol needs to take place by linking the client to the proper support services to have a confirmatory test done and follow-up treatment if needed. Please see HIVHCVReportingGuidance for information in reporting positive HCV results.

To prevent an outbreak of Hepatitis A Virus (HAV) infections among persons who use drugs and persons experiencing homelessness Health care providers are encouraged to vaccinate all persons at high risk including persons experiencing homelessness, persons who use injection or non-injection drugs or have chronic liver disease (including chronic hepatitis C infection or chronic hepatitis B infection), and men who have sex with men. If your site does not provide vaccine, The Connecticut Vaccine Program (CVP) does provide the following adult vaccines for **uninsured HIV adults** in CBO's: Tdap (Boostrix)-ages 19 and older; Hepatitis A (Havrix)-ages 19 and older; Hepatitis B (Heplisav-B)-ages 19 and older; Hep A/Hep B combination (Twinrix)-ages 19 and older. Attached is the link to begin the enrollment process: https://portal.ct.gov/DPH/Immunizations/CVP--Provider-Profile-Enrollment_Reenrollment

Hepatitis A can be prevented. The HAV vaccine is the best protection. The following are recommended to be vaccinated: Travelers to countries with increased rates of hepatitis A; men who have sex with men; Injecting drug users; Persons with chronic liver disease; Persons with clotting factor disorders (such as hemophilia)

Please see the CT DPH HAV Advisory and the CT DPH Hepatitis B Protocol

Conducting HIV Testing with Individuals

All HIV testing sessions in nonclinical settings will generally follow the same overall structure, regardless of where they are being conducted or who is being tested. That is, you will conduct certain steps before delivering the results (called "pre-results steps"), and certain steps after delivering results (called "post-results steps"). This chapter will review these steps, outline essential tasks for each step, and present additional considerations for your HIV testing session with individual clients.

Reduced Counseling Approach

For individual HIV testing, CDC no longer supports extensive pretest and posttest counseling. Instead, HIV testing providers should conduct brief, information-based sessions tailored to their clients, as outlined below. CDC has found this strategy to be more effective in a rapid HIV testing environment.

For couples that are tested together for HIV, the "Testing Together" protocol does include brief counseling in order to establish rapport with the couple as a unit and enhance their ability to communicate about their joint HIV risk concerns. However, this approach can also be done rapidly and follows the same "pre-results steps" and "post-results steps" formats, which are described in the next chapter (Conducting HIV Tests with Couples).

6 Steps for Conducting HIV Tests with Individuals

The steps for individual HIV testing will vary slightly depending on the type of test kit and testing algorithm that is being used. Presented are the steps for the 20-minute rapid test scenario. The steps for the 1-minute INSTI rapid test scenario can be found following the 20-minute scenario.

20-Minute Rapid Test Scenario

Step 1: Introduce and orient the client to the session

Step 2: Prepare for and conduct the rapid HIV test

Step 3: Conduct brief risk screening

Step 4: Deliver results

Step 5: Develop a care, treatment, and prevention plan based on results

Step 6: Refer and link with medical care, social and behavioral services

The first 3 steps are pre-result steps for individual HIV testing and the last 3 are post-result.

Pre-result Steps:

Step 1: Introduce and Orient the Client to the Session

The first thing you will do when conducting an individual HIV testing session is introduce yourself and orient the client to the session. The key tasks for step 1 are:

- Introduce yourself and describe your role
- Provide a brief session overview, including:
    - How long the session will take
    - Process for conducting the test
    - How results are returned (i.e., same day or return for results)
- Collect pertinent client information, including contact and locating information. (See Appendix section for reporting guidance, including forms)
- Obtain concurrence to proceed with the session

This step is important for building rapport and establishing client expectations for what will happen during the HIV testing session. Generally, this step will take about 1–2 minutes.

Step 2: Prepare for and Conduct Rapid HIV Test

In step 2, you will provide the client with basic information about the HIV test. Use simple, clear language that the client can understand. Provide information in a language and at a reading level appropriate to the client. Information can be presented verbally, written, or through videos, computers, or other electronic technology. It should take approximately 1–2 minutes to provide the client with this basic information and answer any questions he or she might have about the rapid testing process. Then you will collect the sample and conduct the rapid HIV test. The key tasks for step 2 are:

- Explain the process of conducting the HIV test, including:
    - Type of test used (rapid vs. non-rapid; antibody vs. combination antibody/antigen test)
    - Sample collected (blood vs. oral)
    - Time until test results are ready
- Explain the meaning of HIV-negative and HIV-positive test results, including:
    - Need for retesting if HIV-negative
    - Need for and process of conducting follow-up testing if HIV-positive
    - Possibility of invalid result
- Obtain consent to test (oral or written)
- Distribute test kit information booklet (required for CLIA-waived tests)
- Collect specimen and conduct rapid HIV test

If you conduct the test in the same room where the session occurs, it is suggested to set the test kits to the side while they are developing,or set up a screen to block the client's view so that the client does not get distracted or anxious watching the test develop. If the test is conducted in an onsite laboratory—or, in the case of mobile or outreach testing, in a central location where one person is responsible for doing multiple tests—you must ensure client confidentiality and

accuracy of test results. Tests should always be performed according to the directions outlined in the test kit insert, and test kits should be clearly labeled to ensure that the correct results are given to the correct client.

Step 3: Conduct Brief Risk Screening

While you are waiting for the test results, take a few moments to conduct brief risk screening to better understand the client's HIV risk. You may use your agency's data collection tools to guide the risk screening, or you may engage the client in a brief discussion of their immediate risk concerns. You may start by asking the client how they decided to be tested, and then listening and probing for additional information about immediate, recent, or ongoing risk. If the client needs to be referred immediately for other services such as nPEP, acute infection testing, or medical care, make linkages with those services at this point. Use the information clients tell you to prepare them for their possible results, and tailor recommendations after you deliver their results.

The timing of step 3 will vary greatly depending on the HIV risk concerns of the client. This step should be conducted in 5-10 minutes. The key tasks for step 3 are:

- Ask how the client decided to be tested; listen and probe for previous testing history and indicators of increased risk including:
    - Potential exposure in last 24–72 hours *(to indicate need for nPEP)*
    - Potential exposure in last 3 months *(to indicate need for acute infection testing)*
    - Symptoms *(to indicate need for acute infection testing and accessing medical care)*
    - Ongoing risk behavior or key population (MSM, PWID, partner with unknown or known HIV-positive status, transgender woman)
- Address indicators of increased risk and make immediate referrals to other services (i.e. nPEP, acute infection testing, or medical care) as indicated
- Assess the client's knowledge of HIV transmission, provide accurate information as needed
- Prepare for possible test results

As you conduct the brief risk screening, your client may have questions about acute infection, the window period, and retesting for HIV, which can also be addressed while you are waiting for the test results.

Testing frequency

CDC recommends that all adolescents and adults get tested at least once for HIV as a routine part of medical care, and that MSM and others at high risk for HIV infection be tested at least annually. In addition, MSM and other high-risk individuals might benefit from more frequent screening, such as every 3 to 6 months.

Post-results Steps:

The 3 post-results steps for individual HIV testing are:

Step 4: Deliver results

Step 5: Develop a care, treatment, and prevention plan based on results

Step 6: Refer and link with medical care, social and behavioral services

If you are conducting laboratory testing, remember that you will include 1 additional step before delivering results. When the client returns to your site for his or her result (ideally no more than 1 week after the initial visit), you should first take a moment to check in with the client to address any HIV risk concerns or issues since the last visit. Then proceed with delivering results.

Step 4: Delivering results

Step 4 is the delivery of results.

If you are conducting a CLIA-waived rapid HIV test, after following the manufacturer's instructions and allowing for the appropriate time for the test to process, you will read the test device and interpret the result. If the test was conducted by another staff at your agency or outside the room where the client is waiting, obtain the result and return to the client. If the client was in the waiting room, call him or her back to the HIV testing room to receive their result. If the test result is preliminary and must be confirmed with a follow-up test, you will indicate this to the client and follow your agency's procedures (as outlined above) for follow-up testing.

The 2 key steps for delivering results are:

- Confirm the client's readiness to receive their result
- Provide a clear explanation of the client's result

Most clients will confirm that they are ready to receive their result because they came to you specifically for this purpose. Their confirmation is also an indication that you have done a successful job preparing them to receive their result during the pre-results steps.

On very rare occasions, clients may change their mind about receiving their result. If clients state that they are not ready to hear their result, engage them in a discussion about reasons they do not feel ready. Provide motivation and support for clients by reminding them of the importance of knowing their status and making decisions for their health based on their status. Once the client has a chance to talk about his or her concerns, they may be ready to hear their result. If

the client still refuses, respect his or her decision, discuss options for getting the result at a later date, and make arrangements to follow-up with the client.

Step 5: Develop a Care, Treatment, and Prevention Plan Based on Results

Step 5 is to develop a care, treatment, and prevention plan with the client based on their HIV test results and risk issues identified during the brief risk screening. After receiving their test result, whether HIV-negative or HIV-positive, clients may have a hard time absorbing lots of information so it may be most effective to identify key referral services, make linkages with those services, and schedule follow-up visits if the client has additional concerns. Alternatively, another provider, such as a linkage coordinator or patient navigator, can also address the client's concerns during follow-up visits.

The overall flow of step 5 should be similar for clients who receive an HIV-negative or HIV-positive test result, but the specific tasks will be different based on their result. The tasks will also vary slightly depending on your agency's process for conducting follow-up testing for clients with an initial reactive rapid HIV test.

HIV-Negative Clients

For clients testing *HIV-negative*, the specific tasks for step 5 are:

- Explore client's reaction to result
- Discuss need for retesting based on window period of test used and client's risk
- Emphasize key risk reduction strategies that will help the client remain HIV-negative:
    - Choose less risky sexual behaviors
    - Get tested for HIV together with partner(s)
    - Use condoms consistently and correctly
    - Reduce number of sex partners
    - Talk to doctor about PrEP (as indicated, according to PrEP screening indicators)
    - Talk to doctor about nPEP (as indicated, within 3 days following a specific exposure to HIV)
    - Get tested and treated for other STDs and encourage partners to do the same
    - If partner is HIV-positive, encourage partner to get and stay on treatment
- Provide condoms

Clients receiving an HIV-negative test result may experience a range of emotions, including relief, shock, joy, or dismay. HIV testing providers should be prepared for any number of responses from clients and should remain neutral as they explore the client's reaction.

It is important to reinforce HIV prevention messages, to motivate the client to remain HIV-negative, and support them to access medical, social, and behavioral referral services, as indicated based on their risk and specific situation.

Indications for PrEP

As the first point of contact for many high-risk HIV negative clients, HIV testing providers in nonclinical settings should not only educate clients about PrEP, but they should also know and assess for PrEP indications and refer persons at substantial risk for acquiring HIV to a PrEP counselor or medical provider where PrEP is available. PrEP providers will conduct additional risk behavior assessments or use a risk index to determine if clients are appropriate for PrEP.

The criteria that HIV testing providers use to determine whether HIV-negative clients are at substantial risk of acquiring HIV and should be offered PrEP may be assessed over the course of the client's HIV testing session or at the end of the session after you have delivered their results. This is considered an important part of revisiting the risk discussion and reinforcing decisions that will help the client remain HIV-negative. PrEP is currently indicated for MSM at substantial risk of HIV acquisition, as well as heterosexual men and women and PWID at substantial risk of HIV acquisition. This may include persons who have unprotected sex or inject drugs with multiple partners of unknown HIV status, or persons who are in known HIV-discordant relationships, where one partner is HIV-negative and the other partner is HIV-positive.

HIV-Reactive Clients

For clients who test *HIV-reactive*, the specific tasks for step 5 are:

- Explore client's reaction to result
- Advise on next steps for follow-up testing
- Discuss disclosure and inform about processes for partner services
- Advise to access care and treatment for HIV
    - Treatment can help people with HIV live long, healthy lives and prevent transmission
    - Other health issues can be addressed
- Emphasize key risk reduction strategies that will prevent transmission
    - Choose less risky sexual and drug-using behaviors
    - Get tested together with their partners
    - Use condoms consistently and correctly
    - Reduce number of sex partners
    - Encourage partners to be tested
- Provide condoms

Clients receiving an HIV-positive result for the first time might also experience a wide range of emotions, including shock, grief, or other strong feelings. While exploring the client's reaction to his or her result, you can effectively use silence to express empathy and give the client space to absorb this new information. Attend to the client's immediate needs before moving on with the other tasks.

Advise the client on their next steps for follow-up testing to confirm the HIV-positive test result. Follow-up testing can be addressed in a number of ways:

1. Immediately link clients to medical care for follow-up testing after the initial reactive rapid test result.
2. Collect a specimen to send to a lab for follow-up testing after the initial reactive rapid test result; discuss the importance of returning to the agency to get the test result; and schedule a day and time for the client to return to the agency to get the result of the follow-up test.
3. Collect a specimen and run a second rapid test using a different rapid test to confirm the result (see Chapter 4 for additional information, including suggested language for what to do if the second test is also reactive, which is to proceed with steps 5 and 6, versus a nonreactive result, which is to refer the client to a clinical provider or collect a sample to send to the laboratory).

Although it might be difficult in this moment for clients to grasp everything you are telling them, it is important to discuss disclosure to sex partners, inform them about the processes for partner services and to reinforce the importance of accessing care and treatment. Most clients will be referred for follow-up testing to confirm their result and to be enrolled in HIV medical care, so that they can begin accessing treatment as soon as possible to prevent transmission and help them stay healthy.

Remember that this is not the last encounter clients will have with the health care system, your primary goal should be to link clients with medical care and other necessary follow-up services—either directly or through a patient navigator or linkage counselor—as discussed in the next step.

Step 6: Refer and Link to Medical Care, Social, and Behavioral Services

Throughout the HIV testing session, you will receive information from clients that will help you determine what additional services they need in order to stay healthy, safe, and prevent HIV transmission or acquisition. Before you close the session, you will identify the necessary medical, social, and behavioral services that are appropriate for the client, and then provide the client with referrals and link them to these services. Some of these services may be provided by your agency; for others, you will need to refer outside your agency.

The 3 tasks for step 6 are:

1. Identify necessary medical, social, and behavioral referral services
2. Make referrals as indicated
3. Track linkage to HIV medical care

For clients who test HIV-negative, some of the services you might refer them to include:

- nPEP
- PrEP
- Partner or Couples HIV testing

- Retesting for HIV
- Screening and treatment for STDs, hepatitis, and/or TB
- High-impact behavioral interventions that can reduce their risk of acquiring HIV
- Reproductive health services
- Counseling and services for mental health, substance abuse, and/or domestic violence
- Insurance navigation and enrollment
- Housing
- Other social and behavioral services

For clients who test HIV-positive, some of the services you might refer them to include:

- HIV care and treatment
- Partner services
- Medication adherence services
- Partner or Couples HIV testing
- Screening and treatment for STDs, hepatitis, and/or TB
- High-impact behavioral interventions for newly diagnosed HIV-positive persons
- Reproductive health services
- Counseling and services for mental health, substance abuse and/or domestic violence
- Insurance navigation and enrollment
- Housing
- Other social and behavioral services

1-Minute INSTI Test Scenario

The INSTI test scenario only slightly differs from the 20-minute version in that the risk screening needs to happen prior to conducting the test. Being that the INSTI test has a processing time of only 1 minute, the tester will require more time to access the client's level of risk to determine their candidacy for PrEP.

The following are steps for the 1-minute INSTI test:

Step 1: Introduce and orient the client to the session

Step 2: Prepare for INSTI HIV test and conduct brief risk screening

Step 3: Conduct the HIV test

Step 4: Deliver results

Step 5: Develop a care, treatment, and prevention plan based on results

Step 6: Refer and link with medical care, social and behavioral services

Partner Services (PS)

PS is implemented with all persons who test HIV-positive. The primary function of PS is to notify the sex and drug-injecting partners of HIV-positive individuals about their potential exposure to HIV. It is a voluntary service that involves interviewing newly diagnosed HIV-positive persons to elicit names of their previous sex and drug-injecting partners who might have been exposed to HIV, then confidentially notifying these persons of their potential exposure, and offering them HIV testing and linkage to HIV medical care, social, and behavioral services. Local health departments play a key role in implementing PS, and nonclinical HIV testing providers should be aware of the PS protocol followed by their agency.

Examples of partner services protocols include:

1. **Refer to local health department**—persons newly diagnosed with HIV are referred to the local health department where a Disease Intervention Specialist (DIS) conducts an interview to elicit the names and locating information of previous partners who may have been exposed to HIV. The DIS then contacts these partners and offers them HIV testing. In some jurisdictions, the health department initiates PS automatically when it receives an HIV case report form. Clients should be informed that the health department will contact them to discuss PS.

2. **DIS onsite**—some agencies have health department DIS staff onsite to interview clients who test HIV-positive.

3. **DIS on call**—some agencies work with the local health department to have DIS staff on call. When an individual is newly diagnosed with HIV, the DIS can be contacted and can arrive quickly at the agency to interview the client.

4. **CBO elicitation**—some CBOs have authorization from the health department to interview newly diagnosed clients and elicit their partner names and locating information. This information is provided to the health department to locate and notify partners of their potential exposure to HIV and provide HIV testing.

Referral to clinical provider for follow-up testing

If your agency refers to a clinical provider immediately following an initial rapid reactive HIV test, confirmatory testing will be done by the clinical provider.

Send sample to offsite laboratory for follow-up testing

If, following an initial rapid reactive HIV test, your agency collects a sample from the client and sends this to an offsite laboratory for follow-up testing, you will need to schedule a second visit with the client to return their confirmed results. Ideally these results should be returned no more than 1 week from the initial testing date.

Following the initial reactive HIV test result, you should still proceed with steps 4–6, you will just tailor these to the client's situation and the reality of the initial HIV test results. For example, you will still provide information about HIV care, treatment, and prevention, but you will indicate that

these recommendations are based on the *preliminary positive* result, not the confirmed result. You will revisit these recommendations once you have the confirmed result.

Conducting Social Network Strategy

Social Networking Strategy (SNS) is a peer-driven approach to recruitment that involves identifying HIV- positive or high-risk HIV-negative persons from the community to serve as "recruiters" for your agency. Recruiters deliver key messages and encourage HIV testing among high-risk persons in their social, sexual, or drug-using networks. They may use coupons or invitations as a way of documenting that they have delivered these messages to potential clients. The recruiters are trained or "coached" on the best approaches to reach their peers, including who should be reached through this approach and what messages can motivate their peers to be tested for HIV. Partner referral is a type of social networking that involves recruiters referring their sexual partners to an HIV testing program. Recruiters may refer their sexual partners to be tested alone, or recruiters may accompany their partners and be tested together, as outlined in Chapter 6 on Couples HIV Testing and Counseling.

Conducting & Implementing SNS

The Social Network Strategy for HIV Testing Recruitment is conducted by completing ten various procedures. The procedures are as follows:

1. Community and Focus Population Engagement
2. Recruiter Enlistment
3. Recruiter Engagement
4. Recruitment of Network Associates
5. HIV Testing
6. Inviting Network Associate to Become Recruiters
7. Ensuring Confidentiality for Social Network Strategy for HIV Testing Recruitment
8. Potential Risks for Recruiters
9. Data Collection and Program Monitoring
10. Quality Assurance

For the complete Operating Procedures Manual, click the link below for a downloadable PDF.

Social Network Strategy Link:

HTTPS://WWW.CDC.GOV/HIV/EFFECTIVE-INTERVENTIONS/LIBRARY/SOCIAL-NETWORK-STRATEGY/IMPLEMENTATION-MATERIALS/CDC-HIV-EI-SNS-STANDARD-OPERATING-PROCEDURES.PDF

Conducting Testing Together

Couples HIV testing and counseling (CHTC), or *Testing Together*, is an approach to HIV testing, whereby two or more persons who are in—or are planning to be in—a sexual relationship are tested for HIV together. Couples go through the entire process together and receive their results together. Testing Together is different from individual testing because it is not focused on past risk behavior, but rather supports couples to address their joint risk concerns with a focus on the present and the future. Couples are only separated if there is suspicion of coercion or to confirm information collected on individual data forms. Testing Together is voluntary, and couples may decide at any time during the session that they prefer to be tested separately.

Differences from Individual Testing

Testing Together follows a very similar structure to individual HIV testing but with some key differences.

Comparing Individual HIV Testing with Testing Together

Individual HIV testing	Testing Together
Clients learn their individual HIV status alone.	Clients learn their own HIV status as well as that of their partner(s).
Clients must disclose to their partner on their own, or use PS.	Counselor-facilitated mutual disclosure among partners is immediate and 100%.
Clients deal with issues of tension and blame on their own.	Provider is there to help ease tension and diffuse blame.
Individual risk screening is based on past risk behavior.	Couple's joint risk concerns are discussed with a focus on the present and the future.
Focus is on health education.	Skill building is focused on couple's communication and sexual agreements.
Referrals and linkage are based only on client's HIV status and needs.	Referrals and linkage are tailored to the results and needs of both partners.

Steps for Conducting Testing Together

The protocol for Testing Together looks very similar to the steps for conducting individual HIV testing. Compared to individual testing, which uses a very streamlined approach with minimal counseling, Testing Together may require brief counseling in order to establish rapport and enhance their communication as a couple. Similar to individual testing, the format includes "pre-results steps" and "post-results steps".

Rapid HIV Testing Together (20-minute read time)

Pre-Results Steps

Step 1: Introduce Testing Together and obtain concurrence

Step 2: Prepare for and conduct rapid HIV test (20-minute read time)

Step 3: Explore couple's relationship

Step 4: Discuss HIV risk concerns and reasons for seeking testing together

Step 5: Discuss couple's agreement

Post-Results Steps

Step 6: Provide results of initial rapid HIVB test and follow your agency's protocol for conducting follow-up confirmatory testing

Step 7: Develop care, treatment, and prevention plan based on results

Step 8: Refer and link with medical care, social and behavioral services

Just like with individual testing, the HIV test is conducted as step 2. Just as with individual testing, this list does not represent what to do if the results of the initial rapid are reactive. If your agency refers to a clinical provider immediately following an initial rapid reactive HIV test, confirmatory testing will be done by the clinical provider. If you send a sample to an offsite laboratory for follow-up testing after an initial rapid reactive HIV test, you would collect that sample after step 6 and return the confirmed results in a separate session, again ideally scheduled no more than 1 week after the initial visit. You will still proceed with steps 6–8, but you will tailor these to the couple's situation. If your agency conducts a second rapid HIV test onsite, you can perform this test immediately following delivery of the initial reactive HIV test result in step 6.

Implementing Testing Together

HIV testing providers must be trained in this approach before offering Testing Together services. In the training, providers learn the specific tasks that should be conducted for each step of the Testing Together protocol and practice skills-building exercises around couple's communication, self-awareness, sexual agreements, and discordant test results. There are also opportunities to practice delivering the steps of the Testing Together protocol through role plays. Because of the additional skills required for providing high-quality Testing Together services, it is recommended that HIV testing providers have provided individual HIV testing for at least 6 months or to at least 50 individual clients before receiving Testing Together training.

The same resources that are used for individual HIV testing can, and should, be used to offer Testing Together. All of the information in this Implementation Guide applies to both individual and couples testing, including the need to adhere to program principles and standards, the need for monitoring and evaluating Testing Together service delivery, and the need for quality assurance to ensure high-quality service provision. Because Testing Together is for couples agencies will need to revisit and revise their targeting and recruitment plans to include couples.

More information about Testing Together training and how to access technical assistance for implementation support at your agency is available atTesting together . This site also hosts a Testing Together toolkit with implementation support materials including videos, marketing materials, manuals, and worksheets.

Referral, Linkage, and Navigation Services

A primary goal of HIV testing in nonclinical settings is to identify clients with undiagnosed HIV infection and link them to HIV medical care as soon as possible. Additionally, HIV testing providers may play a role in the reengagement of previously diagnosed HIV-positive persons who are not currently engaged in care. Referral and linkage to HIV care services and initiation of ART facilitate better health outcomes for HIV-infected persons and can help prevent HIV transmission. Furthermore, HIV-negative persons at substantial risk for HIV infection may also benefit from referral and linkage to care for PrEP, STD testing and treatment, or other information and HIV prevention support. Both HIV-positive and HIV-negative clients may benefit from referral and linkage to other health services, including social and behavioral services as outlined in Chapter 5, and may need assistance navigating the health system in order to access these services.

This chapter discusses referral processes, linkage outcomes, and navigation services, and describes the steps that HIV testing providers can take to facilitate successful referral and linkage to HIV medical care, social, and behavioral services for their clients.

In some nonclinical settings, HIV testing providers may conduct referral and linkage services and, in others, they will refer clients to a linkage navigator or other staff who has this designated role. Keep in mind that there are often multiple factors that influence a client's ability or willingness to accept or access referral services, and it is not always appropriate or recommended to address all of these factors at one time. Referral and linkage is a process. It will likely extend beyond the initial HIV testing session and may warrant multiple visits with the client after they receive their HIV test results. Although you will do your best to support and motivate clients to seek referral services, it is ultimately in their hands to accept these services. In order to effectively implement referral and linkage services, you should be aware of the available and relevant resources to support your clients' health. You should also build partnerships with other health care organizations and community agencies to get your clients the services and care they need.

Defining Referral, Linkage, and Navigation

Referral is the process by which you actively provide clients with information and assistance in accessing medical care, social, and behavioral services. The referral process includes conducting an initial assessment of the client's needs, identifying, and prioritizing those needs based on this assessment, identifying barriers to accessing referral services, developing a plan for accessing referral services with the client, and facilitating his or her access to these referral services.

Linkage is the outcome verifying the successful completion of your referral by the client. Linkage includes following up with either clients or providers to confirm linkage and documenting the results. For example, when you confirm and document that a client made it to the first medical appointment within 30 days following the initial diagnosis, this is considered successful linkage.

Navigation is the overarching system that includes referral and linkage, but which may also extend beyond these steps to include continuous engagement with clients or patients to ensure they remain engaged in HIV medical care, social, and behavioral services for as long as necessary to support viral suppression and HIV prevention. HIV navigation services are intended to serve both clients living with HIV as well as HIV-negative individuals who are at risk of acquiring HIV.

The objectives of HIV navigation services are twofold: (1) to provide direct assistance to clients in accessing services, and (2) to support clients in building the knowledge and skills necessary to access and use the system on their own. This process may require contacting clients or patients on a regular basis to identify and address their barriers to staying engaged in care. Navigation often extends beyond the HIV testing encounter.

Linkage Staff and Navigators

In some agencies, HIV testing providers will also provide referrals and linkage, but in other agencies, specialized staff will be hired as navigators and dedicated to helping clients with this process. The training and development of navigators (e.g., community health workers, peer advocates, outreach workers, case coordinators) will help facilitate access to and retention in HIV medical care and social and behavioral services. Navigators are sometimes peers—persons living with HIV who have successfully accessed medical, risk reduction, and other services. Additionally, depending on an agency or region's existing systems and programs, navigation services may be performed by several staff members—not just a single person—who may offer assistance at various points along the HIV care continuum.

Implementing Referral, Linkage and Navigation Services

Regardless of whether a client is newly diagnosed with HIV infection, has been previously diagnosed, or is HIV-negative, the steps for referral, linkage, and navigation follow the same basic process:

1. **Identify and prioritize referral needs:** In collaboration with clients, identify what services are most important for keeping the client healthy and safe and for preventing HIV transmission or acquisition. Prioritize these services based on the client's situation and needs. It may not be possible or appropriate to address all of the client's referral needs at one time, so efforts should be focused on facilitating referrals to services that can have the greatest impact on the client's health and risk reduction.

2. **Develop a plan:** Elicit the client's strengths that can be used to implement the referral plan successfully. Furthermore, help the client identify challenges or barriers he or she might have in completing referrals and develop strategies to overcome these challenges. Together with the client, identify the methods you will use to facilitate a referral and help the client complete this referral. Work out a plan to help the client successfully and regularly access the necessary care and services.

3. **Facilitate access to services:** Provide clients with the information and support they need in order to access referrals. This includes supplying them with provider contact information, cost, hours of service, eligibility information, and processes and timelines for making appointments; help in deciphering insurance and financial information; and support for maintaining strong and ongoing communication with service providers. Scheduling appointments for or with clients, accompanying clients to appointments, providing transportation information and assistance, giving ongoing patient education

and motivation, and sending appointment reminders can significantly increase the chance of successful referrals. Also be sure to make referrals that are culturally appropriate with regard to age, gender, race, ethnicity, sexual orientation, and other factors.

4. **Confirm and document linkage:** After a designated period of time, confirm and document linkage to referral services by contacting the referral provider or the client to determine if they accessed these services. Obtain client feedback, if possible. If the client was not successfully linked, attempt to determine the reasons for this and provide additional assistance, if appropriate. If the client was successfully linked, document this in the client's file, chart, or referral log. Electronic tracking systems are used by many organizations to track and document linkage.

5. **Maintain contact with client to support navigation:** Once a client has been successfully linked with HIV medical care, social and behavioral services, it may be necessary to remain in contact with them to help them navigate the health care system and other services they might need. Navigation may include accompanying persons to medical appointments, sending reminders and encouraging messages, providing counseling support, and identifying persons who have dropped out of medical care and helping them get reengaged.

Referral, Linkage, and Navigation Strategies

Step 6 of the individual HIV testing protocol and step 8 in the HIV testing protocol for couples is to refer and link clients to HIV medical care and essential social and behavioral support services.

In order to get clients to these services, CDC supports a number of navigation strategies for helping agencies manage the referral and linkage process. You can learn more about how to access training and technical assistance for these strategies in Chapter #.

- Antiretroviral Treatment and Access to Services (ARTAS): ARTAS is for linking individuals who have recently been diagnosed with HIV to medical care. ARTAS consists of up to 5 sessions with a client within a 90-day period or until the client is successfully linked to HIV medical care, whichever comes first. A client may be transitioned to a medical case manager for longer-term assistance and support.
- HIV Navigation Services (HNS): A model for helping clients understand the entire range of services across the HIV care continuum, including services for high-risk HIV-negative individuals. It is important to ensure that HNS roles and services complement and do not duplicate existing services, programs, and staffing. HNS is not new but is a different way of addressing a longstanding challenge of helping clients stay engaged in care by addressing the myriad of issues that might keep them out of care.
- Linkage Case Management: Intensive, short-term assistance to facilitate entry into care. A linkage case manager helps clients to develop a personalized plan to acquire needed services.

- Medical Case Management: Ongoing coordination of medical services and follow-up of a client's medical treatments in order to engage and retain HIV-infected persons in medical care. Some HIV testing providers also operate medical case management programs, often at the same site where HIV testing is provided.
- Outreach and Peer Support: Linkage services provided by and for individuals living with HIV. Through one-on-one and/or group interactions, peers can play an integral role in recruiting HIV-positive persons into services, particularly individuals from hard-to-reach populations, clients who have been reluctant to enter into HIV medical care, or individuals who have left medical care.

Each facility should have a list of community resources available to help meet the needs of their clients, and providers should be familiar with these resources. It may be helpful for HIV testing agencies to establish memorandum of agreement (MOAs) with local referral agencies, to streamline the referral process, to ensure high standards of service delivery, and to hold agencies accountable. Client confidentiality or anonymity must be maintained when making referrals.

Documenting Referrals and Monitoring Linkage

Referrals and linkage should be offered to all clients based on their needs. Due to funding requirements and resource capacity, agencies may need to prioritize the linkages that they monitor. In line with agency procedures, linkages can be documented in a client's chart or in a centralized referral log. You may wish to collect the following information about each linkage:

- Date and time linkage was made
- Name of staff person linking the client
- Type of linkage service
- Name of linkage service provider
- Type of assistance and/or incentives provided to help the client complete the linkage
- Date linkage was successfully achieved, if applicable
- Reasons that linkage was not successfully achieved, if applicable (e.g., client feedback on challenges to accessing services or satisfaction with services)

If an authorization of release of information was necessary to determine if a client was successfully linked to services, place a copy of the authorization in the client chart. Agencies should regularly monitor data to evaluate the extent to which referral and linkage strategies are successful in linking clients with needed services. This ongoing assessment enables agencies to determine whether referral and linkage practices should be changed to better meet the needs of their clients.

Tracking Linkage to HIV Medical Care

It is particularly important to track linkages for HIV-positive clients to medical care, and HIV-negative clients to PrEP providers. Agencies should adhere to state and local requirements for tracking and reporting these linkages, which may include periodically reporting the proportion of HIV-positive clients linked to medical care who accessed their first appointment within 30 days.

Two main strategies for monitoring whether clients are successfully linked to follow-up services are (1) provider confirmation and (2) client self-report.

Provider Confirmation: Provider confirmation is the preferred method for confirming linkage. The medical provider is contacted by an HIV testing staff member and asked whether the client accessed services. The provider then confirms "yes" or "no". The provider should also report the date that the client accessed services, if applicable or discuss the reasons why the client hasn't yet come in. It is recommended that HIV testing sites authorize specific staff to track these linkages with medical providers. Likewise, clinics should also assign specific staff to confirm the client's linkage. In the case of linkage to medical care, a physician, clinical social worker, or nurse practitioner is the appropriate authorized party.

Client Self-Report: You may sometimes have ongoing contact or interactions with clients beyond the initial HIV testing event. The next contact with a client after he or she is linked to services provides a good opportunity for asking the client whether he or she successfully accessed the service. This also provides a good opportunity for obtaining client feedback about any challenges they encountered and their satisfaction with the services received. While client self-report is an acceptable means to confirm linkage, clients sometimes tell us what we want to hear rather than what actually happened. For this reason, provider confirmation is the preferred means for confirming linkage.

Conclusion

HIV testing is a core component of the high-impact prevention approach. To make improvements along the HIV care continuum, to meet the goals of the NHAS, and to reduce the number of new HIV infections occurring each year in the United States, high-quality HIV testing services must be provided to the right populations in a timely way and with a focus on linkage to medical care, social, and behavioral services based on the client's test results and needs. HIV testing is important for identifying persons living with HIV early in their infection and for successfully linking them with medical care and treatment and prevention services. It is also important for identifying high-risk HIV-negative persons and successfully linking them with preventive services and treatment such as nPEP, PrEP, and social and behavioral services.

Chapter Summary

This Policy and Procedure has offered key information and operational guidance for HIV testing providers. We have outlined key principles and standards that all nonclinical HIV testing programs should meet, reviewed the importance of targeting and recruitment for HIV testing services, and provided an overview of HIV tests and testing technologies. We have provided step-by-step instructions for how to conduct an HIV testing session with your clients in nonclinical settings, discussed the importance of testing couples and sexual partners together, and reviewed the key elements of referral, linkage, and navigation services.

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Thank You

Lastly, CT DPH acknowledges the hard work and dedication of all frontline HIV testing providers, HIV prevention staff, and health care workers in the state of Connecticut. It is because of your care for the communities you live and work in, your compassion for your patients and clients, and your commitment to working smarter that advances continue to be made in HIV prevention in Connecticut. Thank you.

Glossary

AIDS: Acquired immunodeficiency syndrome. AIDS can affect the immune and central nervous systems and can result in neurological problems, infections, or cancers. It is caused by human immunodeficiency virus (HIV).

Anal sex: A type of sexual intercourse in which a man inserts his penis in his partner's anus. Anal sex can be insertive or receptive.

Anonymous: In anonymous testing, client identifying information is not linked to testing information, including the request for tests or test results.

Antiretroviral therapy: Treatment with drugs designed to prevent HIV from replicating in HIV-infected persons. Highly active antiretroviral therapy (HAART) is an antiretroviral regimen that includes multiple classifications of antiretroviral drugs.

Client-centered HIV prevention counseling: An interactive risk-reduction counseling model usually conducted with HIV testing, in which the counselor helps the client identify and acknowledge personal HIV risk behaviors and commit to a single, achievable behavior change step that could reduce the client's HIV risk.

CDC is the federal Centers for Disease Control and Prevention.

Client Recruitment: Strategies for identifying and engaging individuals living with HIV or at high risk of HIV infection in prevention interventions, including outreach encounters, receiving supported referrals from other agencies and MDPH disease intervention specialists, active in-reach within an agency, and public information activities. Recruitment should happen through street and off-site outreach (including Internet).

Confidentiality: Pertains to the disclosure of personal information in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the original disclosure. Confidentiality must be maintained for persons who are recommended and/or who receive HIV counseling, testing, and referral (CTR) services.

Confidential HIV test: An HIV test for which a record of the test and the test results are recorded in the client's chart.

Confirmatory test: A highly specific test designed to confirm the results of an earlier (screening) test. For HIV testing, a Western blot or, less commonly, an immunofluorescence assay (IFA) is used as a confirmatory test.

Cultural Competence: A set of attitudes, practices, or policies that respects rather than merely understands the differences between the cultures of individuals. This includes a thorough knowledge of a particular group's values, norms, mores, traditions, customs, arts, history, folklore, and institutions. The planning and provision of community activities, services and care should be conducted with capacity in culture, language, disabilities, developmental stage, socioeconomic status, sexual orientation, age, and gender identity. The selected interventions must be well suited to the language, culture, and behaviors of the given priority population.

Health service organizations and programs should be welcoming, physically accessible, and able to provide clients with appropriate resources and materials. Agencies should implement policies and practices, prohibit discrimination, and promote access and inclusion. The following knowledge, skills, and attitudes are critical to the successful implementation of culturally competent services:

- Understanding of the cultural factors affecting responsiveness to varying strategies;
- Understanding of clients' cultural norms, biases, and preferences;
- Knowledge of and understanding the impact that cultural norms can have on clients' decision making processes;
- Ability to adapt strategies to unique client characteristics and circumstances;
- Development of the willingness to be flexible in meeting clients' needs; and
- Development of a nonjudgmental and respectful acceptance of cultural, behavioral, and value differences.[1]

DIS: Disease Intervention Specialist is a professionally trained counselor who provides partner notification services for those who are HIV +. The goal of the DIS as it relates to Partner Notification is to work with HIV + clients on how to disclose their HIV status to partners at risk.

Early Linkage and Referral Initiative (ERLI) is a secondary prevention and early intervention service system developed by DPH to link HIV/AIDS-positive clients and high-risk HIV/AIDS-negative clients to Program and other support services.

eAuthentication is the process of establishing confidence in user identities electronically presented to an information system. It requires that users of CDC data systems have their identity 'authenticated', or verified, at the local level by authorized persons checking government issued IDs, such as driver licenses, U.S. passport or U.S. military ID cards.

EIA: Enzyme immunoassay. Sometimes referred to as ELISA (see next definition). A commonly used screening test to detect antibodies to HIV.

ELISA: Enzyme-linked immunosorbent assay. A type of EIA (see previous definition). A commonly used screening test to detect antibodies to HIV.

Engagement: The participation of a client and provider in an activity that involves positive interaction, whereby the client is made to feel as comfortable as possible while speaking to and listening to the provider. The first stage of engagement involves identifying and making contacts with priority population members and establishing rapport. The second stage of engagement involves supporting the client in considering the possibility of behavior change and providing information and skills building opportunities about risk behaviors and strategies to reduce or

[1] Adapted from the OFFICE OF HIV/AIDS Prevention & Education RFR and from "Outreach Competencies minimum standards for conducting street outreach for hard-to-reach populations." Developed by the Center for HIV, Hepatitis, and Addiction Training and Technology of the DC/Delaware Addiction Technology Transfer Center.

eliminate risk and reduce the harm that occurs as a result of these behaviors. The third stage of engagement involves supporting clients through the behavior change process and in maintaining the behaviors once they are established.[2]

Ethics: Standards, behavior, or principles of conduct governing an individual or profession. As the field of HIV/AIDS prevention functions within a public health framework, the Public Health Code of Ethics[3] provides a general guide to ethical behavior for this field. Within the field of HIV/AIDS prevention staff are expected to treat all clients and colleagues with dignity and respect to foster an environment that is supportive of healthy behavior change that embraces harm reduction. As a general guide, any behavior that would cause potential current or future harm or distress to a client or colleague should be avoided. All OHA funded providers are required to develop a code of ethics to guide the delivery of their HIV/AIDS prevention & education activities.

As a minimum, the two following principles should be included in all ethical codes:

- Protect the confidentiality and privacy of all clients and client information, including written client records and information shared with the provider in the context of interventions or conversations. Program Managers/Coordinators should be familiar with local, state, and federal laws that govern confidentiality. Within CT, it is illegal to share information about an individual's HIV status with anyone or to test an individual for HIV without that individual's written consent.[4] Providers are expected to implement record keeping practices that protect client confidentiality. Client records should be maintained in a secure environment without any identifying information present that could link confidential information back to the client.
- Maintain appropriate boundaries with clients. For example, staff are expected to refrain from sexual or substance using behaviors with clients.

Evaluation: A process for determining how well health systems, either public or private, deliver or improve services and for demonstrating the results of resource investments.

EvaluationWeb: An online data collection and reporting system created by Luther Consulting, LLC.

False negative: A negative test result for a person who is actually infected.

False positive: A positive test result for a person who is actually not infected.

Harm Reduction refers to a range of public health policies designed to reduce the harmful consequences associated with human behaviors, even if those behaviors are risky or illegal

[2] "Outreach Competencies: Minimum Standards for Conducting Street Outreach for Hard to Reach Populations." Center for HIV, Hepatitis, and Addiction Training and Technology of the DC/Delaware Addiction Technology Transfer Center. (Page 16).
[3] http://www.apha.org/codeofethics/ The American Psychological Code of Ethics may be found at: http://www.apa.org/ethics/ and the National Association of Social Workers Code of Ethics may be found at: http://www.socialworkers.org/pubs/code/code.asp Both may also serve as useful examples of elements to be included in your agency code of ethics.
[4] Massachusetts General Laws, Ch. 11, sec. 70F

HIV: Human immunodeficiency virus, which causes AIDS. Several types of HIV exist, with HIV-1 being the most common in the United States.

HIV test: More correctly referred to as an HIV antibody test, the HIV test is a laboratory procedure that detects antibodies to HIV, rather than the virus itself.

HIV prevention counseling: An interactive process between client and counselor aimed at reducing risky sex and needle-sharing behaviors related to HIV acquisition (for HIV-uninfected clients) or transmission (for HIV-infected clients). See also client centered HIV prevention counseling.

Home sample collection test: A test that a consumer purchases and uses to collect blood (or other bodily fluid) and then send it out for testing. Counseling and test results are typically provided by telephone using user-generated codes to ensure confidentiality and anonymity.

Implementation Plan: A required annual intervention plan that describes how each intervention supported by the DPH HIV Prevention Unit will be implemented.

Incidence: In epidemiology, the number of new cases of infection or disease that occur in a defined population within a specified time.

Indeterminate test result: A possible result of a Western blot, which might represent a recent HIV infection or a false-positive.

Information: In the context of HIV counseling, information encompasses the topics HIV transmission and prevention and the meaning of HIV test results.

Informed consent: The legally effective permission of a client or legally authorized representative (e.g., parent or legal guardian of a minor child) to undergo a medical test or procedure.

Medication Adherence Program Services is a comprehensive service to assist People Living with HIV/AIDS who are starting or on HIV medications to adhere to their treatment regimen. Staff offer ongoing support to help clients to develop and implement strategies to overcome barriers in adhering to their medications.

Motivational Interviewing (MI): A clinical approach that helps people with mental health and substance use disorders and other chronic conditions such as diabetes, cardiovascular conditions, and asthma make positive behavioral changes to support better health.

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Nonoccupational HIV exposure: A reported sexual, injection-drug–use, or other nonoccupational HIV exposure that might put a patient at high risk for acquiring HIV infection.

Nucleic acid amplification testing: A type of testing that identifies viral genes (e.g., specific sequences of nucleic acids) using gene amplification technologies such as polymerase chain reaction (PCR).

Occupational HIV exposure: An occupational exposure to HIV that occurs during the performance of job duties. Defined as a percutaneous injury (e.g., a needlestick or cut with a

sharp object), contact of mucous membranes, or contact of skin (especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area) with blood, tissues, or other body fluids to which universal precautions apply.

Oral sex: A type of sexual intercourse in which the partner's genitals are stimulated by mouth and tongue.

Outreach is defined as approaching program eligible persons and recruiting them for enrollment into a program.

Partner Services (PS): A prevention activity that aims to a) provide services to HIV-infected persons and their sex and needle-sharing partners so they can reduce their risk for infection or, if already infected, can prevent transmission to others and b) help partners gain earlier access to individualized counseling, HIV testing, medical evaluation, treatment, and other prevention and support services.

Perinatal HIV transmission: Transmission of HIV from the mother to the fetus or infant during pregnancy, delivery, or breast-feeding.

Prevention Counseling: Is an interactive client-focused, using education, skills-building, role plays, support, crisis management, and other strategies to help clients reduce and eliminate risk behaviors and maintains thee changes over the long term.

Positive test: For HIV, a specimen sample that is reactive on an initial ELISA test or a confirmed positive on Western blot or other supplemental test indicates that the client is infected.

Prevalence: The number or percentage of persons in a given population with a disease or condition at a given point in time.

Prevention counseling: An interactive process between client and counselor aimed at reducing risky sex and needle-sharing behaviors related to HIV acquisition (for HIV uninfected clients) or transmission (for HIV-infected clients). See also client-centered HIV prevention counseling and HIV prevention counseling.

Quality assurance: An ongoing process for ensuring that the prevention program effectively delivers a consistently high level of service to the clients.

Rapid HIV test: A test to detect antibodies to HIV that can be collected and processed within a short interval of time (e.g., approximately 10–60 minutes).

Referral: The process through which a client is connected with services to address prevention needs (medical, prevention, and psychosocial support).

Risk assessment: Risk assessment is a fundamental part of a client-centered HIV prevention counseling session in which the client is encouraged to identify, acknowledge, and discuss in detail his or her personal risk for acquiring or transmitting HIV.

Risk screening: A brief evaluation of HIV risk factors, both behavioral and clinical, used for decisions about who should be recommended HIV counseling and testing. Risk screening is different from risk assessment.

Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87, October 30, 2009). The legislation was first enacted in 1990 as the Ryan White CARE (Comprehensive AIDS Resources Emergency) Act. It has been amended and reauthorized four times: in 1996, 2000, 2006, and 2009.

Screening test: An initial test, usually designed to be sensitive, to identify all persons with a given condition or infection (e.g., enzyme immunoassay [EIA] or enzyme-linked immunosorbent assay [ELISA]).

Sensitivity: The probability that a test will be positive when infection or condition is present.

Seroconversion: Initial development of detectable antibodies specific to a particular antigen; the change of a serologic test result from negative to positive as a result of antibodies induced by the introduction of antigens or microorganisms into the host.

Specificity: The probability that a test will be negative when the infection or condition is not present.

Tuberculosis (TB) disease: Active disease caused by Mycobacterium tuberculosis, as evidenced by a confirmatory culture, or, in the absence of culture, suggestive clinical symptoms, including productive cough lasting >3 weeks, chest pain, hemoptysis, fever, night sweats, weight loss, and easy fatigability. Active TB is a communicable disease that is treatable, curable, and preventable, and persons with active TB disease should be under the care of a health-care provider. Active TB disease could indicate immune deficiency. For HIV-infected persons, active TB disease is considered an opportunistic infection and a qualifying condition for AIDS.

Tuberculosis (TB) infection: Infection with the bacteria M. tuberculosis, as evidenced by a positive tuberculin skin test (TST) that screens for infection with this organism. Sometimes, TST is called a purified protein derivative (PPD) or Mantoux test. A positive skin test might or might not indicate active TB disease (see tuberculosis disease). Thus, any person with a positive TST should be screened for active TB and, once active TB is excluded, evaluated for treatment to prevent the development of TB disease. TB infection alone is not considered an opportunistic infection indicating possible immune deficiency.

Vaginal sex: A type of sexual intercourse in which the man's penis enters the woman's vagina.

Venue: A descriptor of the context or setting within which HIV prevention interventions are delivered with specific reference to the physical or institutional environment where a given intervention is located (e.g. clinic, drop-in-center, bar, etc.). The prevention intervention can take place in a variety of venues, including but not limited to, the Internet, public sex environments, drug purchasing and using environments, sex work environments, drop-in centers, clinical settings, religious institutions and settings, community centers and social centers, educational settings, prisons, jails and other correctional facilities, and homeless shelters. The venue should be a place where the priority population is comfortable and where the education can be successfully executed. In all cases, the program must describe why a chosen venue is well suited to the needs of their stated priority population and should indicate the specific nature of the chosen venue.

Voluntary HIV testing: HIV testing that is offered free of coercion. With voluntary HIV testing, participants have the opportunity to accept or refuse HIV testing.

Western blot: A laboratory test that detects specific antibodies to components of a virus. Chiefly used to confirm HIV antibodies in specimens found repeatedly reactive using ELISA.

Work Plan: Required annual plan that describes the performance goals and objectives of each intervention supported by the DPH HIV Prevention Unit.

Appendices


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LinkageToCare
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US Public Health Service

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

A CLINICAL PRACTICE GUIDELINE

What's New in the Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2021 Update – A Clinical Practice Guideline

The Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update – A Clinical Practice Guideline includes revisions to several sections. These revisions are intended to update existing guidance using the current evidence base, to incorporate recent FDA PrEP medication approvals, and to clarify specific aspects of clinical care. Other revisions were made to improve usability and increase implementation of the guideline based on comments received from clinicians providing PrEP care. Minor revisions were also made to correct typographical errors, add or update references, and update content from cited guidelines and source materials.

What's new…

In anticipation of likely FDA approval of a PrEP indication for cabotegravir (CAB) in late 2021, we added a new section about prescribing PrEP with intramuscular injections of CAB every 2 months for sexually active men, women, and transgender persons with indications for PrEP use.

Summary (of graded recommendations)

- We added a recommendation to inform all sexually active adults and adolescents about PrEP **(IIIB).**

- We added a recommendation: PrEP with intramuscular cabotegravir (CAB) injections (conditional on FDA approval) is recommended for HIV prevention in adults reporting sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition (**IA).**

Table Summarizing Clinical Guidance

- We added a table specific for CAB (as CAB has a different dosing and recommended follow-up schedule than oral PrEP, and no renal or lipid monitoring is required) (Table 1b).

Identifying Indications for PrEP

- We simplified the determination of indications for PrEP use for sexually-active persons. We replaced boxes with flow charts for assessing indications for sexually active persons and persons who inject drugs.

Laboratory Tests and other Diagnostic Procedures

- We revised the HIV testing algorithm to provide two algorithms; one for assessing HIV status in persons with no history of recent antiretroviral exposure starting (or restarting) PrEP and, the other for assessing HIV status at follow-up visits while persons are taking, or have recently taken, PrEP.

Providing PrEP

- We added F/TAF as an FDA-approved choice for sexually active men and transgender women at risk of HIV acquisition; the FDA approval for F/TAF excluded persons at risk through receptive vaginal sex including cisgender women (persons assigned female sex at birth whose gender identity is female).
- We revised and reordered the sections on initiation and follow-up care to first describe guidelines applicable to all PrEP patients and then describe guidelines applicable only to selected patients.
- We revised frequency of assessing eCrCl to every 12 months for persons <50 years of age or with eCrCL ≥90 ml/min at PrEP initiation and every 6 months for all other patients.
- We added medications to Table 4 of drug interactions for TAF.
- We outlined options for PrEP initiation and follow-up care by telehealth ("Tele-PrEP").
- We outlined procedures for providing or prescribing PrEP medication to select patients on the same day as initial evaluation for its use ("same-day PrEP").
- We outlined procedures for the off-label prescription of TDF/FTC to men who have sex with men on a non-daily regimen ("2-1-1") and their follow-up care.
- We added a brief section on primary care considerations for PrEP patients (Table 6).
- We added a section on providing CAB for PrEP.

Evidence Review

- We updated the evidence review and moved it to Appendix 2.
- We added evidence reviews for CAB trials.
- We separated clinical trial results for transgender women and MSM into separate rows in evidence tables.

Revisions post FDA approval of cabotegravir injections for PrEP

It is anticipated that FDA will review and may approve cabotegravir injections for PrEP within 2-3 months after the publication of this guideline. We will then post a revised version of this guideline that replaces references to pending FDA approval with statements indicating that approval has been given.

Disclaimers:

References to non-CDC sites on the internet are provided as a service to readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of these sites. URL addresses listed were current as of the date of publication.

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Potential Conflicts of Interest:

CDC and individual employees involved in the guideline development process are named in US government patents and patent applications related to methods for HIV prophylaxis.

Suggested Citation:

Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published XXX 2021.

For More Clinical Advice About PrEP Guidelines:

- Call the National Clinicians Consultation Center PrEPline at **855-448-7737**;
- Go to the National Clinicians Consultation Center PrEPline website at http://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/; and/or
- Go to the CDC HIV website for clinician resources at https://www.cdc.gov/hiv/clinicians/index.html.

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List of Tables, Figures, and Boxes

Abbreviations (In Guideline and Clinical Providers' Supplement)

ACTG	AIDS Clinical Trials Group
AHRQ	Agency for Healthcare Research and Quality
AIDS	acquired immunodeficiency syndrome
BMD	bone mineral density
CAB	cabotegravir
CDC	Centers for Disease Control and Prevention
CPT	common procedural terminology
DEXA	dual-emission X-ray absorptiometry
DHAP	Division of HIV/AIDS Prevention, CDC
DHHS	Department of Health and Human Services
DP	diphosphate
eCrCl	estimated creatinine clearance rate (ml/min)
EIA	enzyme-linked immunoassay
EPT	expedited partner therapy
FDA	Food and Drug Administration
FHI	Family Health International
F	emtricitabine (trade name Emtriva®), also called FTC
F/TAF	emtricitabine coformulated with tenofovir alafenamide (trade name Descovy®)
F/TDF	emtricitabine coformulated with tenofovir disoproxil fumarate (trade name Truvada®)
GEM	Guidelines Elements Model
GLIA	GuideLine Implementability Appraisal
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
ICD	International Classification of Diseases
IDU	injection drug users (also referred to as PWID)
IFA	indirect immunofluorescence assay
IHS	Indian Health Service
INSTI	integrase strand transfer inhibitor
IQR	interquartile range
MSM	men who have sex with men
MTN	Microbicide Trials Network
NASTAD	National Association of State and Territorial AIDS Directors
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
NGC	National Guidelines Clearinghouse
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
nPEP	nonoccupational postexposure prophylaxis
NSAID	non-steroidal anti-inflammatory drug
NQMC	National Quality Measures Clearinghouse

OHAP	Office of HIV/AIDS Policy, DHHS
ONAP	Office of National AIDS Policy
ONDCP	Office of National Drug Control Policy
OPA	Office of Population Affairs, DHHS
PCR	polymerase chain reaction
PEP	postexposure prophylaxis
PHS	(U.S.) Public Health Service
PWID	persons who inject drugs
PrEP	preexposure prophylaxis
SAMHSA	Substance Abuse and Mental Health Services Administration
STD	sexually transmitted disease
STI	sexually transmitted infection
TB	tuberculosis
TDF	tenofovir disoproxil fumarate (trade name Viread®)
TAF	tenofovir alafenamide
TGW	transgender women
UNAIDS	Joint United National Programme on HIV/AIDS
USPSTF	United States Preventive Services Task Force
VA	Veterans Administration
WHO	World Health Organization

Summary

Preexposure Prophylaxis for HIV Prevention in the United States – 2021 Update: A Clinical Practice Guideline provides comprehensive information for the use of antiretroviral preexposure prophylaxis (PrEP) to reduce the risk of acquiring HIV infection. The key messages of the guideline are as follows:

- Daily oral PrEP with emtricitabine (F) 200 mg in combination with 1) tenofovir disoproxil fumarate (TDF) 300 mg for men and women or 2) tenofovir alafenamide (TAF) 25 mg, for men and transgender women, has been shown to be safe and effective in reducing the risk of sexual HIV acquisition
  therefore,
  - All sexually active adult and adolescent patients should receive information about PrEP. **(IIIB)**
  - For both men and women, PrEP with daily F/TDF is recommended for HIV prevention for sexually-active adults and adolescents weighing at least 35 kg (77 lb) who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition. **(IA)**[1]
  - For both men and women, PrEP with daily F/TDF is recommended for HIV prevention for adult and adolescents weighing at least 35 kg (77 lb) who inject drugs (PWID) (also referred to as injection drug users [IDU]) and report injection practices that place them at substantial ongoing risk of HIV exposure and acquisition. **(IA)**
  - For men only, daily oral PrEP with F/TAF is a recommended option for HIV prevention for sexually active adults and adolescents weighing at least 35 kg (77 lb) who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition. PrEP with F/TAF has not yet been studied in women (persons assigned female sex at birth whose gender identify is female) and so F/TAF is not recommended for HIV prevention for women or other persons at risk through receptive vaginal sex. **(IA)**
  - For transgender women (persons assigned male sex at birth whose gender identity is female) who have sex with men, and who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition, daily oral PrEP with F/TAF is a recommended option for HIV prevention **(IIB)**
  - The efficacy and safety of other daily oral antiretroviral medications for PrEP, either in place of, or in addition to, F/TDF or F/TAF, have not been studied extensively and are not recommended. **(IIIA)**
- Renal function should be assessed by estimated creatinine clearance (eCrCl) at baseline for PrEP patients taking daily oral F/TDF or F/TAF, and monitored periodically so that persons in whom clinically significant renal dysfunction is developing do not continue to take it.
  - Estimated creatinine clearance (eCrCl) should be assessed every 6 months for patients over age 50 or those who have an eCrCl <90 ml/min at initiation. **(IIA)**
  - For all other daily oral PrEP patients, eCrCl should be assessed at least every 12 months. **(IIA)**
- Conditioned on a PrEP indication approved by FDA, PrEP with intramuscular cabotegravir (CAB) injections is recommended for HIV prevention in adults and adolescents who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition. **(IA)**
- Acute and chronic HIV infection must be excluded by symptom history and HIV testing immediately before any PrEP regimen is prescribed. **(IA)**
- HIV infection should be assessed at least every 3 months for patients taking daily oral PrEP, and every 4 months for patients receiving CAB injections for PrEP so that persons with incident infection do not continue taking it. The 2-drug regimens of F/TDF or F/TAF and the single drug CAB are inadequate therapy

[1] See Appendix 1, Grading of Strength of Recommendations and Quality of Evidence (Tables 12-13)

for established HIV infection, and their use in persons with early HIV infection may engender resistance to one or more of the PrEP medications. **(IA)**

- When PrEP is prescribed, clinicians should provide access, directly or by facilitated referral, to:
    - Support for medication adherence and continuation in follow-up PrEP care, because high medication adherence and persistent use are critical to PrEP effectiveness for prevention of HIV acquisition. **(IIA)**
    - Additional proven effective risk-reduction services, as indicated by reported HIV exposure-prone behaviors, to enable the use of PrEP in combination with other effective prevention methods to reduce risk for sexual acquisition of STIs or acquisition of bloodborne bacterial and viral infections through injection drug use. (**IIIA**)

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

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

	• Re-educate patients about the “tail” and the risks during declining CAB levels • Assess ongoing HIV risk and prevention plans • If PrEP is indicated, prescribe daily oral F/TDF or F/TAF beginning within 8 weeks after last injection • Continue follow-up visits with HIV testing quarterly for 12 months

Introduction

Daily oral antiretroviral preexposure prophylaxis (PrEP) with a fixed-dose combination of either tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF) with emtricitabine (F). has been found to be safe[1] and effective in substantially reducing HIV acquisition in gay, bisexual, and other men who have sex with men (MSM) [2-4], men and women in heterosexual HIV-discordant couples [5], and heterosexual men and women recruited as individuals.[6] In addition, one clinical trial among persons who inject drugs (PWID) (also referred to as injection drug users [IDU])[7] and one among men and women in heterosexual HIV-discordant couples[5] have demonstrated substantial efficacy and safety of daily oral PrEP with TDF alone. The demonstrated efficacy of daily oral PrEP was in addition to the effects of repeated condom provision, sexual risk-reduction counseling, and the diagnosis and treatment of sexually transmitted infections (STI), all of which were provided to trial participants, including persons in the drug treatment group and persons in the placebo group. In July 2012, after reviewing the available trial results, the U.S. Food and Drug Administration (FDA) approved an indication for the use of Truvada (F/TDF) "in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk"[8]. In May 2018, the approval for F/TDF was extended to adolescents weighing at least 35 kg (77 lb) based on safety trials in adolescents[9] and young adults.[10] In June 2019, the US Preventive Services Task Force recommended PrEP for adults and adolescents at risk of HIV acquisition with an "A" rating (high certainty that the net benefit of the use of PrEP to reduce the risk of acquisition of HIV infection in persons at high risk of HIV infection is substantial).[11] In 2021, based on this recommendation, DHHS determined that most commercial insurers and some Medicaid programs are required to provide oral PrEP medication, necessary laboratory tests, and clinic visits with no out-of-pocket cost to patients., And in October 2019, based on a clinical trial conducted with 5,387 MSM and 74 transgender women, the FDA approved a PrEP indication for daily Descovy (F/TAF) for sexually active men and transgender women at risk of HIV acquisition.[3, 4] Women (persons assigned female sex at birth) and other persons at risk through receptive vaginal sex were specifically excluded from the F/TAF approval, because no women or transgender men were included in the efficacy and safety PrEP trial. In 2020, results from a clinical trial conducted with MSM and transgender women, and another conducted with women, reported high efficacy and safety for injections of cabotegravir (CAB) every 2 months for PrEP.[12, 13] Submission of data for review by the FDA for approval of a PrEP indication is planned in 2021.

On the basis of these trial results and the FDA approvals, the U.S. Public Health Service guidelines recommend that clinicians inform all sexually-active patients about PrEP and its role in preventing HIV acquisition. Clinicians should evaluate all adult and adolescent patients who are sexually active or who are injecting illicit drugs and offer to prescribe PrEP to persons whose sexual or injection behaviors and epidemiologic context place them at substantial risk of acquiring HIV infection.

An estimated 1.2 million persons have indications for PrEP use.[14] Both the soon to be updated HIV National Strategic Plan: A Roadmap to End the Epidemic for the United States - 2021–2025. (https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf) and the federal initiative "Ending the HIV Epidemic in the United States" (https://www.cdc.gov/endhiv/index.html) have called for rapid and large scale up of PrEP provision by clinicians providing health care to HIV-uninfected persons at risk for HIV acquisition. Since FDA approval, the minimum estimate of the number of persons receiving PrEP prescriptions for F/TDF has risen from 8,800 in 2012 to nearly 220,000 in 2018.[15, 16] However, the geographic, sex, and racial/ethnic distribution of persons prescribed PrEP is not equitable when compared to the distribution of new HIV diagnoses that could be prevented. African Americans, Hispanics, women, and residents of southern states have disproportionately low numbers of PrEP users.[17]

The evidence base for this 2021 update of CDC's PrEP guidelines was derived from a systematic search and review of published literature. To identify all oral PrEP safety and efficacy trials and observational studies pertaining to the prevention of sexual and injection acquisition of HIV, a search was performed of the clinical trials registry (http://www.clinicaltrials.gov) by using combinations of search terms (preexposure prophylaxis, pre-exposure prophylaxis, PrEP, HIV, Truvada, Descovy, tenofovir, and antiretroviral). These search terms were used to search PubMed, Web of Science, MEDLINE, Embase, CINAHL, and Cochrane Library databases for January 2006-December 2020. Finally, a review of references from published PrEP trial data confirmed that no additional trial results were available. For additional information about the systematic review process, see the Clinical Providers' Supplement, Section 12 at https://www.cdc.gov/hiv/pdf/risk/prep-cdc-hiv-prep-provider-supplement-2021.pdf.

This publication provides a comprehensive clinical practice guideline for the use of PrEP for the prevention of HIV infection in the United States. Currently, prescribing daily oral PrEP with F/TDF is recommended for MSM, heterosexual men, heterosexual women, and PWID at substantial risk of HIV acquisition; F/TAF is a recommended option for sexually active persons except women and other persons at risk through receptive vaginal sex. FDA review of injections of CAB every 2 months as PrEP is pending. As the results of additional PrEP clinical trials and studies in these and other populations at risk of HIV acquisition become known, this guideline will be updated.

Many of the studies that informed these guidelines included small numbers of transgender women and none included transgender men, as a result, data specifically relevant for transgender and non-binary people are often limited or not available. Most sections of these guidelines, therefore, use the terminology, 'women' and 'men' unless specifically referring to transgender women or men. Based on current data showing potentially high levels for protection with PrEP for people exposed to HIV during rectal, vaginal, and /or oral sex we recommend gender-inclusive models of PrEP care to ensure that services encompass and address the needs of all

persons who would benefit from its use including cisgender and transgender adults and adolescents as well as PWID.

The intended users of this guideline include:

- primary care clinicians who provide care to persons at risk of acquiring HIV infection;
- clinicians who provide substance abuse treatment or reproductive health care;
- infectious disease, HIV treatment, and STD treatment specialists who may provide PrEP or serve as consultants to primary care clinicians about the use of antiretroviral medications; and
- health program policymakers
- counselors and other adherence support providers

Evidence of Need for Additional HIV Prevention Methods

Approximately 36,400 people in the United States acquired HIV in 2018. From 2014 through 2018, overall estimated annual HIV incidence remained stable. No decline or increase was observed in the estimated number of annual HIV infections among persons of both sexes, black/African American, Hispanic/Latino, or white persons, any transmission risk group, or any region of the US. Estimated HIV incidence decreased from 2014 through 2018 among persons of multiple races and among persons aged 13–24, and remained stable among all other age groups.[18]

In 2018, 67% of the 38,739 newly diagnosed HIV infections were attributed to male-male sexual activity without injection drug use, 3% to male-male sexual activity with injection drug use, 24% to male-female sexual contact without injection drug use, and 6% to injection drug use.[17] Among all adults and adolescents, diagnoses of HIV infection among transgender persons accounted for approximately 2% of diagnoses of HIV infections in the United States and 6 dependent areas; of whom 92% of diagnoses of HIV infections were for transgender women. Among the 24% of persons with newly diagnosed HIV infection attributed to heterosexual activity, 62% were African-American women and men.[14] These data indicate a need for additional methods of HIV prevention to further reduce new HIV infections, especially (but not exclusively) among young adult and adolescent MSM of all races and Hispanic/Latino ethnicity and for African American heterosexuals (populations with higher HIV prevalence and at higher risk of HIV infection among persons without HIV infection).

Since 2012, when the FDA first approved a F/TDF indication for PrEP and clinical trial data showed the efficacy and safety of daily, oral F/TDF for HIV prevention, the number of persons prescribed PrEP has gradually increased each year[14]. In 2018, of the estimated 1.2 million adults and adolescents with indication for PrEP use[12], an estimated 220,000 persons received an oral PrEP prescription, or about 18% of persons who would benefit from its use.[13] Equitable provision of PrEP to populations at highest risk of HIV acquisition is not occurring. Black persons constituted 42% of new HIV diagnoses in 2018 but only 6% of Black persons with indications for its use were estimated to have received an oral PrEP prescription. Hispanic/Latino persons constituted 27% of new HIV diagnoses but only 10% of Hispanic/Latino persons with indications for its use had received an oral PrEP prescription. While women are 19% of persons with new HIV diagnoses, they comprise only 7% of those prescribed oral PrEP.[17, 19]

These guidelines are intended to inform clinicians and other partners to respond to both the soon to be updated HIV National Strategic Plan: A Roadmap to End the Epidemic for the United States - 2021–2025 (https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf) and the federal initiative Ending the HIV Epidemic in the United States (https://www.cdc.gov/endhiv/index.html) through rapid expansion of PrEP delivery to all persons who could benefit from its use as highly effective HIV prevention.

All Patients Being Assessed for PrEP Provision

Identifying Indications for PrEP

All sexually active adults and adolescents should be informed about PrEP for prevention of HIV acquisition. This information will enable patients to both respond openly to risk assessment questions and to discuss PrEP with persons in their social networks and family members who might benefit from its use. Studies have shown that patients often do not disclose stigmatized sexual or substance use behaviors to their health care providers (especially when not asked about specific behaviors).[20-25]

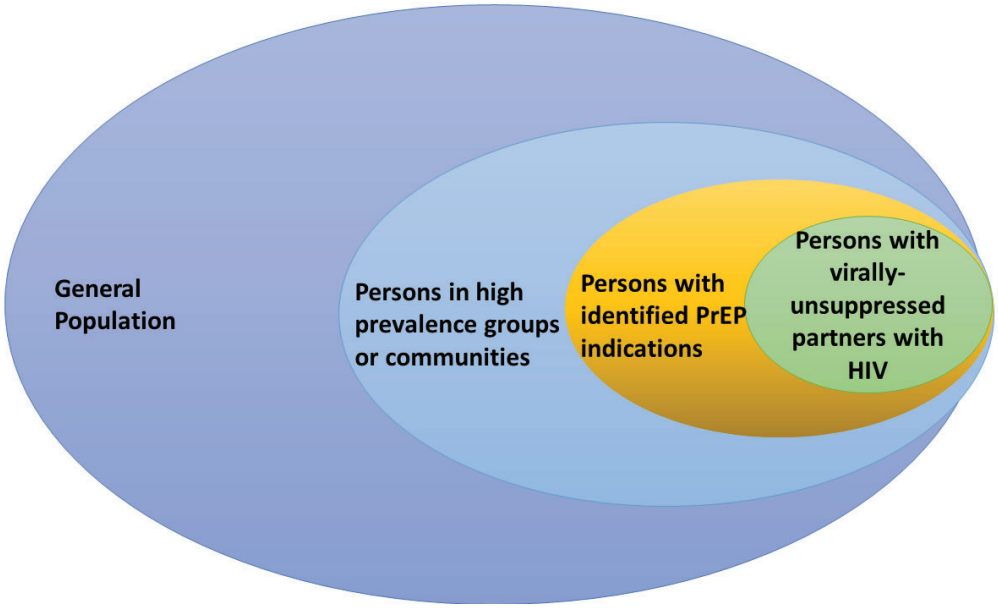
Taking a brief, targeted sexual history is recommended for all adult and adolescent patients as part of ongoing primary care,[26] but the sexual history is often deferred because of urgent care issues, provider discomfort, or anticipated patient discomfort. This deferral is common among providers of primary care,[27] STI care,[28] and HIV care.[29-31]

Routinely taking a sexual history is a necessary first step to identify which patients in a clinical practice are having sex with same-sex partners, which are having sex with partners, and what specific sexual behaviors may place them at risk for, or protect them from, HIV acquisition. To identify the sexual health needs of all their patients, clinicians should not limit sexual history assessments to only selected patients (e.g., young, unmarried persons, or women seeking contraception), because new HIV infections and STIs are occurring in all adult and adolescent age groups, both sexes, all genders, and both married and unmarried persons. The clinician can introduce this topic by stating that taking a brief sexual history is routine practice for all patients, go on to explain that the information is necessary to the provision of individually appropriate sexual health care, and close by reaffirming the confidentiality of patient information.

Transgender persons are those whose sex at birth differs from their current self-identified gender. Although the effectiveness of oral PrEP for transgender women has been more definitively proven in some trials than in others[32], cabotegravir injections for PrEP have been shown to reduce the risk for HIV acquisition among transgender women and MSM during anal sex[13] and women during vaginal sex[12]. Trials have not been conducted among transgender men. Nonetheless, its use should be considered in all persons at risk of acquiring HIV sexually.

Patients may request PrEP because of concern about acquiring HIV but not feel comfortable reporting sexual or injection behaviors to avoid anticipated stigmatizing responses in health care settings.[33-36] For this reason, after attempts to assess patient sexual and injection behaviors, patients who request PrEP should be offered it, even when no specific risk behaviors are elicited.

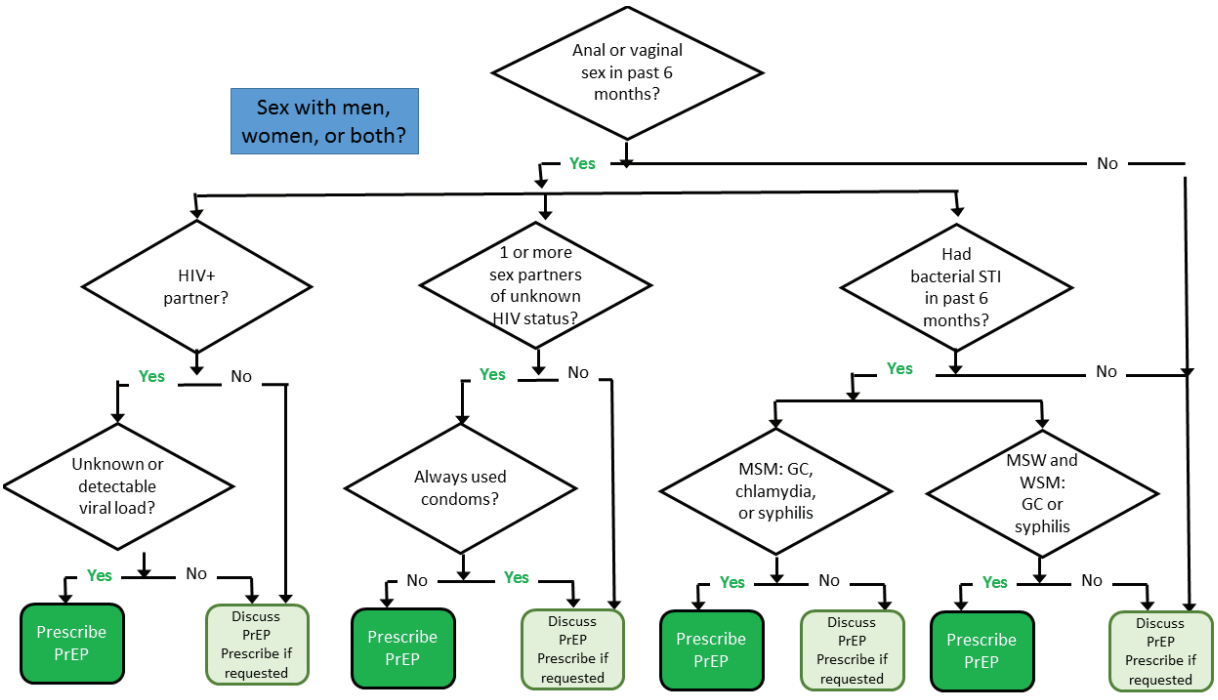
Figure 1 Populations and HIV Acquisition Risk



Assessing Risk of Sexual HIV Acquisition

PrEP should be offered to sexually active adults and adolescents at substantial risk of HIV acquisition. Figure 2 outlines a set of brief questions designed to assess a key set of sexual practices that are associated with the risk of HIV acquisition.

Figure 2 Assessing Indications for PrEP in Sexually Active Persons



A patient who reports that one or more regular sex partners is of unknown HIV status should be offered HIV testing for those partners, either in the clinician's practice or at a confidential testing site (see zip code lookup at https://www. gettested.cdc.gov/).

When a patient reports that one or more regular sex partners is known to have HIV, the clinician should determine whether the patient being considered for PrEP use knows if the HIV-positive partner is receiving antiretroviral therapy and has had an undetectable viral load (<200 copies/ml) for at least the prior 6 months.[37] Persons with HIV who have an undetectable viral load pose effectively no risk for HIV transmission to sexual partners (see section below on considerations for HIV discordant couples). PrEP for an HIV-uninfected patient may be indicated if a sexual partner with HIV has been inconsistently virally suppressed or his/her viral load status is unknown. In addition, PrEP may be indicated if the partner without HIV seeking PrEP either has other sexual partners or wants the additional reassurance of protection that PrEP can provide.

Clinicians should ask all sexually-active patients about any diagnoses of bacterial STIs (chlamydia, syphilis, gonorrhea) during the past 6 months, because they provide evidence of sexual activity that could result in HIV exposure. For heterosexual women and men, risk of HIV exposure during condomless sex may also be indicated by recent pregnancy of a female patient or a female sexual partner of a male patient considering PrEP. A scored risk index predictive of incident HIV infection among MSM[38, 39] (see Clinical Providers' Supplement, Section 5) is also available.

Only a few questions are needed to establish whether indications for PrEP are present, However, clinicians may want to ask additional questions to obtain a more complete sexual history that includes information about a patient's gender identity, partners, sexual practices, HIV/STI protective practices, past history of STDs, and pregnancy intentions/preventive methods (https://www.cdc.gov/std/treatment/sexualhistory.pdf). Clinicians should become familiar with the evolving terminology referring to sex, gender identity, and sexual orientation.

Sex The assignment of a person as male or female usually based on the appearance of their external anatomy at birth. This is what is written on the birth certificate.

Gender Identity A person's internal, deeply held sense of their gender. Most people have a gender identity of man or woman (or boy or girl). Gender identity is not visible to others.

Sexual Orientation A person's enduring physical, romantic, and/or emotional attraction to another person. Gender identity and sexual orientation are not the same. Persons of varied gender identities may be straight, lesbian, gay, bisexual, or queer

Transgender (adj.)
People whose gender identity differs from the sex they were assigned at birth. Many transgender people are prescribed hormones by their doctors and some undergo surgery to bring their bodies into alignment with their gender identity. A transgender identity is not dependent upon physical appearance or medical procedures. Trans can be used as shorthand for transgender

Cisgender (adj.) People whose gender identity is the same as the sex they were assigned at birth **Cis** can be used as shorthand for cisgender.

Gender Expression External manifestations of gender, expressed through a person's name, pronouns, clothing, haircut, behavior, voice, and/or body characteristics.

Gender Non-Conforming People whose gender expression is different from conventional expectations of masculinity and femininity. Many people have gender expressions that are not entirely conventional – that fact alone does not make them transgender. The term is not a synonym for transgender or transsexual and should only be used if someone self-identifies as gender non-conforming.

Non-binary and/or genderqueer Terms used by some people who experience their gender identity and/or gender expression as falling outside or somewhere in between the categories of man and woman. The term should only be used if someone self-identifies as non-binary and/or genderqueer.

Adapted from GLAAD Media Reference Guide at
https://www.glaad.org/reference/transgender

Clinicians should also briefly screen all patients for alcohol use disorder[40] (especially before sexual activity), and the use of illicit non-injection drugs (e.g., amyl nitrite, stimulants).[41, 42] The use of these substances may affect sexual risk behavior,[43] hepatic or renal health, or medication adherence, any of which may affect decisions about the appropriateness of prescribing PrEP medication. In addition, if a substance use disorder is identified, the clinician should provide referral for appropriate treatment or harm-reduction services acceptable to the patient.

Lastly, clinicians should consider the epidemiologic context of the sexual practices reported by the patient. The risk of HIV acquisition is determined by both the frequency of specific sexual practices (e.g., condomless anal intercourse) and the likelihood that a sex partner has HIV. The same behaviors when reported as occurring in communities and demographic populations with high HIV prevalence or occurring with partners known to have HIV, are more likely to result in exposure to HIV and so will indicate greater need for intensive risk-reduction methods (e.g., PrEP, multisession behavioral counseling) than when they occur in a community or population with low HIV prevalence (for local prevalence estimates see http://www.AIDSvu.org or http://www.cdc.gov/nchhstp/atlas/).

Reported consistent ("always") condom use is associated with an 80% reduction in HIV acquisition among heterosexual couples[44] and 70% among MSM.[45] Inconsistent condom use is considerably less effective,[46, 47] and studies have reported low rates of recent consistent condom use among MSM[48, 49] and other sexually active adults.[48] Especially low rates have been reported when condom use was measured over several months rather than during most recent sex or the past 30 days.[50] Therefore, unless the patient reports confidence that consistent condom use can be achieved, PrEP should be prescribed while continuing to support condom use for prevention of STIs and unplanned pregnancy (See Supplement Section 5).

Assessing Risk of HIV Acquisition Through Injection Practices

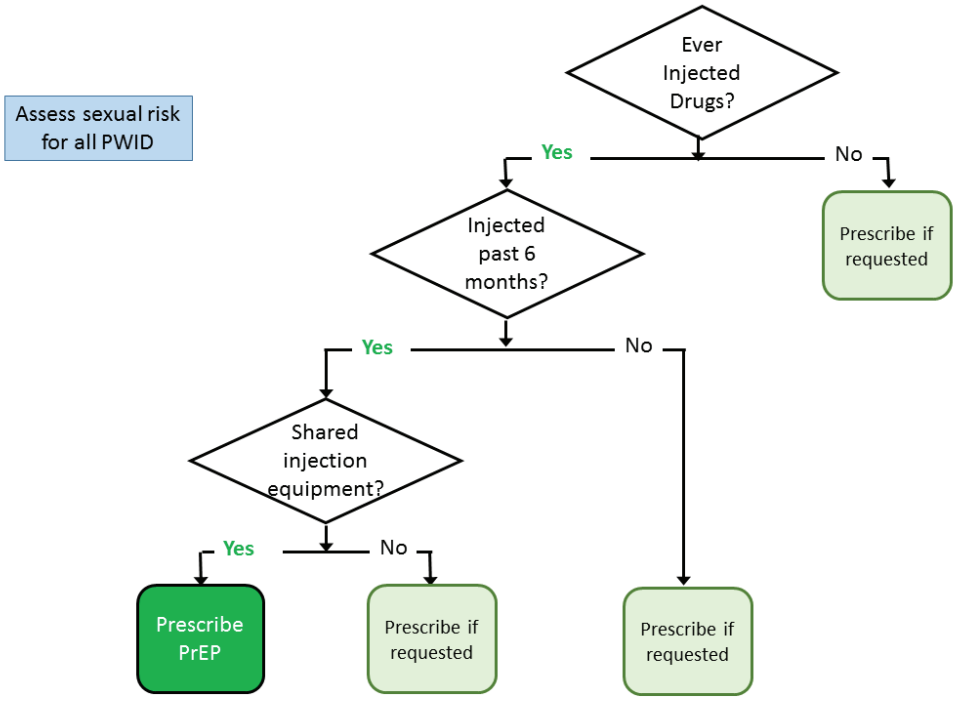
Although the annual number of new HIV infections among PWID in the United States has declined, a sizable number occur each year. In 2018, PWID (including MSM/PWID) accounted for 7% of estimated incident HIV infections.[19] According to the National HIV Behavioral Surveillance System (NHBS)[51] data collected in 2018, substantial proportions of HIV-negative PWID report receptive sharing of syringes (33%) and receptive sharing of injection equipment (55%), both of which may lead to HIV exposure. Few (1%) reported using PrEP in the previous 12 months. Data from NHBS also demonstrate that most PWID report sexual behaviors that confer risk of HIV acquisition. Among HIV-negative PWID males, 69% reported having had condomless vaginal sex in the prior 12 months, and 4% reported having had condomless anal sex with a male partner. Among HIV-negative PWID females, 79% reported having had condomless vaginal sex, and 27% reported having had condomless anal sex. 33% of HIV negative PWID reported their most recent sex was condomless sex with a partner known to have HIV. Because most PWID are sexually active, and many acquire HIV from sexual exposures,[52, 53] they should be assessed for both sexual and injection behaviors that indicate HIV risk. The only randomized clinical PrEP trial conducted with PWID found that TDF was effective in preventing HIV acquisition but somewhat less effective than F/TDF in person with only sexual risk of HIV acquisition.[7] In addition, antiretrovirals are effective as post-exposure prophylaxis against needlestick exposures[54] and as treatment for HIV infection in PWID. Therefore, PWID are likely to benefit from PrEP with any FDA-approved medication with or without an identified sexual behavior risk of HIV acquisition.

Lastly, non-sterile injection with shared syringes or other injection equipment sometimes occurs among transgender persons while administering non-prescribed gender-affirming hormones or among persons altering body shape with silicone or other "fillers."[55-57] Providing PrEP to persons who report non-sterile injection behaviors that can place them at substantial risk of acquiring HIV will contribute to HIV prevention efforts.

Current evidence is sufficient to recommend that all adult patients be screened for injection practices or other illicit drug use. The USPSTF[22] recommends that clinicians be alert to the signs and symptoms of illicit drug use in patients. Clinicians should determine whether patients who are currently using illicit drugs are in (or want to receive) medication-assisted therapy, in-patient drug treatment, or behavioral therapy for substance use disorder. For persons with a history of injecting illicit drugs but who are currently not injecting, clinicians should assess the risk of relapse along with the patients' use of relapse prevention services (e.g., a drug-related behavioral support program, use of mental health services, medication-assisted therapy,12-step program).

Figure 3 outlines a set of brief questions designed to assess a key set of injection practices that are associated with the risk of HIV acquisition. For a scored risk index predictive of incident HIV infection among PWID,[58] see the Clinical Providers' Supplement, Section 7.

Figure 3 Assessing Indications for PrEP in Persons Who Inject Drugs



PrEP and other HIV prevention should be provided and integrated with prevention and clinical care services for the other non-HIV health threats PWID may face (e.g., hepatitis B and C infection, abscesses, septicemia, endocarditis, overdose).[59] In addition, referrals for treatment of substance use disorder, mental health services, harm reduction programs, syringe service programs (SSPs) where available or access to sterile injection equipment, and social services may be indicated.

Laboratory Tests and Other Diagnostic Procedures

All patients whose sexual or drug injection history indicates consideration of PrEP and who are interested in taking PrEP, as well as patients without indications who request PrEP, must undergo laboratory testing to identify persons for whom this intervention could be harmful or for whom it could present specific health risks that would require close monitoring.

HIV testing

HIV testing with confirmed results is required to document that patients do not have HIV when they start taking PrEP medications (Figure 4a). For patient safety, HIV testing should be repeated at least every 3 months after oral PrEP initiation (i.e., before prescriptions are refilled or reissued) or every 2 months when CAB injections are being given. This requirement should be explained to patients during the discussion about whether PrEP is appropriate for them.

The CDC and USPSTF recommend that MSM, PWID, patients with a sex partner who has HIV, and others at substantial risk of HIV acquisition undergo an HIV test at least annually or for those with additional risk factors, every 3-6 months.[60, 61] However, outside the context of PrEP delivery, testing is often not done as frequently as recommended.[62-64]

Clinicians should document a negative HIV test result within the week before initiating (or reinitiating) PrEP medications, ideally with an antigen/antibody test conducted by a laboratory. The required HIV testing before initiation can be accomplished by (1) drawing blood (serum) and sending the specimen to a laboratory for an antigen/antibody test or (2) performing a rapid, point-of-care, FDA-approved, fingerstick antigen/antibody blood test (see figure 4a). In the context of PrEP, rapid tests that use oral fluid should not be used to screen for HIV infection because they are less sensitive for the detection of acute or recent infection than blood tests.[65] Clinicians should not accept patient-reported test results or documented anonymous test results. PrEP should not be prescribed in the event of a preliminary positive HIV antibody-only test unless negative HIV status is confirmed according to the local laboratory standard practice.[66] If a diagnosis of HIV infection is confirmed, HIV viral load, resistance testing, and CD4 lymphocyte tests should be ordered to assist in future treatment decisions.

See http://www.cdc.gov/hiv/testing/laboratorytests.html for FDA-approved HIV tests, specimen requirements, and time to detection of HIV infection.

Acute HIV Infection

In clinical trials of oral tenofovir-based PrEP, drug-resistant virus has developed in a small number of trial participants with unrecognized acute HIV infection and for whom PrEP had been dispensed, including most often the M184V/I mutation associated with emtricitabine resistance and less frequently the K65R mutation associated with tenofovir resistance.[67] In these trials, no resistance mutations emerged among persons who acquired antiretroviral-sensitive HIV while taking PrEP as prescribed. Therefore, identifying people with possible acute infection is critical to ensure persons with HIV are not exposed to drug pressure from PrEP that might induce antiretroviral resistance and limit future treatment options.[68] Among persons receiving CAB injections for PrEP, integrase strand transfer inhibitor (INSTI) resistance mutations were found in 4 of 9 patients with incident HIV infections and was not seen in patients who have stopped injections (i.e., during the "tail" period when drug levels are slowly declining).[13]

Clinicians should suspect acute HIV infection in persons who report having engaged in exposure-prone behaviors in the 4 weeks prior to evaluation for PrEP (e.g., a condom broke during sex with an HIV-infected partner, relapse to injection drug use with shared injection equipment). For all PrEP candidates with a negative or an indeterminate result on an HIV antigen/antibody, and those reporting a recent possible HIV exposure event, clinicians should next solicit a history of nonspecific signs or symptoms of viral infection during the preceding month or on the day of evaluation[69, 70] (Table 2).

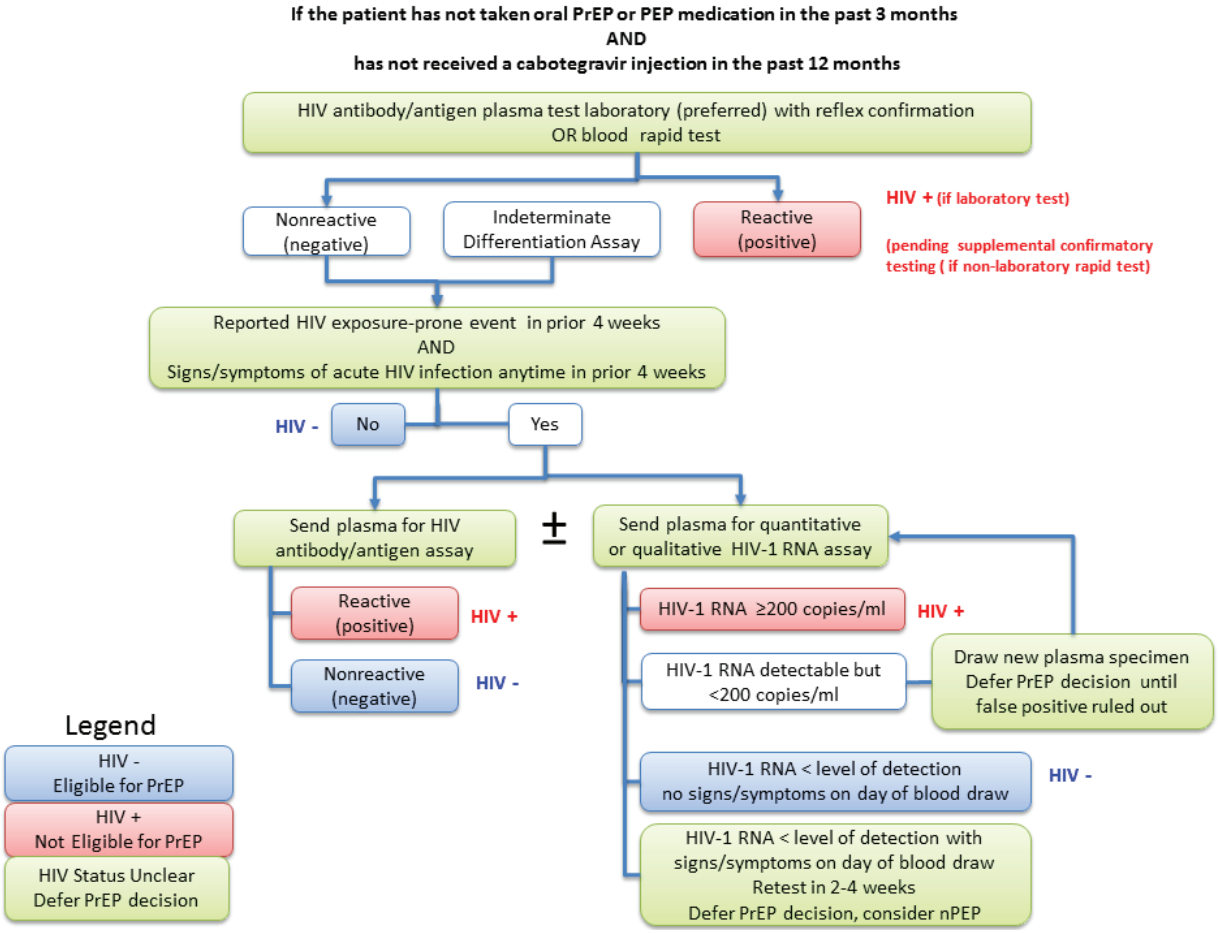
Table 2: Clinical Signs and Symptoms of Acute (Primary) HIV Infection[71]

Features	Overall (n = 375) %	Sex		Route of transmission	
		Male (n = 355) %	Female (n = 23) %	Sexual (n = 324) %	Injection Drug Use (n = 34) %
Fever	75	74	83	77	50
Fatigue	68	67	78	71	50
Myalgia	49	50	26	52	29
Skin rash	48	48	48	51	21
Headache	45	45	44	47	30
Pharyngitis	40	40	48	43	18
Cervical adenopathy	39	39	39	41	27
Arthralgia	30	30	26	28	26
Night sweats	28	28	22	30	27
Diarrhea	27	27	21	28	23

Figure 4a below illustrates the recommended clinical testing algorithm to establish HIV status before the initiation of PrEP in persons without recent antiretroviral prophylaxis use. Laboratory

antigen/antibody tests are preferred over rapid antigen/antibody tests (less preferred) because they have the highest sensitivity for detecting acute HIV infection, which is associated with high viral loads. While HIV-1 RNA testing is sensitive (a preferred option), healthcare providers should be aware that available assays might yield false-positive low viral load results (e.g., <200 copies/ml) among persons without HIV.[72, 73] Without confirmatory tests, such false-positive results can lead to misdiagnosis of HIV infection.[37, 74, 75] When clinicians prescribe PrEP based solely on the results of point of care rapid tests, a laboratory antigen/antibody test should always be ordered at the time baseline labs are drawn. This will increase the likelihood of detecting unrecognized acute infection so that the patient can be transitioned from PrEP to antiretroviral treatment in a timely manner.

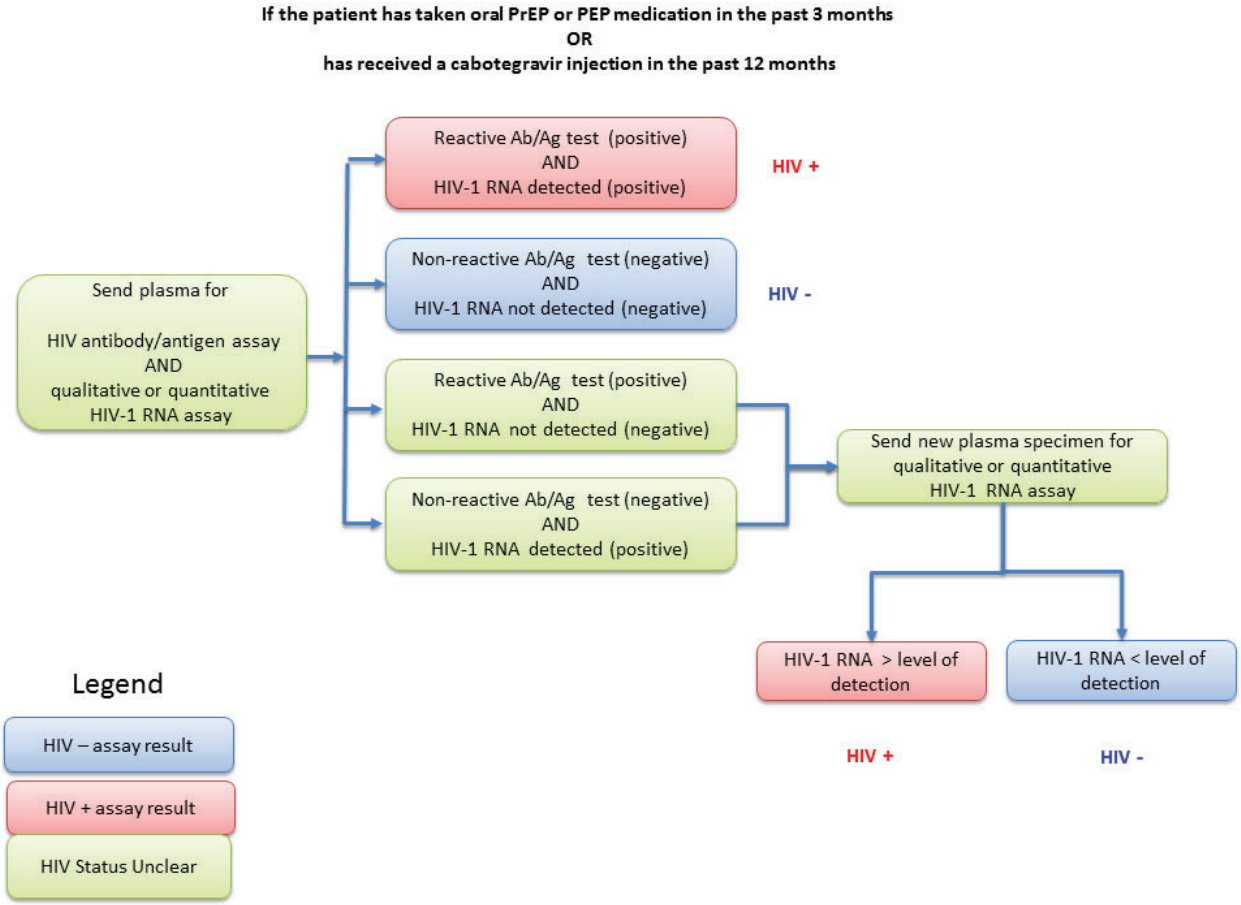
Figure 4a Clinician Determination of HIV Status for PrEP Provision to Persons without Recent Antiretroviral Prophylaxis Use



Recent data have shown that the performance of HIV tests in persons who acquire HIV infection while taking antiretroviral medications for PrEP differs from test performance in persons not exposed to antiretrovirals at or after the time of HIV acquisition[76, 77]. The antiretrovirals used for PrEP can suppress early viral replication which can affect the timing of antibody development.

In HPTN 083, detection among participants in the cabotegravir group with antigen/antibody testing was delayed by a mean of 62 days compared to detection by qualitative HIV-1 RNA assay for infections determined to have been present at baseline; the delay was 98 days for incident infections. Among participants in the F/TDF group, detection by antigen/antibody testing was delayed by a mean of 34 days from qualitative HIV-1 RNA detection for baseline infections and 31 days for incident infections[78]. In retrospective testing of stored specimens, reversion of Ag/Ab tests was seen for some specimens from persons who received cabotegravir injections near the time of infection. For that reason, a different HIV testing algorithm is recommended at follow-up visits for persons taking PrEP medication (Figure 4b).

Figure 4b Clinician Determination of HIV Status for PrEP Provision to Persons with Recent or Ongoing Antiretroviral Prophylaxis Use



Testing for Sexually Transmitted Infections

Tests to screen for syphilis are recommended for all adults prescribed PrEP, both at screening and at semi-annual visits. See the 2021 STD guidelines for recommended assays.[79]

Tests to screen for gonorrhea are recommended for all sexually active adults prescribed PrEP, both at screening, for MSM at quarterly visits, and for women at semi-annual visits. Tests to screen for chlamydia are recommended for all sexually active MSM prescribed PrEP, both at screening prior to initiation and at quarterly visits.

Chlamydia is very common, especially in young women[80] and does not correlate strongly with risk of HIV acquisition[81, 82] so does not serve as an indication for initiating PrEP. However, because it is a frequent infection among sexually active women at high risk, screening for chlamydia is recommended at initiation and every 12 months for all sexually active women as a component of PrEP care.[83]

For MSM, gonorrhea and chlamydia screening using NAAT tests are preferred because of their sensitivity. Pharyngeal, rectal, and urine specimens should be collected ("3-site testing") to maximize the identification of infection, which may occur at any of these sites of exposure during sex. Patient self-collected samples have equivalent performance as clinician-obtained samples[84-86] and can help streamline patient visit flow.

For women, both syphilis and gonorrhea correlate with risk of HIV acquisition.[81, 82, 87] Gonorrhea screening of vaginal specimens by NAAT tests are preferred and may also be self-collected. Although not indicated for all women who report anal sex, women being prescribed PrEP who report engaging in anal sex are at higher risk[88] and so rectal specimens for gonorrhea and chlamydia testing should be collected in addition to vaginal specimens.[88-91] Studies have estimated that 29% of HIV infections in women are linked to sex with MSM (i.e., bisexual men),[92, 93] a population with significantly higher prevalence of gonorrhea than men who have sex only with women. More than one-third of women report having ever had anal sex,[94, 95] and 38% of women at high risk of HIV acquisition in the HPTN 064 trial reported condomless anal sex in the 6 months prior to enrollment.[96] Identifying asymptomatic rectal gonorrhea in women at substantial risk for HIV acquisition and providing treatment can benefit the woman's health and help reduce the burden of infection in her sexual networks as well.[97, 98]

Heterosexually-active adults and adolescents being evaluated for, or being prescribed PrEP, in whom gonorrhea or chlamydia infection is detected, should be offered expedited partner therapy (EPT),[99-101] especially for those patients whose partners are unlikely to access timely evaluation and treatment. EPT is legal in most states but varies by chlamydia or gonorrhea infection. Providers should visit http://www.cdc.gov/std/ept to obtain updated information for their state. In light of limited data on the use of EPT for gonorrhea or chlamydial infection among MSM and the potential for other bacterial STIs in MSM partners, shared clinical decision-making regarding EPT is recommended. Patients with syphilis or HIV diagnosed should be referred for partner services.[102, 103]

Laboratory Tests for Patients Being Considered for Oral PrEP

RENAL FUNCTION

In addition to confirming that any patient starting PrEP medication is not infected with HIV, a clinician must assess renal function because decreased renal function is a potential safety issue for the use of F/TDF or F/TAF as PrEP.

Both F/TDF and F/TAF are widely used in combination antiretroviral regimens for HIV treatment.[37] Among persons with HIV prescribed TDF-containing regimens, mild decreases in renal function (as measured by estimated creatinine clearance (eCrCl) have been documented, and occasional cases of acute renal failure, including Fanconi's syndrome, have occurred.

In observational studies and clinical trials of F/TDF PrEP use, small decreases in renal function were likewise observed; these mostly reversed when PrEP was discontinued.[104, 105] In one observational study with F/TDF, the development of decreased renal function was more likely in patients >50 years of age or who had an eCrCl <90 ml/min when initiating PrEP with F/TDF.[106, 107] In the single clinical trial of F/TAF for PrEP among MSM (and a small number of TGW), no decrease in renal function was observed.[4, 108] There was no difference in clinically important renal health measures (e.g., grade 3 or 4 serious adverse renal events) between men taking F/TDF or F/TAF in the DISCOVER trial. However, changes were seen in some biochemical markers of proximal tubular function (e.g., β2-microlobulin:creatinine ratio, retinol binding protein:creatinine ratio) that favored F/TAF.[4] This may indicate a longer-term safety benefit of prescribing F/TAF for men with pre-existing risk factors for renal dysfunction (e.g., hypertension, diabetes).

Clinical trials and observational studies of F/TDF for PrEP have demonstrated safety when prescribed to healthy, HIV-uninfected adults with an eCrCl≥60 ml/min. Safety data for F/TDF prescribed for PrEP to patients with renal function <60 ml/min are not available. F/TAF is approved for PrEP use in patients with an eCrCl ≥30 ml/min.[4] Therefore, for all persons considered for PrEP with either F/TDF or F/TAF, a serum creatinine test should be done, and an eCrCL should be calculated by using the Cockcroft-Gault formula (see Box A). Any person with an eCrCl of ≥60 ml/min can safely be prescribed PrEP with F/TDF. PrEP with F/TAF can be safely prescribed for persons with eCrCl of <60 ml/min but ≥30 ml/min.

Box A: Cockcroft-Gault Formula

Basic Formula[109]

$eCrCl_{CG}$ = [[(140 - age) × IBW × 0.85 for females] ÷ (serum creatinine × 72)]

IBW = ideal body weight Males: IBW = 50 kg + 2.3 kg for each inch over 5 feet
Females: IBW = 45.5 kg + 2.3 kg for each inch over 5 feet

Age in years, weight in kg, and serum creatinine in mg/100mL

Testing for Infection with Hepatitis B Virus (HBV)

Tenofovir and emtricitabine are also used to treat chronic HBV infection. When these drugs are discontinued, patients with HBV infection may experience clinically significant hepatitis flares. Ideally, prior to prescribing PrEP, patients should be screened for HBV (https://www.cdc.gov/hepatitis/HBV/PDFs/SerologicChartv8.pdf) so that in the event they have HBV infection, they can be informed of the danger of stopping PrEP medication without appropriate monitoring for potential hepatitis flares. However, PrEP initiation should not be withheld while waiting for HBV test results. Patients who are not immune and do not have HBV infection should be vaccinated. Providers prescribing F/TDF or F/TAF as PrEP for patients who have HBV infection (either known or first diagnosed as part of a PrEP evaluation) should do so in consultation with a provider expert in HBV treatment.

Lipid Profile (F/TAF)

In the DISCOVER clinical trial comparing F/TDF and F/TAF for PrEP in MSM and transgender women, higher rates of triglyceride elevation and of weight gain were seen among men taking F/TAF than among men taking F/TDF. F/TDF has been associated with reductions in HDL and LDL cholesterol that are not seen with F/TAF in the DISCOVER Trial.[4] This may indicate a longer-term safety risk when prescribing F/TAF PrEP for men with pre-existing cardiovascular health risk factors (e.g., obesity, age, lipid profiles). All persons prescribed F/TAF for PrEP should have monitoring of triglyceride and cholesterol levels every 12 months. Lipid-lowering medications should be prescribed when indicated.

Testing not Indicated Routinely for Oral PrEP Patients

In clinical trials for PrEP with F/TDF or F/TAF, additional testing was done to evaluate safety. Findings in those trials indicated that DEXA scans to monitor bone mineral density (see section on optional tests below), liver function tests, hematologic assays, and urinalysis are not indicated for the routine care of all persons prescribed daily oral PrEP.

Initial PrEP Prescription Visit for All Patients

Goals of PrEP Therapy

The ultimate goal of PrEP is to prevent the acquisition of HIV infection with its resulting morbidity, mortality, and cost to individuals and society. Therefore, clinicians initiating the provision of PrEP should:

- Prescribe medication regimens that are proven safe and effective for uninfected patients who meet recommended criteria for PrEP initiation to reduce their risk of HIV acquisition;
- Educate patients about the medications and the regimen to maximize their safe use;
- Provide support for medication-adherence to help patients achieve and maintain protective levels of medication in their bodies;
- Provide HIV risk-reduction support and prevention services or service referrals to help patients minimize their exposure to HIV and other STIs;
- Provide (or refer for) effective contraception to persons with childbearing potential who are taking PrEP and who do not wish to become pregnant; and
  Monitor patients to detect HIV infection, medication toxicities, and levels of risk behavior in order to make indicated changes in strategies to support patients' long-term health.

Same Day PrEP Prescribing

For all patients, safely initiating PrEP requires determination of HIV status and assessment of renal function. Safely shortening the time to initiation of PrEP may be useful for some patients. For example, some patients may have time or work constraints that impose a significant burden to return to the clinic a week or two after evaluation for a prescription visit. Other patients report risk behaviors that put them at substantial risk of acquiring HIV infection in the time between visits for evaluation and PrEP prescription. However, for all patients, safely initiating PrEP requires determination of HIV status and assessment of renal function. Some sites have developed protocols that allow them to safely initiate PrEP on the same day as the initial evaluation for many patients.[110-112]

To use a same-day PrEP initiation protocol, the clinic must be able to:

- Conduct point-of-care HIV testing, ideally with an antigen/antibody fingerstick or other blood test
  - Where same-day results can be obtained, laboratory-based antigen/antibody test or an HIV-1 RNA test can be used (and is preferred)
  - Oral fluid HIV testing should not be used in the context of PrEP initiation
- Draw blood for laboratory creatinine and HIV testing when same day HIV and creatinine test results are not available

    - Where available, a point of care blood creatinine test may be used
- Provide assistance for eligible patients to enroll in health insurance, medication co-payment assistance, or medication assistance programs for those who are uninsured or underinsured
- Provide rapid follow-up contact for patients whose laboratory test results indicate HIV infection or renal dysfunction
- Provide scheduled follow-up care appointments
- Have clinicians available to dispense or prescribe oral PrEP medication, to administer a gluteal intramuscular injection of CAB, or optionally prescribe a daily oral CAB lead-in for 4 weeks.

Optionally, clinics would be able to provide (on the first day):

- STI specimen collection for laboratory testing

Same-day PrEP initiation **is not appropriate** for:

- Patients who express ambivalence about starting PrEP (e.g., need more time to think)
- Patients for whom blood cannot be drawn for laboratory testing
- Patients with signs/symptoms and sexual history indicating possible acute HIV infection
- Patients with history of renal disease or associated conditions (e.g., hypertension, diabetes)
- Patients without insurance or a means to pay when picking up the prescribed medication that day
- Patients who do not have a **confirmed** means of contact should laboratory test indicate a need to discontinue PrEP (e.g., HIV infection, unanticipated renal dysfunction)

Same-day PrEP initiation **may not be appropriate** for:

- Patients with a very recent possible HIV exposure but no signs and symptoms of acute infection (should be evaluated for nPEP before PrEP)
- Patients who may not be easily contacted for return appointments
- Patients with mental health conditions that are severe enough to interfere with understanding of PrEP requirements (adherence, follow-up visits)

Nonoccupational Postexposure Prophylaxis

Patients not receiving PrEP who seek care within 72 hours after an isolated sexual or injection-related HIV exposure should be evaluated for the potential need for nPEP.[113] If the exposure is isolated (e.g., sexual assault, infrequent condom failure), nPEP should be prescribed, but PrEP or other continued antiretroviral medication is not indicated after completion of the 28-day PEP course.

Patients who seek one or more courses of nPEP and who are at risk for ongoing HIV exposures should be evaluated for possible PrEP use after confirming they have not acquired HIV[142]. Because HIV infection has been reported in association with exposures soon after completing an nPEP course,[114, 115] daily PrEP may be more protective than repeated intermittent episodes of nPEP. Patients who engage in behaviors that result in frequent, recurrent exposures that would require sequential or near-continuous courses of nPEP should be offered PrEP at the conclusion of their 28-day nPEP medication course. Because nPEP is highly effective when taken as prescribed, a gap is unnecessary between ending nPEP and beginning PrEP. Upon documenting HIV-negative status, preferably by using a laboratory-based Ag/Ab test or plasma HIV-1 RNA test (see figure 4), daily use of F/TDF OR F/TAF or CAB injections every 2 months can begin immediately for patients for whom PrEP is indicated. See Clinical Providers' Supplement Section 8 for a recommended transition management strategy.

In contrast, patients fully adhering to a daily PrEP regimen or who have received CAB injections on schedule do not need nPEP if they experience a potential HIV exposure while on PrEP. PrEP is highly effective when taken daily or near daily. For patients who report taking their PrEP medication sporadically, and those who did not take it within the week before the recent exposure, initiating a 28-day course of nPEP might be indicated. In that instance, all nPEP baseline and follow-up laboratory evaluations should be conducted (https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf). If, after the 28-day nPEP regimen is completed, the patient is confirmed to be HIV uninfected, any previously experienced barriers to PrEP adherence should be evaluated and if addressed, a PrEP regimen can be reinitiated.

Prescribing Oral PrEP

Recommended Oral Medication

The fixed-dose combination of F/TDF in a single daily dose (see Table 3), is approved by FDA for PrEP in healthy adults and adolescents at risk of acquiring HIV. F/TDF continues to be most commonly prescribed for PrEP (including PWID) who meet criteria for PrEP use. F/TDF is available as a generic medication that is equivalent to the brand name medication (Truvada).

F/TAF has recently been approved for daily PrEP use by men and transgender women at sexual risk. F/TAF is not approved for PrEP use by women at risk through receptive vaginal sex for whom F/TDF should be prescribed instead. F/TAF and F/TDF have equivalent high efficacy and safety as PrEP for men at sexual risk.[3, 116] Generic F/TAF is not available.

For most patients, there is no need to switch from F/TDF to F/TAF. While incremental differences in laboratory markers of bone metabolism and renal function have been seen in some studies, no differences in clinically meaningful adverse events have been seen[4]. However, F/TAF is indicated for patients with eCrCl <60 ml/min but ≥30 ml/min. Either F/TDF or F/TAF can be

used when eCrCl ≥60 ml/min.[117] Clinicians may prefer F/TAF for persons with previously documented osteoporosis or related bone disease but routine screening for bone density is not recommended for PrEP patients.

Table 3: Recommended Oral PrEP Medications

Generic Name	Trade Name	Dose	Frequency	Most Common Side Effects[109,110]
F/TDF	Truvada	200 mg/300 mg	Once a day	Headache, abdominal pain, weight loss
F/TAF	Descovy	200 mg/25 mg	Once a day	Diarrhea

WHAT NOT TO USE FOR ORAL PREP

No antiretroviral regimens should be used for PrEP other than a daily oral dose of F/TDF or F/TAF or injections of CAB every 2 months
No other medications or other dosing schedules are approved by FDA for PrEP to prevent HIV acquisition among otherwise healthy adults and adolescents.

- Do not prescribe other antiretroviral medications either in place of, or in addition to F/TDF or F/TAF.
- Do not prescribe other than continuous daily dosing of oral PrEP with the possible exception of MSM (see section on clinical considerations for MSM).
- Do not provide oral PrEP as expedited partner therapy (i.e., do not prescribe for a person not in your care).

Data on drug interactions and longer-term toxicities of TDF and TAF have been obtained mostly from studies of their use in treatment of HIV-infected persons. Small studies have also been done in HIV-uninfected, healthy adults (see Table 4).

Table 4: Oral PrEP Medication Drug Interactions[37, 118, 119]

	TDF	TAF
Buprenorphine	No significant effect No dosage adjustment necessary	
Methadone	No significant effect No dosage adjustment necessary	
Oral contraceptives	No significant effect No dosage adjustment necessary	
Feminizing hormones (Spironolactone, estrogens)	Lower tenofovir-diphosphate rectal tissue levels (unknown if it affects PrEP effectiveness). TDF does not affect hormone levels	*No data available*
Acyclovir, valacyclovir, cidofovir, ganciclovir, valganciclovir, aminoglycosides, high-dose or multiple NSAIDS or other drugs that reduce renal function or compete for active renal tubular secretion	Serum concentrations of these drugs and/or TDF may be increased. Monitor for dose-related renal toxicities	*No data available*
Adefovir	**Do not co-administer with TDF** Serum concentration of TDF may be increased, monitor for toxicities	*No data available*
Ledipasvir, sofosbuvir, velpatasvir, voxilaprevir	Serum concentrations of TDF may be increased. Monitor for toxicities	No significant effect
St John's Wort	No significant effect	**Do not co-administer with TAF** Decrease in TAF concentration possible
Rifampin	No significant effect	**Do not co-administer with TAF unless benefits outweigh risks**
Rifabutin, Rifapentine	No significant effect	**Do not co-administer with TAF**

Providing PrEP by Telehealth

Recent expansion of telehealth visits to replace some or all in-clinic visits have led to adaptations for provision of PrEP.[120, 121] These adaptations can include the following procedures:

- Conduct PrEP screening, initiation, or follow-up visits by phone or web-based consult with clinicians
- Obtain specimens for HIV, STI, or other PrEP-related laboratory tests by:
    - Laboratory visits for specimen collection only
    - Order home specimen collection kits for specified tests.
        - Specimen kits are mailed to the patient's home and contain supplies to collect blood from a fingerstick or other appropriate method (e.g. self-collected swabs and urine).
        - The kit is then mailed back to the lab with test results returned to the clinician who acts on results accordingly.
    - For HIV testing, only if a patient has no possible access to a lab (in-person or by mail), clinicians can provide an oral swab-based self-test that the patient can conduct and report the result to the clinician (e.g., photo of the test result). Because of the low sensitivity of oral Ab tests in detection of acute HIV infection, this should only be used for PrEP patients as a last resort.
- When HIV-negative status is confirmed, provide a prescription for a 90-day supply of PrEP medication (rather than a 30-day supply with two refills) to minimize trips to the pharmacy and to facilitate PrEP adherence.

Counseling to Support Oral Medication Adherence and Persistence in Care

Data from the published clinical trials and observational studies of daily oral PrEP indicate that medication adherence is critical to achieving the maximum prevention benefit (see Figure 5) and reduce the risk of selecting for a drug-resistant virus if HIV infection occurs.[122-124]

Figure 5: Adherence and F/TDF PrEP Efficacy in MSM

Weekly Medication Adherence Estimated by Drug Concentration	HIV Incidence per 100 person/years
None	4.2
≤2 pills/week	2.3
2-3 pills/week	0.6
≥4 pills/week	0.0

Data from a pharmacokinetics study with MSM given directly observed TDF dosing were applied in a statistical model to assess the relationship of dosing frequency to protective efficacy. Based on the intracellular concentrations of the active form of TDF (tenofovir diphosphate), HIV risk reduction efficacy was estimated to be of 99% for 7 doses per week, 96% for 4 doses per week, and 76% for 2 doses per week.[125, 126] This finding suggests that although there is some "forgiveness" for occasional missed doses of F/TDF PrEP for MSM, a high level of prevention efficacy requires a high level of adherence to daily medication.

However, a laboratory study comparing vaginal and colorectal tissue levels of active metabolites of TDF and FTC found that drug levels associated with significant protection against HIV

infection required 6-7 doses per week (>85% adherence) for lower vaginal tract tissues but only 2 doses per week (28% adherence) for colorectal tissues.[127] This strongly suggests that there is less "forgiveness" for missed doses among women than among MSM.

Approaches that can effectively support medication adherence include educating patients about their medications; helping them anticipate and manage side effects; asking about adherence successes and issues at follow-up visits (Box B),[128] helping them establish dosing routines that mesh with their work and social schedules; providing reminder systems and tools; addressing financial, substance use disorder, or mental health needs that may impede adherence; and facilitating social support. Data from PrEP trials and observational studies have observed lower adherence among younger MSM when seen quarterly but higher adherence when visits were monthly.[9, 10]

A brief medication adherence question

"Many people find it difficult to take a medicine every day.

Thinking about the last week; on how many days have you **not** taken your medicine?"

In terms of patient education, clinicians must ensure that patients understand clearly how to take their medications (i.e., when to take them, how many pills to take at each dose) and what to do if they experience problems (e.g., what constitutes a missed dose [number of hours after the failure to take a scheduled dose], what to do if they miss a dose). Patients should be told to take a single missed dose as soon as they remember it, unless it is almost time for the next dose. If it is almost time for the next dose, patients should skip the missed dose and continue with the regular dosing schedule.

Side effects can lead to non-adherence, so clinicians need a plan for addressing them. Clinicians should tell patients about the most common side effects and should work with patients to develop a specific plan for handling them, including the use of specific over-the-counter medications that can mitigate symptoms. The importance of using condoms during sex for STI prevention, and for HIV prevention in patients who decide to stop taking their PrEP medications, should be reinforced.

Clinicians should reinforce patient understanding that the benefits of PrEP medication use outweigh its reported risks and that the schedule of follow-up monitoring visits is designed to address any potential medication-related harm in a timely manner. Clinician should review signs and symptoms of active HIV infection and the need for rapid evaluation and HIV testing and should review how to safely discontinue or restart PrEP use (e.g., get an HIV test).

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

Using a broad array of health care professionals (e.g., physicians, nurses, case-managers, physician assistants, clinic-based and community pharmacists) that work together on a health care team to influence and reinforce adherence instructions[129] significantly improves medication adherence and may alleviate the time constraints of individual providers.[130, 131] This team-based approach may also provide a larger number of providers to counsel patients about self-management of behavioral risks.

Managing Side Effects of Oral PrEP

Patients taking PrEP should be informed of potential side effects. Some (<10%) of patients prescribed F/TDF or F/TAF experience a "start-up syndrome" that usually resolves within the first month of taking PrEP medication. This may include headache, nausea, or abdominal discomfort. Clinicians should discuss the use of over-the-counter medications should these temporary side effects occur. Patients should also be counseled about signs or symptoms that indicate a need for urgent evaluation when they occur between scheduled follow-up visits (e.g., those suggesting possible acute renal injury or acute HIV infection). Weight gain is a reported side effect of F/TAF for PrEP.[4, 119]

Time to Achieving Protection with Daily Oral PrEP

The time from initiation of daily PrEP use to maximal protection against HIV infection is unknown. It has been shown that the pharmacokinetics of TDF and FTC vary by tissue,[127, 132]

but there is not scientific consensus on what tissue-specific intracellular concentrations are protective (see review of available data here: https://www.youtube.com/watch?v=5WfNqJPIIH8).

Data from exploratory F/TDF pharmacokinetic studies suggest that maximum intracellular concentrations of TFV-DP, the active form of tenofovir, are reached in blood PMBCs after approximately 7 days of daily oral dosing, in rectal tissue at approximately 7 days, and in cervicovaginal tissues at approximately 20 days.

F/TAF pharmacokinetic study data related to potential time to tissue-specific maximum concentrations are not yet available, so the time from initiation of daily F/TAF for PrEP to maximal tissue protection from HIV infection is not known.

Data is not available for either F/TDF or F/TAF PrEP in penile tissues susceptible to HIV infection to inform considerations of time to protection for male insertive sex partners.

Follow-up PrEP Care Visits for Oral PrEP Patients

Clinical Follow-up and Monitoring For Oral PrEP

Once daily oral PrEP is initiated, patients should return for follow-up approximately every 3 months by in-person, virtual, or phone visits. Clinicians may wish to schedule contact with patients more frequently at the beginning of PrEP either by phone or clinic visit (e.g., 1 month after initiation, to assess and confirm HIV-negative test status, assess for early side effects, discuss any difficulties with medication adherence, and answer questions.

All patients receiving oral PrEP should be seen in follow-up:

- **At least every 3 months to:**
  - Repeat HIV testing and assess for signs or symptoms of acute infection to document that patients are still HIV negative (see Figure 4);
  - Provide a prescription or refill authorization of daily PrEP medication for no more than 90 days (until the next HIV test);
  - Assess and provide support for medication adherence and risk-reduction behaviors;
  - Conduct STI testing for sexually active persons with signs or symptoms of infection and screening for asymptomatic MSM at high risk for recurrent bacterial STIs (e.g., those with syphilis, gonorrhea, or chlamydia at prior visits or multiple sex partners); and
  - Respond to new questions and provide any new information about PrEP use.
- **At least every 6 months to:**
  - Monitor eCrCl for persons age ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation.

- If other threats to renal safety are present (e.g., hypertension, diabetes), renal function may require more frequent monitoring or may need to include additional tests (e.g., urinalysis for proteinuria).
- A rise in serum creatinine is not a reason to withhold treatment if eCrCl remains ≥60 ml/min for F/TDF or ≥30 for F/TAF.
- If eCrCl is declining steadily (but still ≥60 ml/min for F/TDF or ≥30 ml/min for F/TAF), ask if the patient is taking high doses of NSAID or using protein powders; consultation with a nephrologist or other evaluation of possible threats to renal health may be indicated.

- Conduct STI screening for sexually active persons (i.e., syphilis, gonorrhea, for all PrEP patients and chlamydia for MSM and TGW even if asymptomatic.
- Assess interest in continuing or discontinuing PrEP.

- **At least every 12 months to:**
  - Monitor eCrCl for all patients continuing on PrEP medication.
  - Monitor triglyceride, cholesterol levels, and weight for patients prescribed F/TAF for PrEP.
  - Conduct chlamydia screening for heterosexual women and men even if asymptomatic

Laboratory Testing Schedule for Oral PrEP Patients

Table 5 Timing of Oral PrEP-associated Laboratory Tests

Test	Screening/Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP
HIV Test	X*	X			X*
eCrCl	X		If age ≥50 or eCrCL <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	X
Syphilis	X	MSM /TGW	X		MSM/TGW
Gonorrhea	X	MSM /TGW	X		MSM /TGW
Chlamydia	X	MSM /TGW	X		MSM /TGW
Lipid panel (F/TAF)	X			X	
Hep B serology	X				
Hep C serology	MSM, TGW, and PWID only			MSM,TGW, and PWID only	

* Assess for acute HIV infection (see Figure 4)

Optional Assessments for Patients Prescribed Oral PrEP

Bone Health

Decreases in bone mineral density (BMD) have been observed in HIV-infected persons treated with combination antiretroviral therapy (including TDF-containing regimes).[114,115] However, it is unclear whether this 3%-4% decline would be seen in HIV-uninfected persons taking fewer antiretroviral medications for PrEP. The iPrEx trial evaluating F/TDF and the CDC PrEP safety trial in MSM evaluating TDF conducted serial dual-emission x-ray absorptiometry (DEXA) scans on a subset of MSM in the trials and determined that a small (~1%) decline in BMD that occurred during the first few months of PrEP either stabilized or returned to normal.[23,116] There was no increase in fragility (atraumatic) fractures over the 1-2 years of observation in these studies comparing those persons randomized to receive PrEP medication and those randomized to receive placebo.[117] In the DEXA substudy of the DISCOVER trial, men randomized to F/TAF showed slight mean percentage increases in BMD at the hip and spine through 96 weeks of observation, while men randomized to F/TDF showed mild decreases at both anatomic sites. However, there was no difference in the frequency of fractures between the treatment groups with 91% of fractures related to trauma.[3,76]

Therefore, DEXA scans or other assessments of bone health are not recommended before the initiation of PrEP or for the monitoring of persons while taking PrEP. However, any person being considered for PrEP who has a history of pathologic or fragility bone fractures or who has significant risk factors for osteoporosis should be referred for appropriate consultation and management.

Medication adherence drug monitoring

Several factors limit the utility of routine use of laboratory measures of medication adherence during PrEP. These factors include: (1) a lack of established concentrations in blood associated with robust efficacy of tenofovir (either TDF or TAF), or emtricitabine for the prevention of HIV acquisition in adults after exposure during penile-rectal or penile-vaginal intercourse[133] and (2) the limited but growing availability of clinical laboratories that can perform quantitation of antiretroviral medicine concentrations under rigorous quality assurance and quality control standards.

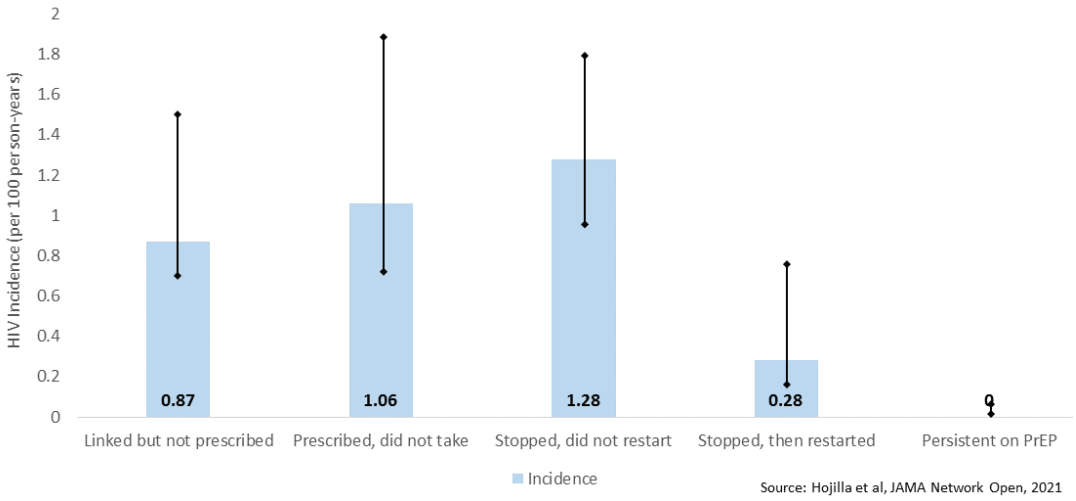
Several point-of-care tests are being used in research to assess adherence to daily oral PrEP. None are yet FDA approved and CLIA waived for point-of-care use. These tests include: a urine test that can assess adherence over the past few days,[134, 135] and a dried blood spot test that measures red blood cell concentrations of tenofovir (from either TDF or TAF) and emtricitabine active metabolites and can measure both short term (past few days) and longer term (past 6 weeks) adherence. [126, 136] A hair analysis test is being used in research to measure longer term adherence (from past 1-6 months, depending on the length of hair available).[137] For any of these measures, undetectable or low PrEP drug levels indicate the need to reinforce medication adherence. Conversely, documented high drug levels may positively reinforce patients'

adherence efforts. A home specimen-collection kit for a validated, CLIA-waived urine (very recent adherence) or dried blood spot (longer term adherence) tenofovir assay is now available from some laboratories.[121]

Discontinuing and Restarting Daily Oral PrEP

PrEP medication may be discontinued for several reasons, including patient choice, changed life situations resulting in lowered risk of HIV acquisition, intolerable toxicities, chronic nonadherence to the prescribed dosing regimen or scheduled follow-up care visits, or acquisition of HIV. How to safely discontinue and restart daily PrEP use should be discussed with patients both when starting PrEP and when discontinuing PrEP. Protection from HIV infection will wane over 7-10 days after ceasing daily PrEP use.[138, 139] Because some patients have acquired HIV soon after stopping PrEP use,[140] alternative methods to reduce risk for HIV acquisition should be discussed, including indications for nPEP and how to access it quickly if needed.

Figure 6 HIV Incidence in MSM Before, While Taking, and After Discontinuing F/TDF PrEP Use[140, 141]



Upon discontinuation of PrEP for any reason, the following should be documented in the health record:

- HIV status at the time of discontinuation;
- Reason for discontinuation; and
- Recent medication adherence and reported sexual risk behavior.

For persons with incident HIV infection, see Persons with Documented HIV Infection. See also Clinical Providers' Supplement Section 8 for a suggested management protocol.

Patients with HBV infection who discontinue taking PrEP medication should be monitored closely for hepatitis flares. Although documented to occur in some patients discontinuing tenofovir-containing medication as part of their treatment regimens, such flares have not yet been seen in HIV-uninfected patients with chronic active HBV infection who have stopped taking TDF-containing PrEP regimens. Nonetheless, when such patients discontinue PrEP, they should continue to receive care from a clinician experienced in the management of HBV infection so that if flares occur, they can be detected promptly and treated appropriately.

Any person who wishes to resume taking PrEP medications after having stopped requires the same pre-prescription evaluation as a person being newly prescribed PrEP, including an HIV test to establish that they have not acquired HIV. In addition, discuss and document the changed circumstances since discontinuing PrEP that indicate the need to restart medication and confirm the commitment to take it as prescribed.

Prescribing Cabotegravir PrEP Injections

Patients considering PrEP should be informed of all FDA approved options. Cabotegravir injections may be especially appropriate for patients with significant renal disease, those who have had difficulty with adherent use of oral PrEP and those who prefer injections every 2 months to an oral PrEP dosing schedule. Cabotegravir should not be administered to persons with a history of hypersensitivity reaction to cabotegravir.

Recommended Medication

- 600 mg of cabotegravir injected into gluteal muscle every 2 months is recommended (conditional on FDA approval) for PrEP in adults at risk of acquiring HIV.
- 30 mg daily oral cabotegravir is optional for a 4-week lead-in prior to injections.

What Not to Use

Other than those recommended in this guideline, no other injectable antiretrovirals, injection sites, or dosing schedules should be used as their efficacy is unknown.

- Do not administer or prescribe other antiretroviral medications in combination with CAB for PrEP.
- Do not administer CAB injections at any site other than gluteal muscle because the pharmacokinetics of drug absorption with injection at other sites is unknown
- Do not dispense CAB injections for use by patients for home administration (unless and until self-administration is FDA approved).
- Do not prescribe ongoing daily oral CAB (other than for lead-in prior to initiating or restarting injections).

Table 6 Cabotegravir PrEP Drug Interactions (https://www.hiv-druginteractions.org/)

Rifampicin, rifapentin	**Do not co-administer with CAB** Rifampicin and rifapentine increase metabolism of CAB and may result in significantly reduced exposure to protective levels of CAB [142, 143]
Rifabutin	**Co-administer with caution** Rifabutin moderately increases metabolism of CAB and may result in somewhat reduced exposure to protective levels of CAB[144]
Hormonal contraceptives	No significant effect[145]
Feminizing hormones (Spironolactone, estrogens)	No data yet available[146]
Carbamazepine, oxcarbazepine, phenytoin, phenobarbital	**Do not co-administer with CAB** Concern that these anticonvulsants may result in significantly reduced exposure to protective levels of CAB but strength of evidence is weak

CAB PrEP Initiation Visit

In the clinical trials of CAB injections for PrEP, patients were provided oral CAB 30 mg tablets daily for 5 weeks prior to receiving the first injection.[147] Because there were no safety concerns identified during this lead-in period or during the injection phase of the studies, an oral lead-in is not required when initiating CAB PrEP. It may be optionally used for patients who are especially worried about side effects to relieve anxiety about using the long-acting CAB injection. However, continued daily oral CAB is not recommended or FDA-approved for PrEP.

Patients who have been taking daily oral PrEP, can initiate CAB injections as soon as HIV-1 RNA test results confirm that they remain HIV negative.

Laboratory Testing For CAB PrEP Patients

Patients whose HIV test results indicate that they do not have acute or chronic HIV infection can be considered for initiation of cabotegravir injections (see Figure 4b). Because of the long duration of drug exposure following injection, exclusion of acute HIV infection is necessary with the most sensitive test available, an HIV-1 RNA assay. Ideally, this testing will be done within 1

week prior to the initiation visit. If clinicians wish to provide the first injection at the first PrEP evaluation visit based on the result of a rapid combined antigen/antibody assay, blood should always be drawn for laboratory confirmatory testing that includes an HIV RNA assay.

All PrEP patients should have baseline STI tests (see Table 1b).

Table 7 Timing of CAB PrEP-associated Laboratory Tests

Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	Q12 months	When Stopping CAB
HIV*	X	X	X	X	X	X	X
Syphilis	X			MSM^/TGW~ only	Heterosexually active women and men only	X	MSM/TGW only
Gonorrhea	X			MSM/TGW only	Heterosexually active women and men only	X	MSM/TGW only
Chlamydia	X			MSM/TGW only	MSM/TGW only	Heterosexually active women and men only	MSM/TGW only

* HIV-1 RNA assay

X all PrEP patients

^ men who have sex with men

~ persons assigned male sex at birth whose gender identification is female

Testing Not Indicated Routinely for CAB PrEP Patients

Based on the results of the CAB clinical trials,[12, 147, 148] the following laboratory tests are NOT indicated before starting CAB injection or for monitoring patients during its use: creatinine, eCrCl, hepatitis B serology, lipid panels, liver function tests.

Screening tests associated with routine primary care and not specific to the provision of CAB for PrEP are discussed in the primary care section (see Table 8)

Recommended CAB Injection

- 3 ml suspension of CAB 600 mg IM in gluteal muscle (gluteus medius or gluteus maximus)
- The use of a 2-inch needle is recommended for intramuscular injection for participants with a body-mass index (BMI) of 30 or greater, and a 1.5-inch needle for participants with a BMI of less than 30

Managing Injection site reactions

In the clinical trials, injection site reactions (pain, tenderness, induration) were frequent following CAB injections. These reactions were generally mild or moderate, lasted only a few days, and occurred most frequently after the first 2-3 injections. Patients should be informed that these reactions are common and transient. In addition, they should be provided with proactive management advice

- for the first 2-3 injections
    - take an over-the-counter pain medication within a couple of hours before or soon after the injection and continue as needed for one to two days
    - 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)
- thereafter, as needed for subsequent injections

Patient Education/Counseling

Patients should be provided an appointment for the next injection 1 month after the initial one. Patients should be educated about:

- the long "tail" of gradually declining drug levels when discontinuing CAB injections and the risk of developing a drug-resistant strain if HIV infection is acquired during that time
- the importance of keeping their follow-up appointments if they have decided not to continue with CAB injections for PrEP

Clinical Follow-Up and Monitoring For CAB Injections

Once CAB injections are initiated, patients should return for follow-up visits 1 month after the initial injection and then every 2 months.

- **At visit 1 month after initial injection (month 1, second injection)**
  - Repeat HIV-1 RNA test and assess for signs or symptoms of acute infection
  - Administer CAB injection
  - Respond to new questions

- **At each bimonthly visit (beginning with the third injection – month 3)**
  - Repeat HIV-1 RNA test and assess for signs or symptoms of acute infection
  - Administer CAB injection
  - Provide access to clean needles/syringes and drug treatment services for PWID
  - Respond to new questions and provide any new information about CAB PrEP
  - Discuss the benefits of persistent CAB PrEP use and adherence to scheduled injection visits

- **At least every 4 months (every other injection visit, beginning with the third injection-month 3)**
  - Conduct bacterial STI screening for MSM and transgender women who have sex with men – oral, rectal, urethral, blood (see Table 1b)

- **At least every 6 months (beginning with the fifth injection – month 7)**
  - Conduct bacterial STI screening for all heterosexually active women and men– [vaginal, rectal, urine - as indicated], blood (see Table 1b)

- **At least every 12 months (after the first injection)**
  - Assess desire to continue injections for PrEP
  - Conduct chlamydia screening for heterosexually active women and men even if asymptomatic

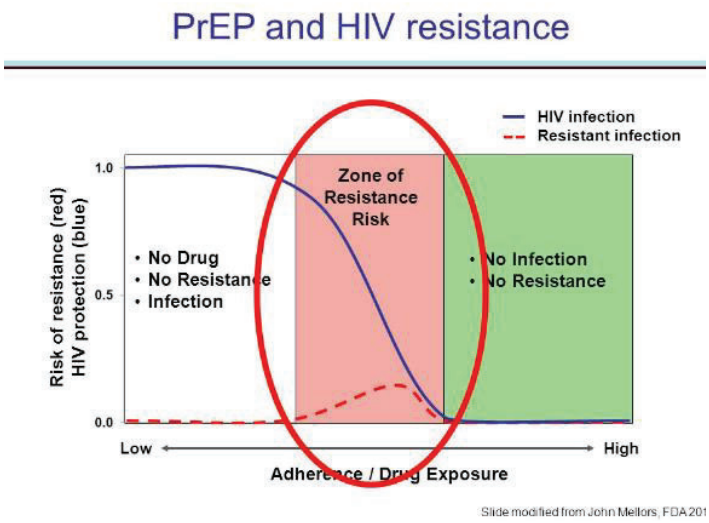
Discontinuing or Restarting CAB PrEP

Patients without HIV on follow-up visit who wish to discontinue CAB injections for PrEP or those who are a month or more late for an injection should be counseled about:

- How to safely discontinue or restart CAB injections for PrEP
- The risk of developing drug resistant HIV during the period of waning drug levels (the "tail period")
- Need for daily oral PrEP or other effective HIV prevention methods if ongoing risk of HIV exposure is anticipated

CAB levels slowly wane over many months after injections are discontinued. In the HPTN 077 trial, the median time to undetectable CAB plasma levels was 44 weeks for men and 67 weeks for women with a wide range for both sexes [149]. At some point during this "tail" phase, CAB levels will fall below a protective threshold and persist for some time at nonprotective levels exposing the patient to the risk of HIV acquisition. These lower levels of CAB may however be sufficient to apply selective pressure that selects for existing or de-novo viral strains with mutations that confer resistance to CAB or other INSTI medications. Infection with INSTI-resistant virus may complicate HIV treatment[150, 151].

Figure 7 The trade-off of PrEP drug levels and risk of HIV infection with resistant virus



For these reasons, patients discontinuing CAB injections who may be at ongoing risk of sexual and injection HIV exposure should be provided with another highly effective HIV prevention method during the months following their last injection. As with daily oral PrEP, CAB PrEP has been associated with delayed seroconversion and detection of HIV acquisition. CAB injections can be restarted at any point after determining HIV status with HIV-1 RNA testing.

When helping patients discontinue CAB PrEP safely, clinicians should:

- Re-educate patients about the "tail" and the risks during declining CAB levels
- Assess ongoing risk/indications
- If PrEP is indicated, prescribe daily oral F/TDF or F/TAF beginning within 8 weeks after last injection
- Educate about nPEP
- Continue follow-up visits quarterly for 12 months
- Conduct HIV-1 RNA tests at each quarterly follow-up visit after discontinuing CAB injections

Time to Protection With CAB PrEP

No data are yet available from clinical trials in men or women to estimate the time from initiation of CAB injections to maximal protection against HIV acquisition.

Managing PrEP Patients with Ambiguous HIV test Results

Acquiring HIV while taking daily PrEP as prescribed is very uncommon. While PrEP use has steadily increased since 2012, with more than 220,000 persons prescribed PrEP in 2018,[152] only a handful of incident HIV infections in PrEP-adherent patients have been documented in the US. However, with quarterly HIV testing of persons prescribed PrEP, there is a small but increasing number of PrEP patients with test results that are indeterminate (ambiguous) or that may be false positive.[153, 154] Use of antiretroviral PrEP medications at the time of infection can alter the dynamics of viremia and the patient's immune response and lead to ambiguous test results using standard HIV testing algorithms. For example, such patients may have positive point-of-care antibody results but negative antigen results or may have a reactive qualitative NAT test result but no virus detected by quantitative NAT testing.

Clinicians can call the National Clinicians Consultation Center PrEPline at 855-448-7737 for advice about interpretation of HIV test results and management of patients who acquire HIV infection while taking PrEP medication.

Clinicians who encounter ambiguous test results for a PrEP patient at a follow-up visit have several options to confirm true HIV status:

- Carefully assess with the patient their medication adherence since the last negative HIV test visit;
- Draw a new blood specimen after a few days for repeat laboratory HIV testing including Ag/Ab and quantitative NAT testing; and
- If results are still ambiguous, contact the PrEPline (855-448-7737) for further testing advice and identification of a laboratory that can do specialized testing.

While HIV status is being confirmed, clinicians have 3 antiretroviral management options for the patient.

- Continue PrEP medication
    - Because of the high effectiveness of PrEP, the pretest probability that adherent patients are uninfected is high. If infected with HIV, continuing PrEP offers some level of viral suppression but may select for drug resistance (particularly M184v). However, if resistance occurs, well-tolerated and high effective treatment regimens are available to the patient.
- Add a third drug to provide PEP for 28 days
    - Adding a third drug to the PrEP regimen while HIV status is being confirmed provides a fully suppressive treatment regimen while avoiding the need for an

HIV diagnosis that may be difficult to undo if the patient is truly uninfected. If the patient is confirmed to have acquired HIV, the three-drug regimen constitutes early ART initiation and can be continued. This option is especially applicable when a patient reports nonadherence to daily PrEP.

- Discontinue PrEP for 1-2 weeks
    - Drawing blood for retesting after a patient has discontinued PrEP may facilitate diagnosis by allowing viral replication resulting in a detectable viral load in a patient who has acquired HIV. However, in persons who have not acquired HIV, this leaves them without the protection of PrEP for a period of time.
- For patients receiving CAB injections for PrEP
    - While HIV status is being confirmed, clinicians should not administer a new CAB injection. During the 1-2 weeks needed for additional HIV testing to determine HIV status, CAB is likely to remain at protective levels.
    - If the final determination is that the patient has acquired HIV, treatment should be immediately started. Follow guidance in section on "Persons with Documented HIV Infection"
    - If determined not to have acquired HIV, CAB injections every 2 months should resume.

Considerations and Options for Selected Patients

The patient with certain clinical conditions may have indications for specific PrEP regimens or may require special attention and follow-up by the clinician.

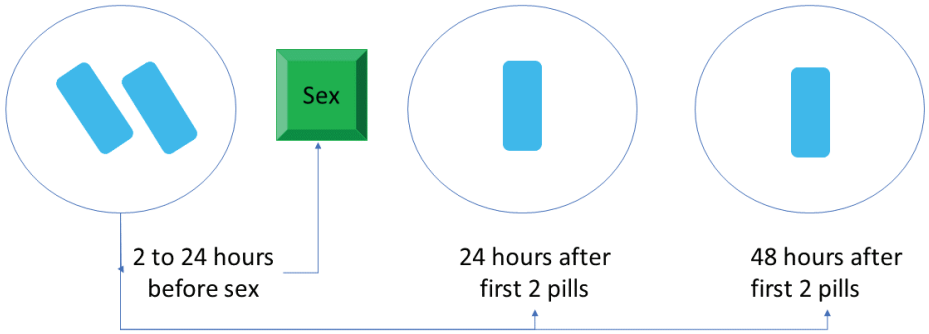
Nondaily Oral PrEP Regimens for MSM

The "2-1-1" regimen (also called event-driven, intermittent, or "on-demand") is a nondaily PrEP regimen that times oral F/TDF doses in relation to sexual intercourse events. While not an FDA-approved regimen, two clinical trials, IPERGAY[155] and the subsequent Prévenir open label study in Paris,[156] have demonstrated the HIV prevention efficacy of 2-1-1 dosing only with F/TDF and only for MSM. These trials were conducted with European and Canadian adult MSM.

Based on trial experience, MSM prescribed the 2-1-1 regimen should be instructed to take F/TDF as follows:

- 2 pills in the 2-24 hours before sex (closer to 24 hours preferred)
- 1 pill 24 hours after the initial two-pill dose
- 1 pill 48 hours after the initial two-pill dose

Figure 8 Schedule for "2-1-1" Dosing



Based on the timing of subsequent sexual events, MSM should be instructed to take additional doses as follows:

- If sex occurs on the consecutive day after completing the 2-1-1 doses, take 1 pill per day until 48 hours after the last sexual event.
- If a gap of <7 days occurs between the last pill and the next sexual event, resume 1 pill daily.
- If a gap of ≥7 days occurs between the last pill and next sexual event, start again with 2 pills.

The dosing was designed and tested primarily to meet the needs of men who had infrequent sex and thus for whom daily dosing might not be necessary. Yet in these trials, men took an average 3-4 doses per week which has been associated with high levels of protection in men prescribed daily F/TDF. The IPERGAY and Prévenir trials showed high preventive efficacy of 86% or more (see evidence review in Appendix 2). There are fewer data on the efficacy of "2-1-1" dosing in MSM having less frequent sex.[157]

The only U.S. data concerning nondaily dosing among MSM came from the ADAPT HPTN 067 study participants in Harlem, New York. Investigators estimated PrEP effectiveness among those MSM prescribed a time-driven regimen (two doses per week 3-4 days apart) or an event-driven regimen (one pill taken before and another after sex) compared to MSM who were prescribed daily dosing. When assessing PrEP coverage of reported sex acts, predicted effectiveness was significantly lower for the two nondaily dosing patterns (62% and 68%, respectively) compared to daily dosing (80%).[158]

No clinical trial or observational cohort data are yet available that assess the efficacy of the 2-1-1 regimen in US MSM and no submission of data has been made for FDA review and approval of this dosing schedule. However, given the efficacy demonstrated in the IPERGAY and Prévenir trials, the International AIDS Society-USA has recommended "2-1-1" dosing as an optional, off-label, alternative to daily dosing for MSM,[159] and some local guidelines have also recommended it for selected MSM.

Some clinicians may choose to prescribe F/TDF off-label using "2-1-1" dosing for adult MSM who request non-daily dosing and who:

- have sex infrequently (e.g., less often than once a week) and
- can anticipate sex (or delay sex) to permit the doses at least 2 hours prior to sex.

Clinicians who elect to provide the 2-1-1 regimen off-label should prescribe no more than 30 pills without follow-up and documentation of another negative HIV test. Patients having sex less than once weekly will have sufficient medication to cover up to 7 intermittent sexual events.

Clinicians who elect to provide the 2-1-1 regimen should also discuss with patients:

- the importance of taking both pre-sex and post-sex doses of F/TDF to achieve good protection;
- the importance of using PrEP for all sexual encounters, not for only some partners or events;
- the possibility of recurrent "start-up" symptoms with infrequent PrEP dosing;
- the possibility of inadvertent disclosure of same-sex behavior to peers or family members since 2-1-1 dosing is only used by MSM;
- how to change between daily and 2-1-1 dosing;
- the continued need for follow-up visits for HIV and STI testing; and
- the possibility that this off-label use will not be covered by insurance.

2-1-1 dosing should not be prescribed:

- for populations other than adult MSM because it has been studied only in adult MSM;
- for MSM who it is anticipated will have difficulty adhering to a complex dosing regimen (e.g., adolescents, patient with an active substance use disorder);
- with F/TAF because its use for pericoital dosing has not been studied; or
- for MSM with active hepatitis B infection because of the danger of hepatic flares with episodic F/TDF exposure.

TRANSGENDER PERSONS

Transgender persons are those whose gender identity or expression differs from their sex at birth. Among all adults and adolescents, diagnoses of HIV infection among transgender persons accounted for approximately 2% of diagnoses of HIV infections in the United States and 6 dependent areas; of whom 92% of diagnoses of HIV infections were for transgender women.[19] The effectiveness of PrEP with either F/TDF or F/TAF for transgender women has not yet been definitively proven in trials that were underpowered because of the small number of transgender women included.[3, 4, 32] All studies conducted to date have shown no effect of F/TDF on hormone levels. Some studies have shown that the high-doses of feminizing hormones prescribed to

transgender women result in lowering of activated tenofovir diphosphate levels in rectal tissue.[160, 161] However, other studies do not show significantly lower levels of tenofovir diphosphate among TGW taking PrEP with a feminizing hormone regimen.[162]. It is unclear whether the extent of any possible reduction at the site of exposure affects PrEP effectiveness but the observed decrease in some studies suggests that daily adherence is especially important for transgender women taking feminizing hormones. Other studies have shown that medication adherence and persistence is low in some cohorts of transgender women.[163, 164] Transgender women were not specifically included in the FDA approval for F/TDF for PrEP. However, FDA approved F/TAF for PrEP was based on an analysis that combined 5,387 MSM (2,694 given F/TAF) and 74 transgender women (45 given F/TAF). Only 24 transgender women remained in the study and on PrEP through the period of analysis. There were too few transgender women remaining in the study for a separate analysis, leaving unresolved questions about the level of proof of effectiveness for them.[3] No data are available about the prevention effectiveness of either F/TDF or F/TAF for PrEP in transgender men.

In HPTN 083, there were a sufficient number of transgender women analyzed separately from MSM. Transgender women in the F/TDF group had similar HIV incidence (1.8 per 100 py) as MSM (1.14 per 100 py) and similar hazard ratios compared to the cabotegravir MSM groups (0.34 for TGW, 0.35 for MSM). F/TDF PrEP has been shown to reduce the risk for HIV acquisition during both anal sex and penile-vaginal sex. F/TAF has been proven effective in persons exposed to HIV through non-vaginal sex, and efficacy has been shown for cabotegravir injection, therefore PrEP is recommended for transgender women at risk for HIV acquisition[165]. When prescribed, clinicians should discuss the need for high medication adherence and reassure patients that PrEP medications do not impact the effects of feminizing hormones.

Persons Who Inject Drugs

Persons who inject drugs not prescribed to them should be offered PrEP. In addition, reducing or eliminating injection risk practices can be achieved by providing access to drug treatment and relapse prevention services[59]. Persons who inject opioids can be offered medication-assisted treatment, either within the PrEP clinical setting (e.g., provision of daily oral buprenorphine or naltrexone) or by referral to a drug treatment clinic (e.g., methadone program). Local substance use disorder treatment resources can be found at https://findtreatment.samhsa.gov/locator.

For persons not able (e.g., on a waiting list or lacking insurance) or not motivated to engage in drug treatment, providing access to sterile injection equipment through syringe service programs (where legal and available), and through prescriptions of syringes or purchase of syringes from pharmacies without a prescription (where legal), can reduce exposure to HIV and other infectious agents (e.g., HCV). In addition, providing or referring PWID for cognitive or behavioral counseling and any indicated mental health or social services may help reduce risky injection practices.

Patients with Renal Disease

Patients with eCrCl ≥ 60 ml/min may be prescribed daily F/TDF for PrEP; those with an eCrCl between 30 and 60 ml/min may be prescribed daily F/TAF (but not F/TDF) for PrEP.[119] Persons with an eCrCl of <30 ml/min, should not be prescribed F/TDF or F/TAF for PrEP, because the safety of tenofovir-containing regimens for such persons was not evaluated in the clinical trials.

Dose reduction of either F/TDF or F/TAF is not recommended for PrEP prescribed to patients with significant renal disease.

CAB for PrEP can be especially considered for patients with significant renal disease (e.g., eCrCl <30 ml/min) in whom tenofovir-containing regimens are not recommended.

HIV Discordant Partnerships

When assessing indications for PrEP use in an HIV discordant couple, clinicians should ask about the treatment and viral load status of the partner with HIV (if the negative partner knows it). Persons with HIV who achieve and maintain a plasma HIV RNA viral load <200 copies/ml with antiretroviral therapy have effectively no risk of sexually transmitting HIV.[166] This is sometimes referred to as "undetectable equals untransmittable" ("U=U") or "treatment as prevention" (TASP).[167]
However, some partners who know they have HIV may not be in care, may not be receiving antiretroviral therapy, may not be receiving highly effective regimens, may not be adherent to their medications, or for other reasons may not consistently have viral loads that are associated with the least risk of transmission to an uninfected sex partner. In addition, studies have shown that patient-reported viral load status may not be accurate, [168, 169] but clinicians providing care to the HIV-negative patient may not have access to the medical records of the HIV-positive partner to document their recent viral load status and the consistency of their viral suppression over time. In the HIV discordant couples studies, reported sex with outside partners was not uncommon and HIV infections occurred that were genetically unlinked to the partner in the couple with HIV.[170-172]

PrEP may be indicated if the partner with HIV has been inconsistently virally suppressed or their viral load status is unknown, if the partner without HIV has other sexual partners (especially if of unknown HIV status), or if the partner without HIV wants the additional reassurance of protection that PrEP can provide. PrEP should not be withheld from HIV-uninfected patients who request it even if their sexual partner with HIV is reported to have achieved and maintained a suppressed viral load. Several studies, using viral genotyping, have documented HIV infection in a previously uninfected patient that was acquired from a partner outside the relationship with the partner known to have HIV[173].

For patients in an HIV discordant partnership for whom PrEP is being considered, especially where the partner with HIV is not virally suppressed, either CAB injections or daily oral PrEP are recommended options.

Persons with Documented HIV Infection

All persons with an HIV-positive test result whether at screening or while taking F/TDF or F/TAF or receiving CAB injections as PrEP should be provided the following services:[37]

- Laboratory confirmation of HIV status (see Figure 4).
- Determination of CD4 lymphocyte count and plasma HIV RNA viral load to guide therapeutic decisions.
- Documentation of results of genotypic HIV viral resistance testing to guide future treatment decisions.
- If on PrEP, conversion of the PrEP regimen to an HIV treatment regimen recommended by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents [37] without waiting for additional laboratory test results. See Clinical Providers' Supplement Section 8.
- Provision of, or referral to, an experienced provider for the ongoing medical management of HIV infection.
- Counseling about their HIV status and steps they should take to prevent HIV transmission to others and to improve their own health.
- Assistance with, or referral to, the local health department for the identification of sex partners who may have been recently exposed to HIV so that they can be tested for HIV infection, considered for nonoccupational postexposure prophylaxis (nPEP),[113] and counseled about their risk-reduction practices.

Clinicians can call the National Clinicians Consultation Center PrEPline at 855-448-7737 for advice about interpretation of HIV test results and management of patients who acquire HIV infection while taking PrEP medication.

In addition, a confidential report of new HIV infection should be provided to the local health department.

Women who Become Pregnant or Breastfeed While Taking PrEP

The guidance in this section focuses on the use of PrEP during periconception, pregnancy, and breastfeeding. All research on PrEP cited here was conducted with cisgender women. There are no data yet about transgender men, genderqueer, or non-binary individuals who have become pregnant and given birth while taking PrEP medication. Therefore, this section uses the terminology, 'women'.

An increased risk of HIV acquisition has been documented for women during periods of conception, pregnancy, and breastfeeding.[174, 175] Providers should offer PrEP with F/TDF to

women seeking to conceive (i.e., sex without a condom) and pregnant or breastfeeding women whose sexual partner has HIV, especially when their current partner's viral load is unknown, is detectable, or cannot be documented as undetectable.[176] Women whose sexual partner with HIV achieves and maintains an HIV-1 viral load <200 copies/ml are at effectively no risk of sexual acquisition of HIV.[177] The extent to which PrEP use further decreases risk of HIV acquisition when the male partner has a documented recent undetectable viral load is unknown but there may be benefit when viral suppression is not durable or the woman has other partners. F/TAF is not approved for PrEP for women.

Clinicians providing pre-conception and pregnancy care to women often do not provide care to their male partners. When partner's HIV status is unknown or not recently assessed, clinicians should offer HIV testing for the partner. When a woman's sexual partner is reported to be HIV-positive, but his recent viral load status is not known, documentation of the recent viral load status can be requested.

The FDA labeling information[6] is permissive of use of F/TDF for PrEP in pregnant and breastfeeding women. The perinatal antiretroviral treatment guidelines[178] recommend PrEP with F/TDF. Data directly related to the safety of PrEP use for a developing fetus were initially limited.[179] In the F/TDF PrEP trials with heterosexual women, medication was promptly discontinued for women who became pregnant, so the safety for exposed fetuses could not be adequately assessed. However a recent analysis of 206 Kenyan women with prenatal PrEP use and 1,324 without found no difference in pregnancy outcomes (preterm birth of low birthweight) and similar infant growth at 6 weeks postpartum.[180] In the parent Kenyan study, of 193 pregnant or postpartum women with partners living with HIV, 153 initiated PrEP and none acquired HIV.[181]

Additionally, TDF and FTC (also TAF) are widely used for the treatment of HIV infection and are continued during pregnancies that occur.[182-184.] Data on pregnancy outcomes in the Antiretroviral Pregnancy Registry provide no evidence of adverse effects among fetuses exposed to these medications when used for either HIV treatment or prevention of HIV acquisition during pregnancy.[185]

Providers should discuss the potential risks and benefits of all available alternatives for safer conception[186] and if indicated make referrals for assisted reproduction therapies. Providers should include discussion of the potential risks and benefits of beginning or continuing PrEP during pregnancy and breastfeeding so that an informed decision can be made. Whether or not PrEP is elected, the partner with HIV should be taking maximally effective antiretroviral therapy before conception attempts.[5]

Health care providers are strongly encouraged to prospectively and anonymously submit information about any pregnancies in which PrEP is used to the Antiretroviral Pregnancy Registry at: http://www.apregistry.com/.

The safety of PrEP with F/TDF or F/TAF for infants exposed during lactation has not been adequately studied. However, data from studies of infants born to HIV-infected mothers and exposed to TDF or FTC through breast milk suggest limited drug exposure.[187-189] The World Health Organization recommends the use of F/TDF (or 3TC/efavirenz) for all pregnant and breastfeeding women with HIV to prevent perinatal and postpartum mother-to-child HIV transmission.[190] Therefore, providers should discuss current evidence about the potential risks and benefits of beginning or continuing PrEP during breastfeeding so that an informed decision can be made.[§]

Conditioned on FDA approval, CAB for PrEP may be initiated or continued in women who may become pregnant while receiving injections when it is determined that the anticipated benefits outweigh the risks.

Health care providers should prospectively and anonymously submit information about any pregnancies in which F/TDF or cabotegravir for PrEP is used to the Antiretroviral Pregnancy Registry at: http://www.apregistry.com/.

The published data on cabotegravir-exposed pregnancies among women without HIV are sparse, with only 4 pregnancies documented in HPTN 077[148]. Data from additional pregnancies that occurred among participants in HPTN 084 will be available in the near term.

The known increased risk of HIV acquisition during pregnancy and subsequent risk of HIV transmission to the infant during pregnancy and breastfeeding exceed any theoretical risk to maternal or infant health yet identified or observed in cabotegravir PrEP trials or in pregnancies occurring during treatment trials with cabotegravir-containing regimens.

Adolescent Minors

PrEP is recommended for adolescents (weighing at least 35 kg or 77 lb) who report sexual or injection behaviors that indicate a risk of HIV acquisition. As a part of primary health care, HIV screening should be discussed with all adolescents who are sexually active or have a history of injection drug use. USPSTF recommends (grade "A") that all adolescents (age ≥15 years) be screened for HIV.[61] Parental/guardian involvement in an adolescent's health care is often desirable but is sometimes contraindicated for the safety of the adolescent. Laws and regulations that may be relevant for PrEP-related services provided to adolescent minors (including HIV

[§]The DHHS Perinatal HIV Guidelines state that "Health care providers should offer and promote oral combination tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) pre-exposure prophylaxis (PrEP) to individuals who are at risk for HIV and are trying to conceive or arepregnant, postpartum, or breastfeeding:"[9] The FDA-approved package insert for F/TDF[6] says "In HIV-uninfected women, the developmental and health benefits of breastfeeding and the mother's clinical need for TRUVADA for HIV-1 PrEP should be considered along with any potential adverse effects on the breastfed child from TRUVADA and the risk of HIV-1 acquisition due to nonadherence and subsequent mother to child transmission."

testing), such as those concerning consent, confidentiality,[191] parental disclosure, and circumstances requiring reporting to local agencies, differ by jurisdiction. Clinicians considering providing PrEP to a person under the age of legal adulthood (a minor) should be aware of local laws, regulations, and policies that may apply[192] (see (https://www.cdc.gov/hiv/policies/law/states/minors.html). Clinicians should explicitly discuss any limits of confidentiality based on these local laws, regulations and policies and what methods will be used to assure confidentiality is maintained to the extent permitted.

Nearly all trials and observational studies have shown lower adherence and persistence rates in adolescents and young adults prescribed daily F/TDF for PrEP, particularly African American young MSM.[193] This is not unexpected as adolescents have low adherence to many medications they are prescribed.[194, 195] Therefore, to help adolescents achieve adequate protection from acquiring HIV, it will be critical to provide supportive counseling and interventions (e.g., phone apps) when they have been proven effective.

In the ATN 110 (ages 18-22 years) and 113 studies (ages 15-17 years), bone density changes in young MSM were measured during PrEP use and after completing the PrEP trial period (48 weeks). They reported decreased bone mineral density during the period of F/TDF PrEP use with larger declines in those ages 15-19 years than in those ages 20-22 years. While men ages 18-22 years had full improvement during the 48 weeks after PrEP use stopped, declines were persistent in younger men.[196] The bone changes were more frequently seen in young men with greatest adherence (i.e., higher drug exposure).[197]

Likelihood of adherence problems and effects on long-term bone health should be weighed against the potential benefit of providing PrEP for an individual adolescent at substantial risk of HIV acquisition. Because differences in pharmacodynamics suggest less bone effect with F/TAF than with F/TDF, clinicians may want to preferentially prescribe F/TAF to adolescent males initiating PrEP.

CAB for PrEP has not been studied in men or women < 18 years of age. These studies are underway but until safety is determined for this population, and reviewed by FDA, CAB is not recommended for adolescents <18 years old.

Primary Care Considerations

Provision of PrEP affords the opportunity to manage other preventive health measures during both initial and follow-up visits, especially for persons who may not otherwise be engaged in primary care. These health measures include: vaccinations, screening for sex-specific conditions, and screening for mental health, tobacco/nicotine use, and alcohol use disorder. When providing sex-specific health care for transgender persons, the principle of "screen what you have" should be applied. For example, all persons with a cervix should be screened for cervical cancer and all persons with a prostate should be considered for prostate cancer screening, regardless of gender identification.

Table 8 Primary Care Health Measures

		MSM	MSW*	Women*	PWID
Vaccines# (if not previously vaccinated)	Hepatitis A vaccine	Yes	Yes	Yes	Yes
	Hepatitis B vaccine	Yes	Yes	Yes	Yes
	HPV vaccine	Through age 26	Through age 26	Through age 26	Through age 26
	Meningococcal B vaccine	Ages 16-18	Ages 16-18	Ages 16-18	Ages 16-18
	Influenza vaccine	Yes	Yes	Yes	Yes
General Health	Hepatitis C infection^	Ages 18-79	Ages 18-79	Ages 18-79	Ages 18-79
	Screen for depression^	Yes	Yes	Yes	Yes
	Screen for unhealthy alcohol use^	Ages 18 and older	Ages 18 and older	Ages 18 and older	Ages 18 and older
	Screen for smoking^	Yes	Yes	Yes	Yes
	Screen for Intimate Partner Violence^	Yes		Yes	If female, Yes
Women's Health	Mammography^			Ages 50-74 every two years	If female, Ages 50-74 every two years
	Screen for cervical cancer^~			Ages 21-65 every three years	If female, Ages 21-65 every three years
Men's Health	Screen for prostate cancer^	Ages 55-69	Ages 55-69		If male, Ages 55-69

*"screen what you have" principle for transgender persons
per ACIP recommendations
^per USPSTF recommendations
~per ASCCP (American Society of Colposcopy and Cervical Pathology} guidelines[198]

Financial Case-Management Issues for PrEP

A means to pay for PrEP medications and recommended clinical and counseling services is required for successful PrEP use. Nearly all public and private insurers cover PrEP, but co-pay, co-insurance, and prior authorization policies differ.

Clinicians should provide benefits counseling to assist eligible patients to obtain insurance (e.g., Medicaid, Medicare, ACA plans) either by in-clinic benefits counseling or by referral to community resources.

The USPSTF recommends that PrEP be provided to "persons who are at high risk of HIV acquisition" with an A grade indicating that there is high certainty that the net benefit is substantial.[11] This rating requires most commercial insurers and some Medicaid programs to provide oral PrEP with no out-of-pocket cost to patients. In addition to PrEP medication, DHHS has determined that laboratory tests necessary for PrEP are included in this provision as well as clinic visits when the primary purpose of the office visit is the delivery of PrEP care[199].

A guide to billing codes for PrEP coverage is available at https://www.nastad.org/resource/billing-coding-guide-hiv-prevention (see Clinical Providers' Supplement Section 10)

For patients residing in the US without health insurance or whose insurance does not cover PrEP medication, there are two programs that can provide free F/TDF or F/TAF for PrEP.

For patients who lack outpatient prescription drug coverage, the HHS "Ready, Set, PrEP" program makes prescribed PrEP medication (either F/TDF or F/TAF) available at no cost. With a clinician's prescription, patients can enroll on the website at https://www.getyourprep.com/ or by calling toll-free 855-447-8410.

For patients without health insurance or whose insurance does not cover PrEP medication, and whose household income is <500% of the federal poverty level, Gilead Sciences has established a PrEP medication assistance program (includes both F/TDF and F/TAF). In addition to providing medication at no cost for eligible patients, this program also provides access to free HIV testing. For commercially insured patients whose personal resources are insufficient to pay out-of-pocket costs for medication co-pay or co-insurance, the Gilead co-pay assistance program provides assistance and other co-pay programs are also available.[165] Providers may obtain, complete, and sign applications for their patients to receive free PrEP medication or co-pay assistance at www.gileadadvancingaccess.com or by calling toll-free 855-330-5479.

In addition, some states have PrEP-specific financial assistance programs that cover medication, clinical care, or both. (see Table 9). These change over time and a current list can be found at https://www.nastad.org/prepcost-resources/prep-assistance-programs.

Table 9 NASTAD Table of State PrEP Financial Assistance Programs (as of August 2022)

STATE	DRUG ASSISTANCE		CLINICAL VISITS AND LAB TEST ASSISTANCE	PATIENT INCOME LIMIT
	COPAY ASSISTANCE	MEDICATION ASSISTANCE		
California	Yes	Yes	Any participating provider	Up to 500%
Colorado	Yes	Yes	Any participating provider	Below 500%
District of Columbia	Yes	No	Local health department clinicst	Up to 500%
Florida	No	Yes*	Local health department clinics	No threshold
Illinois	Yes	No	Select grantees	No threshold
Indiana	Yes	No	Contracted Providers	400%
Iowa	Yes	No	Sub-recipients	No threshold
Massachusetts	Yes	No	Select Grantees	Up to 500%
New Mexico	Yes	Yes	Contracted Providers	No threshold
New York State	No	No	Any participating provider	Up to 435%
Ohio	Yes	No	Any participating provider	Up to 500%
Oklahoma	Yes	Yes	Contracted Providers	No threshold
Virginia	No	Yes*	Local health departments and contracted providers	No Threshold
Washington State	Yes	Yes	Any participating provider	No Threshold

** Table provided by NASTAD (source: https://www.nastad.org/prepcost-resources/prep-assistance-programs)

At the time of this guideline update, FDA approval of CAB has not yet occurred. So no medication assistance programs are yet available. It is anticipated that when FDA approves a CAB indication for PrEP, one or more assistance programs will become available for uninsured and underinsured patients with low income. A USPSTF determination about CAB for PrEP has not yet been made.

Decision Support, Training and Technical Assistance

Decision support systems (electronic and paper), flow sheets, checklists (see Clinical Providers' Supplement, Section 1 for a PrEP provider/patient checklist at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf), feedback reminders, and involvement of nurse clinicians and pharmacists can help manage the many steps indicated for the safe use of PrEP and increase the likelihood that patients will follow them. Often these systems are locally developed but may become available from various sources

including training centers and Websites funded by government agencies, professional associations, or interested private companies. Examples include downloadable applications (widgets) to support the delivery of nPEP or locate nearby sites for confidential HIV tests (http://www.hivtest.org); and confidential commercial services to electronically monitor medication-taking, send text message reminders, or provide telephone assistance to help patients with problems concerning medication adherence.

Training and technical assistance in providing components of PrEP-related services, medications, and counseling are available at the following Web sites:

- PrEPline: National Clinician's Consultation Center (http://nccc.ucsf.edu/clinical-resources/prep-guidelines-and-resources/)
- Integrating HIV Care, Treatment & Prevention Services into Primary Care – A Toolkit for Health Centers (https://bphc.hrsa.gov/media/p4c-toolkit-2018.pdf)
- National PrEP Clinician Locator (https://preplocator.org/)
- Decision-Making Guide for the Provision of PrEP Services in Title X-Funded Family Planning Service Sites (https://opa.hhs.gov/sites/default/files/2020-07/OPA-PrEP-Decision-Guide_0.pdf)
- HIV Nexus Clinician Resources (https://www.cdc.gov/hiv/clinicians/index.html)
- The AIDS Education Training Centers National Resource Center (http://www.aids-ed.org)
- The Addiction Technology Transfer Center Network (http://www.attcnetwork.org)
- AIDS Info (http://www.aidsinfo.nih.gov, http://www.aids.gov)
- The National Network of STD Clinical Prevention Training Centers (http://nnptc.org/)

Related DHHS Guidelines

This document is consistent with several other guidelines from several organizations related to sexual health, HIV prevention, and the use of antiretroviral medications. Clinicians should refer to these other documents for detailed guidance in their respective areas of care.

- Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis Final Recommendation USPSTF, 2019[11]
- Screening For HIV Infection: Current Recommendations USPSTF, 2019[61]
- Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings[200]
- Recommendations for HIV Screening of Gay, Bisexual, and Other Men Who Have Sex with Men — United States, 2017[60]
- Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents[201]
- Recommendations for Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States[158]

- Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Non-occupational Exposure to HIV -United States, 2017[202]
- Sexually Transmitted Diseases Treatment Guidelines, 2021[79]
- Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection[102]
- Expedited Partner Therapy in the Management of Sexually Transmitted Diseases, 2006[101]
- Guidance on the Use of Expedited Partner Therapy in the Treatment of Gonorrhea, 2016[100]
- Behavioral counseling interventions to prevent sexually transmitted infections: U.S. Preventive Services Task Force recommendation statement[203]
- CDC Recommendations for Hepatitis C Screening Among Adults — United States, 2020[204]
- Hepatitis C guidance: AASLD-I DSA recommendations for testing, managing, and treating adults infected with hepatitis C virus[205]
- Integrated prevention services for HIV infection, viral hepatitis, sexually transmitted diseases, and tuberculosis for persons who use drugs illicitly: summary guidance from CDC and the U.S. Department of Health and Human Services[185]

Appendices

APPENDIX 1 GRADING OF STRENGTH OF RECOMMENDATIONS AND QUALITY OF EVIDENCE

Key recommendations in this guideline are based on the review of published scientific evidence and expert opinions. For details on the guidelines development process used, see the Clinical Providers' Supplement, Section 11 at https://www.cdc.gov/hiv/pdf/risk/prep-cdc-hiv-prep-provider-supplement-2021.pdf.

Using the same grading system as the DHHS antiretroviral treatment guidelines,[201] these key recommendations are rated with a letter to indicate the strength of the recommendation and with a numeral to indicate the quality of the combined evidence supporting each recommendation.

Table 10: Rating Scheme for Recommendations

Strength of Recommendation	Quality of Evidence Supporting a Recommendation
A. Strong recommendation for the statement	**I.** One or more well-executed randomized, controlled trials with clinical outcomes, validated laboratory endpoints, or both
B. Moderate recommendation for the statement	**II.** One or more well-executed, nonrandomized trials or observational cohort studies with clinical outcomes
C. Optional recommendation for the statement	**III.** Expert opinion

The quality of scientific evidence ratings in Table 11 are based on the GRADE rating system[206].

Table 11: Criteria for rating quality of scientific evidence

Type of evidence	Randomized trial = high Observational study = low Any other evidence = very low
Decrease grade if[**]	▪ Serious or very serious limitation to study quality ▪ Important inconsistency ▪ Some or major uncertainty about directness ▪ Imprecise or sparse data ▪ High probability of reporting bias
Increase grade if	▪ Strong evidence of association – significant relative risk >2 based on consistent evidence from 2 or more observational studies, with no plausible confounders (+1) ▪ Very strong evidence of association – significant relative risk of >5 based on direct evidence with no major threats to validity (+2) ▪ Evidence of a dose-response gradient (+1) ▪ All plausible confounders would have reduced the effect (+1)
Range	High-quality evidence Moderate-quality evidence Low-quality evidence Very-low quality evidence

[**] Each quality criterion can reduce or increase the quality by 1 or, if very significant, by 2 levels.

APPENDIX 2 EVIDENCE OF THE SAFETY AND EFFICACY OF ORAL ANTIRETROVIRAL PROPHYLAXIS

Clinical trials were conducted to evaluate the safety and efficacy of oral PrEP in populations at risk of HIV acquisition through several routes of exposure. The results of completed trials and open label or observational studies published as of January 2020 are summarized below. See also Tables 12-17 that follow. The quality of evidence in each study was assessed using GRADE criteria (https://bestpractice.bmj.com/info/us/toolkit/learn-ebm/what-is-grade/) and the strength of evidence for all studies relevant to a specific recommendation was assessed by the method used in the DHHS antiretroviral treatment guidelines (See Appendix 1).

PUBLISHED TRIALS OF ANTIRETROVIRAL PREEXPOSURE PROPHYLAXIS AMONG MEN WHO HAVE SEX WITH MEN

iPrEx (Preexposure Prophylaxis Initiative) Trial

The iPrEx study [2]was a phase 3, randomized, double-blind, placebo-controlled trial conducted in Peru, Ecuador, Brazil, Thailand, South Africa, and the United States among men and male-to-female transgender adults who reported sex with a man during the 6 months preceding enrollment. Participants were randomly assigned to receive a daily oral dose of either the fixed-dose combination of TDF and FTC or a placebo. All participants (drug and placebo groups) were seen every 4 weeks for an interview, HIV testing, counseling about risk- reduction and adherence to PrEP medication doses, verifying returned pill count, and dispensing of pills and condoms.

Analysis of data through May 1, 2010, revealed that after the exclusion of 58 participants (10 later determined to be HIV- infected at enrollment and 48 who did not have an HIV test after enrollment), 36 of 1,224 participants in the F/TDF group and 64 of 1,217 in the placebo group had acquired HIV. Enrollment in the F/TDF group was associated with a 44% reduction in the risk of HIV acquisition (95% CI, 15-63). The reduction was greater in the as-treated analysis: at the visits at which adherence was ≥50% (by self-report and pill count/dispensing), the reduction in HIV acquisition was 50% (95% CI, 18-70). The reduction in the risk of HIV acquisition was 73% at visits at which self-reported adherence was ≥90% (95% CI, 41-88) during the preceding 30 days. Among participants randomly assigned to the F/TDF group, plasma and intracellular drug-level testing was performed for all persons who acquired HIV during the trial and for a matched subset who remained HIV- uninfected: a 92% reduction in the risk of HIV acquisition (95% CI, 40-99) was found in participants with detectable levels of F/TDF versus those with no drug detected.

Generally, F/TDF was well tolerated, although nausea in the first month was more common among participants taking medication than among those taking placebo (9% versus 5%). No differences in severe (grade 3) or life-threatening (grade 4) adverse laboratory events were observed between the active and placebo group, and no drug-resistant virus was found in the 100 participants infected after enrollment. Among 10 participants who were HIV-negative at enrollment but later found to have been infected before enrollment, FTC-resistant virus was detected in 2 of 2 men in the active group and 1 of 8 men in the placebo group. Compared to participant reports at baseline, over the course of the study, participants in both the F/TDF and placebo groups reported fewer total numbers of sex partners with

whom the participants had receptive anal intercourse and higher percentages of partners who used condoms.

In the original iPrEx publication,[2, 125] of 2,499 MSM, 29 identified as female (i.e., transgender women). In a subsequent subgroup analysis,[19] men were categorized as transgender women (n=339) if they were born male and either identified as women (n=29), identified as transgender (n=296), or identified as male and used feminizing hormones (n=14). Using this expanded definition, among transgender women, no efficacy of F/TDF for PrEP was demonstrated.[207] There were 11 infections among the PrEP group and 10 in the placebo group (HR 1.1, 95% CI: 0.5-2.7). By drug level testing (*always* versus *less than always*), compared with MSM, transgender women had less consistent PrEP use OR 0.39 (95% CI: 0.16-0.96). In the subsequent open-label extension study (see below), one transgender woman seroconverted while receiving PrEP and one seroconversion occurred in a woman who elected not to use PrEP.

US MSM Safety Trial

The US MSM Safety Trial[1] was a phase 2 randomized, double-blind, placebo-controlled study of the clinical safety and behavioral effects of TDF for HIV prevention among 400 MSM in San Francisco, Boston, and Atlanta. Participants were randomly assigned 1:1:1:1 to receive daily oral TDF or placebo immediately or after a 9- month delay. Participants were seen for follow-up visits 1 month after enrollment and quarterly thereafter. Among MSM without directed drug interruptions, medication adherence was high: 92% by pill count and 77% by pill bottle openings recorded by Medication Event Monitoring System (MEMS) caps. Temporary drug interruptions and the overall frequency of adverse events did not differ significantly between TDF and placebo groups. In multivariable analyses, back pain was the only adverse event associated with receipt of TDF. In a subset of men at the San Francisco site (n=184) for whom bone mineral density (BMD) was assessed, receipt of TDF was associated with small decrease in BMD (1% decrease at the femoral neck, 0.8% decrease for total hip). TDF was not associated with reported bone fractures at any anatomical site. Among 7 seroconversions, no HIV with mutations associated with TDF resistance was detected. No HIV infections occurred while participants were being given TDF; 3 occurred in men while taking placebo; 3 occurred among men in the delayed TDF group who had not started receiving drug; 1 occurred in a man who had been randomly assigned to receive placebo and who was later determined to have had acute HIV infection at the enrollment visit.

Adolescent Trials Network (ATN) 082

ATN 082[208] was a randomized, blinded, pilot feasibility study comparing daily PrEP with F/TDF with and without a behavioral intervention (Many Men, Many Voices) to a third group with no pill and no behavioral intervention. Participants had study visits every 4 weeks with audio-computer assisted interviews (ACASI), blood draws, and risk-reduction counseling. The outcomes of interest were acceptability of study procedures, adherence to pill-taking, safety of F/TDF, and levels of sexual risk behaviors among a population of young (ages 18-22 years) MSM in Chicago. One hundred participants

were to be followed for 24 weeks, but enrollment was stopped, and the study was unblinded early when the iPrEx study published its efficacy result. Sixty-eight participants were enrolled. By drug level detection, adherence was modest at week 4 (62%), and declined to 20% by week 24. No HIV seroconversions were observed.

IPERGAY (Intervention Préventive de l'Exposition aux Risques avec et pour les Gays)

The results of a randomized, blinded, trial of non-daily dosing of F/TDF or placebo for HIV preexposure prophylaxis has also been published[155] and is included here for completeness, although non-daily dosing is not currently recommended by the FDA or CDC.

Four-hundred MSM in France and Canada were randomized to a complex peri-coital dosing regimen that involved taking: 1) 2 pills (F/TDF or placebo) between 2 and 24 hours before sex, 2) 1 pill 24 hours after the first dose, 3) 1 pill 48 hours after the first dose, 4) continuing daily pills if sexual activity continues until 48 hours after the last sex. If more than a 1week break occurred since the last pill, retreatment initiation was with 2 pills before sex or if less than a 1 week break occurred since the last pill, retreatment initiation was with 1 pill before sex. Each pre-sex dose was then followed by the 2 post-sex doses. Study visits were scheduled at 4 and 8 weeks after enrollment, and then every 8 weeks. At study visits, participants completed a computer-assisted interview, had blood drawn, received adherence and risk reduction counseling, received diagnosis and treatment of STIs as indicated, and had a pill count and a medication refill. Following an interim analysis by the data and safety monitoring board at which efficacy was determined, the placebo group was discontinued and all study participants were offered F/TDF. In the blinded phase of the trial, efficacy was 86% (95% CI: 40-98). By self-report, patients took a median of 15 pills per month. By measured plasma drug levels in a subset of those randomized to F/TDF, 86% had TDF levels consistent with having taken the drug during the previous week.

Because of the high frequency of sex and therefore of pill-taking among MSM in this study, it is not yet known whether the regimen will work if taken only a few hours or days before sex, without any buildup of the drug in rectal tissue from prior use. Studies suggest that it may take days, depending on the site of sexual exposure, for the active drug in PrEP to build up to an optimal level for preventing HIV infection. No data yet exist on how effective this regimen would be for heterosexual persons or those who inject drugs, or on adherence to this relatively complex PrEP regimen outside a trial setting. IPERGAY findings, combined with other recent research, suggest that even with less than perfect daily adherence, PrEP may still offer substantial protection for MSM if taken consistently.

DISCOVER Trial

The DISCOVER Trial [3, 4] was a phase 3, randomized, double-blind, active-controlled, non-inferiority trial conducted in 11 European and North American countries among men and male-to-female transgender persons ≥ 18 years of age who reported: 1) two or more condomless anal sex episodes with a man during the 12 weeks preceding enrollment or 2) a diagnosis of syphilis, rectal gonorrhea or rectal chlamydia in the 24 weeks prior to enrollment. Participants were randomly assigned to receive a daily oral dose of either F/TDF or F/TAF. All participants were seen at 4 weeks, 12 weeks, and every 12 weeks thereafter for an interview, HIV testing, focused physical exam, specimen collection for clinical

laboratory tests, counseling about risk- reduction and adherence to PrEP medication doses, pill count, and dispensing of pills and condoms. 200 persons in each study group (F/TDF or F/TAF) were enrolled in a substudy to assess BMD by DEXA scans at the hip and spine.

Analysis of data through 96 weeks of follow-up, revealed that after 8,756 person-years of follow-up, 15 HIV infections occurred in the F/TDF group and 7 infections occurred in the F/TAF group. The incidence rate ratio (0.47, 95% CI=0.19-1.15) was below the upper bound of the value (1.62) needed to demonstrate non-inferiority of F/TAF compared to F/TDF. Five participants (4 in the F/TDF arm and 1 in the F/TAF arm) were suspected to have acquired HIV before baseline; M184V or M184I mutations were found in the 4 participants in the F/TDF arm who may have acquired HIV before initiating PrEP at baseline. No resistance was detected among persons in either arm with incident infections that occurred after baseline.

Generally, F/TDF and F/TAF were equally well tolerated and low rates of side-effects (≤6% of participants) were observed with no difference between treatment groups. No differences were observed between the treatment groups in severe (grade 3) or life-threatening (grade 4) adverse laboratory or clinical events. No clinically significant declines in median eGFR were seen in either treatment group between baseline and 48 weeks: +1.8 ml/min for F/TAF (from baseline median 123 ml/min) and -2.3 ml/min for F/TDF (from baseline median 121 ml/min). Compared to participants randomized to F/TAF, participants randomized to F/TDF had greater decreases from baseline in serum fasting lipid levels. Conversely, participants randomized to F/TAF had increases in fasting triglycerides while participants receiving F/TDF had declines. The number and percentage of subjects who initiated lipid-lowering agents was two-fold higher in the F/TAF group (43 [1.6%]) compared to the F/TDF group (21 [0.8%]; p=0.008). BMD declines of >3% were more common in participants taking F/TDF than participants taking F/TAF with larger differences in younger men.

Daily oral PrEP with F/TDF or F/TAF is recommended for sexually-active MSM at substantial risk of HIV acquisition, because the iPrEx and DISCOVER trials present evidence of safety and efficacy in this population, especially when medication adherence is high. **(IA).**
Daily oral PrEP with F/TDF or F/TAF is recommended for sexually-active TGW at substantial risk of HIV acquisition although the evidence of efficacy in this population is limited **(IIIB).**

Published Observational and Open-Label Studies of Antiretroviral Preexposure Prophylaxis Among Men Who Have Sex with Men

iPrEx Open-Label Extension (OLE) Study

Persons previously enrolled in the iPrEx, ATN 082, and CDC safety PrEP clinical trials were enrolled in a 72-week open-label study and were offered PrEP free of charge.[125] Seventy-six percent of 1,603 persons (1,428 MSM and 175 transgender women) enrolled received PrEP. HIV incidence among participants receiving PrEP was 1.8 per 100 person-years (py) versus 2.6 per 100 py in participants concurrently not choosing PrEP (HR 0.51, 95% CI: 0.26-1.01), adjusted for baseline sexual behaviors. Among participants receiving PrEP, by dried blood spot drug levels, there were no infections in persons

with drug levels associated with having taken 4 or more doses per week (p<0.0001) compared with participants taking < 2 doses per week.

PROUD Open-Label Extension (OLE) Study

PROUD was an open-label, randomized, wait-list controlled trial designed for MSM attending sexual health clinics in England.[209] A pilot was initiated to enroll 500 MSM, in which 275 men were randomized to receive daily oral F/TDF immediately, and 269 were deferred to start after 1 year. At an interim analysis, the data monitoring committee stopped the trial early for efficacy at an interim analysis and recommended that all deferred participants be offered PrEP. Follow-up was completed for 94% of those in the immediate PrEP arm and 90% of participants in the deferred arm. PrEP efficacy was 86% (90% CI: 64-96).

Kaiser Permanente Observational Study

An evaluation of a specialized PrEP program provided at the Kaiser Permanente San Francisco Medical Center[210] reported on a cohort of 653 MSM, 3 heterosexual women, and 1 transgender man (with male sexual partners) who initiated F/TDF for PrEP between July 2012 and February 2015. Of these participants, 20 restarted PrEP after discontinuing it during the study period. The mean duration of use was 7.2 months. No HIV diagnoses were made during 388 py of follow-up on PrEP. No medication adherence measures were reported. After 12 months of use, 50% of PrEP users had received a diagnosis of one or more STI (95% CI: 26-35). In a subsequent report on PrEP patients seen at this center, as of February 2017, there were no HIV infections during 5,104 py of PrEP use while they were being prescribed medication.[26]

Demo Project Open-Label Study

In this demonstration project, conducted at 3 community-based clinics in the United States,[211] MSM (n = 430) and transgender women (n=5) were offered daily oral F/TDF free of charge for 48 weeks. All patients received HIV testing, brief counseling, clinical monitoring, and STI diagnosis and treatment at quarterly follow-up visits. A subset of men underwent drug level monitoring with dried-blood spot testing and protective levels (associated with ≥4 doses per week) were high (80.0%-85.6%) at follow-up visits across the sites. STI incidence remained high but did not increase over time. Two men became infected (HIV incidence 0.43 infections per 100 py, 95% CI: 0.05-1.54), both of whom had drug levels consistent with having taken fewer than 2 doses per week at the visit when seroconversion was detected.

IPERGAY Open-Label Extension (OLE) Study

Findings have been reported from the open-label phase of the IPERGAY trial that enrolled 361 of the original trial participants.[212] All of the open-label study participants were provided peri-coital PrEP as in the original trial. After a mean follow-up time of 18.4 months (IQR: 17.7-19.1), the HIV incidence observed was 0.19 per 100 py which, compared to the incidence in the placebo group of the original trial (6.60 per 100 py), represented a 97% (95% CI: 81-100) relative reduction in HIV incidence. The one participant who acquired HIV had not taken any PrEP in the 30 days before his reactive HIV test and was in an ongoing relationship with an HIV positive partner. Of 336 participants with plasma drug levels obtained at the 6-month visit, 71% had tenofovir detected. By self-report, PrEP was used at the

prescribed dosing for the most recent sexual intercourse by 50% of participants, with suboptimal dosing by 24%, and not used by 26%. Reported condomless receptive anal sex at most recent sexual intercourse increased from 77% at baseline to 86% at the 18-month follow-up visit (p=0.0004). The incidence of a first bacterial STI in the observational study (59.0 per 100 py) was not higher than that seen in the randomized trial (49.1 per 100 py) (p=0.11).

The frequency of pill-taking in the open label study population was higher (median 18 pills per month) than that in the original trial (median 15 pills per month). Therefore, it remains unclear whether the regimen will be highly protective if taken only a few hours or days before sex, without any buildup of the drug from prior use.

Published Trials of Antiretroviral Preexposure Prophylaxis Among Heterosexual Men and Women

Partners PrEP Trial

The Partners PrEP trial [5] was a phase 3 randomized, double-blind, placebo-controlled study of daily oral F/TDF or TDF for the prevention of acquisition of HIV by the uninfected partner in 4,758 HIV-discordant heterosexual couples in Uganda and Kenya. The trial was stopped after an interim analysis in mid-2011 showed statistically significant efficacy in the medication groups (F/TDF or TDF) compared with the placebo group. In 48% of couples, the infected partner was male. HIV-positive partners had a median CD4 count of 495 cells/µL and were not being prescribed antiretroviral therapy, because they were not eligible by local treatment guidelines. Participants had monthly follow-up visits, and the study drug was discontinued among women who became pregnant during the trial.

Adherence to medication was very high: 98% by pills dispensed, 92% by pill count, and 82% by plasma drug-level testing among randomly selected participants in the TDF and F/TDF study groups. Rates of serious adverse events and serum creatinine or phosphorus abnormalities did not differ by study group. Modest increases in gastrointestinal symptoms and fatigue were reported in the antiretroviral medication groups compared with the placebo group, primarily in the first month of use. Among participants of both sexes combined, efficacy estimates for each of the 2 antiretroviral regimens compared with placebo were 67% (95% CI, 44-81) for TDF and 75% (95% CI, 55-87) for F/TDF. Among women, the estimated efficacy was 71% for TDF and 66% for F/TDF. Among men, the estimated efficacy was 63% for TDF and 84% for F/TDF. Efficacy estimates by drug regimen were not statistically different among men, women, men and women combined, or between men and women. In a Partners PrEP substudy that measured plasma TFV levels among participants randomly assigned to receive F/TDF, detectable drug was associated with a 90% reduction in the risk of HIV acquisition. TDF- or FTC- resistant virus was detected in 3 of 14 persons determined to have been infected when enrolled (2 of 5 in the TDF group; 1 of 3 in the F/TDF group).[213] No TDF or FTC resistant virus was detected among those infected after enrollment. Among women, the pregnancy rate was high (10.3 per 100 py), and rates did not differ significantly between the study groups.

TDF2 Trial

The Botswana TDF2 Trial[6], a phase 2 randomized, double-blind, placebo-controlled study of the safety and efficacy of daily oral F/TDF, enrolled 1,219 heterosexual men and women in Botswana, and follow-up has been completed. Participants were seen for monthly follow-up visits, and study drug was discontinued in women who became pregnant during the trial.

Among participants of both sexes combined, the efficacy of F/TDF was 62% (95% CI 22%-83%). Efficacy estimates by sex did not statistically differ from each other or from the overall estimate, although the small number of endpoints in the subsets of men and women limited the statistical power to detect a difference. Compliance with study visits was low: 33.1% of participants did not complete the study per protocol. However, many were re-engaged for an exit visit, and 89.3% of enrolled participants had a final HIV test.

Among 3 participants later found to have been infected at enrollment, F/TDF -resistant virus was detected in 1 participant in the F/TDF group and a low level of F/TDF -resistant virus was transiently detected in 1 participant in the placebo group. No resistant virus was detected in the 33 participants who seroconverted after enrollment.

Medication adherence by pill count was 84% in both groups. Nausea, vomiting, and dizziness occurred more commonly, primarily during the first month of use, among those randomly assigned to F/TDF than among those assigned to placebo. The groups did not differ in rates of serious clinical or laboratory adverse events. Pregnancy rates and rates of fetal loss did not differ by study group.

FEM-PrEP Trial

The FEM-PrEP trial [214] was a phase 3 randomized, double-blind, placebo-controlled study of the HIV prevention efficacy and clinical safety of daily F/TDF among heterosexual women in South Africa, Kenya, and Tanzania. Participants were seen at monthly follow-up visits, and study drug was discontinued among women who became pregnant during the trial. The trial was stopped in 2011, when an interim analysis determined that the trial would be unlikely to detect a statistically significant difference in efficacy between the two study groups.

Adherence was low in this trial: study drug was detected in plasma samples of <50% of women randomly assigned to F/TDF. Among adverse events, only nausea and vomiting (in the first month) and transient, modest elevations in liver function test values were more common among those assigned to F/TDF than those assigned to placebo. No changes in renal function were seen in either group. Initial analyses of efficacy results showed 4.7 infections per 100/ person-years in the F/TDF group and 5.0 infections per 100 person-years in the placebo group. The hazard ratio 0.94 (95% CI, 0.59-1.52) indicated no reduction in HIV incidence associated with F/TDF use. Of the 68 women who acquired HIV during the trial, TDF or FTC resistant virus was detected in 5 women: 1 in the placebo group and 4 in the F/TDF group. In multivariate analyses, there was no association between pregnancy rate and study group.

Phase 2 Trial of Preexposure Prophylaxis with Tenofovir Among Women in Ghana, Cameroon, and Nigeria

A randomized, double-blind, placebo-controlled trial of oral tenofovir TDF was conducted among heterosexual women in West Africa - Ghana (n = 200), Cameroon (n = 200), and Nigeria (n = 136).[215] The study was designed to assess the safety of TDF use and the efficacy of daily TDF in reducing the rate of HIV infection. The Cameroon and Nigeria study sites were closed prematurely because operational obstacles developed, so participant follow-up data were insufficient for the planned efficacy analysis. Analysis of trial safety data from Ghana and Cameroon found no statistically significant differences in grade 3 or 4 hepatic or renal events or in reports of clinical adverse events. Eight HIV seroconversions occurred among women in the trial: 2 among women in the TDF group (rate=0.86 per 100 person-years) and 6 among women receiving placebo (rate= 2.48 per 100 person-years), yielding a rate ratio of 0.35 (95% CI, 0.03-1.93; *p*=0.24). Blood specimens were available from 1 of the 2 participants who seroconverted while taking TDF; standard genotypic analysis revealed no evidence of drug-resistance mutations.

VOICE (Vaginal and Oral Interventions to Control the Epidemic) Trial

VOICE (MTN-003)[216] was a phase 2B randomized, double-blind study comparing oral (TDF or F/TDF) and topical vaginal (tenofovir) antiretroviral regimens against corresponding oral and topical placebos among 5,029 heterosexual women enrolled in eastern and southern Africa. Of these women, 3,019 were randomly assigned to daily oral medication (F/TDF, 1,003; TDF, 1,007; oral placebo, 1,009). In 2011, the trial group receiving oral TDF and the group receiving topical tenofovir were stopped after interim analyses determined futility. The group receiving oral F/TDF continued to the planned trial conclusion.

After the exclusion of 15 women later determined to have had acute HIV infection when enrolled in an oral medication group and 27 with no follow-up visit after baseline, 52 incident HIV infections occurred in the oral TDF group, 61 in the F/TDF group, and 60 in the oral placebo group. Effectiveness was not significant for either oral PrEP medication group; −49%% for TDF (hazard ratio [HR] 1.49; 95% CI, 0.97-2.29) and −4.4% for F/TDF (HR, 1.04; 95% CI, 0.73-1.49) in the modified-intent-to-treat (mITT) analysis.

Face-to-face interview, audio computer-assisted self-interview, and pill-count medication adherence were high in all 3 groups (84%-91%). However, among 315 participants in the random cohort of the case-cohort subset for whom quarterly plasma samples were available, tenofovir was detected, on average, in 30% of samples from women randomly assigned to TDF and in 29% of samples from women randomly assigned to F/TDF. No drug was detected at any quarterly visit during study participation for 58% of women in the TDF group and 50% of women in the F/TDF group. The percentage of samples with detectable drug was less than 40% in all study drug groups and declined throughout the study. In a multivariate analysis that adjusted for baseline confounding variables (including age, marital status), the detection of study drug was not associated with reduced risk of HIV acquisition.

The number of confirmed creatinine elevations (grade not specified) observed was higher in the oral F/TDF group than in the oral placebo group. However, there were no significant differences between active product and placebo groups for other safety outcomes. Of women determined after enrollment to have had acute HIV infection at baseline, two women from the F/TDF group had virus with the M184I/V mutation associated with FTC resistance. One woman in the F/TDF group who acquired HIV

after enrollment had virus with the M184I/V mutation; no participants with HIV had virus with a mutation associated with tenofovir resistance.

In summary, although low adherence and operational issues precluded reliable conclusions regarding efficacy in 3 trials (VOICE, FEM-PrEP and the West African trial),[217] 2 trials (Partners PrEP and TDF2) with high medication adherence have provided substantial evidence of efficacy among heterosexual men and women. All 5 trials have found PrEP to be safe for these populations.

Daily oral PrEP with F/TDF is recommended for heterosexually-active men and women at substantial risk of HIV acquisition, because these trials present evidence of its safety and 2 present evidence of efficacy in these populations, especially when medication adherence is high. Daily oral PrEP with F/TAF is recommended for heterosexually active men based on the results of the DISCOVER trial but is not yet recommended for women (assigned female sex at birth) who may be exposed to HIV through vaginal sex, because no trial data for women are available (IA).

Published Trial of Antiretroviral Preexposure Prophylaxis Among Persons Who Inject Drugs

Bangkok Tenofovir Study (BTS)

BTS was a phase 3 randomized, double-blind, placebo-controlled study of the safety and efficacy of daily oral TDF for HIV prevention among 2,413 PWID (also called IDU) in Bangkok, Thailand[7]. The study was conducted at drug treatment clinics; 22% of participants were receiving methadone treatment at baseline. At each monthly visit, participants could choose to receive either a 28-day supply of pills or to receive medication daily by directly-observed therapy. Study clinics (n=17) provided condoms, bleach (for cleaning injection equipment), methadone, primary medical care, and social services free of charge. Participants were followed for 4.6 years (mean) and received directly- observed therapy 87% of the time.

In the modified intent- to-treat analysis (excluding 2 participants with evidence of HIV infection at enrollment), efficacy of TDF was 48.9% (95% CI, 9.6-72.2; $P = .01$). A post-hoc modified intent-to-treat analysis was done, removing 2 additional participants in whom HIV infection was identified within 28 days of enrollment, including only participants on directly observed therapy who met pre-established criteria for high adherence (taking a pill at least 71% of days and missing no more than two consecutive doses), and had detectable levels of tenofovir in their blood. Among this set of participants, the efficacy of TDF in plasma was associated with a 73.5% reduction in the risk for HIV acquisition (95% CI, 16.6-94.0; $P = .03$). Among participants in an unmatched case-control study that included the 50 persons with incident HIV infection and 282 participants at 4 clinics who remained HIV uninfected, detection of TDF in plasma was associated with a 70.0% reduction in the risk for acquiring HIV (95% CI, 2.3-90.6; $P = .04$).

Rates of nausea and vomiting were higher among TDF than among placebo recipients in the first 2 months of medication but not thereafter. The rates of adverse events, deaths, or elevated creatinine did not differ significantly between the TDF and the placebo groups. Among the 49 HIV infections for

which viral RNA could be amplified (of 50 incident infections and 2 infections later determined to have been present at enrollment), no viruses with mutations associated with TDF resistance were identified.

Among participants with HIV followed up for a maximum of 24 months, HIV plasma viral load was lower in the TDF than in the placebo group at the visit when HIV infection was detected (P =0.01) but not thereafter (P =0.10).

Published Open-Label Study of Antiretroviral Preexposure Prophylaxis Among Person Who Inject Drugs

Bangkok Tenofovir Study (BTS) Open-Label Extension (OLE) Study

All 1,315 participants in the randomized trial (BTS) who were HIV-negative and had no renal contraindication were offered daily oral TDF for 1 year in an open label extension study.[218] Sixty-one percent (n=798) elected to take PrEP. Participants who were older (≥30 years, p<0.0001), injected heroin (p=0.007) or had been in prison (p=0.0007) were more likely to start PrEP than participants without these characteristics. Twenty-eight percent (n=220) did not return for any follow-up visits. Participants who had injected heroin (p=0.01) or had been in prison (p=0.0007) during the 3 months before the open label study returned for a follow-up visit. Overall, by diary, adherence was lower in the open label study (38.5 % of days) than in the randomized clinical trial (83.8% of days). Participants who injected midazolam (p=0.02) or were in prison (p<0.0001) during the open label study were more likely to be more than 90% adherent than those without these characteristics. During a median 335 days of follow-up, one HIV infection occurred in a participant who reported not taking any doses during the 60 days before the positive test, yielding an HIV incidence of 2.1 per 1000 py (95% CI: 0.05-11.7). Among the 339 (42%) who completed a 12-month follow-up visit, injection and needle sharing did not increase during the open-label study.

Daily oral PrEP with F/TDF is recommended for PWID at substantial risk of HIV acquisition, because this trial presents evidence of the safety and efficacy of TDF as PrEP in this population, especially when medication adherence is high. **(IA)**

Trials of Injectable Antiretroviral Preexposure Prophylaxis

HPTN 077

HPTN 077[219] was a double-blind, placebo-controlled phase 2a trial conducted in Brazil, Malawi, South Africa, and the US. Healthy men and women (sex at birth) age 18-65 years at low HIV risk were randomized (3:1) to receive cabotegravir or placebo injections. For the initial 4 weeks, trial participants received 1 daily oral tablet containing either CAB or placebo to monitor for short term adverse events. Participants without safety concerns in the oral phase then received injections in one of two cohorts that were enrolled sequentially. Cohort 1 enrolled 110 participants to receive 3 intramuscular (IM) injections of CAB 800 mg or 0.9% saline as placebo every 12 weeks for 3 injection cycles. Cohort 2 enrolled 89 participants to receive IM injections of CAB 600 mg or placebo for 5 injection cycles with the first 2

injections separated by 4 weeks and the remaining 3 injections separated by 8 weeks. Primary analyses assessed safety tolerability, and pharmacokinetics during the injection phase (weeks 5-41) and adverse events during both the oral and injection phases. After the last CAB injection at 41 weeks had been completed for all participants, the study was unblinded. Consenting participants were then seen for quarterly follow-up visits through 52-76 weeks to assess adverse events and pharmacokinetics during the "tail" (post-injection) period. HPTN 077 followed the ÉCLAIR trial that showed safety, acceptability, and tolerability of CAB 800 mg injections in US men without HIV.[220]

In the primary analysis through 41 weeks of observation, the only statistically significant difference in clinical adverse events between those receiving CAB and those receiving placebo was for injection site pain. A grade 2 (moderate) or higher injection site reaction (ISR) occurred in 38% of participants receiving CAB and 2% of participants receiving placebo injections (p<0.001). Approximately 90% of participants in both CAB cohorts experienced any ISRs but most were mild or moderate, and led to discontinuation of injections for only 1 participant.

Analysis of the pharmacokinetic data through 41 weeks of follow-up showed that the 600 mg every 8 weeks dose used in cohort 2 consistently met prespecified pharmacokinetic targets (e.g., trough concentrations). All participants met the targets of 80% and 95% of participants with trough concentrations above 4× and 1× PA-IC90 (protein-adjusted 90% maximum inhibitory concentration), respectively. Participants with lower body mass index were found to generally exhibit higher pharmacokinetic peak concentrations after injection, as well as increased AUC (area under the curve) concentrations. However, the 800 mg every 12 weeks dose used in cohort 1 did not consistently achieve target concentrations with some differences between male and female participants.

Among 85 women (46 in cohort 1, 39 in cohort 2), 79 reported using hormonal contraception at baseline and 6 reported that they did not[221]. Reported oral contraception use was associated with lower peak CAB concentration but was not associated with significant differences in other pharmacokinetic parameters (including trough levels, AUC, and time to LLOQ) when compared to reported non-use of hormonal contraception. No other hormonal contraceptive type (injectable, implants, and other) was associated with significant differences in CAB pharmacokinetic parameters.

The tail-phase analyses[149] included 177 participants, including 43 placebo recipients and 134 persons who had at least one CAB injection and had at least three cabotegravir measurements higher than the LLOQ after the final injection at 41 weeks. 117 women and 60 men were followed, 74 participants in CAB cohort 1 and in CAB cohort 2, 25 in placebo cohort 1 and 18 in placebo cohort 2.

The incidence of grade 2 or worse adverse events was significantly lower during the tail phase than the injection phase (p<0·0001). The pharmacokinetic analysis found that the median time from the last injection to the time when cabotegravir concentration decreased below the LLOQ was approximately 33% longer for women (67.3 weeks [IQR 29.1–89.6; range 17.7–225.5] (p=0·0003)) than for men (43.7 weeks [IQR 31·1–66·6; range 20.4–152.5] (geometric mean by sex at birth found a fold-change 1.33, 95% CI 1·06–1.68; p=0.014)). The median time to LLOQ was 31% longer 65.4 weeks (IQR 49.8–95.3; range 19.7–198.2) for participants with a high body-mass index (BMI) than for those with a low BMI

57.7 weeks (IQR 36.2–76.3; range 17.7–225.5) (geometric mean fold-change 1.31, 95% CI 1.06–1.63; *p*=0·015). However, sex at birth and BMI accounted for, less than 10% of the variability observed in the duration of the pharmacologic tail.

In these low-risk cohorts, one female participant in cohort 1 acquired HIV. The seroconversion occurred 48 weeks after the final injection of CAB. Her plasma CAB concentrations were below the level of quantitation at both the visit when HIV infection was first detected and at her visit 12 weeks earlier when she had undetectable HIV RNA. No integrase resistance mutations were detected with next generation sequencing.

Four pregnancies occurred, two among women receiving placebo (one full-term healthy infant, 1one miscarriage likely due to Zika virus infection) and 2 among women receiving CAB. Both CAB pregnancies occurred during the tail phase one 32 weeks after her final CAB injection (early term, healthy infant) cohort 2) and one 108 weeks after her final injection (full-term, healthy infant, cohort 1). No birth defects were identified in newborns.

A post-hoc analysis[222] found no significant changes in weight or fasting glucose or lipid parameters when comparing participants receiving CAB injections to those receiving placebo.

The low number of transgender men (n=6) and transgender women (n=1) in this low-risk cohort did not allow the investigation of the effects of gender affirming hormone therapy.

HPTN 083

HPTN 083 is a phase 3, randomized, double-blind, active control trial conducted in Argentina, Peru, Brazil, Thailand, Vietnam, South Africa, and the United States among adult men and transgender women who reported sex with a man during the 6 months preceding enrollment. Participants were randomly assigned to receive cabotegravir [13]or oral F/TDF. During a 5-week lead-in phase, 2282 persons in the cabotegravir group received daily oral cabotegravir tablets (30 mg) and 2284 persons in the F/TDF arm received placebo tablets for daily use. Following completion of the lead-in period, those randomized to the cabotegravir group received daily oral placebo tablets and intramuscular injections of 600 mg cabotegravir at weeks 5 and 9 and every 8 weeks thereafter. Those randomized to the F/TDF group received F/TDF tablets for daily use and placebo intramuscular injections at weeks 5 and 9 and every 8 weeks thereafter. All participants (cabotegravir and F/TDF groups) had regularly scheduled interviews, HIV testing, counseling about risk-reduction and adherence to oral pills prescribed.

A scheduled interim analysis review by the Data Safety and Monitoring Board in May 2020 determined that CAB was non-inferior to F/TDF, the study was unblinded, and CAB was offered to all study participants and study follow-up visits were continued. The final prespecified primary analysis determined that the statistical criteria for superiority of CAB compared to F/TDF was met. After the exclusion of participants later determined to have been HIV- infected at enrollment and those who did not have an HIV test after enrollment, 39 of 2247 participants in the F/TDF group and 13 of 2243 in the

CAB group had acquired HIV. HIV incidence was low in both groups; 1.22/100 person-years in the F/TDF group and 0.41/100 person-years in the CAB group. Participation in the CAB group was associated with a 66% reduction in the risk of HIV acquisition (95% CI, 38%-82%) compared to the F/TDF group. Post-hoc centralized testing of stored plasma specimens led to readjudication of the timing identification of the first HIV-positive test from incident to baseline infection for 2 participants in the CAB group and none in the F/TDF group. Based on this post-hoc readjudication, incidence in the CAB group was revised to 0.37/100 person-years with a 68% reduction in the risk of HIV acquisition (95% CI, 35%-81%) compared to the F/TDF group.

In the group randomized to CAB, 1 in 4 baseline infections and 4 of 9 incident infections with a resistance test result had one or more INSTI resistance mutations detected[78]. No resistance mutations were detected among 4 infections that occurred after the last CAB injection (i.e., during the tail phase). Among the 5 participants with INSTI resistance mutations detected, phenotyping results for 3 participants found low replication capacity and susceptibility to dolutegravir. Some showed partial or significant resistance to one or more INSTI medications.

CAB was well tolerated. ISRs (e.g., pain, tenderness, induration at the site) occurred in 81% of participants in the CAB group and 31% of those in the F/TDF group who received normal saline placebo injections. These were most common after the first, second, or third injection. Nearly all were mild or moderate severity and resolved within 1 week of injection. Only 2.4% of CAB participants discontinued receiving injections because of the discomfort of injection site reactions. 33% of participants had grade 3 or higher laboratory adverse events with no statistically significant differences between the CAB and F/TDF groups. In the first 40 weeks of the study, participants in the CAB group had a median weight gain from enrollment of 1.54 kg (95% CI 1.0-2.0). but from week 40-105, median weight gain was only 1.07 kg (95% CI 0.61-1.5).

Additional trials to assess the safety of PrEP with CAB injections for adolescent men and transgender women who have sex with men are planned.

HPTN 084

HPTN 084[13] is a phase 3, randomized, double-blind, active control trial conducted in Botswana, Eswatini, Kenya, Malawi, South Africa, Uganda, and Zimbabwe among adult women who reported sex with a man during the 6 months preceding enrollment. Participants were randomly assigned to receive cabotegravir or oral F/TDF. During a 5-week lead-in phase, 2282 women in the cabotegravir group received daily oral cabotegravir tablets and 2284 women in the F/TDF arm received placebo tablets for daily use. Following completion of the lead-in period, those randomized to the cabotegravir group received daily oral placebo tablets and intramuscular injections of cabotegravir at weeks 5 and 9 and every 8 weeks thereafter. Those randomized to the F/TDF group received F/TDF tablets for daily use and placebo intramuscular injections at weeks 5 and 9 and every 8 weeks thereafter. All participants (cabotegravir and F/TDF groups) had regularly scheduled interviews, HIV testing, counseling about risk-reduction and adherence to oral pills prescribed.

A scheduled interim analysis review by the Data Safety and Monitoring Board in November 2020 determined that CAB was superior to F/TDF, the study was unblinded, CAB was offered to all study participants, and study follow-up visits were continued. After the exclusion of participants later determined to have been HIV-infected at enrollment and those who did not have an HIV test after enrollment, 38 HIV infections occurred during follow-up, with 4 infections in the CAB group (incidence rate 0.21/100 person/years) and 34 infections in the F/TDF group (incidence rate 1.79/100 person/years). The hazard ratio comparing the CAB and F/TDF groups was 0.11 (95% CI 0.04-0.32). HIV incidence was lower than expected in both groups demonstrating that both drugs offered high levels of protection but participation in the CAB group was associated with an 89% reduction in the risk of HIV acquisition compared to the F/TDF group.

CAB was well tolerated with ISRs (e.g., pain, tenderness, induration at the site) the most commonly occurring adverse event. Nearly all were mild or moderate severity.

Additional studies to determine the safety of PrEP with CAB injections for adolescent women and confirm safety for pregnant women and their newborns are planned.

PrEP with cabotegravir intramuscular injections is recommended for adults at substantial risk of HIV acquisition, because clinical trials present evidence of its safety and efficacy in these populations (**IA**).

TABLE 12: EVIDENCE SUMMARY — OVERALL EVIDENCE QUALITY OF RANDOMIZED PREP CLINICAL TRIALS (PER GRADE CRITERIA[186])

Oral Tenofovir-based PrEP Trials

Study	Design[a]	Participants		Limitations	Quality of Evidence (See Table 11, Appendix 1)
		Agent	Control		
Among Men Who have Sex with Men					
iPrEx Trial	Phase 3	F/TDF (n = 1251)	Placebo (n = 1248)	Adherence	High
US MSM Safety Trial	Phase 2	TDF (n = 201)	Placebo (n = 199)	Minimal	High
ATN 082	Pilot	F/TDF (n=20)	Placebo (n=19) No pill (n=19)	Small size, stopped early, limited follow-up time, low medication adherence	Low
DISCOVER	Phase 3	F/TAF (n=2694)	F/TDF (n=2693)	Minimal	High
Among Heterosexual Men and Women					
Partners PrEP	Phase 3	TDF (n = 1589) F/TDF (n = 1583)	Placebo (n = 1586)	Minimal	High
TDF2	Phase 2	F/TDF (n = 611)	Placebo (n = 608)	High loss to follow-up; modest sample size	Moderate
Among Heterosexual Women					
FEM-PrEP	Phase 3	F/TDF (n = 1062)	Placebo (n = 1058)	Stopped at interim analysis, limited follow-up time; very low adherence to drug regimen	Low
West African Trial	Phase 2	TDF (n = 469)	Placebo (n = 467)	Stopped early for operational concerns; small sample size; limited follow-up time on assigned drug	Low
VOICE	Phase 2B	TDF (n = 1007) F/TDF (n = 1003)	Placebo (n = 1009)	TDF arm stopped at interim analysis (futility); very low adherence to drug regimen in both TDF and F/TDF arms	Low

[a] All trials in this table were randomized, double-blind, prospective clinical trials of daily oral PrEP

Among Injection Drug Users					
BTS	Phase 3	TDF (n = 1204)	Placebo (n = 1207)	Minimal	High

Injectable Cabotegravir PrEP Trials

Study	Design	Participants		Limitations	Quality of Evidence
		Agent	Control		
Among Men and Women					
HPTN 077	Phase 2a	Cabotegravir 800 mg injection (n=82) Cabotegravir 600 mg injection(n=69)	Placebo (n=28) Placebo (n=20)	High follow-up discontinuation rates Limited sample size	Moderate
Among Men Who have Sex with Men and Transgender Women					
HPTN 083	Phase 2b/3	Cabotegravir 600 mg injection (n=2282)	F/TDF daily oral (n=2284)	Minimal	High
Among Transgender Women					
HPTN 083	Phase 2b/3	Cabotegravir 600 mg injection (n=)	F/TDF daily oral (n=)	Minimal	High
Among Heterosexual Women					
HPTN 084	Phase 3	Cabotegravir 600 mg injection (n=1613)	F/TDF daily oral (n=1610)	Minimal	High

Note: GRADE quality ratings:
high = further research is very unlikely to change our confidence in the estimate of effect;
moderate = further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate;
low = further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate;
very low = any estimate of effect is very uncertain.

TABLE 13: EVIDENCE SUMMARY OF RANDOMIZED CLINICAL TRIALS — HIV INCIDENCE FINDINGS

Study	Outcome Analyses— HIV incidence (mITT)		Effect — HR [Efficacy Estimate] (95% CI)		
	Agent	Control			
iPrEx (MSM and TGW)	36 infections among 1,224 persons	64 infections among 1,217 persons	0.56 [44%] (0.37–0.85)		
iPrEx (TGW) expanded TGW definition	11 infections (# on F/TDF not reported)	10 infections (# on placebo not reported)	1.1 (0.5-2.7)		
US MSM Safety Trial	3 infections among 201 persons (all 3 in delayed arm, not on TDF)	4 infections among 199 persons (1 acute infection at enrollment)	Not Reported		
Partners PrEP (heterosexual men and women)	TDF 17 infections among 1572 persons F/TDF 13 infections among 1568 persons	52 infections among 1568 persons		TDF	F/TDF
			All	0. 33 [67%] (0.19–0.56)	0.25 [75%] (0.13–0.45)
			Women	0.29 [71%] (0.13–0.63)	0.34 [66%] (0.16–0.72)
			Men	0.37 [63%] (0.17–0.80)	0.16 [84%] (0.06–0.46)
TDF2 (heterosexual men and women)	9 infections among 601 persons 1.2 infections/100 person-years	24 infections among 599 persons 3.1 infections per 100 person-years	0.38 [62%] (0.17–0.79)		
FEM-PrEP (heterosexual women)	33 infections among 1024 persons 4.7 infections per 100 person-years	35 infections among 1032 persons 5.0 infections per 100 person-years	0.94 [6%] [a] (0.59–1.52)		
West African Trial (heterosexual women)	2 infections among 427 persons 0.86 infections per 100 person-years	6 infections among 432 persons 2.48 infections per 100 person-years	0.35 [65%] [a] (0.03–1.93)		

[a] Not statistically significant.

VOICE (heterosexual women)	TDF 52 infections among 993 persons 6.3 infections per 100 person-years F/TDF 61 infections among 985 persons 4.7 infections per 100 person-years	35 infections among 999 persons 4.2 infections per 100 person-years	TDF	F/TDF
			1.49 [-50 %][a] (0.97–2.3)	1.04 [-4%][a] (0.73, 1.5)
BTS (persons who inject drugs)	17 infections among 1204 persons 0.35 infections per 100 person-years	33 infections among 1207 persons 0.68 infections per 100 person-years	0.51 [49%] (9.6, 72.2)	
DISCOVER (MSM and TGW)	F/TAF 7 infections among 2670 persons 0.16 infections per 100 person-years	F/TDF 15 infections among 2665 persons 0.34 infections per 100 person-years	0.47 [-53%] (0.19-1.15)	
DISCOVER (TGW)	Not reported	Not reported	Not reported Included 74 TGW of which 26 prematurely discontinued study drug (F/TAF 16, F/TDF 10) and 24 dropped out of the study by 48 weeks of follow-up	
HPTN 077 (men and women)	Cabotegravir 800 mg injection 1 infection among 82 persons 48 weeks after final injection Cabotegravir 600 mg injection 0 infections among 69 persons	Placebo injection 0 infections among 151 persons	Not reported	
HPTN 083 (MSM and TGW)	Cabotegravir 600 mg injection 13 infections among 2244 persons 5 during continuous, on-time injections 3 during oral lead in phase 5 after hiatus of injections 0.41 infections per 100 person-years	daily oral F/TDF 39 infections among 2250 persons 7 after hiatus of pill receipt 32 during continuous, on-time pill receipt 1.22 infections per 100 person-years	0.34 (0.18-0.62)	
HPTN 083 (TGW)	Cabotegravir 600 mg injection 2 infections among 266 persons 0.54 infections per 100 person-years	daily oral F/TDF 7 infections among 304 persons 1.80 infections per 100 person-years	0.34 (.08-1.56)	

HPTN 084 (heterosexual women)	Cabotegravir 600 mg injection 4 infections among 1613 persons	daily oral F/TDF 34 infections among 1613 persons	0.11 (0.04-0.32)

mITT: modified intent to treat analysis; HR: hazard ratio; IRR: incidence rate ratio

TABLE 14: MEASURES OF EFFICACY, BY MEDICATION ADHERENCE, PERCENTAGE REDUCTION IN HIV INCIDENCE IN RANDOMIZED CLINICAL TRIALS

Study	Modified Intent-to-Treat Efficacy			Efficacy by Self-report Adherence Measures	Efficacy by Pill-count Adherence Measures (95% CI)	Efficacy by Blood Detection of Drug Measures[a] (95% CI)
iPrEx (F/TDF)	44% (15–63%)			>50% 50% (18–70%) >90% 73% (41–88%)		92% (40–99%)
Partners PrEP	All TDF: 67% F/TDF: 75%	Men TDF: 63% F/TDF: 84%	Women TDF: 71% F/TDF: 66%	NR	100% (87–100%)	TDF: 86% (67–94%) F/TDF: 90% (58–98%)
TDF2 (F/TDF)	All 63%	Men 80%	Women 49%[b]	NR	NR	TDF detected: 85%[b]
FEM-PrEP (F/TDF)	NR			NR	NR	NR
VOICE (TDF, F/TDF)	NR			NR	NR	NR
BTS (TDF)	49%			NR	56% (-19 to 86%)[c]	74% (17–94%)

NR, not reported.

[a] Tenofovir detection assays were done in subsets of persons randomly assigned to receive TDF or TDF/FTC

[b] Finding not statistically significant

[c] Among participants on directly observed therapy

TABLE 15: EVIDENCE SUMMARY OF RANDOMIZED CLINICAL TRIALS — SAFETY AND TOXICITY

Study	Outcome Analyses	
	Agent	**Control**
Grade 3/4 Adverse Clinical Events[a]		
iPrEx	52 events	59 events
ATN 082	1 event	1 event
TDF2	21 events	32 events
West African Trial	NR	NR
Grade 3/4 Adverse Laboratory Events [a]		
iPrEx	59 events	48 events
ATN 082	3 events	0 events
TDF2	32 events	32 events
West African Trial	1 event	5 events
Grade 3/4 Adverse Events (Clinical and Laboratory)[a]		
Partners PrEP	TDF: 323 events TDF/FTC: 337 events	307 events
FEM-PrEP	NR	NR
US MSM Safety Trial	36 events	26 events
VOICE	NR	NR
BTS	175 events	173 events
DISCOVER	F/TAF: 6% of participants	F/TDF: 5 % of participants
HPTN 077	Not reported	Not reported
HPTN 083	Cabotegravir: 31.8% of participants	F/TDF: 33.6% of participants
HPTN 084	Pending*	Pending*
Injection Site Reactions (≥ Grade 2)		
HPTN 077	Cabotegravir: 38.1%	Placebo: 2.3%
HPTN 083	Cabotegravir: 31.8% of participants	Not applicable
HPTN 084	Pending*	Not applicable

NR, not reported.

[a] RDBPCT = randomized, double-blind, prospective clinical trial

TABLE 16: EVIDENCE SUMMARY OF RANDOMIZED CLINICAL TRIALS — HIV RESISTANCE FINDINGS

Study	Outcome Analyses	
	Agent	Control
iPrEx	2 resistant viruses among 2 persons infected at baseline 0 resistant viruses among 36 persons infected after baseline	1 resistant virus among 8 persons infected at baseline 0 resistant viruses among 64 persons infected after baseline
US MSM Safety Trial	0 resistant viruses among 3 persons infected after baseline (in delayed arm before starting drug)	1 resistant virus among 1 person infected at baseline 0 resistant viruses among 3 persons infected after baseline
Partners PrEP	2 resistant viruses among 5 persons infected at baseline and randomly assigned to TDF 1 resistant virus among 3 persons infected at baseline and randomly assigned to F/TDF 0 resistant viruses among 27 persons infected after baseline	0 resistant viruses among 6 persons infected at baseline 0 resistant viruses among 51 persons infected after baseline
TDF2	1 resistant virus in 1 person infected at baseline 0 resistant viruses among 9 persons infected after baseline	1 resistant virus in 1 person infected at baseline (very low frequency and transient detection) 0 resistant viruses among 24 persons infected after baseline
FEM-PrEP	4 resistant viruses among 33 persons infected after baseline	1 resistant virus in 35 persons infected after baseline
West African Trial	0 resistant viruses among 2 persons infected while on TDF	NR
VOICE	NR	—
BTS	0 resistant viruses among 49 persons infected after baseline	
DISCOVER	0 resistant viruses among 1 person infected at baseline and randomly assigned to F/TAF 0 resistant viruses among 7 persons infected after baseline	4 resistant viruses among 4 persons infected at baseline and randomly assigned to F/TDF 0 resistant viruses among 11 persons infected after baseline
HPTN 083	1 resistant virus among 4 persons infected at baseline and randomly assigned to F/TAF 4 resistant viruses among 9 persons infected after baseline	2 resistant viruses among 3 persons infected at baseline and randomly assigned to F/TDF 4 resistant viruses among 39 persons infected after baseline
HPTN 084	Not yet reported	Not yet reported

NR, not reported.

TABLE 17: EVIDENCE SUMMARY OF OPEN-LABEL STUDIES

Study	Design	Population	Effect HR [Efficacy Estimate]	Efficacy by Blood Detection of Drug Measure	Resistance
PROUD	Wait-list Control	MSM	[86%] [90% CI: 64%-96%] comparing immediate vs. deferred group	Not reported	2 resistant viruses among 3 persons infected at baseline 0 resistant viruses among 23 persons infected after baseline
iPrEx OLE[a]	RCT Open-Label Extension	MSM	0.51 [49%] (95% CI: 0.26-1.01) comparing those electing to use PrEP with those who did not, adjusted for baseline sexual risk behavior	Compared with being off PrEP, HRs for seroconversion stratified by weekly dosing inferred from blood drug levels: <2 doses/week 0.56 [44%] (0.23-1.31) 2-3 doses/week 0.16 [84%] (0.01-0.79) 4-6 doses/week 0.0 [100%] (0.0-0.21) 7 doses/week 0.0 [100%] (0.0-0.43)	0 resistant viruses among 2 persons infected at baseline (not started on PrEP) 1 resistant virus among 28 persons infected after baseline started on PrEP 0 resistant viruses among 13 persons infected after baseline not started on PrEP
Demo Project	Clinical Cohort	MSM[b]	HIV incidence 0.43 per 100 py (no comparison group) in a population with an STI incidence of 90 per 100 py observed during follow-up.[b]	Both seroconverters had blood drug levels associated with <2 doses/week	1 resistant virus among 3 persons infected at enrollment and started on PrEP 0 resistant viruses among 2 persons infected after baseline started on PrEP
Kaiser Permanente	Clinical Cohort	MSM	0 HIV diagnoses in 5104 py of follow-up	Not reported	Not applicable

[a] included men who had participated in the iPrEx, CDC Safety, and Adolescent Trials Network 082 PrEP trials
[b] 653 MSM, 3 heterosexual women, 1 transgender man who has sex with men

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Connecticut

Department of Public Health Syringe Services Program (SSP) Development and Implementation Guidelines

CONNECTICUT
Public Health

TB, HIV, STD, and Viral Hepatitis Program

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INTRODUCTION

In Connecticut, there has been significant reduction in the transmission of the human immunodeficiency virus (HIV) and other blood-borne viral infections among injection drug users (IDUs) over the last decade. In 2017, injection drug users (IDUs) accounted for approximately 1 in 12 (8%) of all new HIV infections in Connecticut.[1] IDUs continue to be at risk for Hepatitis C virus (HCV) and Hepatitis B virus (HBV) infection through the sharing of needles and drug-preparation equipment.[2]

In addition, outbreaks of Hepatitis A infection have been reported among IDUs; such outbreaks are believed to occur through both percutaneous and fecal-oral routes.[2] To help address this continuing public health problem, the White House Office of National AIDS Policy (ONAP) released the National HIV/AIDS Strategy(NHAS) for the United States: Updated to 2020 in July 2015.[3] An integral step to reaching the NHAS goals to (1) reduce new HIV infections, (2) increase access to care and improve health outcomes for people living with HIV (3) reduce HIV-related health disparities and health inequities, and (4) Achieving a more coordinated national response to the HIV epidemic.

Furthermore, the National Viral Hepatitis Plan 2017-2020 (NVHP) -- developed by the U.S. Department of Health and Human Services -- is the nation's battle plan for fighting viral hepatitis. The NVHP's goals are to (1) prevent new viral hepatitis infections, (2) reduce deaths and improve the health of people living with viral hepatitis, (3) reduce viral hepatitis health disparities, and (4) coordinate, monitor, and report on implementation of viral hepatitis activities.[4] The plan's success cannot be achieved by federal action alone—it requires the support and commitment of a broad mix of stakeholders from various sectors, both public and private.

Drawing from a field of SSP expertise that has existed in the U.S. since the late 1980s, NASTAD and UCHAPS developed this SSP implementation guidelines that will be used by the Connecticut Department of Public Health (CT DPH) HIV Prevention Program to further assist CT DPH funded drug user health organizations to plan and successfully implement SSPs as a part of their HIV/HCV/Overdose prevention efforts in Connecticut.

Today, we have the knowledge and tools to save lives and win the fight against HIV, viral hepatitis and overdoses. This *'Connecticut Department of Public Health Syringe Services Program (SSP) Development and Implementation Guidelines'* uses this knowledge and these tools to prevent new infections, improve the lives of drug users, and map a course toward elimination of public health threats faced by the drug user population. This can be achieved by aligning goals and sharing strategies among key partners, engaging stakeholders across all sectors, advocating for drugs user health, confronting challenges, and prioritizing our efforts to reach the populations most impacted by HIV, viral hepatitis and overdose.

1.1 Purpose and Use of the Guidelines

These guidelines provide assistance to organizations within Connecticut that wish to support SSPs for IDUs to prevent transmission of HIV and other blood-borne viruses such as HCV, and to link IDUs to vital prevention, medical and social services. For CT DPH funded Drug User Health organizations currently implementing SSPs, these program implementation guidelines provide information that can be used to enhance or expand services. For new organizations interested in initiating an SSP, these guidelines address key issues to be considered before implementing an SSP.

1.2 Determination of Need for Syringes Services Programs (SSPs)

Under the Consolidated Appropriation Act of 2016, federal law permits use of funds from the Department of Health and Human Services (DHHS) to support syringe service programs with the exception that funds may not be used to purchase needles or syringes. In order to use DHHS funds for this purpose, eligible state, local, tribal, and territorial health departments must first consult with CDC and provide evidence that their jurisdiction is experiencing or at risk for significant increases in hepatitis infections or an HIV outbreak due to injection drug use.[5] CT DPH have consulted CDC and demonstrated the need according to federal law. The CDC concurrence date was April 5, 2017.[5]

Source: https://www.cdc.gov/ssp/determination-of-need-for-ssp.html

1.2 Organization of the Guidelines

These guidelines are designed to provide an overview of the core components of, and issues related to, implementing and maintaining SSPs.

Section 2 presents background on SSPs, including the epidemiology of HIV, HCV and overdose among IDUs.

Section 3 describes the structural elements that need to be considered before SSP implementation.

Section 4 explains the philosophical underpinnings and operating principles of SSPs.

Section 5 describes a range of existing SSP delivery models.

Section 6 presents suggestions for monitoring SSPs.

Section 7 outlines how to address capacity building needs for SSP implementation and maintenance.

BACKGROUND

This section provides background information on syringe services programs (SSPs) and injection drug users (IDUs), including the definition of SSPs; the demographic characteristics of IDUs; epidemiology of HIV, HCV and overdose among IDUs; a discussion of how SSPs benefit IDUs; and the history and evolution of SSPs in the U.S and Connecticut.

2.1 Definition of SSPs

SSPs are programs that provide syringe access, disposal and/or exchange to IDUs, while also referring and linking IDUs to HIV and viral hepatitis prevention services, overdose prevention services, substance abuse treatment, and medical and mental health care. Various types of SSPs provide syringe services to IDUs, including syringe exchange programs (SEPs), pharmacies, physician prescription and health care services.

2.2 IDUs in U.S.

The national data on demographics of IDUs in the U.S. are limited. SAMHSA conducts the annual National Household Survey on Drug Use and Health. Combined data from 2016 to 2017 indicate that an annual average of 4,480,500 persons aged 12 or older used a needle to inject non- prescribed drugs.[5] It is estimated that in Connecticut there are as many as 9,600 IDUs within specific year.[6] As a result, the role of SSPs will be essential in recruiting more clients each year, and providing client-centered drug user health services to the Connecticut IDU population.

2.3 HIV, HCV and Overdose in Connecticut

HIV: As of 2017, in Connecticut, there were 2,914 people living with HIV who attributed IDUs as their risk of transmission.[7] Of these HIV diagnosis attributed to IDU, 35.8% (1,043) were among females and 64.2% (1,871) percent were among males; 22% (639) were among White, 35%(1,010) were among Black/AA and 42% (1,221) were among Hispanic/Latinx.[7] During this same time period, an additional 247 HIV cases were attributed to IDUs who have sex with men (MSM) .[7] Data from the CDC-funded National HIV Behavioral Surveillance System (NHBSS) indicate that approximately a third (27%) of IDUs shared syringes in the past year.[8] These findings underscore the need for continued and enhanced efforts to address syringe-related risk among IDUs.

HCV: Currently, the majority of the 2.7 to 3.9 million HCV infections among people in the U.S. are attributable to injection drug use.[2] HCV is much more readily transmitted than HIV through multi-person use of injecting equipment, including drug preparation equipment (cottons, cookers, and rinse water).[9,10] In Connecticut –using the same estimates as of the U.S. -- HCV prevalence among IDUs is generally between 60 percent and 90 percent; length of injecting career is the strongest predictor of being HCV seropositive.[11,12]

Overdose is the leading cause of death among IDUs[13] and the second leading cause of accidental death in the U.S.[14] Prevalence of nonfatal overdose among opioid users is up to 60 percent among injection heroin users.[15] Other urban heroin users have lifetime overdose prevalence of 29 percent to 68 percent.[16,17,18,19] In 2017, there were 1,038 opioid overdose deaths in Connecticut. Of those deaths, 65% (677) were confirmed fentanyl-involved overdose deaths.20 Connecticut Accidental Drug Related Deaths data revealed that the number of fentanyl-involved overdose deaths in Connecticut increased 40% from 2016 to 2017 (483 in 2016 and 677 in 2017).[20]

2.4 Prevention of Blood Borne Viruses through SSPs

Blood borne viruses are those viruses that are transmitted from the blood of one person to the blood of another person. Of particular concern are HIV and HCV. IDUs are at especially high risk for HIV and HCV through sharing injection equipment, particularly syringes, for one or multiple substances such as heroin, cocaine, amphetamines, hormones, and/or steroids. IDUs are also at high risk for HIV and other sexually transmitted infections through unprotected sex.

Therefore, the HIV- and HCV-specific public health benefits of SSPs arise from (1) removing potentially infectious syringes from the community, (2) providing IDUs with sterile syringes and other clean injection equipment, and (3) distributing condoms. Several studies have found that SSPs reduce HIV incidence among IDUs.[21,22,23,24] Most studies of injection-related HIV and HCV risk have found SSPs to be associated with a lower likelihood of syringe sharing or reductions in syringe sharing.[25,26,27,28,29,30,31,32,33,34,35] Ecological studies have found that locales with SSPs tend to have lower HIV seroprevalence among IDUs,[36,37,38,39] and one study reported that closing an SSP resulted in increased prevalence of HIV risk behaviors among IDUs.[40] In addition, the reach of SSPs can extend beyond its primary participants by using social networks of IDUs to deliver and dispose of syringes through secondary or peer exchange models.[41,42,43] Other public health benefits of SSPs include the linkage of IDUs to critical services and programs and promoting integrative care among drug treatment programs, HIV/AIDS prevention and treatment services, HCV prevention and treatment programs, and social and mental health services. The evidence for the public health benefits of SSPs is strong and consistent over time.

2.5 History of SSPs in U.S. and Connecticut

The history of SSPs in the U.S. is primarily the history of SEPs. The first SEPs in the U.S. began in the late 1980s in Boston, Massachusetts; Tacoma, Washington; and San Francisco, California. With a few exceptions, these SEPs were primarily activist-initiated programs without support from governmental sources.[44,45,46] In May of 1990, the Connecticut House passed Public Act No. 90-214, An Act Concerning a Demonstration Needle and Syringes Exchange, by a vote of 96 to 36. The Connecticut Senate followed suit by a 26 to 10 margin. In June 1990, Governor William O'Neill signed the bill authorizing Connecticut's first legal needle exchange program effective July 1st. In November 13, 1990, the city of New Haven Health Department launched the first syringe exchange program in Connecticut. [47]

2.5.1 Connecticut SSPs Mission Statement

Connecticut's SSP seeks to reduce the morbidity and mortality associated with HIV, hepatitis and overdose among injection drug users by:

1. removing contaminated syringes from circulation,

2. offering syringe exchange participants health education information and tools to reduce their risk of contracting blood borne diseases,

3. offering overdose prevention training/ naloxone distribution, and

4. offering injection drug users a bridge to drug treatment.

LAYING THE GROUNDWORK FOR PROGRAM IMPLEMENTATION

This section discusses the various factors that CT DPH funded Drug User Health organizations will need to consider as they plan and implement syringe services programs (SSPs) in their jurisdictions, including the importance and necessity of assessing the community's need and readiness for SSPs, ways of working with law enforcement and strategies for building strong community relationships. General principles of community inclusion and creating programs and policies that are culturally, and linguistically appropriate and reflect the makeup of the community should be incorporated.

All SSP programs should be designed in a manner that enables funded agencies to effectively serve culturally diverse communities. Specifically, all program components, materials and marketing messages should reflect the history and culture of the target population and be linguistically- appropriate. Further, as is standard procedure, all materials should be reviewed and approved by a content review panel prior to use to ensure community support for the appropriateness of the materials. Additionally, funded agencies should employ a culturally competent workforce, including a diverse management team, have organizational policies that support the delivery of culturally competent services and care and a process for establishing if cultural competency goals have been met.

3.1 Assessing the Community's Need for SSPs

The first step in considering whether to implement an SSP is to determine whether the need exists in the health department jurisdiction. Health departments and/or HIV prevention planning groups (HPPGs) may identify IDUs as a target population by using assessments of key epidemiological factors including HIV and/or HCV prevalence and demographics of risk groups, and select SSP as an appropriate intervention.[48]

After the needs assessment is complete, CT DPH funded Drug User Health organizations may work with other partners to (1) identify ways to tailor services based on the specific needs of special risk subgroups of IDUs in the community, (2) select the types of syringe distribution and service delivery models most appropriate given resources and context and (3) identify potential locations for SSPs. CT DPH funded Drug User Health organizations may need to educate their partners about IDU-related epidemiological data and the importance of SSPs as an intervention to further address the shared goal of reducing HIV, HCV and overdose related deaths in the community.

3.2 Assessing Community's Readiness for SSPs

This section of the guidelines discusses the importance of assessing the legalities and community support for implementation of SSPs by the state or local health department.

3.2.1 Legalities Surrounding the Operation of SSPs

Once the CT DPH Drug User Health organization has determined that a SSP is needed to address the HIV prevention needs of IDUs, the next step is to assess whether the community is "ready" or receptive to an SSP. A starting point is to review the laws and ordinances that currently govern SSPs within the State of Connecticut. Please see **Sec. 19a-124. Needle and syringe exchange programs.**

Be conscious of Law enforcement agencies may have their own interpretations of laws governing SSPs, as well as differing priorities. Consequently, laws that appear similar may be enforced differently depending on the locale.

For organizations interested in implementing a new SSP or funding an existing SSP, the challenge is to resolve any confusion about the types of interventions that are legal in a particular community.

Resolving this confusion requires a clear vision of the best approach to achieve desired public health outcomes, combined with a willingness to work with health department legal advisors to reconcile any uncertainties. The legal advisors help the health department achieve its goals in a legally responsible manner. For each SSP model (see Section 5), health departments' legal advisors should identify and analyze the laws that govern syringe access.

3.2.2 Building Community Support for SSPs

Providing sterile syringes to IDUs has been shown to reduce sharing of syringes (see Section 2.4). But like other important public health interventions, in order to successfully implement SSPs, there must be an enabling environment consistent of support from key stakeholders such as selected public officials, other government agencies, the general public and consumers. Building community support for SSPs is an integral part of successful SSP implementation. A careful and systematic process can help build community support for SSPs, including assembling the facts and intervention options, assessing stakeholder knowledge and attitudes, and developing an action plan.[49] As described below, several steps can be taken to successfully implement SSPs.

- *Assemble the Facts and Intervention Options*

Start by assessing the characteristics of the local IDU epidemic and identifying current modes of syringe access. SSPs take many forms, and depending on the spatial distribution of IDUs, the accessibility of pharmacies or other health care facilities, and other relevant factors, more than one approach may be worth considering. Having identified potential SSP models (see Section 5), organizations will also need to consult with legal advisors and other stakeholders to discuss the viability of each prospective SSP option for the specific jurisdictions.

- *Assess Stakeholder Knowledge and Attitudes*

Identify key stakeholders and assess their knowledge of and attitudes toward SSPs. Even a legal SSP may fail if elected public officials do not support it, the media frames it negatively, or communities resist it. Police, prosecutors, and public defenders can be engaged to ensure that SSP staff and participants are not mistakenly treated as lawbreakers. Pharmaceutical industry support is crucial to SSPs that work through pharmacies.

- *Community Advisory Board*

In order to enlist broader community support and to assist with the integration of syringe exchange services within the community a community advisory board (CAB) needs to be created to ensure an appropriate procedure for soliciting community advice, for identifying community problems, and for proposing solutions to problems regarding the on-going operation of the syringe exchange program in the community. Individuals identified for participation on the advisory board should be representative of a broad cross-section of the community, including community residents, program participants, representatives of area community-based organizations, and professionals in the fields of substance use, syringe exchange, harm reduction, law, medicine, religion, and other relevant disciplines. Community stake holders such as Community Boards and local elected officials may designate representatives to the advisory board.

3.3 Working with Law enforcement

This section of the guidelines discusses the public law under which the use of federal funds for SSPs is authorized, certification requirements, and strategies for collaboration between SSPs, organizations and law enforcement.

3.3.1 An Opportunity for Collaboration

Law enforcement is an essential partner for SSPs to achieve beneficial public health outcomes. Law enforcement officials, prosecutors, the judiciary, and correctional officials are all coping with the societal challenges that can result from public health problems such as HIV, HCV, substance abuse, and mental illness.[50,51] Efforts to develop more effective, coordinated responses include law enforcement crisis intervention teams, courts that address drug and mental health issues, correctional drug abuse treatment programs and transitional services for people leaving jail and prisons. Organizations can work with other social service agencies to improve the overall system response to these common health threats and link individuals to appropriate services.

There may be concern that law enforcement officials who oppose SSPs will object to any proposed location as a way of preventing an SSP from being implemented. However, law enforcement officials may be willing to generally support implementation of an SSP without providing written approval for a specific location. It is important to negotiate with law enforcement officials and receive their approval because of the effect law enforcement can have on injection behavior and SSP utilization. The language in Public Law 111-117 provides an opportunity to further develop more formal partnerships with law enforcement. Research and experience show that law enforcement will understand, accept, and support SSPs.[52,53]

Addressing the occupational risks to law enforcement officers is good public health practice, and it demonstrates the benefits of SSPs. Law enforcement officials and other first responders may need education and services to reduce their own occupational health risks and better understand the public health benefits of SSPs. For example, law enforcement officers may experience and worry about needle stick injuries during encounters with IDUs.[27, 28] SSPs are associated with reduced risk of needle stick injuries to law enforcement officers.[29]Law enforcement may also benefit from, and appreciate, access to protective training and equipment from SSPs, as well as to prophylaxis after an injury.

3.3.2 Taking Action

Like other large organizations, law enforcement organizations can be diverse, decentralized and challenged in the uniform implementation of policies. One metropolitan area may have numerous law enforcement agencies, many district legal attorneys and multiple correctional facilities with varying levels of support for SSPs. Support at the organizational top level does not guarantee the same level of support at the street level, and vice versa. In this section, we describe recommended approaches for working with law enforcement organizations.

- *Importance of Top-Level Support*

Claims that SSPs encourage drug abuse and/or crime have been proven unfounded.[30, 31] Open and unambiguous public support for SSPs among political and social leaders, including the local media, reinforces the need to work with law enforcement officials. Winning support from law enforcement unions and peer organizations such as fire and rescue departments can also help. For example, if the district attorney's office will not prosecute syringe possession or drug residue arrests, law enforcement officials are less likely to make these types of arrests. Addressing related issues, such as access to drug

abuse treatment, syringe disposal, and drug overdose, can broaden the base of community support for SSPs. Top-level support within the political and law enforcement leadership may also help ensure that clear messages about the value and legality of SSPs are transmitted to mid-level law enforcement managers and it will provide SSP staff with points of contact regarding issues of law enforcement interference.

- *Importance of Support from Law Enforcement Officers on the Street*

Although street-level law enforcement officers often have considerable experience interacting with and observing IDUs, some law enforcement officers may not be aware of the public health aspects of drug use and infectious diseases, such as HIV. CT DPH funded Drug User Health- SSP staff play a pivotal role in communicating the public health benefits of SSPs, and can provide guidance, as needed, on ways to decrease health risks to law enforcement personnel when interacting with IDUs or handling syringe equipment on the streets. Formal training can be challenging both financially and logistically for SSP operators. Consequently, it is important to build good relationships with police on the street and mid-level commanders, and to consider these activities in SSP budgets.

- *Open Dialogue between Law Enforcement and SSPs*

Building good relationships with law enforcement usually takes time, and the results may vary. Community leaders can act as a liaison between SSPs and law enforcement to ensure that communication between these two entities is effective. Most SSPs have a Community Advisory Board or a Board of Trustees. By including law enforcement representatives on these boards, health departments can also help build support and ensure that communication flows both ways.

3.4 Building Community Relationships

SSPs operate best in a supportive community environment. Staff, volunteers, and SSP participants should be involved in community engagement programs. Several strategies have proven effective across a broad range of programs and locations, including: (1) building relationships with community leaders, officials, opinion leaders, law enforcement, public health officials, religious leaders and groups, and businesses most affected by SSP site location; (2) educating the community about drug use, SSPs, and safe syringe disposal; (3) framing messages about SSPs to emphasize the community benefits, including reduced HIV and HCV infection rates, proper syringe disposal and cost-effectiveness; (4) understanding and addressing the concerns of resistant stakeholders in the community; (5) recruiting staff and volunteers who represent the community where the site is located; and (6) involving IDUs in the SSP planning process so their voices and concerns are heard.

This section discusses ways to build relationships with neighborhood groups, potential program participants, pharmacies and pharmacists, and waste management organizations.

3.4.1 Neighborhood Groups

Neighborhood groups can facilitate or impede the location of new SSP sites or maintenance of existing sites. Thus, it is important to partner with the following groups: medical and social service providers, neighborhood and/or homeowners associations, business owners, schools and faith-based groups.

A good way to work with neighborhood groups is to first meet with their boards and ask to participate in or present at larger group meetings. It also can be helpful to become a member of neighborhood groups when possible; however, membership requires that SSP staff members consistently attend and participate in group activities. If appropriate, including both a staff member and an SSP participant in the

neighborhood groups may be helpful. IDUs' concerns should be kept in mind when participating in community meetings. Presentations to community groups ideally convey the community-level benefits of SSPs, such as reduced HIV and HCV infection rates, proper syringe disposal, and cost-effectiveness. Presentations are opportunities for education and open dialogue, and it is helpful to anticipate concerns within the community and to come prepared with data and answer difficult questions.

3.4.2 Reaching Potential SSP Participants

To reach potential program participants, outreach workers need to have the IDU community's support and trust. Contacting IDUs initially may require time and patience but will help build a good foundation for the outreach effort. When outreach workers first approach potential SSP participants, they should introduce themselves and indicate the agency in which they work. Initially, outreach workers should be sensitive to any cues the potential participant provides to indicate she/ he is not interested in talking at that moment. They can simply let people know what services are provided and when they are offered. It is important for outreach workers to develop a comfortable relationship, while also keeping outreach and service delivery as priorities. Maintaining potential SSP participants' confidentiality is of the utmost importance, especially when program staff are talking with people in groups and people's personal information might be overheard. As they build a relationship with participants, outreach workers can discuss safer injection methods and health matters with them in a way that does not seem threatening. Furthermore, culturally competent outreach practices consider the distinct needs of IDU subpopulations (e.g., MSM, women, youth and transgender persons) and also help build support for the program within the community.

Another good resource for conducting street outreach is peers, because they have access to social networks of IDUs. Since they are a part of the IDU community, they may be able to gain peoples' trust faster than non-peer workers. In addition, peers often know the best locations for outreach efforts, can foresee potential challenges to getting IDUs into the program and can help outreach workers assess situations and offer solutions.

When an agency engages in street outreach, it is important to consider the safety of outreach teams, including secondary exchangers (see Section 5.3); culturally appropriate personnel and attire; culturally relevant educational materials and supplies; training and materials for safe syringe disposal; outreach worker training in overdose prevention, recognition and response; and procedures for documentation of outreach activities, including any adverse incidents.

3.4.3 Emergency Departments

For some IDUs seeking health care services for detoxification, wound infections, abscesses and overdose, emergency departments may serve as access points to locate and recruit IDUs for SSPs. Emergency departments can refer IDUs to SSPs for not only sterile syringes, but also for wound care and overdose prevention education, HIV and STD screening, and substance abuse treatment services. SSPs can provide information about the partnering medical facility and refer IDUs for medical care. Other potential partnership strategies may include having a medical practitioner imbedded within a fixed site or mobile-based SSP, and SSP staff accompanying IDUs to emergency departments to better facilitate access to medical care.

3.4.4 Pharmacies and Pharmacy Organizations

Pharmacies and pharmacists can not only provide sterile syringes to IDUs, they can also be a good resource and a strong ally for other SSP modalities. As health care providers who generally work with large and highly diverse populations, pharmacists may be willing to speak directly with their colleagues

about SSPs. Professional pharmacy organizations, most of which are registered with their state pharmacy governing body, and pharmacy schools have regular meetings and conferences that can be important venues for presentations on issues related to community health. To reach pharmacists working at large chains, contacting the pharmacist supervisor at the parent company and offering to work with them on strategies to get information to other pharmacists within the company are often good strategies.[54,55]

After determining the geographical reach of the SSP, the SSP can easily locate all of the pharmacies through the telephone book or the internet. It is recommended to telephone or approach pharmacists in person and schedule times to come in and talk to them about the SSP.56 Successful SSP outreach to pharmacists should include information and handouts about: (1) the local program(s), including the available services, target population demographics, and the location and hours of sites; (2) local laws that might allow them to enhance syringe access independently of the SSP; and (3) general education about common concerns (e.g., "Will SSPs increase discarded syringes?", "Increase crime?", "Increase drug use?," etc.); and (4) the epidemiological evidence for SSP efficacy.[56,57] It also may be useful to maintain a list of supportive pharmacies and the services they are willing to provide to IDUs, their hours and locations, and all of the necessary information for IDUs to use the services.

3.4.5 Waste Management for Syringe Disposal

As part of building community partnerships, it is useful to engage city, county or state waste management boards and their leadership, meet with them to introduce the program, and outline waste management plans. Working with waste management staff is a good way to discuss how to expand syringe disposal through hazardous waste disposal programs already in place or stand-alone syringe disposal kiosks.

OPERATING PRINCIPLES of SSPs

Several elements should be considered in developing local operating principles for syringe services programs (SSPs). This section first describes strategies to reduce the consequences of drug use, the philosophy underpinning SSP operating principles. Also provided in the section is a detailed description of program implementation, registration procedures, three types of syringe transaction models, safe syringe disposal practices, and the types of health and social services that can be offered on-site or through linkages with outside agencies.

4.1 Reducing Drug Use Consequences

Over time, strategies like SSPs reduce the risks and negative effects associated with substance use and addictive behaviors for the individual, the community and society as a whole. While one must take care not to promote drug use, these strategies consider the situations drug users are in by addressing the conditions of drug use. The following principles represent a general understanding of the underpinnings of such interventions:

- Drug use is complex, encompassing a spectrum of behaviors from occasional use to extreme abuse.
- All illegal drug use is harmful. Some forms of drug use are manifested differently than others in terms of the mental and physical health consequences (e.g., overdose, HIV and HCV transmission risks).
- Social inequalities, such as poverty, racism, classism, past trauma, social isolation and sex-based discrimination, influence people's ability to deal with drug use and its consequences effectively. Additionally, environmental factors, like drug availability and non-enforcement, can lead to different outcomes of drug use.
- People in recovery from drug addiction should be involved in the creation and implementation of SSP programs and policies. Services need to be provided in a manner that will help to guide people into services rather than keep them from accessing needed services. Services need to be available to everyone, regardless of gender, race/ethnicity, age, socioeconomic status or sexual orientation.
- Drug users are primarily responsible for reducing the negative outcomes of their drug use. Thus, SSPs strive to get drug users to share information about strategies that might work in their situations and support each other in using those strategies.

4.2 Program Registration

In many SSPs, the formal establishment of a relationship between IDUs and the SSP begins with intake or enrollment. The enrollment experience can be important in gaining the participant's trust and setting the tone for future interactions. SSP staff may need to use a longer intake process for referral to additional services, such as medical care or social services.

SSP registration can serve two potential purposes:

1. The registration process can serve as a formal welcome to the SSP and provide an opportunity for educating participants in the range of services offered and assessing participants' needs. However, it is important for the program to take cues from participants in terms of how much to engage them at first, because some people may initially be reluctant to disclose information or stay at the site for any length of time.
2. By registering participants, the SSP can collect statistical data that staff can use to monitor the program. The purpose of monitoring is to ensure that the program is operating in conformity to its design, reaching its specific target population, and achieving anticipated implementation goals (see Section 6). Future monitoring activities can then be linked to the same participant through a unique participant code.

Table 3 presents the types of information that might be collected at intake/enrollment. This list offers a range of ideas and is not an intake template.

4.2.1 SSP Identification (ID) Cards

In areas where SSP participants receive legal protection for needle possession as a result of being formally enrolled in the SSP, ID cards can be a useful tool (See Figure 1. for example). Using ID cards can also facilitate transactions once participants have been enrolled in the program. Similar to other enrollment procedures, the use of ID cards should be instituted only if there is a clear benefit to the participant, such as legal protection. Using ID cards may cause concerns about the lack of anonymity for program participants. If ID cards are used, it is recommended that the program construct unique codes using non-identifiable information the participant can easily recall.

Figure 1. Syringe Services Participant Identification Card Example.

Table 3. Types of Information Potentially Collected at Syringe Services Program Intake	
Information	**Purpose**
First name *only*	Identifies the individual as a participant, which may protect him/her from law enforcement
Initials	As an alternative to participants' names
Birth year	To describe the service population
ZIP code or area of current residence	To describe the program's reach and identify geographic areas where there are gaps
Sex or gender	To describe the service population
Sexual Orientation	To describe the service population
Race/ethnicity	To describe the service population
Preferred Language	To tailor program services to participants' needs
Injection frequency	To estimate syringe needs for needs-based distribution models (see Section 4.3.1)
Drug preferences	To evaluate program services and tailor them to participants' needs.
Medical Home	To identify access point for medical care for program planning and referrals
Access to Other Services	To identify needed medical, substance abuse, and mental health services for program planning, referrals, and quality improvement
Social Determinants of Health	To identify homelessness, unemployment, and other social factors for program planning and referrals
Overdose History	To identify needed overdose prevention trainings
HIV/HCV status	To identify HIV/HCV prevention and care services needed

4.3 Syringe Transaction Model

The goal of SSPs is to provide as close to 100 percent syringe coverage as possible, which means a sterile syringe for every injection of every IDU in a jurisdiction. CT DPH funded SSPs are required to use SSP client's needs-based/negotiated distribution model. The sections below describe the different types of syringe transaction models followed by a discussion of the strengths and limitations of each.

4.3.1 Needs-Based/Negotiated Distribution

In the needs-based/negotiated syringe distribution model, the program does not set a limit on the syringes a participant can receive regardless of the number of returned syringes. Although SSPs using this model generally encourage participants to return used syringes, participants can still receive sterile syringes even if they do not. The number of syringes distributed is negotiated based on the participant's need, taking into account the number of people the participant is serving, the frequency of injection and the length of time until she/he can next access the SSP. Some SSPs place an upper limit on the number of syringes distributed under this model (e.g., 100 or 500-syringe limit), but they do not place a limit on how often a participant can access services.

4.3.2 Strengths and Limitations of Needs-Based/Negotiated Transaction Model

Prior research has shown that the needs-based/negotiated distribution model is best at achieving the goal of reaching as close to 100 percent coverage as possible.[45] Although the needs-based/negotiated distribution model is better at increasing syringe coverage to both primary and secondary exchangers, programs may have other reasons for using a one-for-one exchange model. In some communities, it is more politically palatable to assure everyone that the program is exchanging needles as opposed to distributing them. The one-for-one exchange model may also be better than the needs-based/ negotiated model at encouraging IDUs to access the SSP more often, which may increase opportunities for them to dispose of used syringes and the chances they will use other services, including HIV/HCV testing and drug treatment. Lastly, the needs- based/negotiated model may require spending more money on syringes, which depends on budgets and funding agencies.

4.4 Safe Syringe Disposal

All disposal venues, including SSPs, must comply with federal, state and local regulations for disposing of used syringes, which qualify as regulated medical waste (RMW). According to these regulations, CT DPH must ensure proper disposal of used syringes by SSPs. Proper disposal of used syringes is critical to protecting individual health and public safety. Safe disposal procedures help prevent accidental needle stick injuries among staff, volunteers, participants and the public. Infectious diseases can be transmitted during an accidental needle stick; therefore, the experience can be very stressful for the people involved. Furthermore, making disposal resources available to IDUs helps reduce the amount of syringes and other injection equipment found "on the street," helping to protect the SSP from public scrutiny.

SSPs must document policies and procedures governing disposal of RMW and supervise disposal to ensure that staff and volunteers are adhering to the rules. It is also important to examine statewide regulations for the proper handling and disposal of RMW.

The following suggestions may help guide safe disposal procedures:

- OSHA training on universal precautions is required for all new SSP staff in order to ensure employees' safety, health, and well-being.
- Examine potential partnerships with waste management companies to obtain and dispose of RMW.
- Reserve funds to hire a private waste management service to collect and dispose of RMW. In many cases, these services include any necessary supplies to properly package RMW for disposal. Hiring a service also helps document proper disposal of used injection supplies.
- Do not require that returned syringes be counted by hand. Estimates can be made by observation or by weighing the returned syringes to determine the number of syringes disposed of for monitoring purposes.
- If the SPP uses a mobile unit, close sharps containers when the vehicle is moving in case the vehicle stops short or there is an accident. Similar strategies should be used when conducting street outreach.

4.4.1 Prevention of Occupational HIV/HCV Transmission among SSP Staff

As is the case for other health care workers, SSP staff can be at risk for acquiring HIV/HCV from needle stick injuries and cuts during syringe exchange and disposal. As a result, SSP staff is require to always practice OSHA universal precautions. To prevent the occupational transmission of HIV/HCV, CDC offers these recommendations:[57]

SSP staff should assume that blood and other bodily fluids from SSP participants are potentially infectious, therefore requiring infection control precautions at all times including:
•Routine use of barriers (e.g., gloves, goggles, closed-toe and closed-heel shoes) when anticipating contact with blood;
•Immediate washing of hands and other skin surfaces after contact with blood or body fluids; and
•Careful handling and disposing of sharp instruments during and after use.

Although prevention of occupational HIV transmission is the most important strategy, SSPs should have plans in place for post-exposure management of staff. CDC has issued guidelines for management of health care worker exposure to HIV and recommendations for post-exposure prophylaxis (PEP).[58] These guidelines provide considerations in determining whether health care workers should receive PEP and in choosing the type of PEP regimen. For most HIV exposures that warrant PEP, a basic four week, two-drug (multiple options) regimen is recommended. For HIV exposures that pose an increased risk of transmission (due to infection status of the source and type of exposure), a three-drug regimen may be recommended. Issues such as delayed exposure reporting, unknown source person, pregnancy in the exposed person, resistance of the source virus to antiviral agents and toxicity of PEP regimens are also discussed in the guidance. Occupational exposures should be considered urgent medical concerns.

SSPs should demonstrate continued due diligence to reduce the risk of occupational HIV transmission by:

- Annually train all staff in infection control procedures and the importance of reporting occupational exposure; and
- promoting and monitoring the availability and use of safety devices to prevent sharps injuries, and developing a post-exposure management plan.

4.5 Health and Social Services: Provision and Linkage

IDUs participating in SSPs may need services to prevent HIV and HCV infection and to address other health and basic human needs. CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) has developed a strategy called Program Collaboration and Service Integration (PCSI) to help health departments, CBOs and other NCHHSTP-funded entities improve health outcomes, efficiency and cost-effectiveness. PCSI is a mechanism for organizing and blending interrelated health issues, activities, and prevention strategies to facilitate a comprehensive delivery of services.58 SSPs and state and local health departments can use PCSI to structure health delivery to populations of IDUs and specifically to address the challenges associated with integrating services at a SSP location or through linkage to community service providers.

The key principles of effective PCSI include the following:[59]

Appropriateness: Integration of services must make epidemiologic and programmatic sense and should be contextually appropriate.

Effectiveness: Prevention resources cannot be wasted on ineffective or unproven interventions.

Flexibility: Organizations need the ability to rapidly change and assemble new prevention services to meet changing epidemiology, population demographics, advances in technology, or policy/ political imperatives.

Accountability: Prevention partners need the ability to monitor key aspects of their prevention services and gain insight on optimizing operations.

Acceptability: PCSI must lead to improved acceptability to clients, programs, and providers through improved quantity and quality of the integrated services.

Agreements: All partners having a formal document such as a Memorandum of understanding (MOU), describing the broad outlines of an agreement that two or more partners have reached through negotiations.

Understanding: Prevention partners need to have an understanding of the Drug User Health frame work which states that all drug users should:

- have the means by which to protect their health, including access to sterile injection equipment sufficient to meet their needs.
- receive accurate, non-biased and non-judgmental information on illicit drugs and other substances.
- receive the same level of care as any other individual accessing health care or social services.
- have access to drug and alcohol treatment on demand.

Providers should:

- recognize the valid and valuable expertise that people who use drugs can give to designing, delivering and evaluating effective services.
- ensure that the provision of services to drug users is not contingent upon the individual's agreement to enter drug treatment, or abstain from drug use. Service providers must not withhold appropriate treatments or services from drug users.

Services should:

- be provided to encourage engagement and retention in care.

With PCSI principles as the foundation, the next sections outline strategies SSPs can undertake to increase access to services, describe the array of services that SSPs can offer and discuss how to decide whether to provide services on-site or through referral agencies.

4.5.1 Strategies to Increase Access to Services

SSPs can enhance their success by employing the following strategies:

- Establish collaborative relationships with referral agencies.
- Make referrals, when possible, to social service agencies that aim to reduce drug use and its consequences.
- Address barriers to accessing services (e.g., financial, transportation, child care, arrest warrants).
- Have designated staff call ahead and escort participants to referral sites and advocate for their care.

Local health departments can work with community agencies to ensure that SSP participants are able to access services. Specific strategies include the following:

- Develop protocols for referrals to relevant medical, mental health, substance abuse treatment, and social services.
- Identify points of contact within each referral agency that can facilitate SSP participant access to needed services.
- Work with SSPs to train other agencies about SSPs.
- Provide incentives or mandates for collaboration with SSPs, including referrals to SSPs by community agencies.
- Address barriers to care at community programs, including stigmatization of drug users and abstinence as a requirement for receiving services.
- Support flexible community programs that are inclusive of drug users.
- Involve state HIV/ hepatitis /sexually transmitted disease (STD) coordinators.

Using a combination of motivational interviewing and financial incentives has shown promise in increasing enrollment of referred participants in drug abuse treatment.[60]

4.5.2 Specific Health and Social Services

Education and Counseling

SSPs play an important role in providing information and counseling to IDUs that allow them to reduce the consequences associated with drug use and to increase their general well-being. SSP staff can benefit from training on providing accurate information and using evidence-based approaches to counseling. Educational materials need to be accurate, up to date and matched to the population served in terms of cultural relevance, language and reading level. Specific areas to be covered can include:

- SSP services, location and hours;
- local health centers and clinics locations and hours;
- safer injection practices and vein care;
- safer sex practices;
- identification and treatment of soft-tissue infections;
- HIV, HCV, HBV, and STD prevention and treatment associated with unsafe drug injection and sexual practices;
- drug abuse treatment options;
- overdose prevention and response; and
- accidental needle stick response.

Social Services

SSPs can help participants meet basic needs and increase engagement by providing an array of services that are appropriate for the population served and by providing appropriate referrals for services not offered on-site. Potential services can include:

- food and clothing distribution;
- hygiene supplies (e.g., feminine products, soap);
- child care;
- telephone, mail, and computer access;
- vocational assistance;
- legal aid; and
- housing.

Medical Care

IDUs have the same preventive and general medical care needs as the general population. However, they also are at higher risk for specific health problems, such as blood-borne infections and wounds. Medical services can range from screening to comprehensive care, including:

- HIV, HBV, HCV, tuberculosis (TB) and STD screening;
- linkage to and retention in care for IDUs living with HIV and/or HCV;
- primary medical care;
- pregnancy testing and prenatal care;
- vaccinations (hepatitis A/B, influenza, pneumonia);
- TB prophylaxis;
- wound care; and
- evidence-based complementary and alternative medicine (e.g., to reduce drug dependency, massage, acupuncture).

Mental Health Services

IDUs using SSP services have a high prevalence of psychiatric disorders, such as major depression and antisocial personality disorder.[60] SSP staff may benefit from training on recognizing the signs and symptoms of common psychiatric disorders so that appropriate services can be provided on-site or through a referral agency. SSP mental health services can include:

- screening and referral;
- individual and group therapy;
- psychiatric evaluation and treatment; and
- suicide prevention.

Sex Worker Care

Sex work is defined as the use of sexual activity for income or employment or for non-monetary items (CDC, 2014). Given the nature of the work, sex workers, their clients, and their regular partners are at increased risk of becoming infected with HIV or other sexually transmitted infections. Some sex workers or clients may be involved in additional types of risky behavior, such as injection drug use (World Health Organization, n.d.). SSP should aimed at empowering sex workers and providing them with:

- HIV prevention and care;
- STD prevention and care
- support services
- harm reduction outreach
- non-judgmental care

Centers for Disease Control and Prevention (CDC). (2014). HIV Risk among Adult Sex Workers in the United States. Retrieved April 22, 2014, from http://www.cdc.gov/hiv/risk/other/sexworkers.html

World Health Organization (WHO). HIV/AIDS: Sex Work. Retrieved May 9, 2014, from http://www.who.int/hiv/topics/sex_work/en/

Drug Abuse Treatment

IDUs using SSP services are often characterized by a high severity of drug dependence and the abuse of multiple substances.[61] Although they report high levels of interest in drug abuse treatment, IDUs have relatively low levels of enrollment.[62] Barriers to accessing drug abuse treatment may be related to lack of finances or transportation, an inadequate number of treatment slots and a lack of dual-diagnosis services.

Locating drug abuse treatment services on-site at SSPs can be an effective solution. Community drug abuse treatment programs that do not have restrictive eligibility criteria enable more SSP participants to use the services. Services available on-site or by referral can include:

- assessment, counseling and referral;
- drug counseling and support groups;
- buprenorphine treatment for opioid dependence (on-site or by referral);
- methadone treatment (payment vouchers and dedicated SSP treatment slots facilitate entry);
- medically assisted detoxification; and
- residential treatment.

Overdose Prevention

Overdose is a major cause of mortality among drug users, [63] and SSPs can address overdose prevention and response with both staff and participants. Naloxone is a drug used to counter the effects of opiate overdose. Making naloxone available to trained staff, volunteers, and participants is a recommended evidence-based strategy that reduces opioid overdose fatalities.[63] Key overdose prevention strategies include: [64]

- providing comprehensive training on overdose prevention, recognition and response for all SSP staff and volunteers, including rescue breathing and the use of naloxone;
- developing protocols for responding to overdoses on-site;
- educating program participants about overdose prevention and response;
- referring program participants to where they could naloxone; and
- making naloxone available to program participants, if resources permit.

4.5.3 Provision or Linkage

Based on multiple factors, including location, financial constraints, availability of community resources and participant preference, SSPs will need to decide to either co-locate services or provide linkages to community resources. Research and SSP experience suggest that co-location of services has advantages in both acceptability and effectiveness for SSP participants[64] because IDUs have relatively low rates of utilization of community services. Consequently, the SSP may be the participant's only or most trusted point of contact with service agencies. Moreover, providing services on-site increases utilization rates. For SSPs operating in areas with limited community resources, on-site services may be the only option.

Using community linkages to provide services also has advantages, because these collaborations can help organizations broaden their mission, develop more comprehensive strategies, ensure that participants receive high-quality services, minimize duplication of services and make the most of available resources.

SERVICES DELIVERY MODELS

Various service delivery models can be used to make syringes available. SSPs may find that the best approach is to use a single model exclusively or to combine models to expand the program's reach. When choosing a service delivery model, SSPs will find the results from the needs assessment process helpful. Model selection should be driven by numerous factors such as available resources and budget, the organizational infrastructure, local political concerns, availability of staff and volunteers, and the local drug subculture and geographic context. Staffing needs may vary depending on service modality as well as participant volume. For solely distributing and disposing of syringes in low volume programs, adequate coverage can be achieved with as few as two people. However, a minimum of two workers would be preferable for SSPs. Job tasks break down as:

- syringe distribution;
- syringe collection;
- data collection; and
- referral to services.

Staffing needs increase as more services are added to accompany syringe distribution and collection. The following sections briefly outline the inherent strengths and potential limitations of different SSP models, including fixed site, mobile/street based, secondary/peer delivery, delivery and pharmacy provision. Next, we present factors that affect the choice of syringe service modalities in rural settings. The section closes with a discussion of the benefits of blending program models to achieve the highest possible coverage.

5.1 Fixed Site

Fixed-site models include hospital/clinic-based settings, drop-of-centers, integrated syringe access services, and collaboration or satellite structures. Typically in fixed-site models, the SSP is located in a building or specific location, such as a storefront, office, or other space with street-level access. Fixed sites work best in health jurisdictions where IDUs are clustered in a somewhat centrally located area.

The strengths of fixed-site models include the following:

- It is easier for other social service agencies to refer their clients to the SSP because there is a set location with predictable hours.
- Other services can be integrated with SSP activities, including HIV, HBV, and HCV testing; PrEP navigation, STD testing; TB screening and prophylaxis; food provision; buprenorphine treatment; abscess and wound care; and overdose prevention.
- Having a permanent site makes it easier to tailor the space to the needs and preferences of the participants.
- Computer-based systems (e.g. electronically tracking inventory of syringes) can more easily be supported in a set indoor location.
- SSP services can be provided in private.
- The location provides shelter from weather and street-based activities (e.g., drop-of-centers).
- On-site storage space may be available to house materials.

The potential limitations of fixed-site models include the following:

- A fixed-site is more costly to maintain because of higher overhead and upkeep.
- Drug users may be reluctant to go to the site because of concerns about stigma.
- It can be challenging to stay abreast of and adapt to changes in the drug scene (e.g., if the SSP's location is no longer close to where IDUs congregate).
- The community may not support the site's location.
- Participants must come to the site, which can be a barrier if IDUs are spread apart geographically and do not have transportation.

5.1.1 Hospital/Clinic-Based Settings

One fixed-site model of syringe access is locating services at a hospital or clinic-based setting. In this model, IDUs who come to hospitals or clinics can obtain syringes from health care providers and dispose of them there.[65] Distributing syringes from hospitals may be appropriate in health jurisdictions with greater restrictions on other SSP models and is often used in conjunction with other types of models.

The strengths of hospital/clinic-based settings include the following:

- Access to syringes may be greater with this type of model because doctors in hospitals can more easily write prescriptions for syringes.
- On-site procedures exist for disposing of RMW.
- It is easier to conduct overdose prevention, including providing a prescription for naloxone.
- Exchanges can take place more privately.
- It is possible to provide clients with immediate medical care for abscesses and other wounds or health issues.
- HIV and/or HBV and HCV testing exists on-site.
- Concerns about stigma are lessened because visiting hospitals and clinics is not associated specifically with drug users.

The potential limitations of hospital/clinic-based settings include the following:

- It requires IDUs to identify themselves as IDUs to their health care providers, which means they lose anonymity.
- Staff and clinicians in particular, may have to overcome preconceived notions about drug use and drug users.
- Many IDUs have had negative experiences in hospitals and clinics (i.e., poor medical treatment, stigmatization), which may lessen their interest in going there.
- Securing resources may be difficult.
- The environment may be too "clinical" and uninviting.
- Staff will likely need regular cultural sensitivity trainings.
- Pre-existing rules and regulations may make it challenging to implement certain services (e.g., Hospitals and clinics may require the confidential collection of identifying information from SSP participants. This expectation would conflict with a SSP that permits anonymous access to services by participants.)

5.1.2 Integrated Syringe Access Services

In the integrated syringe access services model, an organization that is already serving IDUs in a fixed site adds syringe services to its existing set of services, rather than creating a separate SSP. In some cases, syringe services in these settings may be restricted to participants who are enrolled in the parent program, rather than being advertised and made available to all IDUs. Methadone maintenance treatment programs, homeless shelters, case management programs, research or clinical studies, and housing providers are all suitable settings for integrated services.

The strengths of integrated syringe access services include the following:

- This model may be easier to implement from a public relations standpoint because the community will already be accustomed to the organization and its participant base.
- Co-location of services increases IDUs' access to other services.
- The cost of this model can be relatively low if integration of syringe provision occurs within the current organizational framework.
- It easier to spread the word about services because there is an established participant base.

The potential limitations of integrated syringe access services include the following:

- Program success may be hampered if SSP services are not prioritized by the agency.
- There may be a lack of culturally appropriate materials.
- Program autonomy may be limited because of multiple funding streams.
- Staff will need cross-training.
- If the agency also serves non-IDUs, interactions between IDUs and non-IDUs may pose problems.
- The addition of syringe services may require additional engagement with relevant stakeholders (e.g., waste management for syringe disposal).

5.1.3 Collaboration or Satellite Structure

In the collaboration or satellite structure model, existing SSPs provide syringe services at partner social service agencies in fixed sites in the community (e.g., social services, shelters). It requires that the SSP provide capacity-building training for the partner agency. This approach works best in health jurisdictions where SSPs are supported and there is a need to increase access through multiple modalities.

The strengths of collaboration or satellite structures include the following:

- Access to services may be enhanced through additional locations and expanded operating hours.
- The existing participant base of IDUs can help advertise the availability of syringe services with their peers.
- The parent program has experience managing public relations, which may help increase community support for syringe services.

Additional operational and human resource costs may be offset because the parent organization already has the requisite systems and expertise, an established training program and sufficient staff to implement the additional services. It may expand the program's reach by attracting new groups of IDUs.

The potential limitations of collaboration or satellite structures include the following:

- It may be challenging to keep track of inventory if specific systems for doing so are not in place.
- The parent organization and satellite site may have different policies or procedures, which can lead to inconsistencies or discord.

5.2 Mobile/Street Based Programs

Mobile/street-based programs are conducted on foot, by bicycle or by vehicle (e.g., van, bus or recreational vehicle). This method is also referred to as outreach. Many mobile SSPs stop at specified locations and times, whereas others may simply roam unplanned. Although this model is often combined with a fixed-site program, it may also operate independently. This model is well suited to jurisdictions where IDUs do not congregate in centralized locations or where participants have limited transportation options.

The cost for mobile sites can vary based on the style of outreach implemented and the transportation needs. For example, some mobile sites involve setting up a cart with supplies (e.g., GHHRC Rover) on a street corner, whereas others use recreational vehicles. Aside from the cost of a vehicle, other costs must be considered, including automobile insurance, parking, maintenance and gasoline. Training should emphasize security and safety. To ensure staff safety, it is also important to collaborate with law enforcement and other community stakeholders about the program.

The strengths of mobile/street-based sites include the following:

- The program may encounter less resistance from the local community because it will not attract congregations of IDUs.
- Mobile sites offer heightened flexibility and the advantage of being closer to a street drug market, increasing accessibility for IDUs who are unable to come to a fixed site.
- The program can adapt to changes in the drug scene or neighborhood and can relocate to places where IDUs congregate.
- The existing participant base of IDUs can help promote the time and place of services to their peers.
- The informal and easily accessible location may help put participants at ease.

The potential limitations of mobile/street-based sites include the following:

- It is less anonymous, because people can see who is using the services in the community.
- Staff need to have a valid driver's license if a motor vehicle is involved.
- Services can be interrupted if the vehicle needs to be repaired.
- It can be harder to provide additional services that require a physical location.

- The work conditions can be stressful for staff because of inclement weather or concerns about safety.
- Supplies need to be stored elsewhere and transported to the sites.
- Participants may be reluctant to come to the SSP in inclement weather.
- It can be costly to maintain because of expenses related to vehicle maintenance and insurance.
- It may be more challenging to obtain law enforcement support for mobile routes comprised of multiple locations.

5.3 Secondary or Peer-Delivery Models

Secondary or peer-delivery models involve SSPs providing IDUs with syringes to distribute and disposal options to their drug-using networks. Peers often get compensated for providing syringe services in a variety of ways. Often, they are paid a stipend. In other cases, they voluntarily provide the services. Ongoing capacity building is both a necessity and a perk for peers. Secondary access is typically combined with a fixed site, such that peers can come to a fixed site and obtain and dispose of syringe equipment that they then provide to other IDUs in their social networks. However, it is also possible to arrange transfer of equipment through pick-up or delivery. Secondary models require a training program that builds the capacity of IDUs to deliver syringe services to their peers. Secondary and peer-based models need to have established policies, procedures and legal protections for peers. Legal restrictions regarding the distribution of paraphernalia may limit peer-delivery options. Secondary models are best suited for health jurisdictions that are very large geographically and where IDUs tend not to be congregated in dense areas.

The strengths of secondary or peer-delivery models include the following:

- For a low cost, the program can reach many IDUs in geographically distant locations.
- Peers' knowledge of the drug market and local drug scene can extend the program's geographical reach.
- Groups of IDUs who may be less likely to visit an SSP can still get sterile syringes and dispose of used ones safely.
- Peers may feel empowered by conducting a public health service in their community.

The potential limitations of secondary or peer-delivery models include the following:

- When peers collect and transport other participants' used injection equipment, they face safety issues.
- It can be difficult for peer workers to separate out their roles as SSP providers and IDUs in the community.
- If peers are unavailable (e.g., quit using, get arrested, move away), IDUs lose their access to supplies.
- Significant costs are associated with training and supervising secondary exchangers.
- Lack of appropriate oversight could result in misinformation disseminated to IDUs.

5.4 Delivery Model

The delivery model involves the delivery of injection supplies to a prearranged site, such as a house, apartment, hotel, shooting gallery or other prearranged location. Service delivery can take place on a regular schedule or by appointment. It is a direct means of observing the more private aspects of participants' living situations, and services can be developed and tailored to meet those needs. Medical and nutritional services, overdose prevention, directly observed therapy and safer injection education, for example, can all occur in the privacy of a person's home. When syringe delivery staff members are in participants' homes, consideration needs to be given to legal concerns about reportable conditions, such as suspected child abuse. On the one hand, parenting skills can be an educational component of delivery; on the other hand, delicate and fragile relationships can be affected by legal requirements.

Delivery is an excellent option in rural jurisdictions, where there are often large geographical areas to cover and privacy is of utmost importance. Delivery may be combined with mobile or fixed sites. Enhanced training for staff and volunteers on safety and confidentiality of participants' needs is necessary.

The strengths of delivery models include the following:

- This form of syringe access is more discreet and consequently reduces negative reactions from the neighboring community, which is rarely aware of the program activity.
- Since participants do not have to transport used injection equipment, it reduces needle stick risk and potential involvement with law enforcement.
- It can be easier to begin a delivery program than other program models due to the reduced need for a physical space.
- Information sharing about injection practices, health, and other issues can occur more privately.
- Participants' safety is enhanced if they do not need to leave their home.
- It increases access to IDUs who may be less likely or unable to attend a fixed site.
- SSP staff have more opportunities to interact with family and peer networks.

The limitations of delivery models include the following:

- It requires the SSP to have and use transportation to provide services.
- It can be challenging to sustain because of staff burnout.
- It can be potentially time consuming, depending on the geographic dispersion of participants.
- It may take time to overcome potential privacy concerns and build a foundation of trust.
- Worker and volunteer safety is a concern.
- It can be expensive to maintain and insure vehicles.

5.5 Pharmacy Distribution Model

Over-the-counter sale of syringes through pharmacies is an important model of syringe access and disposal for IDUs. Pharmacists are knowledgeable and often support community providers. However, they seldom have the time and/or experience to make essential referrals for drug-using SSP participants. Educating pharmacy staff about drug use, SSPs, and the public health benefits of providing syringes, and other related social and medical services is critical. It is also important for pharmacies to consider best disposal practices, including providing sharps containers to drug users just as they do for people with diabetes.

The strengths of pharmacy distribution models include the following:

- Connecticut law allows license Pharmacist to sale up to 10 syringes without prescription. (*Connecticut General Statutes 21a-65 – Sale of hypodermic needles and syringes restricted*)
- Pharmacies often stay open more and later hours than other models.
- Pharmacies often have more locations for IDUs to access than other SSPs.
- Services can be provided in mainstream locations, reducing concerns about stigma and privacy.
- Pharmacies would incur no additional financial cost to add syringe access, particularly if they sell syringes already.
- Participants can take advantage of other services that the pharmacy may offer, such as flu shots.

The potential limitations of pharmacy distribution models include the following:

- Pharmacists and pharmacy staff may not be culturally sensitive to the populations.
- Pharmacies may set a minimum (e.g., 10) or maximum (e.g., 100) number of syringes to distribute per transaction.
- Pharmacies may not want to provide other injection equipment, education, and social and medical service referrals.
- Pharmacies may be unable or unwilling to include syringe disposal services.
- Syringes cost money at pharmacies, which may be a hardship for impoverished IDUs.

5.5.1 Pharmacy Voucher Program

In a pharmacy voucher program, social service agencies work with pharmacies to create a voucher that IDUs can redeem for free syringes at participating pharmacies. This type of program eliminates barriers related to the cost of purchasing syringes at pharmacies. Pharmacy voucher programs are particularly helpful in jurisdictions where other SSPs have not been established and where the law permits the over-the-counter sale of syringes without a prescription. Voucher programs are also beneficial in jurisdictions

where drug use occurs in remote locations and IDUs cannot travel to an SSP. SSPs may provide pharmacies with equipment and disposal services in areas where pharmacy vouchers are used. One drawback is that this model involves two steps in providing syringes to IDUs. First, SSPs must find IDUs and provide them with vouchers. Second, IDUs must go to a pharmacy to receive the syringes.

5.6 Rural Settings

Certain service delivery models are more amenable to rural settings, whereas all models are appropriate for most urban settings. As privacy can be a greater concern in rural settings, having fixed sites outside of hospital settings or a pharmacy distribution model may not be feasible. The preferred model may be a combination of delivery and secondary/peer exchange models. It can be very time intensive and expensive for staff to drive to distant locations to provide services because the geographical area may be very large. Staff burnout and budget restraints may be mitigated by combining such driving with secondary models, then each trip ends up reaching many IDUs.

5.7 Using Multiple Program Models

Incorporating multiple models may be the most effective way for programs to expand syringe coverage and reach the greatest number and diversity of IDUs within a given health jurisdiction. Combining models—for example, a fixed site with a mobile van or a mobile unit with peer-based walking delivery—helps increase the likelihood that diverse populations have access to syringes. Also, using multiple program models is more flexible and can direct resources to the most affected areas, allowing programs to respond to changes in patterns among local IDUs. Using a multiple- model approach can require significant resources and demand more effort from staff. This can make them less sustainable. However, multiple program models can be a valuable, comprehensive approach when they are well executed and have sufficient resources.

MONITORING SYRINGE SERVICES PROGRAMS

The effectiveness of SSPs has already been established through scientific evaluations (see Section 2). Therefore, the main goal of monitoring local SSPs is to assess whether a program is operating in conformity to its design, reaching its specific target population and achieving anticipated implementation goals. CT DPH requires funded SSPs to continually conduct process monitoring and periodically conduct outcome monitoring.

6.1 Process Monitoring

The overarching goal of process monitoring is to document whether the program is being implemented as intended. The process outcomes to be monitored depend on the type of service delivery model selected and the type and number of additional services provided.

Process monitoring serves a number of important and valuable functions for SSPs:

- assesses which services are being used and how often they are used;
- facilitates accounting practices;
- allows SSPs to report back to CT DPH, and others (such as their communities) about program reach; and
- maintains or increases program support.

In addition, data can be used to monitor process outcomes, depending on the type of service delivery model and types of services provided. Appendix A lists additional process indicators that programs may wish to monitor, depending on the service delivery model and types of services that are provided in addition to syringe exchange.

Process monitoring does not require sophisticated statistical methods. Descriptive statistics are usually sufficient to answer process monitoring questions, such as comparing actual program outputs (e.g., number of HIV tests conducted) with target outputs (e.g., projected number of HIV tests conducted). CT DPH Drug User Health coordinator could provide funded SSPs descriptive statistics analysis support services.

CT DPH requires all funded SSPs to collect essential data elements by completing a client intake for each client the first time the client gets enrolled in the program, and maintain a daily transactions log for every time an enrolled client utilizes SSPs' services. Also, CT DPH funded SSPs are required to enter all collected SSPs act

6.2 Outcome Monitoring

SSP clients' satisfaction assessments should occur periodically with SSP participants for outcome monitoring. Outcome monitoring provides important information for improving program efficiency, quality and effectiveness. In general, outcome monitoring methods should aim to minimize participant burden, not disrupt normal program activities and only collect information that is critical for understanding process outcomes. Utilizing a variety of data types and sources, together with program specific outcome monitoring activities, enhances the assessment of the SSP. For example, data that provide information on HIV incidence rates, HCV incidence rates, crime statistics, incarceration rates and arrest rates may provide system-level indicators for the impact of the program on outcomes related to the overarching goals of the SSP.

SSP clients' satisfaction assessments conducted with SSP participants should occur annually or every other year and include between 100 and 200 participants, depending on the size of the program. Choosing participants randomly is preferable but may not be feasible in all locations or for all syringe modalities.

Key domains for SSP outcome monitoring include:

- types of services used at the SSP;
- frequency and duration of SSP use, including estimation of numbers of syringes distributed in a given period;
- receptive and distributive syringe sharing;
- disposal practices;
- overdose risk and history;
- access and linkage to drug treatment and medical and social services (e.g., referrals and linkage to medical homes, mental health services and homes and substance abuse treatment facilities);
- participant satisfaction with program elements, such as hours, locations and staff interactions;
- client characteristics (e.g., demographics, injection drug use history, medical history, and substance abuse treatment history);
- drug use preferences (e.g., types of drugs used, including, fentanyl, hormones or steroids) and practices (e.g., with whom and how often participants use drugs);
- estimates of number of IDUs reached through secondary exchange; and
- changes in drug use, injection, and treatment as a result of SSP participation.

6.3 Program Quality Improvement (QI)

Program quality improvement relies on the systematic collection and use of process monitoring and periodic outcome monitoring to determine if and how well program objectives are being met and to reassess program goals. If goals are not being met, program quality improvement can help SSPs decide if and how to change services to better meet the needs of the target population.

Based on program goals, working with a research partner can be an appropriate method for assessing program quality. Quality improvement may include perspectives from community stakeholders, SSP participants, and others with important perspectives regarding the usefulness and effectiveness of the SSP. For instance, programs can use methods such as key informant interviews and focus groups to assess participant satisfaction with program elements, such as hours, locations and staff interactions; learn how SSP participants use program services; or understand how new services might be received. Using unobtrusive approaches, programs can observe SSP transactions systematically to identify opportunities to provide more education, counseling, or other services or simply time them to determine barriers to providing other activities. Many quality improvement ideas can also be discussed through a participant or community advisory board if the SSP has one.

CAPACITY BUILDING

SSPs have been operating since the mid-1980s in the U.S. Numerous program implementation manuals and guides exist and purveyors of exchange supplies are available for both product development and advice. In addition, many health departments have experience implementing

SSPs and can serve as advisors and mentors to health departments looking to begin these programs. Law enforcement officials, as well as publicly elected officials, are also resources for information and assistance with the process for gaining acceptance and approval of SSPs. Several nonprofit organizations, universities, health departments, research institutes and training centers have many years of experience providing training and technical assistance. SSP participants can also provide valuable testimony to the positive impact of SSPs on their lives, in addition to pragmatic and essential input regarding effective program strategies. In general, it is best for peers to train peers.
For example, health departments may learn best from other health departments, and law enforcement may learn best from other law enforcement agencies.

7.1 Assessing and Addressing Capacity Building Needs

Before initiating or expanding SSPs, a health department may find it useful to assess its readiness with a jurisdiction (described in Section 3.2). In addition to identifying a specific or mix of SSP models that may be appropriate in a specific jurisdiction, health departments can identify areas of strength, potential deficits and promising strategies to mitigate gaps in organizational and programmatic capacity. It could be useful to discuss the results of the readiness assessment with the HPPG and other partners to facilitate the prioritization process.
Numerous tools exist for assessing readiness (see Section 7.3 for a list of resources). Readiness is typically assessed across a variety of domains including law enforcement and political climate, neighborhood receptivity, resource availability, staff availability and capabilities, infrastructure for staff training and development, leadership support, access to the target population, adequate space in which to implement program services, access to referral networks, availability of supplies, and capacity to conduct program monitoring.
It is likely that new and existing SSPs will have different capacity building needs based on their stage of development. For example, new SSPs will be concerned with learning about the many ways they can implement services, whereas existing SSPs may be more interested in learning about strategies for program improvement or expansion.
Section 7.3 includes a variety of capacity-building resources that can benefit new and existing SSP's alike.
To address identified organizational and programmatic needs, health departments may consider the following strategies to build capacity:

- Peer-to-peer delivery is a particularly effective model for capacity building. It is strongly recommended that programs build in time and resources to learn from others in the field. For example, new programs can learn effective implementation strategies from long-standing programs, such as how to work effectively and competently with the IDU community, law enforcement, pharmacists or the community at large. Existing programs, for instance, can benefit from consulting with their peers about program expansion or ways to address emergent barriers to implementation. Law enforcement can reach out to

their peers in other cities or states. Pharmacists can speak with pharmacists in other areas that have already implemented SSPs. Peer-based capacity building may encompass site visits, conference calls, or other forms of communication.

- CDC funds non-governmental organizations to deliver free capacity-building assistance (CBA) designed to assist health department jurisdictions to implement and sustain science-based and culturally proficient HIV prevention behavioral interventions and HIV prevention strategies, including SSPs. CBA comprises information dissemination, training, technical assistance, technology transfer and facilitation of peer-to-peer mentoring and support. CT DPH may request CBA to improve organizational infrastructure and program sustainability, evidence- based interventions and public health strategies, community planning, monitoring and evaluation.

7.2 Building Capacity of SSP Staff

Building capacity of staff increases individual skill level and overall service quality and productivity. In addition to improving service delivery, training staff on the program's philosophy and mission helps ensure that participants feel welcome at the SSP and are comfortable accessing services.

SSPs often have staff or volunteers who can provide training on a regular or ad hoc basis. Other times in-house training is not available on important topics. In such cases, training and technical assistance can be obtained through other mechanisms. A number of organizations and institutions provide training and technical assistance to SSPs (*see Section 7.3 for a list of capacity-building resources on a variety of topics*). Additionally, staff and volunteers can attend conferences and off- site trainings that can be good opportunities to interact with other providers and gain relevant experience and insight.

It is recommended that all staff and volunteers complete a basic training curriculum that encompasses the core topics shown in Table 4. In addition to the core training program, SSPs should prioritize ongoing staff development by offering advanced training on topics such as those shown in Table 4.

Table 4. Basic and Advanced Training Topics for SSP Staff

Basic Training Topics	Advanced Training Topics
• Standard operating procedures • Referral to medical, substance abuse treatment, mental health, other service agencies • Cultural sensitivity • Overview of neighborhood concerns • Outreach strategies • Training secondary exchangers • HIV and viral hepatitis transmission and prevention • Overdose prevention • Syringe safety/disposal • Plan for accidental needle sticks • Legal and law enforcement climate	• Polysubstance use • Conflict resolution and de-escalation • Specialized interviewing techniques (e.g., motivational interviewing) • Principles of case management • Abscess and cellulitis treatment and prevention • Domestic violence issues • Co-occurring mental health and substance use disorders

7.3 Capacity-Building Resources

This section includes links to Web-based resources to build the capacity of health departments to plan and implement SSPs. The contents of non-governmental websites do not necessarily represent the views of CT DPH. Search in the internet for:

Examples of SSP Policies, guidelines and Best Practices from States, cities and CBOs

–District of Columbia Needle Exchange Programs Policies and Procedures Manual:

–The Chicago Recovery Alliance

–San Francisco Department of Public Health, Syringe Access and Disposal Program Policies and Guidelines

–New York State Department of Health, AIDS Institute, Syringe Exchange Programs Policies and Procedures

–Ontario Needle Exchange Programs: Best Practice Recommendations

Evaluation Resources

–CDC Framework for Program Evaluation in Public Health

–W.K. Kellogg Foundation Evaluation Handbook

–Evaluation Guidance Handbook: Strategies for Implementing the Evaluation Guidance for CDC-Funded HIV Prevention Programs

General Resources

–CDC Capacity Building Assistance Portal for HIV Prevention

–Recommended Best Practices for Effective Syringe Exchange Programs in the United States: Results of a Consensus Meeting

–Department of Health and Human Services Implementation Guidance for Syringe Services Programs

–North American Syringe Exchange Network

Legal Strategies

–The Project on Harm Reduction in the Health Care System

–The Public Health Law Network (http://www.publichealthlawnetwork.org/)

–Syringe Access Law in the United States: A State of the Art Assessment of Law and Policy

–State and Local Policies Regarding IDUs' Access to Sterile Syringes

Law Enforcement Strategies

–Law Enforcement and Harm Reduction Network

–Policing for Healthy Communities

–Syringe Possession Information for California Law Enforcement Officers

–COPS HR: Coalition of Police Supporting Harm Reduction

–Do Not Cross: Policing and HIV Risk Faced by People Who Use Drugs

–Needle Exchange Program: Considerations for Criminal Justice

–Attitudes of Police Officers Towards Syringe Access, Occupational Needle-Sticks, and Drug Use: A Qualitative Study of One City Police Department in the United States

–Law Enforcement and Harm Reduction: Advocacy and Action Manual

–Law Enforcement and Harm Reduction

Overdose Prevention

From Chicago Recovery Alliance:

–OD Intervention Card—Using Naloxone

–OD Intervention Poster—Using Naloxone

–Opiate OD Prevention/Intervention Training—Slideshow

–Opiate OD Prevention/Intervention Training—Pre/Post Test

–Injection Partner OD Checklist

Substance Abuse Treatment and Mental Health Resources

–Substance Abuse and Mental Health Administration (SAMHA)

–Department of Mental Health and Addiction Services (DMHAS)

Capacity Building Assistant (CBA) Provider Network

–CBA Request Information System (CRIS)

GLOSSARY

Acquired Immune Deficiency Syndrome (AIDS) is the late stage of HIV infection, when a person'simmune system is severely damaged and has difficulty fighting diseases and certain cancers.

Buprenorphine is used to treat opioid dependence (addiction to opioid drugs, including heroin and narcotic painkillers). Buprenorphine is in a class of medications called opioid partial agonist- antagonists. Buprenorphine alone and in combination with naloxone can prevent withdrawal symptoms when someone stops taking opioid drugs by producing similar effects to these drugs.

Capacity building refers to one or more activities that contribute to an increase in the quality, quantity and efficiency of program services and the infrastructure and organizational systems that support these program services. In the case of HIV prevention capacity building, the activities are associated with the core competencies of an organization that contribute to its ability to develop and implement an effective HIV prevention intervention and to sustain the infrastructure and resource base necessary to support and maintain the intervention.

Cooker is a spoon or bottle cap used to liquefy drugs so they can be injected.

Drug paraphernalia laws, under the Federal Drug Paraphernalia Statute, Controlled Substances Act, make it illegal to possess, sell, transport, import or export drug paraphernalia as defined. The law gives specific guidance on determining what constitutes drug paraphernalia. Many states also have enacted their own laws prohibiting drug paraphernalia.

Drug user health is framework that advocates for the drug users' rights to protect their health and the health of those around them. The framework states that all drug users should: 1) have the means by which to protect their health, including access to sterile injection equipment sufficient to meet their needs; 2) receive accurate, non-biased and non-judgmental information on illicit drugs and other substances; receive the same level of care as any other individual accessing health care or social services; and 3) have access to drug and alcohol treatment on demand. The framework also states that providers should: 1) recognize the valid and valuable expertise that people who use drugs can give to designing, delivering and evaluating effective services; 2) ensure that the provision of services to drug users is not contingent upon the individual's agreement to enter drug treatment, or abstain from drug use; and 3) Service providers must not withhold appropriate treatments or services from drug users. All drug user health services should be provided to encourage engagement and retention in care.

Evaluation is a systematic method for collecting, analyzing and using information to answer questions about projects, policies and programs, particularly about their effectiveness and efficiency.

Fentanyl is a synthetic opioid that is 80-100 times stronger than morphine.

Hepatitis C virus (HCV) causes a liver disease that is the most common IDU-associated infection in the United States. HCV infection sometimes results in an acute illness but most often becomes a chronic condition that can lead to cirrhosis of the liver and liver cancer. It is transmitted by contact with the blood of an infected person, primarily through sharing contaminated needles to inject drugs.

HIV prevention community planning is a collaborative process by which health departments work in partnership with the community to implement a community planning group to develop a comprehensive HIV prevention plan that includes prioritized target populations and a set of prevention activities/ interventions for each target population.

Human Immunodeficiency Virus (HIV) is the virus that can lead to acquired immune deficiency syndrome, or AIDS. There are two types of HIV: HIV-1 and HIV-2. In the U.S., unless otherwise noted, the term "HIV" primarily refers to HIV-1.

Both types of HIV damage a person's body by destroying specific blood cells, called CD4+ T cells, which are crucial to helping the body fight diseases.

Injection Drug User (IDU) is a person who injects illicit drugs, hormones, steroids, or silicone.

Kiosks or drop boxes are places for safely disposing of used syringes. They are usually placed in publicly accessible locations. Syringes can be placed in the kiosk or drop box but cannot be retrieved, reducing reuse of contaminated syringes and risk of accidental needle-sticks.

Methadone is a drug used to prevent withdrawal symptoms in patients who were addicted to opioid drugs and are enrolled in treatment programs in order to stop taking or continue not taking the drugs.

Monitoring is routine documentation of characteristics of the people served, the services provided and the resources used to provide those services.

Motivational interviewing is a client-centered, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence.

Naloxone is a drug used to counter the effects of opioid overdose, for example, a heroin or morphine overdose. Naloxone is used specifically to counteract life-threatening depression of the central nervous system and respiratory system.

Needs-based/negotiated distribution is a program practice that places no limits on the number of syringes an SSP participant may receive, regardless of the number of used syringes returned. While encouraged, participants do not need to return any used syringes in order to receive new, sterile syringes.

neo360 is a web-based data collection system used by CT DPH funded SSPs to captured harm reduction services and overdose prevention activities.

Program collaboration and Service integration (PCSI) is a mechanism of organizing and blending interrelated health issues, separate activities, and services in order to maximize public health impact through new and established linkages between programs to facilitate the delivery of services.

Regulated Medical Waste (RMW), also known as "biohazardous" waste or "infectious medical" waste, is the portion of the waste stream generated by health care facilities that may be contaminated by blood, body fluids, or other potentially infectious materials that may pose a significant risk of transmitting infection and endangering human health.

Secondary exchange is a type of syringe exchange program model whereby participants exchange with their peers after being supplied by the SSP.

Sharps are items with corners, edges, or projections capable of cutting or piercing the skin, such as syringes with needles.

Social networks are social structures made up of individuals (or organizations) called "nodes" that are connected by one or more specific types of interdependency, such as friendship, kinship, common interest, financial exchange, dislike, sexual relationships, or relationships of beliefs, knowledge or prestige.

Subject matter experts (SME) are individuals who have expertise in the area of syringe services programs, whether from a programmatic, governmental, research or evaluation, participant, or administrator perspective.

Syringe exchange programs (SEPs) provide free sterile syringes in exchange for used syringes to reduce transmission of blood-borne pathogens among IDUs.

Syringe prescription laws require a prescription for the legal purchase or possession of a syringe by most or all buyers. Most prescription laws have been repealed or amended to allow purchase of a specified number of syringes without a prescription.

Syringe services programs (SSPs) provide a way for IDUs to safely dispose of used syringes and to obtain new, sterile syringes. SSPs also provide a range of related prevention and care services that are vital to helping IDUs reduce their risk of acquiring and transmitting blood-borne viruses, as well as maintain and improve their overall health. SSPs include syringe access, disposal, and needle exchange programs, as well as referral and linkage to HIV and viral hepatitis prevention services, drug abuse treatment and medical and mental health care.

SAMPLE MONITORING AND EVALUATION PROCESS

Syringe Services Program Process Monitoring indicators

Organizations implementing syringe services programs (SSPs) may wish to incorporate the Syringe Services Program Process Monitoring indicators

Organizations implementing syringe services programs (SSPs) may wish to incorporate the following process and program monitoring indicators.

Minimum required process monitoring indicators for all SSP models:

–Number of clients/participants

–Number of syringes distributed

–Number of syringes returned/disposed

Recommended list of process monitoring indicators for each SSP model:

•**Fixed Site** (e.g., hospital/clinic based settings, integrated syringe access services, collaboration or satellite structure)

–Number of hours open per week for syringe exchange

–Number of HIV tests provided

–Number HIV positive

–Number of HCV antibody tests provided

–Number of tests positive for HCV antibodies

–Number of referrals for HCV antibody testing

–Number of referrals for HIV testing

–Number of overdose kits distributed

–Number of referrals for substance abuse treatment

–Number of each type of service directly provided or referral provided

–Client demographics: age, gender, race/ethnicity

•**Mobile/Street Based**

–Number of hours open per week for syringe exchange

–Number of HIV tests provided

–Number HIV positive

–Number of referrals for HIV testing

–Number of HCV antibody tests provided

–Number of tests positive for HCV antibodies

–Number of overdose kits distributed

–Number of referrals for HCV antibody testing

–Number of referrals for substance abuse treatment

–Number of each type of service directly provided or referral provided

–Client demographics: age, gender, race/ethnicity

- **Secondary or Peer Delivery**

–Number of peers distributed to

–Number of peer distributors

- **Delivery Model**
- **Number of delivery sites**
- **Number of persons served per delivery site**
- **Number of referrals for HIV testing**
- **Number of referrals for HCV antibody testing**
- **Number of referrals for substance abuse treatment**
- **Pharmacy Distribution**

–Number of hours open per week for syringe exchange

–Number of referrals for HIV testing and/or HIV tests provided

–Number of referrals for HCV antibody testing and/or HCV antibody tests provided

–Number of referrals for substance abuse treatment

–Number of each type of service directly provided or referral provided

–Number of vouchers redeemed (if pharmacy distribution program is combined with a voucher program)

- **Multiple Programs**

–Number of hours open per week for syringe exchange

–Number of HIV tests provided

–Number HIV positive

–Number of referrals for HIV testing

–Number of HCV antibody tests provided

–Number of tests positive for HCV antibodies

–Number of referrals for HCV antibody testing

–Number of overdose kits distributed

–Number of referrals for substance abuse treatment

–Number of each type of service directly provided or referrals provided

–Client demographics: age, gender, race/ethnicity

Other process monitoring indicators:

- **Number of participants**
- **Number of new clients**
- **Client demographics:**

–Age

–Gender

–Race/ethnicity

–ZIP code of residence

–Behavioral characteristics

- **Number of syringes distributed**
- **Number of syringes collected/disposed of**
- **Number of syringes each participant is exchanging for**
- **Number of visits per client per month**
- **Number of hours open for syringe exchange per week**
- **Number of peers distributed to**
- **Number of peer distributors**
- **Number of delivery sites**
- **Number of persons served per delivery site**
- **Number of vouchers redeemed (if pharmacy distribution program is combined with a voucher program)**
- **Number of each type of service directly provided or referral provided**
- **Number of referrals made to HIV services**
- **Number of HIV tests provided**
- **Number HIV positive**

- **Number of HCV antibody tests provided**
- **Number of tests positive for HCV antibodies**
- **Number of referrals for HCV antibody testing**
- **Number of overdose kits distributed**
- **Number of syringes distributed**
- **Number of syringes collected/disposed of**
- **Number of syringes each participant is exchanging for**
- **Number of visits per client per month**
- **Number of hours open for syringe exchange per week**
- **Number of peers distributed to**
- **Number of peer distributors**
- **Number of delivery sites**
- **Number of persons served per delivery site**
- **Number of vouchers redeemed (if pharmacy distribution program is combined with a voucher program)**
- **Number of each type of service directly provided or referral provided**
- **Number of referrals made to HIV services**
- **Number of HIV tests provided**
- **Number HIV positive**
- **Number of HCV antibody tests provided**
- **Number of tests positive for HCV antibodies**
- **Number of referrals for HCV antibody testing**
- **Number of overdose kits distributed**
- **Number of referrals for substance abuse treatment**
- **Number of condoms distributed**
- **Number of flu vaccines provided**
- **Number of hepatitis A vaccination doses**
- **Number of hepatitis B vaccination doses**
- **Number of negative events**
- **Number of community-based syringe-disposal kiosks**

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https://www.nastad.org/

https://www.uchaps.org/

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Manisha Juthani, MD
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Governor

Susan Bysiewicz
Lt. Governor

CT Department of Public Health (DPH) Policy for

At-home HIV (Self-Test) Initiative

Background:

Prevention services are a vital component in Public Health. High Impact Prevention (HIP) services, such as HIV Testing, Referral, and Linkage have proven to be the cornerstone in reducing HIV in populations most at risk. COVID-19 has dramatically altered the way we provided prevention services in Connecticut and the need to implement strategies to meet communities hardest hit by HIV is critical during this time. In March 2020, CT DPH launched the **Free At-home HIV Test initiative,** *#RequestFreeHIVTestCT*, as a pilot to enhance access to HIV testing for hard-to-reach populations, such as LGBTQ, and people of color. The At-home HIV Test Kit is an oral-swab rapid HIV test, that is self-administered in the privacy of one's home. The pilot began in March 2020 and the number of organizations participating continues to grow. In the spirit of true harm reduction philosophy, the initiative aims to meet people where they are. CT DPH HIV Prevention Program is committed to working with our community providers to continue to provide access to the prevention services during challenging times.

Purpose:

The purpose of this policy is to assist participating organizations/agencies in developing their own At-home HIV Test program. This policy provides information on how to request the At-home HIV Test Kits, how to market the program using the CT DPH social media/marketing materials, how to collect data to report to CT DPH, and how to access additional resources and materials. To make this pilot initiative most efficient for public health, the DPH has developed the following guidance policy: CT DPH has centralized system for participating partner agencies to order At-home HIV Test Kits for distribution to their clients at no cost to the clients**.**

Policy Guidance:

To make this pilot initiative most efficient for public health, the DPH has developed the following guidance policy: CT DPH has centralized system for participating partner agencies to order At-home HIV Test Kits for distribution to their clients at no cost to the clients.

CONNECTICUT
Public Health

Phone: (860) 509-7101 • Fax: (860) 509-7111
Telecommunications Relay Service 7-1-1
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph

For Agencies to Request to Participate in the Pilot Program (Develop your own At-home HIV Test Program/Initiative):

- Agencies will send a 'Request to Participate' email to Venesha Heron and request the number of box(es) of kits based on their agency's needs and capacity to distribute to clients.
- Agencies will then arrange to pick up the At-home HIV Test kits from DPH.
- CT DPH will provide each agency with a policy guidance and additional resources and materials to support their development and marketing of their own At-home HIV Test program/initiative, as well as how collect and report the data to the DPH.

For Clients to Request Free At-home HIV Test kit from Partnering Agencies or from the DPH:

- Clients are engaged through the DPH social media campaigns and by participating agencies' social media platforms.
- To request the Free At-home HIV test kit, there are two methods a person could use to access the CT DPH At-home Test Kit Request Form (i.e., via Microsoft Forms). First, by visiting: **https://tinyurl.com/ctdphfreehivtest** Second, by scanning a 'QR code' that directs them to the Microsoft Forms.
- Access to the required CT DPH At-home Test Kit Request Form (i.e., via Microsoft Forms), using either **https://tinyurl.com/ctdphfreehivtest** or the provided QR code (see Fig 1).

Fig 1. Tinyurl and QR Code

*****Note to agencies and clients:**

- DPH requires all clients or an agency tester/counselor, on behalf of the client, to fill out the CT DPH At-home Test Kit Request Form prior to mailing or providing the client(s) with the kits.
- If eligible (being a CT resident and not previously testing positive for HIV), clients will be mailed an At-home HIV Test Kit. HIV test kits are manufactured by OraQuick Technologies and are shipped in **confidential** and **discreet** packaging. The kit includes easy to read instructions and if needed, a telephone number for any questions about the test.

- At-home HIV Test kits can also be hand-delivered to clients in a **confidential** and **discreet** manner, to safeguard the client(s) privacy and confidentiality.
- Per OraSure Technologies, the manufacturer of the At-home HIV Test Kits, during COVID-19 pandemic, the At-home HIV tests can also be administered in a rapid HIV test session manner, in a safe, secure, and confidential setting, while adhering to social distancing (COVID-19 pandemic shelter in place/social distance orders). See video link attached for information on Innovative Strategies for HIV Screening During COVID-19: https://www.youtube.com/watch?v=kosVja3t6YQ&feature=youtu.be [time: 9:34]

Marketing and Promotion:

- Participating agencies will create, customize, or use the DPH campaign using #RequestFreeHIVTestCT messaging campaign on agency social platforms or other outreach methods to the community, and will submit to DPH for review. The tiny url (i.e., **https://tinyurl.com/ctdphfreehivtest)** and the QR code to the CT DPH At-home Test Kit Request Form (i.e., via Microsoft Forms) can be used on agencies' promotional materials.
- Participating agencies will use share these materials on their respective social networking apps like Facebook, Instagram, agency webpage, Grindr, etc., to engage these hard-to-reach populations (clients).
- Participating agencies will develop and submit an At-home HIV Test Program Policy and Protocol to DPH for review. (This Policy and Protocol can be revised to reflect improvements and best practices and send to DPH for review)

Data Collection, Reporting, and Quality Improvement:

- Data collection is key to determining who DPH is reaching with this initiative—data collection is very important to monitor and evaluate At-home HIV testing activities and its outcomes
- Clients interested in the At-home HIV Test initiative will use the CT DPH At-home Test Kit Request Form (i.e., via Microsoft Forms), using either **https://tinyurl.com/ctdphfreehivtest** or the provided QR code (see above figure 1).
- Participating agencies are also encouraged to conduct additional client's risk assessment besides the data that is required and reported via the Microsoft Forms for the purpose of providing additional referrals and linkages, should the clients have other needs. This data will be used for future decision making.
- Participating agencies are required report to DPH any narrative information on successes and challenges with the HIV Test Initiative in DPH Tri-Annual Reports.
- Participating agencies are required to report to DPH any issues regarding follow-up and engagement, especially for clients that self-report HIV reactive results.
- Participating agencies are also required to provide monthly reports to DPH on requested data variables
- The overall number of At-home test kits distributed in Connecticut will be reported to the CDC aggregately, via EvaluationWeb.
- Agencies must develop their own agency protocols to submit to DPH for approval.

Confidentiality:

- All participating agencies shall adhere to the CT DPH Confidentiality and Security Standards when participating in any CT DPH pilot programs or initiatives. All testers who will be participating in the In Home HIV Test initiative must review the document in the hyperlink below: https://portal.ct.gov/-/media/DPH/HIV-Surveillance/CT-DPH-TB-HIV-STD-Viral-Hepatitis-Data-Security-andConfidentiality-Policy-and-Procedures-2020.pdf

- All participating organizations/agencies shall adhere to the CDC Principles for Data Collection, Storage, Sharing, and Use to Ensure Security and Confidentiality and protecting the privacy of clients served. https://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf

Mailing and Distribution:

- At-home HIV Test kits requests can be fulfilled through USPS shipment
- The range for shipping/postage can be anywhere from $8.00 - $8.85 with delivery between 1-3 days
- Clients will be sent the At-home HIV Test Kit within 1-2 business days of the request.
- The test kit includes detailed instructions; a video link demonstration on how to administer the test; information about non-reactive and reactive test results; confirmatory test information; PrEP, PEP; and U=U information. Agencies can also include other information and materials about HIV and STI prevention and care resources, condoms, lubrication packets and other informational materials as inserts.

Getting Results:

- Clients will get the results in the comfort of their own space/home, using an At-home Test Kit within 20 minutes of administering the test.
- Agencies should make every effort to engage with clients to inform them to self-report test results within 1-2 weeks of receiving their test kit in the mail, and in a safe and confidential manner.
- Some clients may report back with their results, some may not. If not, the agency should conduct a courtesy follow-up via phone call or in a **secure** and **confidential** manner and document any information in a secured log or secured files within 2 weeks of shipping the At-home HIV Test kits It is each agency's responsibility to ensure that clients/patients have access to services and linkages if needed and document the nature of the services provided or requested.
- To report newly diagnosed HIV positives from the At-home HIV Test Initiative, please refer to the **HIVHCV Rapid Testing Case Reporting Guidance Jan2023**

Resources:

Additional information about the #RequestFreeHIVTestCT initiative can be found below:

- The weblink to CT DPH At-home Test Kit Request Form is **https://tinyurl.com/ctdphfreehivtest**
- OraQuick home test kit materials: A PDF copy of the instruction card deck that is included with each test kit. When the participant opens the test kit, they will flip through the instruction cards, this PDF is a copy of those cards so that agency staff could review with the participant or use some of the graphics and instructions to assist in instructing the client.
- OraQuick provides access to videos and materials at **http://www.oraquick.com/** . The link below demonstrates instructions on how to take the test **http://www.oraquick.com/Taking-the-Test/HowTo-Video**
- Webinar recording: *Innovative Strategies for HIV Screening During COVID-19* **https://www.youtube.com/watch?v=kosVja3t6YQ&feature=youtu.be**

For more information, contact Project Lead, Venesha Heron at Venesha.heron@ct.gov. DPH values our agencies continued commitment to HIV prevention during the COVID-19 pandemic and will continue to work with community to develop and provide additional guidance, resources, and technical assistance (TA) to support reducing HIV in Connecticut.

CT Department of Public Health (DPH)

TB, HIV, STD, & Viral Hepatitis Program

HIV Prevention Program

Beta v2.5

CONNECTICUT

Public Health

HIV and HCV Rapid Testing Case Reporting Guidance for DPH Funded Sites

February 2024

CT Department of Public Health (DPH)

TB, HIV, STD, & Viral Hepatitis Program

HIV Prevention Program

Procedure for Reporting **Newly or Previously Confirmed HIV Positive Cases to DPH:**

a. Complete HIV Test Form Template for all confirmed HIV positive results (See Appendix A). If your site would like a copy of the test template e-mailed, please contact Luis Diaz at luis.diaz@ct.gov.

b. Submit all completed confirmed **HIV positive EvaluationWeb 2018 HIV Test Template Forms** to the CT DPH HIV Prevention Program and e-mail Luis Diaz at luis.diaz@ct.gov when the HIV positive EvaluationWeb 2018 HIV Test Template Forms are sent:

   i. DPH funded and/or supported HIV testing programs should send all confirmed HIV positive Test Forms to DPH, attention to Luis Diaz. A confirmatory email will be sent to programs submitting HIV Test Forms to ensure the receipt of the forms. **Programs can fax forms to 860-730-8404 (RightFax)** or Mail forms to:

   CT DPH
   HIV Prevention
   410 Capitol Ave
   MS#11APV
   Hartford, CT 06134-0308

c. Report to the CT DPH HIV Surveillance Program all confirmed HIV positive results on the Adult HIV Case Report Form (See Appendix B or the links below) via: Adult HIV Case Report Form (https://tinyurl.com/AdultHIVCaseReportFormCT)

1) Phone:

CT DPH HIV Surveillance Program
860-509-7900

OR

2) Mail:

Connecticut Department of Public Health
410 Capitol Ave
P.O. Box 340308, MS #11APV
Hartford, CT 06134-0308

If an HIV Testing in Clinical Settings or HIV Testing in Non-clinical Settings (directly or non-directly funded) site **is not using** the CT DPH State Laboratory for HIV Testing confirmatory results, providers must submit proof of confirmatory result along with the Adult HIV/AIDS Confidential Case Report Form to the CT DPH HIV Surveillance Program.

d. For HIV Testing sites using the CT DPH State Laboratory:

If an HIV testing Program (directly or non-directly funded) site **is using** the CT DPH State Laboratory for HIV Testing Confirmatory results, providers must submit one tube of whole blood, serum or plasma to the CT DPH State Laboratory. Use of Orasure has been discontinued by the CT DPH Lab.

Note. **Copies of the HIV Test Forms for both positive and negative test events must be kept on file at the site and secured in a locked file cabinet.**

e. Report the case to Partner Services (Appendix C). Complete the Partner Service Reporting Forms. Contact the Partner Services Contact in your area. Partner Services Forms can be faxed to RightFax at 860-730-8380.
   Client Referral Form
   Partner Referral Form
   Checklist for Referral to Partner Services

Procedure for Reporting **Hepatitis C Rapid Testing Positive Cases to DPH:**

Complete the HCV Rapid Test Report Form for all Hepatitis C tests performed by HIV Prevention Contractors (See Appendix D).

- Negative HCV Rapid Test Results **DO NOT** need to be reported to the DPH HCV Program using the attached form.
- Positive HCV Rapid Test Results need to be reported to the HCV Program using the revised HCV Rapid Test Report form.
- T**he positive test results can be faxed to 860-730-8404 (RightFax)**

- Please do not email any results

- Enter **all** HCV test results (positive and negative) into EvaluationWeb.

Reporting Do's and Don'ts

Do's:

- ✓ Send the completed 2020 HIV Test Forms
- ✓ Include Client ID and Year of Birth for all positive test forms
- ✓ Client ID = First and Third letter of the First Name + First and Third of Last Name + Date of Birth (MM/DD/YY) + Gender 1 (Male), 2 (Female), 3 (Transgender), 4 (MTF), 5 (FTM), 9 (Unknown), 6 (Refused).
- ✓ Ensure that forms are completed appropriately
- ✓ Send Luis Diaz an e-mail when forms are sent
- ✓ Mail or fax forms as soon as possible
- ✓ Include name and return address on envelopes or fax cover sheet
- ✓ Use the most current HIV Test Forms
- ✓ Make copies of the HIV Test Forms for your records
- ✓ Contact DPH HIV Prevention and HIV Surveillance Programs, if you have any questions regarding submitting all required information

Don'ts:

- ☒ Mail confidential personal health information (PHI) to the HIV Prevention Program that includes any demographic information such as name, date of birth, address, gender, etc.
- ☒ Submit any HIV Test Forms without Form ID Labels

APPENDICES

APPENDIX A

EvaluationWeb® 2018 HIV Test Template

Form ID *(enter or adhere)*

1 Agency and Client Information
(complete for ALL persons)

Session Date

Program Announcement

- ◯ PS15-1506 PrIDE
- ◯ PS15-1509 THRIVE
- ◯ PS17-1711
- ◯ PS18-1802
- ◯ PS18-1802 Demonstration Projects
- ◯ PS19-1901 CDC STD
- ◯ Other CDC funded
- ◯ Other non-CDC funded

Specify Other *(optional)*

Agency Name or ID

Site Name or ID

Site Type *(codes below)*

Site ZIP Code

Site County *(3-digit FIPS code)*

Local Client ID *(optional)*

Year of Birth *(1800 if unknown)*

Client State *(USPS abbreviation)*

Client County *(3-digit FIPS code)*

Client ZIP Code

Client Ethnicity

- ◯ Hispanic or Latino
- ◯ Not Hispanic or Latino
- ◯ Don't Know
- ◯ Declined

Client Race *(select all that apply)*

- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black/African American
- ☐ Native Hawaiian/Pacific Islander
- ☐ White
- ☐ Not Specified
- ☐ Declined to Answer
- ☐ Don't Know

Client Assigned Sex at Birth

- ◯ Male
- ◯ Female
- ◯ Declined to Answer

Client Current Gender Identity

- ◯ Male
- ◯ Female
- ◯ Transgender Male to Female
- ◯ Transgender Female to Male
- ◯ Transgender Unspecified
- ◯ Declined to Answer
- ◯ Another Gender

Has the client had an HIV test previously?

- ◯ No
- ◯ Yes
- ◯ Don't Know

Site Types: Clinical

- F01.01 - Inpatient hospital
- F02.12 - TB clinic
- F02.19 - Substance abuse treatment facility
- F02.51 - Community health center
- F03 - Emergency department
- F08 - Primary care clinic (other than CHC)
- F09 - Pharmacy or other retail-based clinic
- F10 - STD clinic
- F11 - Dental clinic
- F12 - Correctional facility clinic
- F13 - Other

Site Types: Mobile

- F40 - Mobile Unit

Site Types: Non-clinical

- F04.05 - HIV testing site
- F06.02 - Community setting - School/educational facility
- F06.03 - Community setting - Church/mosque/synagogue/temple
- F06.04 - Community Setting - Shelter/transitional housing
- F06.05 - Community setting - Commercial facility
- F06.07 - Community setting - Bar/club/adult entertainment
- F06.08 - Community setting - Public area
- F06.12 - Community setting - Individual residence
- F06.88 - Community setting - Other
- F07 - Correctional facility - Non-healthcare
- F14 - Health department - Field visit
- F15 - Community Setting - Syringe exchange program
- F88 - Other

Form Approved: OMB No. 0920-0696, Exp. 02/28/2019. Public reporting burden of this collection of information is estimated to average 8 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-79, Atlanta, Georgia, 30333, ATTN: PRA 0920-0696. CDC 50.135b(E),10/2007

Form ID *(enter or adhere)*

2 Final Test Information *(complete for ALL persons)*

HIV Test Election

◯ Anonymous ◯ Confidential ◯ Test Not Done

Test Type *(select one only)*

◯ CLIA-waived point-of-care (POC) Rapid Test(s)

◯ Laboratory-based Test

POC Rapid Test Result *(definitions on page 3)*	Laboratory-based Test Result
◯ Preliminary Positive	◯ HIV-1 Positive
◯ Positive	◯ HIV-1 Positive, possible acute
◯ Negative	◯ HIV-2 Positive
◯ Discordant	◯ HIV Positive, undifferentiated
◯ Invalid	◯ HIV-1 Negative, HIV-2 Inconclusive
	◯ HIV-1 Negative
	◯ HIV Negative
	◯ Inconclusive, further testing needed

Result provided to client?

◯ No ◯ Yes ◯ Yes, client obtained the result from another agency

3 Negative Test Result *(complete for persons testing NEGATIVE for HIV)*

Is the client at risk for HIV infection?

◯ No ◯ Yes ◯ Risk Not Known

Was the client screened for PrEP eligibility?

◯ No ◯ Yes ◯ Not Assessed

Is the client eligible for PrEP referral?

◯ No ◯ Yes, by CDC criteria ◯ Yes, by local criteria or protocol

Was the client given a referral to a PrEP provider?

◯ No ◯ Yes

Was the client provided with services to assist with linkage to a PrEP provider?

◯ No ◯ Yes

4 Positive Test Result *(complete for persons testing POSITIVE for HIV)*

Did the client attend an HIV medical care appointment after this positive test?

◯ Yes, confirmed ◯ No

◯ Yes, client/patient self-report ◯ Don't Know

→ Date Attended

Has the client ever had a positive HIV test?

◯ No ◯ Yes ◯ Don't Know

→ Date of first positive result

Was the client provided with individualized behavioral risk-reduction counseling?

◯ No ◯ Yes

Was the client's contact information provided to the health department for Partner Services?

◯ No ◯ Yes

What was the client's most severe housing status in the last 12 months?

◯ Literally homeless ◯ Not Asked

◯ Unstably housed or at risk of losing housing ◯ Declined to Answer

◯ Stably housed ◯ Don't Know

If the client is female, is she pregnant?

◯ No ◯ Declined to Answer

◯ Yes ◯ Don't Know

→ Is the client in prenatal care?

◯ No ◯ Not Asked

◯ Yes ◯ Declined to Answer

◯ Don't Know

→ Was the client screened for need of perinatal HIV service coordination?

◯ No ◯ Yes

→ Does the client need perinatal HIV service coordination?

◯ No ◯ Yes

→ Was the client referred for perinatal HIV service coordination?

◯ No ◯ Yes

Form ID *(enter or adhere)*

5 Additional Tests *(complete for ALL persons)*

Was the client tested for co-infections?
○ No ○ Yes

Tested for Syphilis?
○ No ○ Yes

Syphilis Test Result
○ Newly Identified Infection
○ Not Infected
○ Don't Know

Tested for Gonorrhea?
○ No ○ Yes

Gonorrhea Test Result
○ Positive ○ Negative ○ Don't Know

Tested for Chlamydial infection?
○ No ○ Yes

Chlamydial infection Test Result
○ Positive ○ Negative ○ Don't Know

Tested for Hepatitis C?
○ No ○ Yes

Hepatitis C Test Result
○ Positive ○ Negative ○ Don't Know

Value Definitions for POC Rapid Test Results

Preliminary positive - One or more of the same point-of-care rapid tests were reactive and none are non-reactive and no supplemental testing was done at your agency

Positive - Two or more different (orthogonal) point-of-care rapid tests are reactive and none are non-reactive and no laboratory-based supplemental testing was done

Negative - One or more point-of-care rapid tests are non-reactive and none are reactive and no supplemental testing was done

Discordant - One or more point-of-care rapid tests are reactive and one or more are non-reactive and no laboratory-based supplemental testing was done

Invalid - A CLIA-waived POC rapid test result cannot be confirmed due to conditions related to errors in the testing technology, specimen collection, or transport

6 PrEP Awareness and Use/Priority Populations *(complete for ALL persons)*

Has the client ever heard of PrEP (Pre-Exposure Prophylaxis)?
○ No ○ Yes

Is the client currently taking daily PrEP medication?
○ No ○ Yes

Has the client used PrEP anytime in the last 12 months?
○ No ○ Yes

In the past five years, has the client had sex with a male?
○ No ○ Yes

In the past five years, has the client had sex with a female?
○ No ○ Yes

In the past five years, has the client injected drugs or substances?
○ No ○ Yes

7 Essential Support Services *(complete for ALL persons, EXCEPT as indicated)*

	Screened for need	Need determined	Provided or referred
Navigation services for linkage to HIV medical care *(positive only)*	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Linkage services to HIV medical care *(positive only)*	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Medication adherence support *(positive only)*	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Health benefits navigation and enrollment	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Evidence-based risk reduction intervention	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Behavioral health services	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Social services	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes

APPENDIX B

CONNECTICUT Public Health

Adult HIV Confidential Case Report Form

(Patients ≥13 years of age at diagnosis)

Prior Dx	Surveillance Method	Report Source	STATE #	HARMS #	WEEK	YEAR	LexNex
YR: Site:	☐A ☐P ☐F ☐U					20___	

PATIENT IDENTIFIER INFORMATION

MR #_____ SSN #_____

Patient Name: _____ **Phone**: ( ) _____ - _____

(LAST, FIRST, MI)

Address:_____ **City**: _____ **County**: _____ **State**: ____ **Zip**: _____

PROVIDER INFORMATION

Provider Name: _____ **Phone**: ( ) _____ - _____

Facility: _____ **City**: _____ **State**: _____ **Zip**: _____

FORM INFORMATION

Date Completed: ___/___/_____ **Person reporting**: _____ **Phone**: ( ) _____ - _____

DEMOGRAPHIC INFORMATION

Diagnostic Status:	Date of Birth:	Current Status:	Date of Death:	State/Terr Death:
☐HIV Infection ☐AIDS	/ /	☐Alive ☐Dead ☐Unkn	/ /	

Sex at birth:	Current Gender Identity:	Ethnicity: (select one)	Race: (select one or more)	Country of Birth:
☐Male ☐Female	☐Male ☐Female ☐Trans Male-to-Female ☐Trans Female-to-Male ☐Unknown	☐Hispanic/Latino ☐Not Hispanic/Latino ☐Unknown	☐Black or African Am ☐White ☐Asian ☐American Indian/Alaskan ☐Hawaiian/Other Pacific Islander ☐Unkn	☐US ☐Other _____ ☐Unknown

Residence at Diagnosis: Same as CURRENT address ☐

City:_____ **County**: FFLD HTFD LITCH NH NL MDX TLND WIND **State**: _____ **Zip**: _____

FACILITY OF DIAGNOSIS

Facility Name:

☐Inpatient ☐Outpatient ☐Other_____

City:

State/Country:

Identification Method: ☐Lab Report ☐Lab Audit ☐Viral Load ☐ICD-9 ☐Other:

Report Medium: Paper: ☐Field ☐Mail ☐Faxed ☐Phoned ☐Electronic transfer ☐Disc

RISK FACTOR HISTORY

Before the 1st positive HIV test, this patient had:

☐Sex with male ☐Sex with female Injected drugs: ☐Yes ☐No ☐Unknown

☐Other:

HETEROSEXUAL relations with the following:

☐IDU ☐Bisexual male ☐Person with documented HIV infection

☐Person w/ hemophilia ☐Transfusion/transplant recipient

Date of transfusion or transplant: / /

☐Worked in health-care or clinical lab setting

☐Congenital

☐**NO IDENTIFIED RISK (NIR)**

HIV TESTING HISTORY

Source: ☐Patient ☐Interview ☐Chart abstraction ☐Provider report ☐CW/XPEMS ☐Other

Date patient answered questions: _____/____/_____

Ever had a previous positive HIV test? ☐Yes ☐No ☐Unknown

Date of first positive HIV test: _____/____/_____

Has the patient ever had a *negative* HIV test? ☐Yes ☐No ☐Unknown

Date of the LAST negative HIV test: _____/____/_____

Number of HIV tests in the past 2 years: _____

ANTIRETROVIRAL USE HISTORY

Has the patient ever used antiretroviral medicines? ☐YES ☐NO ☐UNKN

ARV Use Type	ARV Medication	Date Began	Date last used
☐HIV Tx			
☐PrEP			
☐PEP			
☐PMTCT			
☐HBV Tx			
☐Other			

(HIV Tx – HIV treatment; PrEP - PRE-exposure prophylaxis; PEP - POST-exposure prophylaxis; PMTCT - prevention of mother-to-child transmission; HBV Tx – Hepatitis B treatment)

Laboratory Data

☐ Acute

HIV Antibody Tests (Non-type-differentiating)	RESULT	COLLECTION DATE
Test 1: ☐ HIV-1 IA ☐ HIV-1/2 IA ☐ HIV-1/2 Ag/Ab ☐ HIV-2 IA ☐ Other _____	☐ Positive/Reactive ☐ Negative/Nonreactive ☐ Indeterminate Rapid test? ☐ Yes ☐ No	/ /
HIV Antibody Tests (Type-differentiating)		
Test 2: ☐ Multispot ☐ Geenius ☐ Other _____	☐ HIV-1 ☐ HIV-2 ☐ Both HIV-1 and HIV-2 ☐ Neither (negative) ☐ Indeterminate	/ /
HIV Detection Tests (Quantitative)		
Test 3: ☐ HIV-1 RNA ☐ HIV-1 DNA NAAT ☐ Other _____	☐ Undetectable ☐ Det: _____ c/mL	/ /
HIV Detection Tests (Qualitative)		
Test 3: ☐ HIV-1 RNA/DNA NAAT ☐ HIV-1 Culture ☐ HIV-1 P24 Antigen ☐ HIV-2 RNA/DNA NAAT ☐ HIV-2 Culture	☐ Positive/Reactive ☐ Negative/Nonreactive ☐ Indeterminate	/ /

Why was the patient tested for HIV?

☐ Symptoms/dx w/ OI ☐ Routine test ☐ Pre-exposure medication (PrEP) screening ☐ Rule out HIV ☐ 'Just checking'
☐ Partner dx w/ HIV ☐ Regular tester ☐ Dx with STD ☐ Prenatal screening ☐ Establish Care ☐ Other:

Immunologic Testing:	
Closest to current diagnostic status:	COLLECTION DATE
CD4 count _____ cells/ul _____%	/ /
FIRST <200 or <14% of total lymphocytes:	
CD4 count _____ cells/ul _____%	/ /

HIV Genotype done?	COLLECTION DATE
☐ YES, Lab:_____ ☐ No	/ /

Physician Diagnosis:	
If HIV lab tests were not available, is HIV diagnosis documented by a physician?	☐ Yes ☐ No
If **YES**, provide date of documentation:	/ /

Clinical Status

Clinical Record Reviewed? ☐ Yes ☐ No AIDS INDICATOR DISEASES:	**Initial Dx Date** (mo/day/yr)	Presumptive	Definitive
Candidiasis, esophageal	/ /	☐	☐
Kaposi's sarcoma	/ /	☐	☐
M. tuberculosis	/ /	☐	☐
Pneumocystis jiroveci pneumonia	/ /	☐	☐
Pneumonia, recurrent	/ /	☐	☐
Toxoplasmosis of brain	/ /	☐	☐
Wasting syndrome due to HIV	/ /	☐	☐
Other:	/ /	☐	☐

Referrals

Has the patient been informed of their HIV results?	☐ Yes ☐ No ☐ Unkn
This patient's partners will be notified about their HIV exposure and counseled by: ☐ Physician/provider ☐ Patient ☐ Unknown ☐ Not applicable	This patient's medical treatment is primarily reimbursed by: ☐ Medicaid ☐ Medicare ☐ Private insurance ☐ No coverage ☐ Other public funding ☐ Clinical trial/program ☐ Unknown

Where was the patient referred for HIV Care?

Provider Name:_____

Facility: _____

Health care providers can request assistance for notification of potentially exposed partners.

Would you like this assistance from DPH? ☐ Yes ☐ No

For Female Patients

Is patient receiving or been referred for OB/GYN services?	☐ Yes ☐ No ☐ Unkn
Is this patient currently pregnant?	☐ Yes ☐ No ☐ Unkn
If 'YES', when is the due date?	/ /
Where is the patient scheduled to deliver?	Hospital:

Comments: _____

_____

_____ 4.16

CONNECTICUT
Public Health

CLIENT REFERRAL FORM FOR PARTNER SERVICES

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH STD CONTROL PROGRAM

ATTN:_____ **DATE:**_____

AGENCY/ORGANIZATION INFORMATION

REFERRAL SITE (NAME): _____

☐ DOC ☐ ETI ☐ EIS ☐ MCM ☐ OTL ☐ OTHER:_____

PERSON REFERRING (NAME & TITLE): _____

PHONE NUMBER:_____ E-MAIL: _____

REASON FOR REFERRAL

☐ Newly diagnosed HIV client, diagnosed within the last 12 months. **FormID/PFL#:** _____

Client was infected more than 12 months ago and:

☐ Has a new reportable STD diagnosis, infected within the last 3 months.

☐ Unprotected sex within the last 3 months with multiple partners and/or anonymous partner(s) and/or new partner(s).

☐ Known partners are unaware of the client's status, client is having sex after HIV diagnosis.

☐ Client is requesting partner services for a new partner.

CLIENT INFORMATION (complete all of the information below)

NAME (LAST, FIRST):_____ DOB:_____

GENDER: ☐ M ☐ F ☐ MTF ☐ FTM ☐ Unk PRIMARY LANGUAGE: _____

MARITAL/RELATIONSHIP STATUS: ☐ S ☐ M ☐ Div ☐ Sep ☐ W ☐ Cohab ☐ Unk

ETHNICITY: ☐ Hispanic ☐ Not Hispanic

RACE (check all that apply): ☐ Am. Indian/Alaska Native ☐ Asian ☐ Black/African Am.
☐ Native Hawaiian/Other PI ☐ White ☐ Unk

STREET ADDRESS: _____

CITY/TOWN STATE ZIP CODE

PHONE NUMBERS (home/cell):_____ E-MAIL:_____

WEBSITES/PHONE APPS: _____

PHYSICAL DESCRIPTION: _____

GENDER OF SEX PARTNERS (check all that apply): ☐ M ☐ F ☐ MTF ☐ FTM ☐ Unk

RISK FACTORS: ☐ MSM ☐ IDU ☐ Exchanges sex for drugs or money
☐ Other: _____

DATE OF HIV DIAGNOSIS:_____ DATE OF LAST NEGATIVE HIV TEST: _____

HIV Medical Care Physician:_____ **Phone #**: _____

If DOC Referral, what is the earliest date this client may be released from custody? _____

If information on partners is available, complete page 2, Partner Referral form for Partner Services for each partner.

***Note:* Prior to sending any fax, please contact Kelly Russell, Disease Intervention Specialist Supervisor at (860) 558-9514 or (860) 509-7899. Fax completed forms, with a coversheet from your agency marked *ATTN: Kelly Russell*, to (860) 730-8380.**

DO NOT E-MAIL THIS FORM

CONNECTICUT
Public Health

PARTNER REFERRAL FORM FOR PARTNER SERVICES

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH STD CONTROL PROGRAM

ATTN:_____ **DATE:**_____

AGENCY/ORGANIZATION INFORMATION

REFERRAL SITE (NAME): _____

☐ DOC ☐ ETI ☐ EIS ☐ MCM ☐ OTL ☐ OTHER:_____

PERSON REFERRING (NAME & TITLE): _____

PHONE NUMBER:_____ E-MAIL: _____

PARTNER INFORMATION (complete all of the information below)

NAME (LAST, FIRST):_____ DOB:_____

GENDER: ☐ M ☐ F ☐ MTF ☐ FTM ☐ Unk PRIMARY LANGUAGE: _____

MARITAL/RELATIONSHIP STATUS: ☐ S ☐ M ☐ Div ☐ Sep ☐ W ☐ Cohab ☐ Unk

ETHNICITY: ☐ Hispanic ☐ Not Hispanic

RACE (check all that apply): ☐ Am. Indian/Alaska Native ☐ Asian ☐ CheckBox1

STREET ADDRESS: _____

CITY/TOWN STATE ZIP CODE

PHONE NUMBERS (home/cell):_____ E-MAIL: _____

WEBSITES/PHONE APPS: _____

PHYSICAL DESCRIPTION: _____

RISK FACTORS: ☐ MSM ☐ IDU ☐ Exchanges sex for drugs or money
☐ Unaware of Client's status ☐ Other: _____

EXPOSURE TYPE(S):
Check all that apply in the table below and complete information about each type of exposure this Partner had to the Client (see page 1, *Client Referral Form for Partner Services*).

Exposure Information	☐ *Sex*	☐ *Syringe/ works sharing*	☐ *Other, specify:*
Date first contact (mm/dd/yyyy)			
Date last contact (mm/dd/yyyy)			
Frequency (e.g., two times per week)			

COMMENTS: _____

_____

_____

_____

***Note:* Prior to sending any fax, please contact Kelly Russell, Disease Intervention Specialist Supervisor at (860) 558-9514 or (860) 509-7899. Fax completed forms, with a coversheet from your agency marked *ATTN: Kelly Russell*, to (860) 730-8380.**

DO NOT E-MAIL THIS FORM

CONNECTICUT
Public Health

Connecticut Department of Public Health Hepatitis C Program

HCV Rapid Test Report Form – Positive Results Only!

Agency Name: _____ **Date:** _____

Full Name of HCV Tester: _____ **Phone:** (____) _____

Patient information

Name: _____ **DOB:** _____ **Phone:** (____) _____

Street address: _____ **City:** _____ **State:** _____ **Zip:**_____

Country of birth: □ USA □ Unknown □ Other (specify): _____

Client Assigned Sex at Birth: □ Male □ Female □ Declined to Answer

Client Current Gender Identity: □ Male □ Female □ Transgender Male to Female □ Transgender Female to Male □ Transgender Unspecified □ Another Gender: _____ □ Declined to Answer

Ethnicity: □ Hispanic □ Non-Hispanic □ Unknown

Race: □ Black □ White □ Asian Hawaiian/PI □ American Indian □ Unknown □ other (specify): _____

Person Previously Diagnosed with HCV? □ No □ Yes □ Unknown

HCV Rapid Test Result	Result	Date
Antibody Rapid Test	Positive	
Referred for PCR test: □ No □ Yes		
PCR Test Result (if referred):	□ Negative □ Positive	

Risk Factors (check all that apply):	Yes	No	Unknown	Notes
Blood transfusion prior to 1992				
Organ transplant prior to 1992				
Clotting factors prior to 1987				
Long term hemodialysis				
Employed in a medical/dental field involving direct contact with blood				
Injection drug use, past or present (even if only once)				
Used street drugs but did not inject				
History of incarceration				
Tattoo				
Household contact of a person who had Hepatitis C, non-sexual				
Sexual contact with a person who had Hepatitis C				
Treated for a sexually transmitted disease				
Man who has sex with men				
Other risk specify:				
Number of sex partners (lifetime):				

Please send via RightFax to 860-730-8404 or mail in an envelope marked confidential to:

Luis Diaz
CT DPH, 410 Capitol Ave, MS #11APV, Hartford CT 06134
For more information, e-mail Luis Diaz at luis.diaz@ct.gov

CT Department of Public Health (DPH)

TB, HIV, STD, & Viral Hepatitis Program

HIV Prevention Program

If you have any questions regarding the reporting of HIV positives cases to the CT DPH, please contact:

Susan Major, Health Program Supervisor

Email: susan.major@ct.gov

CONNECTICUT Public Health

Adult HIV Confidential Case Report Form

(Patients ≥13 years of age at diagnosis)

Prior Dx	Surveillance Method	Report Source	STATE #	HARMS #	WEEK	YEAR	LexNex
YR: Site:	☐A ☐P ☐F ☐U					20___	

PATIENT IDENTIFIER INFORMATION

MR #_____ SSN #_____

Patient Name: _____ **Phone**: ( ) _____ - _____

(LAST, FIRST, MI)

Address:_____ **City**: _____ **County**: _____ **State**: ____ **Zip**: _____

PROVIDER INFORMATION

Provider Name: _____ **Phone**: ( ) _____ - _____

Facility: _____ **City**: _____ **State**: _____ **Zip**: _____

FORM INFORMATION

Date Completed: ___/___/_____ **Person reporting**: _____ **Phone**: ( ) _____ - _____

DEMOGRAPHIC INFORMATION

Diagnostic Status:	Date of Birth:	Current Status:	Date of Death:	State/Terr Death:
☐HIV Infection ☐AIDS	/ /	☐Alive ☐Dead ☐Unkn	/ /	

Sex at birth:	Current Gender Identity:	Ethnicity: (select one)	Race: (select one or more)	Country of Birth:
☐Male ☐Female	☐Male ☐Female ☐Trans Male-to-Female ☐Trans Female-to-Male ☐Unknown	☐Hispanic/Latino ☐Not Hispanic/Latino ☐Unknown	☐Black or African Am ☐White ☐Asian ☐American Indian/Alaskan ☐Hawaiian/Other Pacific Islander ☐Unkn	☐US ☐Other _____ ☐Unknown

Residence at Diagnosis: Same as CURRENT address ☐

City:_____ **County**: FFLD HTFD LITCH NH NL MDX TLND WIND **State**: _____ **Zip**: _____

FACILITY OF DIAGNOSIS

Facility Name:

☐Inpatient ☐Outpatient ☐Other_____

City:

State/Country:

Identification Method: ☐Lab Report ☐Lab Audit ☐Viral Load ☐ICD-9 ☐Other:

Report Medium: Paper: ☐Field ☐Mail ☐Faxed ☐Phoned ☐Electronic transfer ☐Disc

RISK FACTOR HISTORY

Before the 1st positive HIV test, this patient had:

☐Sex with male ☐Sex with female Injected drugs: ☐Yes ☐No ☐Unknown
☐Other:

HETEROSEXUAL relations with the following:

☐IDU ☐Bisexual male ☐Person with documented HIV infection
☐Person w/ hemophilia ☐Transfusion/transplant recipient

Date of transfusion or transplant: / /

☐Worked in health-care or clinical lab setting

☐Congenital

☐**NO IDENTIFIED RISK (NIR)**

HIV TESTING HISTORY

Source: ☐Patient ☐Interview ☐Chart abstraction ☐Provider report ☐CW/XPEMS ☐Other

Date patient answered questions: _____/____/_____

Ever had a previous positive HIV test? ☐Yes ☐No ☐Unknown

Date of first positive HIV test: _____/____/_____

Has the patient ever had a *negative* HIV test? ☐Yes ☐No ☐Unknown

Date of the LAST negative HIV test: _____/____/_____

Number of HIV tests in the past 2 years: _____

ANTIRETROVIRAL USE HISTORY

Has the patient ever used antiretroviral medicines? ☐YES ☐NO ☐UNKN

ARV Use Type	ARV Medication	Date Began	Date last used
☐HIV Tx			
☐PrEP			
☐PEP			
☐PMTCT			
☐HBV Tx			
☐Other			

(HIV Tx – HIV treatment; PrEP - PRE-exposure prophylaxis; PEP - POST-exposure prophylaxis; PMTCT - prevention of mother-to-child transmission; HBV Tx – Hepatitis B treatment)

Laboratory Data

☐ Acute

HIV Antibody Tests (Non-type-differentiating)	RESULT	COLLECTION DATE
Test 1: ☐ HIV-1 IA ☐ HIV-1/2 IA ☐ HIV-1/2 Ag/Ab ☐ HIV-2 IA ☐ Other _____	☐ Positive/Reactive ☐ Negative/Nonreactive ☐ Indeterminate Rapid test? ☐ Yes ☐ No	/ /
HIV Antibody Tests (Type-differentiating)		
Test 2: ☐ Multispot ☐ Geenius ☐ Other _____	☐ HIV-1 ☐ HIV-2 ☐ Both HIV-1 and HIV-2 ☐ Neither (negative) ☐ Indeterminate	/ /
HIV Detection Tests (Quantitative)		
Test 3: ☐ HIV-1 RNA ☐ HIV-1 DNA NAAT ☐ Other _____	☐ Undetectable ☐ Det: _____ c/mL	/ /
HIV Detection Tests (Qualitative)		
Test 3: ☐ HIV-1 RNA/DNA NAAT ☐ HIV-1 Culture ☐ HIV-1 P24 Antigen ☐ HIV-2 RNA/DNA NAAT ☐ HIV-2 Culture	☐ Positive/Reactive ☐ Negative/Nonreactive ☐ Indeterminate	/ /

Why was the patient tested for HIV?

☐ Symptoms/dx w/ OI ☐ Routine test ☐ Pre-exposure medication (PrEP) screening ☐ Rule out HIV ☐ 'Just checking'
☐ Partner dx w/ HIV ☐ Regular tester ☐ Dx with STD ☐ Prenatal screening ☐ Establish Care ☐ Other:

Immunologic Testing:	
Closest to current diagnostic status:	COLLECTION DATE
CD4 count _____ cells/ul _____%	/ /
FIRST <200 or <14% of total lymphocytes:	
CD4 count _____ cells/ul _____%	/ /

HIV Genotype done?	COLLECTION DATE
☐ YES, Lab:_____ ☐ No	/ /

Physician Diagnosis:	
If HIV lab tests were not available, is HIV diagnosis documented by a physician?	☐ Yes ☐ No
If **YES**, provide date of documentation:	/ /

Clinical Status

Clinical Record Reviewed? ☐ Yes ☐ No AIDS INDICATOR DISEASES:	**Initial Dx Date** (mo/day/yr)	Presumptive	Definitive
Candidiasis, esophageal	/ /	☐	☐
Kaposi's sarcoma	/ /	☐	☐
M. tuberculosis	/ /	☐	☐
Pneumocystis jiroveci pneumonia	/ /	☐	☐
Pneumonia, recurrent	/ /	☐	☐
Toxoplasmosis of brain	/ /	☐	☐
Wasting syndrome due to HIV	/ /	☐	☐
Other:	/ /	☐	☐

Referrals

Has the patient been informed of their HIV results?	☐ Yes ☐ No ☐ Unkn
This patient's partners will be notified about their HIV exposure and counseled by: ☐ Physician/provider ☐ Patient ☐ Unknown ☐ Not applicable	This patient's medical treatment is primarily reimbursed by: ☐ Medicaid ☐ Medicare ☐ Private insurance ☐ No coverage ☐ Other public funding ☐ Clinical trial/program ☐ Unknown

Where was the patient referred for HIV Care?

Provider Name:_____

Facility: _____

Health care providers can request assistance for notification of potentially exposed partners.

Would you like this assistance from DPH? ☐ Yes ☐ No

For Female Patients

Is patient receiving or been referred for OB/GYN services?	☐ Yes ☐ No ☐ Unkn
Is this patient currently pregnant?	☐ Yes ☐ No ☐ Unkn
If 'YES', when is the due date?	/ /
Where is the patient scheduled to deliver?	Hospital:

Comments: _____

_____

_____ 4.16

CONNECTICUT
Public Health

PARTNER REFERRAL FORM FOR PARTNER SERVICES

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH STD CONTROL PROGRAM

ATTN:_____ **DATE:**_____

AGENCY/ORGANIZATION INFORMATION

REFERRAL SITE (NAME): _____

☐ DOC ☐ ETI ☐ EIS ☐ MCM ☐ OTL ☐ OTHER:_____

PERSON REFERRING (NAME & TITLE): _____

PHONE NUMBER:_____ E-MAIL: _____

PARTNER INFORMATION (complete all of the information below)

NAME (LAST, FIRST):_____DOB:_____

GENDER: ☐ M ☐ F ☐ MTF ☐ FTM ☐ Unk PRIMARY LANGUAGE: _____

MARITAL/RELATIONSHIP STATUS: ☐ S ☐ M ☐ Div ☐ Sep ☐ W ☐ Cohab ☐ Unk

ETHNICITY: ☐ Hispanic ☐ Not Hispanic

RACE (check all that apply): ☐ Am. Indian/Alaska Native ☐ Asian ☐ CheckBox1

STREET ADDRESS: _____

CITY/TOWN STATE ZIP CODE

PHONE NUMBERS (home/cell):_____E-MAIL: _____

WEBSITES/PHONE APPS: _____

PHYSICAL DESCRIPTION: _____

RISK FACTORS: ☐ MSM ☐ IDU ☐ Exchanges sex for drugs or money
☐ Unaware of Client's status ☐ Other: _____

EXPOSURE TYPE(S):
Check all that apply in the table below and complete information about each type of exposure this Partner had to the Client (see page 1, *Client Referral Form for Partner Services*).

Exposure Information	☐ *Sex*	☐ *Syringe/ works sharing*	☐ *Other, specify:*
Date first contact (mm/dd/yyyy)			
Date last contact (mm/dd/yyyy)			
Frequency (e.g., two times per week)			

COMMENTS: _____

_____

_____

_____

***Note:* Prior to sending any fax, please contact Kelly Russell, Disease Intervention Specialist Supervisor at (860) 558-9514 or (860) 509-7899. Fax completed forms, with a coversheet from your agency marked *ATTN: Kelly Russell*, to (860) 730-8380.**

DO NOT E-MAIL THIS FORM

State of Connecticut
Reportable Disease Confidential Case Report Form PD-23

(rev. 01/01/2021)

Department of Public Health
410 Capitol Avenue, MS#11FDS
P.O. Box 340308
Hartford, CT 06134-0308

For information or weekday disease reporting call 860-509-7994. For reporting on evenings, weekends, and holidays call 860-509-8000.

Instructions for Submitting the PD-23

The Commissioner of the Department of Public Health (DPH) is required to declare an annual list of Reportable Diseases, Emergency Illnesses and Health Conditions, which has two parts: (A) reportable diseases; and (B) reportable emergency illnesses and conditions. This three-part form is to be used for reporting of the reportable diseases in Part A, as required under Sections 19a-36-A3 and 19a-36-A4 (see back of form) of the Public Health Code and Sections 19a-2a and 19a-215 of the Connecticut General Statutes. Mail the white copy to the Connecticut Department of Public Health, Epidemiology and Emerging Infections Program at the address above. Mail the canary copy to the Director of Health of the patient's town of residence. Retain the pink copy in the patient's medical record. Mail reports in envelopes marked "Confidential." Fillable PDF forms are found at: https://portal.ct.gov/DPH/Communications/Forms/Forms.

Use Other Forms or Methods to Report

Epidemiology and Emerging Infections Program		860-509-7994
Confidential Case Report Form PD-23	FAX	860-509-7910
Hospitalized and Fatal Cases of Influenza Case Report Form		
Healthcare-associated Infections		860-509-7995
Use the National Healthcare Safety Network (NHSN)		
HIV/AIDS		860-509-7900
Adult HIV Confidential Case Report Form	FAX	860-509-8237
Injury and Violence Surveillance Unit		860-509-8251
E-cigarette or vaping product use associated lung injury (EVALI) Case Report Form	FAX	860-509-7910
Immunization Program		860-509-7929
Chickenpox (Varicella) Case Report Form		
Occupational Diseases		860-509-7740
Physician's Report Form		
Sexually Transmitted Diseases		860-509-7920
STD-23 Form	FAX	860-509-7275
Tuberculosis		860-509-7722
Tuberculosis Surveillance Report Form	FAX	860-509-7743

Category 1 Diseases: Report immediately by telephone (860-509-7994) on the day of recognition or strong suspicion of disease for those diseases marked with a telephone (☎). On evenings, weekends, and holidays call 860-509-8000. These diseases must also be reported by mail within 12 hours.

Category 2 Diseases: All other diseases not marked with a telephone must be reported by mail within 12 hours of recognition or strong suspicion.

PART A: REPORTABLE DISEASES

Acquired Immunodeficiency Syndrome (1,2)
Acute flaccid myelitis
☎ Acute HIV infection
☎ Anthrax
Babesiosis
Borrelia miyamotoi disease
☎ Botulism
☎ Brucellosis
California group arbovirus infection
Campylobacteriosis
Candida auris
Chancroid
Chickenpox
Chickenpox-related death
Chikungunya
Chlamydia (*C. trachomatis*)(all sites)
☎ Cholera
Coronavirus disease 2019 (COVID-19)
COVID-19 Hospitalizations
☎ Cryptosporidiosis
Cyclosporiasis
Dengue
☎ Diphtheria
E-cigarette or vaping product use associated lung injury (EVALI)
Eastern equine encephalitis virus infection
Ehrlichia chaffeensis infection
Escherichia coli O157:H7 gastroenteritis
Gonorrhea
Group A Streptococcal disease, invasive (3)
Group B Streptococcal disease, invasive (3)
Haemophilus influenzae disease, invasive (3)
Hansen's disease (Leprosy)
Healthcare-associated infections (4)
Hemolytic-uremic syndrome (5)
Hepatitis A
Hepatitis B
- acute infection (2)
- HBsAg positive pregnant women

Hepatitis C
- acute infection (2)
- perinatal infection
- positive rapid antibody test result

HIV-1/HIV-2 infection in: (1)
- persons with active tuberculosis disease
- persons with latent tuberculosis infection
- persons of any age
- pregnant women

HPV: biopsy proven CIN 2, CIN 3, or AIS or their equivalent (1)
Influenza-associated death (6)
Influenza-associated hospitalization (6)
Legionellosis
Listeriosis
Lyme disease
Malaria
☎ Measles
☎ Melioidosis
☎ Meningococcal disease
Mercury poisoning
Multisystem inflammatory syndrome in children
Mumps
Neonatal bacterial sepsis (7)
Neonatal herpes (≤ 60 days of age)
Occupational asthma
☎ Outbreaks:
- foodborne (involving ≥ 2 persons)
- institutional
- unusual disease or illness (8)

Pertussis
☎ Plague
Pneumococcal disease, invasive (3)
☎ Poliomyelitis
Powassan virus infection
☎ Q fever
☎ Rabies
☎ Ricin poisoning
Rocky Mountain spotted fever
Rubella (including congenital)
Salmonellosis
☎ SARS-CoV
Shiga toxin-related disease (gastroenteritis)
Shigellosis
Silicosis
☎ Smallpox
St. Louis encephalitis virus infection
☎ Staphylococcal enterotoxin B pulmonary poisoning
☎ *Staphylococcus aureus* disease, reduced or resistant susceptibility to vancomycin (1)
Staphylococcus aureus methicillin-resistant disease, invasive, community acquired (3, 9)
Staphylococcus epidermidis disease, reduced or resistant susceptibility to vancomycin (1)
Syphilis
Tetanus
Trichinosis
☎ Tuberculosis
☎ Tularemia
Typhoid fever
Vaccinia disease
☎ Venezuelan equine encephalitis virus infection
Vibrio infection (*parahaemolyticus*, *vulnificus*, other)
☎ Viral hemorrhagic fever
West Nile virus infection
☎ Yellow fever
Zika virus infection

FOOTNOTES

1. Report only to State.
2. As described in the CDC case definition.
3. Invasive disease: from sterile fluid (blood, CSF, pericardial, pleural, peritoneal, joint or vitreous), bone, internal body site, or other normally sterile site including muscle.
4. Report HAIs according to current CMS pay-for-reporting or pay-for-performance requirements. Detailed instructions on the types of HAIs, facility types and locations, and methods of reporting are available on the DPH website: http://www.portal.ct.gov/DPH/Infectious-Diseases/HAI/Healthcare-Associated-Infections-HAIs.
5. On request from the DPH and if adequate serum is available, send serum from patients with HUS to the DPH Laboratory for antibody testing.
6. Reporting requirements are satisfied by submitting the Hospitalized and Fatal Cases of Influenza-Case Report Form in a manner specified by the DPH.
7. Clinical sepsis and blood or CSF isolate obtained from an infant ≤ 72 hours of age.
8. Individual cases of "significant unusual illness" are also reportable.
9. Community-acquired: infection present on admission to hospital, and person has no previous hospitalizations or regular contact with the health-care setting.

State of Connecticut
Reportable Disease Confidential Case Report Form PD-23
(rev. 01/01/2021)

Department of Public Health
410 Capitol Avenue, MS#11FDS
P.O. Box 340308
Hartford, CT 06134-0308

Date Completed:

PLEASE PRINT

☐ **Check for additional PD-23 forms, or call 860-509-7994.**

For information or weekday disease reporting, call 860-509-7994.
For reporting on evenings, weekends, and holidays, call 860-509-8000.

Disease & Patient Information

Disease Name | **Patient Name** (Last, First, MI) | **Age** | **Date of Birth** | **Parent or Guardian Name**

Address (Street, City, State, Zip Code) | **Phone** ☐ Cell ☐ Home ☐ Work

Gender
☐ Male
☐ Female
☐ Other specify: _____
☐ Unknown

Race (check all that apply)
☐ White ☐ Black/African American
☐ Asian ☐ American Indian/Alaska Native
☐ Native Hawaiian/Other Pacific Islander
☐ Unknown ☐ Other specify: _____

Hispanic/Latino
☐ Yes
☐ No
☐ Unknown

Primary Language Spoken
☐ English
☐ Spanish
☐ Other: _____

Is Patient Pregnant
☐ Yes – Due date: _____
☐ No
☐ Unknown

Did Patient Die of Illness
☐ Yes
☐ No
☐ Unknown

Is Condition Work Related
☐ Yes – Occupation: _____
☐ No
☐ Unknown

Is patient a (please check)
☐ Health care worker ☐ Student/Day care attendee
☐ Day care worker ☐ Food handler ☐ LTC Facility resident

Name and address of workplace, school, day care or other facility:

Did patient have recent international travel
☐ Yes ☐ No ☐ Unknown

Country visited: _____

Dates visited from: _____
to: _____

Clinical & Laboratory Information

Onset Date | **Diagnosis Date**

Confirmatory information, include laboratory data, immunization status, dates, and specific comments:

If specimen obtained, collection date: _____

Provider/Reporter & Hospital Information

Healthcare Provider | **Phone** | **Facility Name** | **Address**

Person Completing Report | **Phone** | **Fax** | **Report Date** | **Address** (if different from above)

Hospital Name | **City** | **State** | **Date Admitted** | **Date Discharged** | **Patient ID#**

Viral Hepatitis

Perinatal:
HBV: ☐ Yes ☐ No
HCV: ☐ Yes ☐ No

Symptoms: ☐ Yes ☐ No Onset Date: _____
Jaundice: ☐ Yes ☐ No Onset Date: _____
ALT Result: _____ Test Date: _____
Bilirubin Result: _____ Test Date: _____
IgM anti-HAV: ☐ Pos ☐ Neg Test Date: _____
HBsAg: ☐ Pos ☐ Neg Test Date: _____
IgM anti-HBc: ☐ Pos ☐ Neg Test Date: _____
Anti-HCV: Method: ☐ Rapid ☐ Serology
☐ Pos ☐ Neg Test Date: _____
HCV confirmed by: ☐ RNA ☐ Value: ____ Test Date: _____
☐ HCV negative antibody test within the last 12 months
HBV Chronic/Carrier: ☐ Yes ☐ No ☐ Unknown

Risk Factors: ☐ IDU ☐ Non-injection street drugs
☐ Hemodialysis ☐ Multiple sex partners
☐ Contact w/ infected person (☐ household ☐ sexual)
☐ Blood Transfusion ☐ Incarcerated (☐ present ☐ past)
☐ MSM (men who have sex with men) ☐ Other: _____

Lyme disease surveillance case definition signs and symptoms

When testing for Lyme disease consider testing for other tick-borne diseases.

Physician diagnosed EM rash ≥ 5cm	☐ Yes	☐ No	☐ Unknown
Arthritis (objective joint swelling)	☐ Yes	☐ No	☐ Unknown
Bell's palsy or other cranial neuritis	☐ Yes	☐ No	☐ Unknown
Radiculoneuropathy	☐ Yes	☐ No	☐ Unknown
Lymphocytic meningitis	☐ Yes	☐ No	☐ Unknown
Encephalomyelitis	☐ Yes	☐ No	☐ Unknown
If yes, is antibody to *B. burgdorferi* higher in CSF than serum	☐ Yes	☐ No	☐ Unknown
2nd or 3rd degree atrioventricular block	☐ Yes	☐ No	☐ Unknown
Was patient diagnosed with Lyme disease in current year?	☐ Yes	☐ No	☐ Unknown

Lyme disease laboratory results

EIA/IFA
☐ Positive ☐ Negative ☐ Unknown

Culture
☐ Positive ☐ Negative ☐ Unknown

Western Blot: IgM
☐ Positive ☐ Negative ☐ Unknown

Western Blot: IgG
☐ Positive ☐ Negative ☐ Unknown

State of Connecticut
Health Insurance Portability and Accountability Act (HIPAA) Guidelines

Pursuant to Connecticut General Statutes (CGS) § 19a-2a and § 19a-215 and to the Regulations of Connecticut State Agencies Section 19a-36-A3 and Section 19a-36-A4, the requested information is required to be provided to the Department of Public Health (DPH)

Please note that CGS § 52-146o(b)(1) authorizes the release of these records to the Department without the patient's consent. Additionally, the federal Privacy Regulations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) also authorize you, as a provider, to release this information without an authorization, consent, release, opportunity to object by the patient, as information (i) required by law to be disclosed [HIPAA Privacy regulation, 45 CFR § 164.512(a)] and (ii) as part of the Department's public health activities (HIPAA Privacy regulation, 45 CFR § 165.512(b)(1)(i)]. The requested information is what is minimally necessary to achieve the purpose of the disclosure, and you may rely upon this representation in releasing the requested information, pursuant to 45 CFR § 164.514(d)(3)(iii)(A) of the HIPAA Privacy regulations.

PHC Section 19a-36-A4 - Content of report and reporting of reportable diseases and laboratory findings.

Each report should include: 1) name, address, and phone number of the person reporting and of the physician attending; 2) name, address, date of birth, age, sex, race/ethnicity, and occupation of person affected; and 3) the diagnosed or suspected disease, and date of onset. Reports must be mailed in envelopes marked "CONFIDENTIAL" within 12 hours of recognition or strong suspicion to the:

1. Local Director of Health of the town in which the patient resides
   (Canary copy)

   AND

2. Connecticut Department of Public Health
   410 Capitol Avenue, MS#11FDS
   P.O. Box 340308
   Hartford, CT 06134-0308
   (White copy)

(Retain Pink copy for patient's medical record.)

PHC Section 19a-36-A3 - Persons required to report reportable diseases and laboratory findings.

1. Every health care provider who treats or examines any person who has or is suspected to have a reportable disease shall report the case to the local director of health or other health authority within whose jurisdiction the patient resides and to the DPH.
2. If the case or suspected case of reportable disease is in a health care facility, the person in charge of such facility shall ensure that reports are made to the local director of health and DPH. The person in charge shall designate appropriate infection control or record keeping personnel for this purpose.
3. If the case or suspected case of reportable disease is not in a health care facility, and if a health care provider is not in attendance or is not known to have made a report within the appropriate time, such report of reportable diseases shall be made to the local director of health or other health authority within whose jurisdiction the patient lives and DPH by:
   a. the administrator serving a public or private school or day care center attended by any person affected or apparently affected with such disease;
   b. the person in charge of any camp;
   c. the master or any other person in charge of any vessel lying within the jurisdiction of the state;
   d. the master or any other person in charge of any aircraft landing within the jurisdiction of the state;
   e. the owner or person in charge of any establishment producing, handling, or processing dairy products, other food, or non-alcoholic beverages for sale or distribution;
   f. morticians and funeral directors

CONNECTICUT
Public Health

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH
HIV SURVEILLANCE PROGRAM

Rev 12.15

HIV Reporting: Instructions for HIV counselors

1. **No code reporting:** During 2002-2004, HIV could be reported by code at the client's request. As of January 1, 2005, *the code option is no longer available.*

2. **Pre-test counseling**: HIV counselors will continue to offer confidential and anonymous testing to their clients. The requirement for HIV reporting by name should be explained to all clients as part of the discussion about what happens if a test result is positive. Forms and specimens will be submitted as usual.

3. **Post-test counseling**: Counselor should explain the reporting requirement to clients who test HIV positive. Clients who wish to remain anonymous may do so. Case report forms should not be submitted for positive anonymous tests. The client should understand that the use of their name is only for reporting purposes; other aspects of care will use the client's name (medical records, insurance/Medicaid forms, laboratory tests, prescriptions, etc).

4. **Consent**: Consent is not required for testing or reporting.

5. **Reporting**: HIV cases are reported using the *Adult HIV Confidential Case Report Form (CRF)* - designed specifically for use by HIV testing staff. HIV Surveillance Program staff will mail a CRF to the counselor based on the ID number submitted to Surveillance with the laboratory result.

6. **Client ID number:** It is important that the client's ID number be included on the CRF. Use an excess sticker from the EvaluationWeb form or write it in (see instructions).

7. **Required information:** The sections of the case report form that include required information are denoted in the instructions by an asterisk. Within each of those sections, required information is also asterisked and underlined. Without this information we will be unable to register the report. Fill in all available information and please do not delay a report for information that is not required.

8. **Timely reporting**: We receive requests for data throughout the year and would like our numbers to be as real-time as possible. You can help by reporting cases at least weekly. State law requires reporting within 48 hours of recognition of a reportable condition. In the case of HIV reporting, batch reporting on a weekly basis is acceptable.

9. **Who to call for assistance?** Contact our office at (860) 509-7900 if you have questions about the HIV reporting requirement. Melinda Vazquez is the primary contact for HIV counselors regarding reporting and will follow up by letter to solicit unreported cases.

10. **HIV counselors should mail completed case report forms to:**

    Melinda Vazquez

    Department of Public Health, 410 Capitol Ave, MS# 11ASV, PO Box 340308

    Hartford, CT 06134

Adult HIV Confidential Case Report - Instructions for HIV counselors

* Section 1. Patient Identifier Information

Client ID #:*	Record the patient's Form/ID number.
Patient's name:*	Record name (last, first, middle initial).
Phone number:	Record the patient's best phone number, if available.
Address:	Record the patient's street address.
City, County, State, Zip:*	Record the patient's city, county, state and zip code of current residence.

* Section 2. Counselor Information

Counselor's name:*	Record the name (last, first) of the counselor who ordered the test. This is the person we will contact about the CRF, if needed.
Phone number:*	Record the Counselor's phone number.
Facility:	Record the name of the site where the HIV test was done.

DPH use only

For Connecticut Department of Public Health use only.

* Section 3. Demographic information

Diagnostic status:	Check 'HIV'
Date of birth:*	Record date of birth – MM/DD/YYYY
Current status:	Check the client's current status
Sex:*	Check 'male' or 'female' (defined as 'sex at birth')
Current Gender Identity:	Check the client's current gender identity
Ethnicity:*	Check one ethnicity
Race:*	Check one race
Country of birth:	Record country of birth
Residence:*	Record the city, circle the county, and enter the zip code of residence at the time of the test

* Section 4. Facility of diagnosis

Facility name:*	Record the name and address of the site were the client tested HIV positive
Facility setting:	Check "public" for state-funded site
Facility type:*	Usually, circle: HIV Counseling and Testing Site

Section 5. Patient History

Transmission:	Record risks occurring after 1977. Ask about each one. Check "yes" for each of the listed behaviors or exposures that your client confirms. If the client denies everything, check "no" or "unknown" (if refused) for each category. If this section is left blank we will consider the answer to be unknown.

* **Section 6. Laboratory Data**

HIV antibody test:*	HIV counselors will usually enter HIV-1 EIA and HIV-1/HIV-2 MULTI SPOT. Record the month, day and year that the blood was drawn for HIV testing. If month and/or day is unknown, leave them blank but record the year
Detectable viral load:	Enter if available (HIV CTR/Testing staff may not have results of this test).
Date of neg HIV test:	If available, record the date of the most recent negative HIV test
Immunologic lab tests:	Record CD4 results, if available.
AIDS Indicator Disease:	Record any AIDS indicator disease (opportunistic infections) that you are aware of.

Section 7. For Female Patients

Complete questions regarding pregnancy and/or former births.

Section 8. Referrals

Patient informed	If the patient failed to return for results, select no.
Partner notification	Select how the patient's sex partners will be notified
DPH assistance	Let us know if you'd like DIS staff to assist with partner notification

Section 9. Comments

Record any additional comments that you have about the patient

* **Section 10. HIV Testing and Treatment History**

All new HIV infections must be interviewed. Please review the following section carefully! Text in boxes is suggested script for the counselor.

Select the "Source of Information" for the Testing and Treatment History.

Thank you for providing this information. Remember that all the answers you give will be kept private. First are a few questions about your past HIV tests.

1. Date patient answered the questions __ __/ __ __ / __ __ __ __ (month/day/year)

The next question is used to determine if the client has had a positive test before the one that led to the client being considered eligible for HIV incidence surveillance.

2. Has the patient ever had a previous positive test? ☐ Yes ☐ No ☐ Unkn

3. What was the date (month and year) of the very first time you ever tested positive for HIV? List when you got your test, not when you got your results. We will refer to this test date again.

___ ___ /___ ___ ___ ___ (month/year)

Next, the interviewer should ask if the client has had a prior negative HIV antibody test. If the client has had a negative test, then the interview proceeds to ask when the client had his/her last HIV negative test.

4. What was the date (month and year) of the last negative HIV test?

___ ___ /___ ___ ___ ___ (month/year)

5. In the two years before your first positive test (on the date in question 2), how many times did you get tested for HIV?

___ ___ (tests before the first positive)

6. Why was the patient tested for HIV?

Select the best reason available. If other, please provide the reason.

Finally, it is important to determine the client's use of antiretroviral medications (ARVs). These medications can decrease the level of HIV antibodies circulating in the blood. As a result, a less sensitive EIA would be less likely to detect HIV antibodies, and could therefore produce a result that suggests a recent infection regardless of the length of time since the client's seroconversion.

The interviewer should have a picture that depicts the antiretroviral medication that a client might have taken. This card should be shown when asking about HIV medications because a client may be unsure of the exact medications that he/she has taken or may confuse other medications for antiretroviral medications and incorrectly report that he/she has taken HIV medications.

These last questions are about HIV medicines. Sometimes these are used to try to prevent HIV infection. Some of the medicines are also used to treat Hepatitis B. These medicines can also be used in HIV treatments called HAART. Please refer to an ANTI-RETROVIRAL MEDICINES chart when asking the next questions.

7. In the past 6 months have you taken any medicines shown in the picture on the last page to treat or try to prevent HIV or Hepatitis?

Yes..... ☐1 ⇒ **Please go to question 7a**

No..... ☐0
I don't know..... ☐9 } **STOP, you are finished!**

If the client is currently taking medications, got to the final question:

7a. Why did the patient use ARVs?

On the "ARV USE TABLE" select the reason that the patient took ARV medication and list the medications.

Enter the date that the medication was started and stopped, if applicable.

What was the first day on which you took any of the medicines shown in the pictures? Please make your best guess if you are not sure.

__ __/__ __/ __ __ __ __ (month/day/year)

When was the last day you took any of the medications shown in the pictures?

__ __/__ __/ __ __ __ __ (month/day/year)

You are finished! Thank you!

CLINICAL TEST REQUISITION
STATE OF CONNECTICUT

Dr. Katherine A. Kelley State Public Health Laboratory
395 West Street, Rocky Hill, CT 06067
CLIA ID 07D0644555 / CT License CL-0197
Phone 860-920-6500
CLIENT SERVICES 860-920-6635

ACCESSION LABEL FOR CTDPH LABORATORY USE ONLY

♦**LAB PROFILE Number:**

♦ **DENOTES REQUIRED INFORMATION**

Section 1: Patient Information (*Please Print Clearly*)

♦ **Name (Last, First, M.I.) or Identifier:**

♦ **Street Address:** ♦ **City, State, Zip:**

♦ **Date of Birth:** Gender: ☐ Female ☐ Male ☐ Unknown Home Phone:

Race (check all that apply): **(♦ Race/Ethnicity Information is Required for Blood Lead)**
☐ White ☐ Black/African Amer. ☐ Asian ☐ Amer. Indian/Alaska Nat. ☐ Nat. Hawaiian/Other Pacific Islander ☐ Other ☐ Unknown
Ethnicity: ☐ Hispanic ☐ Non-Hispanic ☐ Unknown

Ordering Healthcare Provider: Phone:

Section 2: Specimen Information

♦ **Specimen Storage (Prior to Delivery):** ☐ Refrigerated (2-8˚C) ☐ Frozen (<-20˚C) ☐ Ambient Temperature
♦ **Specimen Transport/Delivery:** ☐ Cold (Ice pack) ☐ Frozen (Dry Ice) ☐ Ambient Temperature

Submitter Sample ID: ♦ **Date Collected:** Time Collected: ☐ AM ☐ PM

♦ **Specimen Source/Type:**
☐ Blood (whole) ☐ Bronchial Wash ☐ Buccal cavity ☐ Cervix ☐ CSF ☐ Nasopharynx ☐ Oropharynx ☐ Plasma
☐ Rectal ☐ Serum ☐ Sputum ☐ Stool ☐ Urethra ☐ Urine ☐ Vaginal

☐ Body Fluid, specify _____ ☐ Tissue, specify _____
☐ Other, specify

♦ Section 3: Select Testing Requested

Bacteriology

☐ AFB Clinical Specimen (Mycobacteria Smear & Culture)
☐ AFB Referred Culture (Mycobacteria for Identification)
☐ Bioterrorism Agent Identification
specify agent:_____
☐ Bordetella pertussis (DFA, Culture) ☐ (DNA amplification)
☐ Chlamydia/ Gonorrhea Nucleic Acid Amplification Test
☐ CRE panel Organism:_____
☐ EIP Isolates for Identification **(Check one)**
☐ Group A *Streptococcus* ☐ *H. influenzae* ☐ *L. monocytogenes*
☐ *N. meningitidis* ☐ *S. pneumoniae* ☐ Other: _____
☐ Enteric Isolate for Identification
☐ *Campylobacter* ☐ *E. coli O157* ☐ *Salmonella* ☐ *Shigella*
☐ *Shiga-toxin producing E. coli* ☐ *Vibrio* ☐ Other: _____
☐ Enteric (Stool) Culture ☐ CIDT Organism: _____
☐ Shiga-toxin (+) Broth Culture

Bacterial Serology

☐ QuantiFeron-TB Test **(Specify ♦ Date & Time Collected Above)**
☐ Syphilis Screen (VDRL)
☐ Syphilis Confirmation (VDRL & TP-PA)
☐ Syphilis CSF (VDRL Only)

Blood Lead **(Uninsured Patients ONLY)** ♦ Race/Ethnicity Required

☐ Child Lead Screen (Capillary Blood)
☐ Lead Confirmation (Venous Blood)

Mycology

☐ *Candida auris* identification

Parasitology

☐ Blood Parasite - Smear

Virology

☐ Arbovirus IgG/IgM (Encephalitis Viruses)
California Group, Eastern Equine, St. Louis, Western Equine
☐ Hepatitis B Surface Antibody
☐ Hepatitis B Surface Antigen
☐ Hepatitis C Testing
☐ Herpes Simplex IgG Antibody
☐ Herpes Simplex DNA amplification
☐ HIV-1/HIV-2 Ag/Ab
☐ HIV Viral Load
☐ Influenza PCR
☐ Measles PCR
☐ MERS CoV (Novel Coronavirus) **(Epidemiology Approval Required)**
☐ Mumps PCR
☐ Norovirus PCR **(Epidemiology Approval Required)**
☐ Respiratory Virus Antigen Panel: *Adenovirus, Human Metapneumovirus, Parainfluenza, Rhinovirus/Enterovirus, RSV*
☐ Varicella Zoster IgG Antibody
☐ West Nile Virus IgM Antibody
☐ Virus Identification (Tissue Culture)
NOTE: Zika virus testing requires submission of the Zika Virus Clinical Test Requisition
SARS-CoV-2 requires COVID-19 requisition form

Test, Agent or Disease, Not Listed (Specify)

Comments

State of Connecticut Department of Public Health
State Public Health Laboratory Website

- Laboratory Resources:
  - **Collection Supplies and Test Requisition Forms** https://portal.ct.gov/DPH/Laboratory/Scientific-Support/Scientific-Support-Services

    Collection supplies may be requested by calling Scientific Support Services at 860-920-6674 for by submitting an email request to dph.outfitroom@ct.gov

- **Directory of Clinical Testing Services** https://portal.ct.gov/DPH/Laboratory/Clinical-Testing-Services/DCTS-101915

Specimen Requirements for HIV Diagnostic Testing

- **Acceptable specimens:** 1 mL serum (preferred) or 1 mL plasma
  - Serum Separator Tubes (SSTs) are available by request

- **Specimen handling & transport:** Store specimens at 2°-8° C up to 7 days, including transit time. Specimens must be taken off RBCs and stored at <-20° C if stored for more than 7 days. Transport with an ice pack coolant. Avoid temperature extremes. Transport frozen on dry ice if receipt is expected to be > 7 days from collection.

HIV-1 RNA Viral Load – CTPHL

- **Test Description:** Assay for the quantitation of human immunodeficiency virus type 1 (HIV-1) RNA in human plasma from HIV-1 infected individuals.

- **Intended Use:** For newly diagnosed patients or patients who have fallen out of care. Available for individuals with no or limited health insurance.

- **Specimen Requirements:** 1.5 mL plasma collected in tubes containing EDTA or Acid Citrate Dextrose (ACD) anticoagulants, or in Plasma Preparation Tubes (PPTs)
    - Plasma Preparation tubes (PPTs) are available by request.

- **Specimen Handling and Transport:** Whole blood can be stored at 2°C to 30°C and must be centrifuged within 24 hours of collection. Centrifuged specimen can be stored in the primary collection tube at 2°C to 8°C for up to 3 days.

Hepatitis C Antibody Testing - CTPHL

- **Test Description:** Screening assay for the qualitative detection of antibody to hepatitis C virus (anti-HCV) in human serum or plasma.
  - All initially reactive Hep C antibody specimens are tested again in duplicate.
  - All repeatedly reactive Hepatitis C antibody specimens are reflexed to a Hepatitis C RNA (viral load) assay.
- **Specimen Requirements:** 1 mL serum (preferred) or plasma.
- **Specimen Handling and Storage:** Store specimen at 2-8° C. Specimen must be received by the laboratory within 7 days of collection.

Hepatitis C RNA (Viral Load) Testing – CTPHL

- **Test Description:** Assay for the detection and quantitation of Hepatitis C virus (HCV) RNA in human serum and plasma.

- **Test Use:** To aid in the diagnosis of hepatitis C infection following a repeatedly reactive HCV antibody ELISA screening test result.

- **Specimen Requirements:** 2.5 mL serum, collected in serum tubes or Serum Separator Tubes, or plasma, collected in tubes containing EDTA or ACD anticoagulants or in Plasma Preparation Tubes.

- **Specimen Handling and Transport:** Whole blood can be stored at 2°C to 30°C and **must be centrifuged within 6 hours of collection**. Centrifuged specimen can be stored in the primary collection tube at 2°C to 8°C for up to 5 days.

CT DPH HIV Prevention Program –Data Request Form

Overview

CT DPH HIV Prevention Program (HPP) provides a continuum of HIV services monitored through three primary data sources: HIV Testing Interventions, Syringe Services Programs (SSPs), PrEP Navigation Services and Effective Behavior Interventions (EBIs). Data may already be captured in past presentations, publications, reports, fact sheets and other resources that we already created. If you are unable to find the data you need, please complete the request form on the next page. Please note that this data only applies to HPP funded organizations. This data **IS NOT** a representation of all HIV, Hepatitis C (HCV) and SSPs interventions that occur statewide.

Description of Data Sources:

1. **HIV/HCV Testing Interventions**
   HIV/HCV testing interventions provide HIV/HCV testing in healthcare and non-healthcare settings to individuals who don't know their HIV/HCV status and/or who are at substantial risk for HIV/HCV.
   Some of the data that can be obtained from HIV testing interventions:
   - Number of HIV/HCV tests
   - Number of HIV self-tests conducted
   - Type of HIV tests performed (e.g., rapid, standard)
   - Number of new HIV/HCV positives with positivity rates
   - Demographic information
   - Risk factors

2. **Syringe Services Programs (SSPs)**
   SSPs provide harm reduction services to individuals who need linkage to substance use disorder treatment, access to and disposal of sterile syringes and injection equipment, overdose prevention services, and vaccination, testing, and linkage to care and treatment for infectious diseases.
   Some of the data that can be obtained from SSPs:
   - Number of SSP clients
   - Demographic information
   - Number of syringes collected/distributed
   - Number of naloxone kits distributed
   - Risk factors

3. **PrEP Navigation Services**
   PrEP navigation services guide HIV negative individuals in health care systems, assist with health insurance and transportation and identify and reduce barriers to negative health outcomes.
   Some of the data that can be obtained from PrEP navigation interventions:
   - Number of PrEP referrals
   - Number of clients on PrEP
   - Demographic information
   - Client linkage-to-care

4. **Effective Behavior Interventions (EBIs)**
   EBIs pursue a prevention approach to reducing new HIV infections by using combinations of scientifically proven, cost-effective, and scalable interventions directed to the most vulnerable populations in Connecticut.
   Some of the data that can be obtained from EBIs:
   - Number of outreach encounters
   - Number of clients enrolled in the intervention
   - Number of HIV positive clients
   - Demographic information
   - Aggregate intervention completion status

CT DPH HIV Prevention Program
Program Monitoring Evaluation & Data Management
410 Capitol Ave. MS# 11APV Hartford CT, 06134
Phone: (860) 509-7849

Data Request Process

1. Please complete all fields in Sections 1 and 2 below, and submit to HPP Data Manager via email: ramon.rodriguez-santana@ct.gov
2. If approved, your request will be assigned to a data management team member who will contact you for more details as needed.
3. Requests will generally be **completed in three weeks**. However, your request may take longer due to complexity, staff availability and/or competing priorities.
4. For assistance with completing this form or if you have questions about the status of a submitted request, please contact HPP Data Manager via email at ramon.rodriguez-santana@ct.gov.

SECTION I: CONTACT INFORMATION

Full Name:		Agency Name:			
Email:		Phone Number:		Ext.	
Date Requested:					

SECTION II: DATA REQUEST

Desired Completion Date:

Data Visualization Format (e.g., table, figure, map, narrative, PowerPoint):

Purpose: *Why do you need data?*	**Check all that apply:** ☐ Grant/proposal ☐ Program Evaluation ☐ Community Planning Needs Assessment ☐ Progress Report ☐ Research ☐ Other, specify:
What is/are your project/research question(s)?	e.g., What percent of MSMs are HIV positive and inconsistently use condoms?
Specific data source: *What type of service data are you looking for?*	**Select one:** ☐ HIV Testing ☐ HCV Testing ☐ Syringe Services Programs (SSPs) ☐ PrEP Navigation ☐ Effective Behavior Interventions (EBIs) ☐ Other, specify:
Time period of interest: *For what month/year(s) are you requesting data?*	e.g., January 1, 2007 – December 31, 2007 From: To:
Geographic area(s):	e.g., New Haven County, Town of Waterbury
Population(s) of interest:	**Check all that apply:** ☐ HIV Positive Individuals ☐ Transgender ☐ Men ☐ Women ☐ People Who Inject Drugs ☐ Sex Workers ☐ Crack Smoking Population ☐ Other, specify:
Variable(s) of interest:	e.g., HIV/HCV risk groups, substance use type, opioid related overdoses, individuals on PrEP

Program Evaluation & Data Management Use Only:					
Approved by:		Assigned to:		Date:	
☐ Not Approved, specify:					

Clear Form

EvaluationWeb® 2018 HIV Test Template

Form ID *(enter or adhere)*

1 Agency and Client Information
(complete for ALL persons)

Session Date

Program Announcement

- ○ PS15-1506 PrIDE
- ○ PS15-1509 THRIVE
- ○ PS17-1711
- ○ PS18-1802
- ○ PrEP Funded Activities
- ○ PS19-1901 CDC STD
- ○ Other CDC funded
- ○ Other non-CDC funded

Specify Other *(optional)*

Agency Name or ID

Site Name or ID

Site Type *(codes below)*

Site ZIP Code

Site County *(3-digit FIPS code)*

Local Client ID *(optional)*

Year of Birth *(1800 if unknown)*

Client State *(USPS abbreviation)*

Client County *(3-digit FIPS code)*

Client ZIP Code

Client Ethnicity

- ○ Hispanic or Latino
- ○ Not Hispanic or Latino
- ○ Don't know
- ○ Declined to Answer

Client Race *(select all that apply)*

- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black/African American
- ☐ Native Hawaiian/Pacific Islander
- ☐ White
- ☐ Not Specified
- ☐ Declined to Answer
- ☐ Don't Know

Client Assigned Sex at Birth

- ○ Male
- ○ Female
- ○ Declined to Answer

Client Current Gender Identity

- ○ Male
- ○ Female
- ○ Transgender Male to Female
- ○ Transgender Female to Male
- ○ Transgender Unspecified
- ○ Another Gender
- ○ Declined to Answer

Has the client had an HIV test previously?

- ○ No
- ○ Yes
- ○ Don't Know

Site Types: Clinical

- F01.01 - Inpatient hospital
- F02.12 - TB clinic
- F02.19 - Substance abuse treatment facility
- F02.51 - Community health center
- F03 - Emergency department
- F08 - Primary care clinic (other than CHC)
- F09 - Pharmacy or other retail-based clinic
- F10 - STD clinic
- F11 - Dental clinic
- F12 - Correctional facility clinic
- F13 - Other

Site Types: Mobile

- F40 - Mobile Unit

Site Types: Non-clinical

- F04.05 - HIV testing site
- F06.02 - Community setting - School/educational facility
- F06.03 - Community setting - Church/mosque/synagogue/temple
- F06.04 - Community Setting - Shelter/transitional housing
- F06.05 - Community setting - Commercial facility
- F06.07 - Community setting - Bar/club/adult entertainment
- F06.08 - Community setting - Public area
- F06.12 – Community setting – Individual residence
- F06.88 - Community setting - Other
- F07 - Correctional facility - Non-healthcare
- F14 - Health department - Field visit
- F15 - Community Setting - Syringe exchange program
- F88 - Other

Form Approved: OMB No. 0920-0696, Exp. 10/31/2021. Public reporting burden of this collection of information is estimated to average 8 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-79, Atlanta, Georgia, 30333, ATTN: PRA 0920-0696. CDC 50.135b(E),10/2007

EvaluationWeb® 2018 HIV Test Template

Form ID *(enter or adhere)*

2 Final Test Information
(complete for ALL persons)

HIV Test Election

○ Anonymous ○ Confidential ○ Test Not Done

Test Type *(select one only)*

○ CLIA-waived point-of-care (POC) Rapid Test(s) ○ Laboratory-based Test

POC Rapid Test Result *(definitions on page 3)*

- ○ Preliminary Positive
- ○ Positive
- ○ Negative
- ○ Discordant
- ○ Invalid

Laboratory-based Test

- ○ HIV-1 Positive
- ○ HIV-1 Positive, possibly acute
- ○ HIV-2 Positive
- ○ HIV Positive, undifferentiated
- ○ HIV-1 Negative, HIV-2 Inconclusive
- ○ HIV-1 Negative
- ○ HIV Negative
- ○ Inconclusive,

Result provided to client?

○ No ○ Yes ○ Yes, client obtained the result from another agency

3 Negative Test Result
(complete for persons testing NEGATIVE for HIV)

Is the client at risk for HIV infection? (*optional*)

○ No ○ Yes ○ Risk Not Known ○ Not Assessed

Was the client screened for PrEP eligibility?

○ No ○ Yes

Is the client eligible for PrEP referral?

○ No ○ Yes, by CDC criteria ○ Yes, by local criteria or protocol

Was the client given a referral to a PrEP provider?

○ No ○ Yes

Was the client provided with services to assist with linkage to a PrEP provider?

○ No ○ Yes (If Yes, complete section 8 questions)

4 Positive Test Result
(complete for persons testing POSITIVE for HIV)

Did the client attend an HIV medical care appointment after this positive test?

- ○ Yes, confirmed
- ○ Yes, client/patient self-report
- ○ No
- ○ Don't Know

→ Date Attended

Has the client ever had a positive HIV test?

○ No ○ Yes ○ Don't Know

→ Date of first positive result

Was the client provided with individualized behavioral risk-reduction counseling?

○ No ○ Yes

Was the client's contact information provided to the health department for Partner Services?

○ No ○ Yes

What was the client's most severe housing status in the last 12 months?

- ○ Literally homeless
- ○ Unstably house or at risk of losing housing
- ○ Stably housed
- ○ Not asked
- ○ Declined to Answer
- ○ Don't know

If the client is female, is she pregnant?

- ○ No
- ○ Yes
- ○ Declined to Answer
- ○ Don't know

→ Is the client in prenatal care?

○ No ○ Yes ○ Don't know ○ Declined to Answer ○ Not asked

→ Was the client screened for need of perinatal HIV service coordination?

○ No ○ Yes

→ Does the client need perinatal HIV service coordination?

○ No ○ Yes

→ Was the client referred for perinatal HIV service coordination?

○ No ○ Yes

EvaluationWeb® 2018 HIV Test Template

Form ID *(enter or adhere)*

5 Additional Tests
(complete for ALL persons)

Was the client tested for co-infections?

○ No ○ Yes

Tested for Syphilis?

○ No ○ Yes

Syphilis Test Result *(optional)*

○ Newly Identified infection
○ Not Infected
○ Don't know

Tested for Gonorrhea?

○ No ○ Yes

Gonorrhea Test Result *(optional)*

○ Positive ○ Negative ○ Don't Know

Tested for Chlamydial infection?

○ No ○ Yes

Chlamydial infection Test Result *(optional)*

○ Positive ○ Negative ○ Don't Know

Tested for Hepatitis C?

○ No ○ Yes

Hepatitis C Test Result *(optional)*

○ Positive ○ Negative ○ Don't Know

Value Definitions for POC Rapid Test Results

Preliminary positive - One or more of the same point-of-care rapid tests were reactive and none are non-reactive and no supplemental testing was done at your agency

Positive - Two or more different (orthogonal) point-of-care rapid tests are reactive and none are non-reactive and no laboratory-based supplemental testing was done

Negative - One or more point-of-care rapid tests are non-reactive and none are reactive and no supplemental testing was done

Discordant - One or more point-of-care rapid tests are reactive and one or more are non-reactive and no laboratory- based supplemental testing was done

Invalid - A CLIA-waived POC rapid test result cannot be confirmed due to conditions related to errors in the testing technology, specimen collection, or transport

6 PrEP Awareness and Use/Priority Populations
(complete for all persons)

Has the client ever heard of PrEP (Pre-Exposure Prophylaxis)?

○ No ○ Yes

Is the client currently taking daily PrEP medication?

○ No ○ Yes

Has the client used PrEP anytime in the last 12 months?

○ No ○ Yes

In the past five years, has the client had sex with a male?

○ No ○ Yes

In the past five years, has the client had sex with a female?

○ No ○ Yes

In the past five years, has the client had sex with a transgender person?

○ No ○ Yes

In the past five years, has the client injected drugs or substances?

○ No ○ Yes

7 Essential Support Services
(complete for all persons, EXCEPT as indicated)

	Screened for need	Need determined	Provided or referred
Navigation services for linkage to HIV medical care *(positive only)*	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Linkage services to HIV medical care *(positive only)*	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Medication adherence support *(positive only)*	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Health benefits navigation and enrollment	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Evidence-based risk reduction intervention	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Behavioral health services	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes
Social services	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes

EvaluationWeb® 2018 HIV Test Template

Form ID *(enter or adhere)*

8 Texas Specific
(optional for non-funded PrEP activities)

What type(s) of insurance does the client have?
(Answered when referred to prep is 'Yes'; Select all that apply response)

- ☐ Private Insurance
- ☐ Medicare
- ☐ Medicaid/State Insurance
- ☐ Local/County/City Insurance
- ☐ Tricare
- ☐ Uninsured
- ☐ Client Doesn't Know/Declined

What types of linkage services was the client provided?
(If assistance with linkage was answered as 'Yes'; Select all that apply).

- ☐ Transportation
- ☐ Scheduling Appointments
- ☐ Benefits/Insurance Navigation
- ☐ Accompaniment
- ☐ Follow up and Reminders
- ☐ Adherence Support and Counseling
- ☐ Other

Date of first PrEP prescription written: ____ /____ /_____
MM/DD/YYYY

Notes *(optional)*

9 Health Department Use Only
(complete for persons testing POSITIVE for HIV)

eHARS State Number

eHARS City/County Number

New or Previous diagnosis?

- ○ New diagnosis, verified
- ○ New diagnosis, not verified
- ○ Previous diagnosis
- ○ Unable to determine

Has the client seen a medical care provider in the past six months for HIV treatment?

- ○ No
- ○ Yes
- ○ Declined to Answer
- ○ Don't know

Partner Services Case Number

Was the client interviewed for Partner Services?

- ○ Yes, by a health department specialist
- ○ Yes, by a non-health department person trained by the health department to conduct partner services
- ○ No
- ○ Don't Know

Date of Interview

Value Definitions for POC Rapid Test Results

New diagnosis, verified - The HIV surveillance system was checked and no prior report was found and there is no indication of a previous diagnosis by either client self report (if the client was asked) or review of other data sources (if other data sources were checked).

New diagnosis, not verified - The HIV surveillance system was not checked and the classification of new diagnosis is based only on no indication of a previous positive HIV test by client self-report or review of other data sources.

Previous diagnosis - Previously reported to the HIV surveillance system or the client reports a previous positive HIV test or evidence of a previous positive test is found on review of other data sources.

Unable to determine - The HIV surveillance system not checked and no other data sources were reviewed and there is no information from the client about previous HIV test results.

Connecticut HIV Prevention Program

Comprehensive Site Visit Procedure

CONNECTICUT

Public Health

Department of Public Health
Infectious Diseases
TB, HIV, STD, & Viral Hepatitis Programs
HIV Prevention Program

Revised

February 7, 2024

Table of Contents

Appendices:

Connecticut HIV Prevention Program Protocol
for Administrative Site Visit 2024

Introduction

- The HIV Prevention Program established the following site visit protocol for conducting on-site administrative, programmatic, and technical assistance site visits for the HIV Prevention program. HIV Prevention Contract Managers will conduct a minimum of three site visit a year- comprised of the following:
- Administrative Site Visit- conducted at the beginning of year to assess programmatic areas funded services
- Observational Site Visit- to assess provider skills in services delivery and interventions.
- Chart Audit Site Visit- to assess adherence to required documentation of funded services and interventions.
- As needed for addressing problematic items or corrective actions if applicable.
- This protocol is updated on an annual basis.
- Questions on this protocol should be directed to Susan Major, Lead Contract Manager

Purpose of the DPH HIV Prevention site visit is to ensure the following:

- Compliance with contractual requirements,
- Identify program challenges and best practices,
- Evaluate the quality of the service delivery through observations and review of chart documentation,
- Provide technical assistance (TA) as appropriate,
- Provide resources and guidance for improving services and interventions.

Scheduling Procedure

HIV Prevention Contract Managers are responsible for the coordination and scheduling of site visits. The process for site visits is as follows:

- HIV Prevention Contract Manager will coordinate with the contractor to schedule and coordinate the site visit with appropriate staff.

- HIV Prevention Contract Manager will provide the contractor with a brief overview of the site visit, information required prior to the site visit and list of staff who will participate in the site visit. (See Appendix G for a sample e-mail template).

- A final agenda of items that will be discussed will be provided to contractor prior to the date of the site visit.

- All site visits must be documented in the contract manager outlook calendar.

- Site visit agenda, letters and documentation are to be filed in One-drive under Contract Management for Quality Improvement Purposes.

Pre-Review Preparation

To maximize efficiency of comprehensive site visits the program manager must review the following documents in advance and conduct preliminary analysis prior to the site visit. These documents can be accessed at DPH prior to the site visit:

- Copy of signed contract
- Copy of most recent programmatic report
- Copy of most recent financial expenditure report received by the department
- Most recent data report extracted from EvaluationWeb or e2CTPrevention

The below are to be requested from contractor at least one week prior to the site visit if they have not been submitted prior.

- Memorandum of Agreements (MOA) and/or Memorandum of Understandings (MOU)
- Annual Client Satisfaction Survey and results
- Implementation Plan
- HIV Prevention Manuals

Policy and Procedures Manual

Entrance Conference

Purpose of the entrance conference is to facilitate introductions of all individuals involved, describe the site visit process, and address any questions or concerns presented prior to the beginning of the site visit.

- Contractor staff is provided with an overview of the purpose of the site visit.
- Contractor provides overview of the HIV Prevention Program including successes and challenges to delivering services in accordance with the contract.

Types of Site Visits

1) **Administrative Site Visit-** administrative site visit are conducted at the beginning of every contract year. The purpose of the administrative site visit is to provide an introductory meeting with all funded prevention staff that includes the following:
    - Welcome and introductions
    - Overview of DPH site visit process
    - Contractor overview of services provided, services funded, and staff roles/responsibilities
    - Conduct an environmental assessment to ensure files are stored in locked cabinets, facility is safe and clean for clients, and displayed HIV prevention materials have been approved by the Materials Review Board.
    - Review personnel policies and procedures to ensure compliance with staff qualifications, confidentiality agreements, and trainings.
    - Documentation forms and files
    - Check temperature logs and thermometers in storage rooms and refrigerators.
    - Check storage room for DPH funded materials, expiration dates, and inventory log for supplies
    - Expectations of contractual requirements and program outcomes
    - TA or other related training requested by the contractor
    - Assessment is conducted using the Administrative Site Visit Tool

2) **Mid-Year Site Visit**- Mid-year site visits are conducted at the mid-point of the year and include a programmatic review of the following;
    - QI for HIV Testing Procedures that Review temperature logs and HIV testing logs, (See Appendix H)
    - QI for HIV Testing Documentation,
    - Review of incentive logs, social media campaigns, client satisfaction survey data, and mechanisms for tracking referrals to services.
    - Performance Measures and Outcomes - Review number of clients served and activities conducted for each funded intervention.
    - Observational Assessment- conduct observations with funded staff using the DPH observational tool. (See Appendix G).
    - Chart Audit-Review client charts to measure quality of HIV testing services and PrEP Navigation Services, for all HIV negative clients and access care for newly diagnosed persons, and referral and linkage to support services and other prevention services (See Appendix F).
3) Follow-up site visits- to be conducted as needed to address any findings from previous site visits and or corrective actions. These may include:
    - Observations
    - Chart Audits
    - TA or in-service trainings

Exit Conference

Contract Managers will conduct an exit conference with contractor staff to discuss findings and recommendations for improvements. Less significant findings or recommendations that do not warrant a corrective action report are addressed in the site visit letter.

Conclusion of Site Visit

- HIV Contract Manager shall provide any information or resources requested by contractor within 10 days of the site visit.
- If corrective action is necessary, HIV Prevention Contract Manager shall send cover letter, comprehensive site visit report noting findings, and recommendations for corrective action plan and/ or Technical Assistance (TA) within 30 days of the site visit.
- If no corrective action and/or TA is necessary, HIV Prevention contract manager shall send a letter to the contractor within 30 days of the visit. (See Appendix D for sample site visit letter

Reports

- Program supervisor will review and approve site visit reports including applicable findings within three weeks of completed site visit.

Site visit report and applicable findings will be sent via email to contractor within 30 days of completion of site visit.

- Contractor must submit a corrective action plan within 30 days of receipt of site visit report using the corrective action plan template provided by the contract manager. (See Appendix C)
- HIV Prevention program supervisor and contract manager will review contractor's corrective action plan when received and determine if corrective action plan meets program expectations.
- Copy of approved site visit report and corrective action plan must be maintained in the centralized HIV Prevention contract file.

Follow-up

HIV Prevention Contract Manager will follow-up with contractor regarding implementation of corrective action within 30 days of receipt of plan. Corrective action plan activities must be monitored monthly until the corrective action is rectified. Contract Manager must document successful/unsuccessful implementation of corrective action and any additional steps required by the HIV Prevention Program. In the case of unsuccessful implementation, this may include a notice of non-compliance, reduction in contract funds or termination of contract due to documented inability to perform terms of agreement.

These actions will be implemented under the guidance of HIV Prevention program supervisor and section chief as appropriate. The HIV Prevention Contract Manager may provide follow-up.

Conclusion

After all site visit activities have occurred, the Contract Manager must put all documents including site visit report, site visit letter, corrective action report, and follow-up in the central one-drive files.

DEPARTMENT OF PUBLIC HEALTH (DPH)
TB, HIV, STD, & Viral Hepatitis Program – HIV Prevention Unit
Administrative Site Visit Audit Protocol

Instructions:

1. The **Contract Manager** will use the Department of Public Health (DPH) Administrative Site Visit Audit Tool to mark "**Yes**" or "**No**" to indicate whether the general policies and procedures for Prevention Services have been met.

    a. The **Contract Manager** must be familiar with contractual guidelines, in addition to the implementation plan submitted by the agency required under contract with DPH for the provision of Prevention Services.

    b. The **Contract Manager** is required to conduct one (1) administrative site visits and a minimum of two (2) program visits with the agency per year. Contract Managers have an option to conduct an unannounced site visit with the agency. The administrative site visit tool must be completed during the first visit per year. A written letter summarizing the visit must be completed after each visit.

    c. Whenever assessing the site as "**No**", the **Contract Manage**r should provide recommendations for improvements in the Action Plan Section of the report (**VIII. ACTION PLAN & RECOMMENDATIONS**).

    d. Conclusions should be based on the consistency for which the site meets DPH contractual requirements and policies.

2. The DPH requires that each program with one or more deficiencies will file a **Corrective Action Plan** listing the steps that the program will take to correct those deficiencies. The citation of deficiencies, and the corrective action process, can work as aids to programs in focusing resources in specific areas in a process of continuous improvement.

    a. **Corrective Action Plan**: The program will file a plan for the correction of those deficiencies with their Contract Manager within 10 business days of receipt of the DPH Site Visit Letter. The Corrective Action Plan should cite each deficiency and the plan for correcting that deficiency. The plan needs to be verifiable, i.e. what documentation can the program submit that will verify that the deficiency is corrected

3. **Follow-up**: The DPH must offer training and technical assistance, if appropriate, to help contractors correct identified deficiencies or failures to meet DPH requirements. Technical assistance may be offered concurrently with the notification of a deficiency or deficiencies and should focus on the specific issues of the agency to the extent possible.

4. The completed report should be summarized and disseminated to the agency no more than fifteen (15) business days from the day of the initial site visit. If a corrective action plan has been issued, the agency must respond to the plan within ten (10) business days of the receipt of the plan. The Contract Manager will follow-up with agency (site visit) within three (3) months to ensure that the action items from the corrective action plan have been addressed. A template Site Visit Summary Report letter with instructions is attached at the end of this audit tool.

5. Date & File Copy.

Revised on: 02/14/23 SM, LD

GENERAL DATA ENTRY INSTRUCTIONS

Contractor Name/Log# Field
This particular field is a drop down box to make it easier and quicker to put in the contractor name and their log#. It is important to note that this field doesn't tab to/tab off from. So you will click the drop down box, select the name/log and then you will need to click into the next gray-shaded field to continue tabbing through the document. If you cannot find your contractor name/appropriate log# in the list, please let David know so that he can add it to the list.

Date Fields
Date fields have been separated into a 2-digit month, 2-digit day, and 4-digit year. *(mm/dd/yyyy)*.

Phone Number Fields
Phone number fields have been formatted in such a way that they will auto format themselves into a (###) ###-####. It is only necessary for you to enter in the 10 digits of the phone number. There is no need to add parentheticals or the hyphen. Upon tabbing out of the field, the number should put the parentheticals and hyphen in for you.

Text Fields
Text fields are formatted in different ways throughout the document depending on what is being asked for that section. In most cases the length of the text fields will be set to "unlimited" so that narrative can be typed in. It is also important to know that when filling out narrative areas the field will continue to grow as you continue to type. When it reaches the end of a line it will go to the next line. You may see it push certain sections down the page. This is normal and, unfortunately, not easily preventable.

Also, you can still use the "enter button" to add lines / space between paragraphs. If you need to put a bullet into your narrative I would recommend using a "*", "-", "^", or "+" to show distinctions.

General Number Fields
Number fields (like text fields) are formatted in certain ways depending on what is being asked. For example, percentage areas are limited to a 3-digit number (100% for example). Other areas such as Phone Extension will be limited to 4-5 digits. Brochures, Pamphlets, or any areas asking for quantities are also limited to 4-5 digits.

Check Boxes
Check boxes can be selected/de-selected either by clicking on the box or by pressing the space bar.

Clear Form

TB, HIV, STD, & Viral Hepatitis Program-HIV Prevention Services Unit
ADMINISTRATIVE SITE VISIT TOOL

Site Visit Date: Reviewer

Contractor/Sub Name:

Address:

Agency Contact:

Email: Office Phone #: Extension:

Remote Phone #: Funded

Staff: Conferred with:

Purpose of Site Visit ☐ Introductory/Orientation ☐ Follow-up ☐ Other:
☐ Corrective Action/Compliance ☐ Virtual Site Visit

VISIT ACTIVITY REVIEWED:

I. ENVIRONMENTAL ASSESSMENT

A. Location sites where services are provided:

DPH Funded Locations	Services Provided

B.

Do you use tele-web or apps to communicate with staff and clients? If yes, describe what is used, and how often communication occurs.	YES	NO
	☐	☐

COMMENTS

C.

Are staff in the office and in the field? Please explain how often staff are in the field vs in the office	YES	NO
	☐	☐
COMMENTS		

D.

Please explain how clients access services. What are some successes and challenges that happened over the past year?

E.

HIV prevention services including off-site facilities are accessible to target population, with special attention to issues such as transportation, hours of operation, cultural competence, language and literacy needs.	YES	NO
	☐	☐
COMMENTS		

F.

Is there a mechanism in place for advertising/marketing to inform focus populations of how prevention services are conducted? If yes, please describe.	YES	NO
	☐	☐
COMMENTS		

G.

Has your program adopted innovate strategies or interventions that were implemented during the past year? Please describe.	YES	NO
	☐	☐
COMMENTS		

H.

Where are education materials obtained for clients? Have materials developed by the contractor been reviewed by the materials review committee?	YES	NO
	☐	☐
COMMENTS		

I.

Are education materials available in waiting areas? Is the facility welcoming to clients? Are thermometers in storage rooms and in refrigerators?	YES	NO
	☐	☐
COMMENTS		

J.

How is confidentiality ensured when providing HIV Prevention services?	YES	NO
	☐	☐
COMMENTS		

K.

Does you agency have any needs specific to emerging issues (such as MPox, COVID-19, meningitis etc.) that DPH can help facilitate?	YES	NO
	☐	☐
COMMENTS		

II. PERSONNEL

A.

Have there been any staff changes since your last visit?	YES	NO
	☐	☐
COMMENTS		

B.

Is there a mechanism in place to ensure that staffing reflects the populations serviced?	YES	NO
	☐	☐
COMMENTS		

C.

Staff	Bilingual? If so, what language?

D.

Prevention Services are delivered by bilingual staff or is an interpreter made available when needed?	YES	NO
	☐	☐
COMMENTS		

E.

Is your agency providing currently providing outreach services? If so, have any locations changed over the past year?	YES	NO
	☐	☐
COMMENTS		

III. COMPLIANCE WITH CONFIDENTIALITY

A.

Is there a mechanism in place to ensure staff (including interns, volunteers, etc.) adhere to confidentiality policies?	YES ☐	NO ☐
COMMENTS		

B.

If applicable, are client records stored in a secured and locked area/cabinet? How are files stored when in the field or when teleworking?	YES ☐	NO ☐
Who has access to client records and who comes in the office to secure records?		
COMMENTS		

C.

How is the agency providing on-boarding or training for new staff? Please describe training provided by the agency or other entities.
COMMENTS

D.

What data collection database is used other than EvaluationWeb?		
Is it password protected?	YES ☐	NO ☐
COMMENTS		

IV. QUALITY MANAGEMENT MEASURES

(A minimum of two activities conducted twice a year)

A. ☐ Internal Quality Management Activities ☐ Coaching & Feedback ☐ Case Conferences
☐ Direct Observation ☐ Internal Chart Audits (Review Quarterly Reports)

B.

How does your agency determine client satisfaction with services provided? Please provide tools and most recent survey.
COMMENTS

C.

Is there a mechanism for ongoing supervision & for the provision of feedback? How often does supervision occur?	YES	NO
	☐	☐
COMMENTS		

V. PROGRAMMATIC ASSESSMENT

A.

Is there a HIV Prevention Services Policy & Procedures Manual in place?	YES	NO
	☐	☐
When was it last updated? *(mm/dd/yyyy)*		
COMMENTS		

B.

Is there a mechanism in place to track and trend **referrals** and **outcomes** of referrals?	YES	NO
	☐	☐
PLEASE DESCRIBE / COMMENTS		

C.

Does the provider have existing MOU's in place with agencies? Please list the agencies that you have an MOU with and/or any organizations that you partner or collaborate with.	YES	NO
	☐	☐
PLEASE DESCRIBE / COMMENTS		

D.

Are program services being provided as stated in the program's contract objectives? Please list the number of clients served this year.	YES	NO
	☐	☐
PLEASE DESCRIBE / COMMENTS		

E.

How does the program ensure that funded staff is made aware of target objectives, and intervention progress?	YES	NO
	☐	☐
PLEASE DESCRIBE / COMMENTS		

F.

Does the program utilize Quality Management or have a QI Process in place?	YES	NO
	☐	☐
PLEASE DESCRIBE / COMMENTS		

VI. QUARTERLY REPORTS

(Narrative/Data Collection Reporting)

(Please consult Data Unit Administrators prior to scheduled visit with agency)

A.

Have required reports been submitted to DPH in a timely manner?	YES	NO
	☐	☐
COMMENTS		

B.

Who is responsible for completing the narrative and statistical reports?
COMMENTS

C.

Does the current report data align with the EvaluationWeb data?	YES	NO
	☐	☐
IF NOT, PLEASE DESCRIBE WHY		

D.

Have the proposed target populations been reached? (e.g., MSM, AA, IDUs)	YES	NO
	☐	☐
IF NOT, PLEASE DESCRIBE WHY		

E. (EvaluationWeb)

Who is responsible for the routine data entry into EvaluationWeb? (List staff name)		
Has this person completed the mandatory EvaluationWeb training?	**YES** ☐	**NO** ☐
Does this person have an EvaluationWeb username and password?	**YES** ☐	**NO** ☐
Are all data entry staff eAuthenticated?	**YES** ☐	**NO** ☐
COMMENTS		

F.

Have all HIV Test Forms (i.e., Part 1 for all HIV Negatives and Parts 1, 2 and 3 for all confirmed HIV Positives) been entered into EvaluationWeb in a timely manner? ***(Only HIV Positives test forms [Part 1, 2 and 3] are to be sent to DPH by the 15th of every month)***	**YES** ☐	**NO** ☐
IF NOT, PLEASE DESCRIBE WHY		

VII. MONTHLY REPORTS

(Financial)

B.

Who is responsible for completing the financial expenditure reports? Have there been issues submitting fiscal reports? If yes, what was the issue? Name of Person: Agency/Firm: Phone#: Extension:
COMMENTS

B.

Are reports provided in a timely manner? (Including subcontractor, if applicable)	**YES** ☐	**NO** ☐
IF NOT, PLEASE DESCRIBE WHY		

C.

Are reports accurate?	YES	NO
	☐	☐
IF NOT, PLEASE DESCRIBE WHY (inaccurate/additional line items, salary detail, etc.)		

D.

Discussion items?	YES	NO
	☐	☐
IF YES, PLEASE DESCRIBE		
☐ Over-expenditures: Describe:		
☐ Budget Revisions: Describe:		
☐ Other (specify): Describe:		

VIII. NARRATIVE

(Includes an objective summary of discussion and program strengths)

IX. ACTION PLAN & RECOMMENDATIONS (Address program weakness and deficiencies cited. The Contract Manager should discuss during Exit Interview with staff, which includes program managers/coordinators, intervention staff, and when possible Executive Directors). The tool below will be used to develop a completed Site Visit Summary Report. A template Site Visit Summary Report is attached at the end of this audit tool.

Action Plan & Recommendations	
No citations at this time ☐	
Deficiencies Cited	
•	•
•	•
•	•

Recommendations for Improvement

Programmatic Recommendations: (Addresses overall areas for improvement)

Quality Management Recommendations: (Addresses overall areas for improvement for the quality and outcomes of services delivered through observations/chart reviews, if applicable)

Follow-up: The DPH must offer training and technical assistance, if appropriate, to help contractors correct identified deficiencies or failures to meet DPH requirements. Technical assistance may be offered concurrently with the notification of a deficiency or deficiencies and should focus on the specific issues of the agency to the extent possible.

Corrective Action Plan: ☐ **Yes** ☐ **No**

If Yes, Contractors must respond within Ten (10) business days. The contractor will file a plan for the correction of those deficiencies with their Contract Manager within 10 business days of receipt of the DPH Site Visit Letter. The Corrective Action Plan should cite each deficiency and the plan for correcting that deficiency. The plan needs to be verifiable (i.e. What documentation can the program submit that will verify that the deficiency is corrected?).

PrEP Navigation Services

PrEP Navigator Observation Form

Site Visit Date: _____

PrEP Navigator: _____ 1st ☐ 2nd ☐ 3rd ☐ Observation

DPH Contractor Manager

PrEP Navigation Standards	Met	Not Met	Partially Met
Opening and Purpose			
1. Introduced him/herself by name	☐	☐	☐
2. Explained PrEP Navigator role	☐	☐	☐
3. Orients the client to the session	☐	☐	☐
4. States the duration of the session	☐	☐	☐
PrEP Readiness			
1. Described PrEP clinical guidelines	☐	☐	☐
2. Assessed medication adherence	☐	☐	☐
3. Assessed risk compensation	☐	☐	☐
4. Discussed PrEP side effects	☐	☐	☐
5. Assessed personal barriers to PrEP	☐	☐	☐
6. Discussed HIV testing	☐	☐	☐
7. Assessed financial barriers	☐	☐	☐
Session Wrap-up			
1. Asked client for questions or concerns	☐	☐	☐
2. Summarized the action plan	☐	☐	☐
3. Summarized the referral plan	☐	☐	☐
4. Offered support	☐	☐	☐
Overall Quality			
1. PrEP Navigator kept the session focused on barriers and successes to PrEP adherence.	☐	☐	☐
2. Use of open-ended questions	☐	☐	☐
3. Did the PrEP Navigator give information simply and in a manner that the client understood?	☐	☐	☐
4. Motivational Technique(s) used by Navigator:			

Overall Comments:

Recommendations for improvement:

TB, HIV, STD, and Viral Hepatitis Program-HIV Prevention Program
Outreach, Testing, and Linkage (OTL) Services
Site Visit Observation & Chart Audit Tool

Instructions:

1. The **Contract Manager** will use the Department of Public Health (DPH) OTL Site Visit Tool (Attachment 1) to mark "**Yes**" or "**No**" to indicate whether the OTL staff are in compliance with policy and procedures for OTL Services.
    a. The Contract Manager must be familiar with contractual requirements, in addition to the implementation plan submitted by the agency for OTL services required under contract with DPH for the provision of HIV Prevention Services.
    b. The tools must be completed at a minimum of once a year during scheduled site visits with the agency.
    c. Whenever assessing the site as "**No**", the Contract Manager should provide recommendations for improvements in the Action Plan Section of the report (**VIII. ACTION PLAN & RECOMMENDATIONS**).
    d. Conclusions should be based on the consistency for which the site meets DPH contractual requirements and policies.
    e. The Observation Tool (Attachment 2) should be used to assess OTL skills during an observational session with OTL staff. The Chart/Record Audit Tool (Attachment 3) should be used to assess chart/medical record compliance. Contract Managers must randomly select charts/medical records from the previous reporting period. Charts with less than 70% (Not Met) will require a Corrective Action Plan to address deficiencies from the chart review. The chart review form can record up to Ten (10) client records. Use additional forms if needed.
2. The DPH requires that each program with one or more deficiencies will file a **Corrective Action Plan** listing the steps that the program will take to correct those deficiencies. The citation of deficiencies, and the corrective action process, can work as aids to programs in focusing resources in specific areas in a process of continuous improvement.
    a. **Corrective Action Plan**: The program will file a plan for the correction of those deficiencies with their Contract Manager within 10 business days of receipt of the DPH Site Visit Letter. The Corrective Action Plan should cite each deficiency and the plan for correcting that deficiency. The plan needs to be verifiable, i.e. what documentation can the program submit that will verify that the deficiency is corrected
3. **Follow-up**: The DPH must offer training and technical assistance, if appropriate, to help contractors correct identified deficiencies or failures to meet DPH requirements. Technical assistance may be offered concurrently with the notification of a deficiency or deficiencies and should focus on the specific issues of the agency to the extent possible.
4. The completed summary report letter should be summarized and disseminated to the agency no more than thirty (30) business days from the day of the initial site visit. If a corrective action plan has been issued, the agency must respond to the plan within ten (10) business days of the receipt of the plan. The Contract Manager will follow-up with agency (site visit) within three (3) months to ensure that the action items from the corrective action plan have been addressed. A template Site Visit Summary Report letter with instructions is attached at the end of this audit tool.
5. Date & File Copy.

HIV Test Counseling Skills Checklist

Counselor Name: _____ Agency: _____

Reviewer Name: _____ Review Date: _____/_____/_____

Sessions Type: ☐ HIV Rapid Test ☐ Other HIV Test

Instructions: From the reviewer's direct observation of the counselor and the reviewer's understanding of HIV counseling and testing best practices, the reviewer should use the following performance rating to review the counselor. Mark one area only on the performance rating and give written feedback as needed.

MA: Met All Standards **NM: Standards Not Met** **PM: Partially Met Standards** **NA: Not Applicable**	**MA**	**PM**	**NM**	**NA**
I. Content of Client-Centered Counseling Sessions				
1. Counselor introduced self, explained the purpose/process of the testing session, provided assurances of confidentiality, and appropriately gathered informed consent as per site protocol.				
Comments:				
2. Counselor assessed the client's knowledge about HIV, including transmission, risk factors, etc., as needed and provided the client with the opportunity to ask questions.				
Comments:				
3. Counselor explored factors that may put the client at risk for HIV, showing comfort with discussing explicit topics (such as sexual and/or needle sharing behaviors), using terminology most comfortable for the client.				
Comments:				
4. Counselor explained HIV test and had all materials needed for HIV testing accessible				
Comments:				
5. Counselor performed HIV test according to package insert instructions				
Comments:				

HIV Test Counseling Skills Checklist

MA: Met All Standards PM: Partially Met Standards	NM: Standards Not Met NA: Not Applicable	MA	PM	NM	NA
I. Content of Client-Centered Counseling Sessions, Continued					
6. Counselor discussed PrEP/PEP, and assessed for the window period, for HIV negative test. Counselor discussed Partner Services, HIV medical care and follow-up testing for HIV positive test.					
Comments:					
7. Counselor explored the client's support system when appropriate.					
Comments:					
II. Referrals					
1. Counselor provided appropriate referrals for client.					
Comments:					
2. Counselor was knowledgeable of available/necessary resources for client.					
Comments:					
III. Counseling Skills					
1. Counselor asked open-ended questions and allowed the client time to fully respond without interruption (client talked more than the counselor).					
Comments:					
2. Counselor demonstrated active and empathetic listening skills.					
Comments:					
3. Counselor maintained a neutral stance.					
Comments:					

HIV Test Counseling Skills Checklist

MA: Met All Standards PM: Partially Met Standards	NM: Standards Not Met NA: Not Applicable	MA	PM	NM	NA
III. Counseling Skills, Continued					
4. Counselor assessed the client's readiness to receive the test result.					
Comments:					
5. Counselor provided accurate information about the meaning of the test result in plain and clear language.					
Comments:					
IV. Data Collection					
1. Counselor gathered all needed information for testing forms in the course of the testing session, where appropriate.					
Comments:					
2. Counselor did not allow data collection or completion of testing forms to interfere with the client-centered counseling session.					
Comments:					
3. Counselor accurately and fully filled out testing forms and checked them for completion after the close of the session.					
Comments:					

Additional Comments:

_____

_____

_____

_____

Suggestions for Improvement:

_____

_____

_____

_____

Action Plan	
No citations at this time ☐	
Deficiencies Cited	
•	•
•	•
•	•
•	•
Recommendations for Improvement	

Programmatic Recommendations: (Addresses overall areas for improvement)

Quality Management Recommendations: (Addresses overall areas for improvement for the quality and outcomes of services delivered through observations/chart reviews, if applicable)

Follow-up: The DPH must offer training and technical assistance, if appropriate, to help contractors correct identified deficiencies or failures to meet DPH requirements. Technical assistance may be offered concurrently with the notification of a deficiency or deficiencies and should focus on the specific issues of the agency to the extent possible.

Corrective Action Plan: ☐ **Yes** ☐ **No**

If Yes, Contractors must respond within Ten (10) business days. The contractor will file a plan for the correction of those deficiencies with their Contract Manager within 10 business days of receipt of the DPH Site Visit Letter. The Corrective Action Plan should cite each deficiency and the plan for correcting that deficiency. The plan needs to be verifiable (i.e. What documentation can the program submit that will verify that the deficiency is corrected?).

ADD AGENCY LETTERHEAD

Date
Name
Title
Agency
Address

Dear Name:

Thank you for taking time out of your busy schedules to meet with _____ on Date. Below are findings from the site visit:

Overall Comments & Strengths:

Recommendations for Improvement:

Corrective Action Plan (If Applicable)

Follow-Up:

If you have questions or concerns at any time, you can reach _____ via e-mail at _____ or via phone at _____.

Name

CC: DPH Contract Manager
CC: HIV Prevention Supervisor

HIV/HCV Testing Chart Audit Form

Guidelines: Minimum of 10 charts or all charts if less than 10. At least 3 of the 10 charts should be HIV positive clients, or all positive files if less than 3.											
Record/Chart Number	#	#	#	#	#	#	#	#	#	#	**Overall % Met**
I. Completeness of Chart											
1. Documentation of Client Identifying information (client name, unique identifier/code, are listed on all forms/records in chart											
2. Documentation of required CDC EvaluationWeb Test Forms											
3. Signed consent form in chart											
4. Documentation of Risk Assessment											
5. Documentation of Psychosocial Assessment											
6. All referrals are documented (type of referral, confirmation, including documentation when not applicable, or Referrals and Linkage forms)											
7. Copy of HIV Test Result in chart											
8. Copy of CDC HIV Test Forms											
II. Core Elements											
1. Clients perception of his/her own risk for HIV/STD/HCV risk											
2. Documentation of Client readiness to test (impact & sources of support)											
3. Pattern of risk behavior/risk triggers (Action Plan-benefits and barriers addressed)											
4. Documentation of recent risk exposure (window period discussed)											
5. Documentation of attempts to follow-up with client and providers (if applicable) regarding the outcome of referrals or for clients who fall out of care (telephone calls, f/up letters)											

PrEP Navigation Chart Audit Form

III. PrEP Screening/Assessment											
1. Addresses behaviors related to HIV/STD/HCV risk											
2. Pattern of risk behavior/risk triggers (PrEP Risk Reduction Plan-benefits and barriers addressed)											
3. Documentation of readiness for PrEP Services (Completed PrEP Acuity Form)											
IV. PrEP Intake											
1. Documentation of HIV Risk											
2. Documentation of active linkages for clients who require social or financial support services not previous identified at intake											
3. Assessment of Social Determinants of Health (SDH)											
V. PrEP Health Care Navigation											
1. Documentation of follow up within one week of initial PrEP clinical appointment											
2. Documentation of support with medication adherence											
3. Documentation of assisting clients obtaining and enrolling them into financial resources (health insurance plans)											
VI. PrEP Maintenance											
1. Documentation of regular screening at 1 month and three months											
2. Documentation of periodic re-assessment of risk											
3. Documentation of follow-up activities (face to face / client phone consultations)											
4. Documentation of additional referrals and linkages is applicable											
5. Documentation of attempts to Follow-up with client and providers (if applicable) regarding clients who fall out of care (telephone calls, f/up letters)											

HIV Positive Chart Audit Form

VII. HIV Positive (+) Charts Only											
1. Documentation of Partner Services referral, linkage, and outcome of referral to DIS worker (required for contractual sites)											
2. Documentation of HIV + results											
3. Documentation of HIV Confidential Case Report Form (CRF) Surveillance program											
4. Documentation of HIV Incidence											
5. Evidence of Referral Documentation (includes assessment of need, referral forms, type of referral (passive or active), linkages made etc.)											
6. Documentation of outcomes of referrals made to HIV Care, Medical Case Management, Partner Services/ DIS, etc.											
7. Documentation of attempts to Follow-up with client and providers (if applicable) regarding the outcome of referrals (telephone calls, f/up letters)											

Key: 100-95% = M (Met) | 94-70% = PM (Partially Met) | 69-0% = NM (Not Met) | NA = Not Applicable

Please Note: 100%-70% (Met & Partially Met) qualifies as adherence to CDC standards for HIV Testing
<69% requires Corrective Action Plan to which agencies must respond to within 10 of the receipt of the report.

Cc: Prevention Supervisor
Contract Manager
Agency Executive Director

Handout 3-3: Example Temperature Log

Thermometer location _____

Acceptable temperature range** _____

Month/Year _____

Day	*Temp	Min *Temp	Max *Temp	Initials	Day	*Temp	Min *Temp	Max *Temp	Initials
1					17				
2					18				
3					19				
4					20				
5					21				
6					22				
7					23				
8					24				
9					25				
10					26				
11					27				
12					28				
13					29				
14					30				
15					31				
16									

* Temp = Temperature

**The acceptable range for test kit storage is ---° to ---° C or ---° to ---° F
Acceptable range for control kit storage is ---° to ---°C or ---° to ---° F
Acceptable range for the testing area is ---° to ---° C or ---° to ---° F.

NOTE: Periodically (e.g., every six months) check thermometer performance and document.

Corrective Action

Date	Action Taken	Initials

CLIA Certificate Holder: _____

Address: _____

Contact person _____ Tel # _____

Sharps Injury Log—Year _____

Date	Location where injury occurred (facility name, room #, etc.)	Brief description of how the injury occurred (procedure being done, action being performed—fingerstick, venipuncture, waster-disposal include area of the body injured	Type of device (lancet, syringe, etc.)	Brand name of device

OSHA's Bloodborne Pathogens Standard requires an employer to establish and maintain a Sharps Injury Log for recording all punctures of skin occurring from contaminated sharps. The purpose of the Log is to aid in the evaluation of devices being used in healthcare and other facilities and to identify devices or procedures/techniques requiring additional attention or review. This Log must be kept in addition to the Injury and Illness Log required by OSHA. The Sharps Injury Log should not list the names of affected employees (to maintain confidentiality) but, at a minimum, it should contain the type and brand of device involved in the incident, the department or work area where the exposure incident occurred, and an explanation of how the incident occurred. The Log should include all sharps injuries occurring in a calendar year and it must be retained for 5 years following the end of the year to which it relates.

Handout 3-9: Rapid HIV Test Results Log

Client ID*	Test Area Temp	Date/Time Specimen Collected	Specimen Type	Divided Pouch Lot #	Divided Pouch Exp Date	Test Start Time	Test Read Time	Test Result	Tester	Date /Time Result Reported to Client	Confirmatory Testing				Reviewed by and date
											Track-ing #	Specimen Type (blood or oral fluid)	Test Result	Date Result Reported to Client	

* Unique 1D number assigned to client

For Trainer Use:

Performance:

- ❑ Pass
- ❑ Needs additional instruction and practice before testing clients

Comments: _____

_____

Trainer: _____ Date: _____

Handout 3-6: Participant ID: _____

External Controls Results Log

Control Identification	Date	Room Temp*	Divided Pouch Lot #	Divided Pouch Exp.**	Control Box Lot #	Control Box Exp.**	Control Vial Opened Date	Control Vial Discard Date	Test Start Time	Test Read Time	Test Result	Tester	Reviewed by & Date

*Temp = Temperature
** Exp. = Expiration Date

Corrective Action

Date	Action Taken	Initials	Reviewed by & Date

Performance:

☐ Pass

☐ Needs additional instruction and practice before testing unknowns

Trainer: _____

CONNECTICUT
Public Health

GENERAL DATA ENTRY INSTRUCTIONS
HIV PREVENTION - PROGRAM REPORTING FORMS

Note: Using the "Tab Key" is the quickest way to move through the document. You do, however, always have the choice of using a mouse click to go into a certain field.

Date Fields
Date fields have been separated into a 2-digit month, 2-digit day, and 4-digit year. *(mm/dd/yyyy)*.

Phone Number Fields
Phone number fields have been formatted in such a way that they will auto format them into a (###) ###-####. It is only necessary for you to enter in the 10 digits of the phone number. There is no need to have parentheticals or the hyphen. Upon tabbing out of the field, the number should put the parentheticals and hyphen in for you.

Text Fields
Text fields are formatted in different ways throughout the document depending on what is being asked for that section. In most cases the length of the text fields will be set to "unlimited" so that narrative can be typed in. It is also important to know that when filling out narrative areas the field will continue to grow as you continue to type. When it reaches the end of a line it will go to the next line. You may see it push certain sections down the page. This is normal and, unfortunately, not easily preventable.

Also, you can still use the "enter button" to add lines / space between paragraphs. If you need to put a bullet into your narrative I would recommend using a "*", "-", "^", or "+" to show distinctions.

General Number Fields
Number fields (like text fields) are formatted in certain ways depending on what is being asked. For example, percentage areas are limited to a 3-digit number (100% for example). Other areas such as Phone Extension will be limited to 4-5 digits. Brochures, Pamphlets, or any areas asking for quantities are also limited to 4-5 digits.

Check Boxes
Check boxes can be selected/de-selected either by clicking on the box or by pressing the space bar.

If you notice any discrepancies or errors in the calculations please contact: Susan Major at: (860) 509-7821. Thank you!

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Public Health

State of Connecticut
Department of Public Health
TB, HIV, STD, & Viral Hepatitis Program - HIV Prevention Programs

Contractor Name:

Contract Log#: -

(The Contract Log# is located in the upper right corner of your contract)

Quarterly Reporting Period: ☐ **1st** (Jan - Mar) **2nd** (Apr - June) **3rd** (July - Sept) **4th** (Oct - Dec)

HIV Prevention Program:

Component Category: (check all that apply)

☐ HIV/HCV Testing in Clinical Settings ☐ HIV/HCV Testing in Non-clinical Settings

☐ Statewide Harm Reduction Services ☐ Statewide Routine Testing Services

Program Reports:

☐ Intervention Forms

☐ Program Implementation Plan (due with first quarter report only)

☐ EvaluationWeb Report

☐ e2CTPrevention

☐ **Other Report** (specify): _____

Report Submitted By: Full Name:

Title:

Phone#: Ext:

Submission Date: *(mm/dd/yyyy)*

Please include original and 1 copy of each report

Send Reports To:

Department of Public Health
HIV Prevention Reporting Forms
410 Capitol Avenue
P.O. Box 340308, MS# 11APV
Hartford, CT 06134-0308

Revised 2/09/24 LD

CONNECTICUT
Public Health

HIV Prevention Reporting Forms

Quarterly Reporting Period: ☐ 1st (Jan - Mar) ☐ 2nd (Apr - June) ☐ 3rd (July - Sept) ☐ 4th (Oct - Dec)

Person Completing Report/Contact Person:

Phone#: Ext:

Contractor Name:

Total Number of unduplicated patients who visited your agency for testing services in *this* trimester:
Total Number of HIV test sessions in *this* trimester:
Total Number of HIV negative test sessions in *this* trimester:
Total Number of HIV positive tests in *this* trimester:
Total Number of HCV tests in *this* trimester:
Total Number of HCV positive test sessions in *this* trimester:
Total Number of HIV negative clients eligible for PrEP in *this* trimester:
Total Number of HIV negative clients screened for PrEP in *this* trimester:
Total Number of HIV negative clients referred to a PrEP provider in *this* trimester:
Total Number of HIV negative clients linked to PrEP (had a PrEP visit) in *this* trimester:

Activities

Number (#) of Linkages Made (HIV Negatives)	
Overdose Prevention/Naloxone Distribution	
Hepatitis C Screen	
HIV Testing	
Mental Health Services	
Non-Occupational Post-Exposure Prophylaxis (nPEP)	
Post-Exposure Prophylaxis (PEP)	
Insurance Enrollment	
STD Screen & TX	
Substance Use TX	
Drug User Health (SSP)	
Domestic violence programs	
Sexual assault programs	
Other (Specify):	
Total Number of HIV Negatives linked to services:	
Number (#) of Linkages Made (HIV Positives)	
Overdose Prevention/Naloxone Distribution	
HIV Medical Care	
Medical Case Management	
Mental Health Services	
Partner Services	
STD Screen & TX	

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Public Health

Hepatitis C Screening	
TB Screening	
Substance Use TX	
Drug User Health (SSP)	
Domestic violence programs	
Sexual assault programs	
Other (Specify):	
Total Number of HIV Positives linked to services:	

Notes:

This section gives you a concise area for you to **list out specific program successes**.

	Successes
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

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This section gives you a concise area for you to list out specific challenges your program is facing. If you've come up with resolutions to those challenges or if you have (possible resolutions) please feel free to list them below.

If you are not facing any challenges, please check the '*Not Applicable'* checkbox.

Not Applicable ☐

	CHALLENGES	RESOLUTIONS
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

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Program Report for All Funded Categories

NARRATIVE: Please comment on new initiatives, special events, issues impacting program implementation, materials developed for social marketing purposes, surveys conducted. Please include findings/results and attach any materials created for social marketing with your reports. **Reminder**: any materials must be approved by DPH Review Committee prior to use.

(Please use extra pages if needed)

TRAINING/WEBINAR LOG

Staff Name	Name of Training	Training Type		Date of Training *(mm/dd/yyyy)*
		Training	Webinar	
		☐	☐	/ /
		☐	☐	/ /
		☐	☐	/ /
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Department of Public Health
TB, HIV, STD & Viral Hepatitis Section
HIV Prevention Unit

410 Capitol Avenue, MS# 11APV, PO Box 340308, Hartford, CT 06134-0308
Telephone: (860) 509-7801 --- Fax: (860) 509-7853 or (860) 509-7855

New Employee Form

Directions: Please complete this form upon the hiring of new staff. Submit to DPH ***within one week*** of the hire date or as soon as possible.

Contractor's Name: _____

New Employee's Name:

Date of Hire: *(mm/dd/yyyy)*

Title of Position Filled:

Academic/Educational qualifications:

Funding components and hours/week for this DPH funded position:

HIV/AIDS Coordinator: +

HIV/HCV Tester in Clinical Settings +

HIV/HCV Tester in Non-Clinical Settings +

Statewide Harm Reduction Services +

Statewide Routine Testing Service +

* Other funding source +

* Name of "Other Funding Source(s):

Total hours per week:

Signature of Employee: _____
Signature *Date*

Signature of Program Manager/Coordinator: _____
Signature *Date*

Department of Public Health
TB, HIV, STD & Viral Hepatitis Section
HIV Prevention Unit

410 Capitol Avenue, MS# 11APV, PO Box 340308, Hartford, CT 06134-0308
Telephone: (860) 509-7801 --- Fax: (860) 509-7853 or (860) 509-7855

DPH Use Only

Date Received: _____ Form distributed to: _____

Comments: _____

Resignation/Termination of Services Form

Directions: Please complete this form upon the termination/resignation of staff. Submit to DPH within one week of the hire/termination date. Submit to DPH ***within one week*** of resignation of position or as soon as possible.

Contractor's Name: _____

Employee's Name:

Resignation Submitted (check one): Yes ☐ No ☐

Date Submitted: *(mm/dd/yyyy)*

Date services were terminated: / / *(mm/dd/yyyy)*

Funding components and **hours/week** for this DPH funded position:

HIV/AIDS Coordinator: +

HIV/HCV Tester in Clinical Settings +

HIV/HCV Tester in Non-Clinical Settings +

Statewide Harm Reduction Services +

Statewide Routine Testing Service +

* Other funding source +

* Name of "Other Funding Source(s):

Total hours per week:

Signature of Employee: _____
Signature *Date*

Signature of Program Manager/Coordinator: _____
Signature *Date*

Revised 2/9/2024

Patient Navigation TRACKING FORM FOR HIV POSITIVE CLIENTS

Note: Please report separately for each referral for medical care, medical case management, partner services, and other referrals to services separately. Please report in Narrative any cases lost to follow up and actions taken to find patient.

DATE client was referred by Prevention Provider *(mm/dd/yyyy)*	UNIQUE CLIENT IDENTIFIER**	REFERRAL TO	DATE client was Linked / Seen by provider *(mm/dd/yyyy)*	Comments/Outcomes (If No Show, please describe follow up taken)	Is patient still linked with provider in 30 days?	Is patient still linked with provider in 60 days?	Is patient still linked with provider in 90 days?
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				

Patient Navigation TRACKING FORM FOR HCV POSITIVE CLIENTS

Note: Please report separately for each referral for medical care, and other referrals to services separately.

DATE client was referred by Prevention Provider *(mm/dd/yyyy)*	UNIQUE CLIENT IDENTIFIER**	REFERRAL TO	DATE client was Linked / Seen by provider *(mm/dd/yyyy)*	Comments/Outcomes (If No Show, please describe follow up taken)	Is patient still linked with provider in 30 days?	Is patient still linked with provider in 60 days?	Is patient still linked with provider in 90 days?
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				

Instructions for completing TRACKING FORM

Patient Navigation TRACKING FORM FOR HIV POSITIVE CLIENTS

Note: Please report each referral for medical care, medical case management, partner services, and other referrals to services separately. Please report in Narrative all cases lost to follow up and actions taken to find patient.

DATE client was referred by Prevention Provider *(mm/dd/yyyy)*	UNIQUE CLIENT IDENTIFIER**	REFERRAL TO	DATE client was Linked / Seen by provider *(mm/dd/yyyy)*	Comments/Outcomes (If No Show, please describe follow up taken)	Is patient still linked with provider in 30 days?	Is patient still linked with provider in 60 days?	Is patient still linked with provider in 90 days?
04 / 10 / 2017	DLMN070273-2	Dr. Torres	No Show ☐ 04 / 20 / 2017		Yes	Yes	No, Contacted HIV DIS
04 / 11 / 2017	SEMJ061073-1	Dr. A. C.	No Show ☐ / /	Phone call made 4/12/17 Contacted HIV DIS 4/15/17			
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				
/ /			No Show ☐ / /				

Note. ** = Unique Client Identifier -> First and Third letter of the First Name + First and Third of Last Name + date of birth (MMDDYY) + Gender: (1) Male, (2) Female, (3) Transgender Unknown, (4) MTF, (5) FTM, (6) Refused, (9) Unknown. This new client identifier will mirror the client identifier used in the CAREWare System (URN).

SUPPLIES INVENTORY CHECKLIST

Note: Please complete for both contractors and subcontractors

Name of Supply	Expiration Date	Quantity On Hand	Quantity Used in Tri-annual Period	Reorder Date	Reorder Quantity

This form completed by: **Date:**

REVISED: 2/9/2024

CONNECTICUT
Public Health

Department of Public Health (DPH)

Program Materials Review Panel Policy

Purpose:

The purpose of the Program Materials Review Panel Policy is to provide health departments with a process for the development, review and approval of any written materials used in the delivery of HIV prevention activities. The Program Materials Review Panel, guided by the Centers for Disease Control (CDC) Basic Principles (set forth in 57 Federal Register 26742), will be convened by the DPH to review and approve all applicable materials prior to their distribution and use and to ensure content is consistent with the provisions of Section 2500 (b-d) of the Public Health Service Act, 42 U.S.C. Section 300ee (b-d). Note: Only materials that are providing HIV-related information for educational and informational purposes are required to be reviewed by Program Review Panels. Materials that do not require review are those that serve no educational purpose, e.g., organizational notifications, surveillance data, and change to dates/times of marketing materials.

Goals:

- To ensure all HIV Prevention materials developed and distributed by DPH HIV Prevention contractors are reviewed and approved by the Program Materials Review Panel.
- To ensure all HIV educational messages submitted for review align with CDC requirements.
- To ensure that materials promoting funded programs, services and events are clear and include all the information needed to access them.
- To employ a mechanism for the Program Materials Review Panel to process all materials submitted by funded DPH HIV prevention contractors in a timely manner.

Objectives

- To ensure that the DPH maintains a Program Materials Review Panel comprised of no less than five (5) persons representing a reasonable cross-section of the general population; not drawn predominantly from the intended audience. The panel must also include someone proficient in reading and writing Spanish and consult with other subject matter experts when necessary.
- To ensure all HIV prevention education materials created by funded contractors are reviewed and approved. This includes; written materials (e.g. pamphlets, brochures, fliers), audio visual materials, (e.g. motion pictures-DVDs and audio/video clips), and pictorials (e.g. posters, ads and similar educational materials using photographs, slides, drawings or paintings), social marketing and advertising materials (bus ads, billboards, etc.), and social media communications (e.g., Facebook, twitter, tik tok, etc.). Note: Only materials developed for DPH funded HIV Programs using DPH HIV Preventions funds including staff time must be submitted for review.
- To ensure materials include factual information and clear messages appropriate for the intended audience and that the layout is easy to read with the use of appropriate visuals.

- To ensure that educational materials contain terms, descriptors, or displays necessary for the intended audience to understand facts regarding HIV acquisition and transmission.

Procedures:

- HIV prevention contractors shall submit all HIV prevention materials to be reviewed in electronic format directly to Jenny Bobadilla Pincos at jenny.bobadillapinncos@ct.gov, and copy their program's assigned DPH Contract Manager.

- In addition to the materials to be reviewed, contractors shall submit information in the email regarding how the materials will be disseminated and to what audience.

- Upon receipt of materials, DPH will send an acknowledgement to the contractor and forward submitted materials to the Materials Review Panel members.

- DPH Materials Review Panel members will be given one (1) week to submit feedback to DPH.

- DPH will compile reviewer input and provide feedback to HIV prevention contractors within one (1) week of receiving information from the Program Review Panel members.

- Contractors will make corrections and resubmit materials to DPH to receive final approval and MRC Code.

- Once approved, contractors will send final copy with MRC code in the bottom right corner of the copy to DPH to be filed.

- The entire Program Materials Review process will take approximately two (2) weeks or less to complete. Programs submitting flyers for special events must submit materials in advance to allow for the two-week process to take place. Note: Contractors may need to allow additional time for corrections and submission of final copy with MRC code.

- Use of the DPH logo on materials is not required. Use of the DPH logo on any marketing materials requires an additional DPH internal review and approval from the DPH Communications Department separate from this CDC required Materials Review Panel process. Contractors requesting to use the DPH logo can anticipate additional wait time for review and cannot use materials until notified of approval.

- Materials that are approved can be used immediately, especially time sensitive items such as social media posts. However, if changes are recommended, the contractor will be asked to adjust the materials accordingly and resubmit a final copy to DPH before continued use.

- DPH will be provide a Material Reviewed Code (MRC) number (e.g., **DPH1234**) for all approved materials. When displaying, all approved materials must have the assigned MRC in one of the corners of the material prior to distribution.

- When submitting DVD's or audio/video clips, the DPH staff will convene to review and approve materials. Contractors should allow for a minimum of two weeks for the review of DVDs or audio/video/ clips to allow for feedback and approval.

- Contractors are encouraged to use materials developed by CDC or Positive Prevention CT which do not need to be submitted for review.

CONNECTICUT
Public Health

Department of Public Health (DPH)
Condom Distribution Policy

Purpose:

The purpose of this policy is to ensure that HIV Prevention Programs supported by DPH funds design a condom distribution plan that targets HIV-positive persons and persons at highest risk of acquiring HIV infection.

Goal:

To ensure that DPH funded HIV prevention contractors develop a condom distribution plan for their organization in accordance with DPH policy.

Objectives:

- To reduce the risk of HIV and other STD's in the community by increasing the use of condoms by people who are sexually active.
- To reduce the associated barriers in accessing condoms, including financial cost and embarrassment.
- To increase the availability, accessibility and acceptability of condoms.

Policy:

The DPH requires that funded HIV Prevention Programs develop a plan to conduct wide-scale distribution that includes:

- The provision of condoms free of charge
- Target: 1) individuals at high risk for HIV infection or who are HIV+, 2) venues frequented by high-risk individuals, 3) communities at greatest risk for HIV infection, especially those marginalized by social, economic, or other structural conditions, or 4) the general population within jurisdictions with high HIV incidence.
- Distribute condoms in traditional (i.e. clinics, hospitals, etc.) and non-traditional (i.e. soup kitchens, local businesses, etc.) venues. Social media may also be used to deliver condom distribution messages.

Procedures: Develop and submit to the DPH an agency condom distribution plan that includes the following:

- A process for identifying and engaging appropriate community partners for condom distribution activities. Partners may include traditional public health agencies (e.g. clinics, hospitals, CBOs,), schools, and businesses (e.g. health clubs, bars, barbershops, clothing stores, hotels).
- An assessment of any obstacles to reaching members of hard-to-reach populations and strategies to overcome them.
- A review of specific laws, policies, or practices that may support or hinder the condom distribution program.
- A mechanism in place to identify the number of condoms to be disseminated. Examples include a master log for recording the number, types of condoms distributed, including target population, agency names, venues, and settings where condoms are distributed.
- A plan for communicating any campaign messages used for condom distribution.
- Add QR Code label to condom distribution materials (See Appendix A)

References:

Duncan, Ted and Charles Collins. (2011) "Condom Distribution Programs as Structural Interventions." Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention, a Presentation. http://www.effectiveinterventions.org/Libraries/Condom_Distribution_Docs/Condom_Distribution_Programs_as_Structural_Interventions.sflb.ashx

Effective Interventions HIV Prevention that Works: Condom Distribution Programs http://www.effectiveinterventions.org/en/HighImpactPrevention/StructuralInterventions/CondomDistribution.aspx

Condom Distribution as a Structural Level Intervention. October 2010, Centers for Disease Control and Prevention, http://www.cdc.gov/hiv/resources/factsheets/PDF/condom_distribution.pdf

Appendix A


Do you know how
to use a
CONDOM?
FIND OUT!
Scan this QR Code with your Smartphone

CONNECTICUT
Public Health

DPH HIV Prevention Incentives Policy

Purpose:

To ensure that any HIV Prevention Incentives purchased and distributed with state or federal funding through DPH reflect barriers to intervention access, and are "reasonable", meaning small in value.

Goals:

To increase participation and retention of target populations in DPH funded HIV prevention interventions.

To reduce barriers to intervention participation and retention by distributing incentives related to perceived or identified barriers to intervention access.

Objectives

To ensure that DPH funded prevention contractors develop a HIV Prevention Incentives Policy for their organization.

To ensure that all DPH funded prevention contractors utilizing incentives do so in accordance with DPH Policy.

Policy:

HIV prevention incentives are to be used in conjunction with HIV prevention interventions grounded in prevention science.

Incentives should address barriers to HIV prevention intervention access or be relevant to "life issues" for members of the target population.

Incentives should be based on state needs assessment data provided by members of the target population.

Incentives may be a tangible item or may be in the form of services rendered such as transportation or childcare.

Incentives should be small in value as compared to the overall program or incentive budget.

Incentives should **NOT** be in the form of cash but rather a gift card, voucher, or other tangible item (e.g., pre-paid phone card, food voucher, gas card, bus token, child care voucher, condom, etc.)

Incentives should **NOT** be used on a regular basis during HIV prevention counseling or testing for recruitment or participation. However, incentives may be used while implementing social networking strategy but may only be given to the recruiter, **NOT** the person being tested.

Procedures: Develop and submit to DPH an agency HIV Prevention Incentives Policy that includes the following:

- The need for incentives among the target population as well as appropriate uses and contexts for them.
- A process for identifying and engaging community partners in identifying appropriate HIV prevention incentives to be purchased and distributed.
- A clear definition of how incentives will be distributed as well as a plan for distributing them. Distribute incentives at the completion of the intervention to encourage participant retention.
- A record keeping system that tracks incentives purchased and distributed with HIV prevention funding. This includes:

    1) A periodic accounting of all monetary incentives by a staff member segregated from the functions of program implementation.
    2) A system for tracking the number of gift cards/vouchers purchased and distributed with program funds as well as a plan for safeguarding them from theft. For example, a master log for recording the purchase of monetary incentives including the serial number of each gift card, date purchased, date when the item was entrusted to a staff member for program use and name of the person who received the incentive.
    3) A requirement that an original store receipt must be attached to the master log for purchased incentives. The store receipt must have a description of the purpose of the purchase noted directly on the receipt and must be signed by the person who made the purchase. For example: “Wal-Mart Gift cards for client participation in CRCS Program.”

References:

The Policy Resource Group LLC, Policy Brief HIV Prevention Interventions, May 2000

Valdiserri et. al. 1999, Siegel 1997

CDC Compendium of HIV Prevention Interventions with Evidence of Effectiveness, 1999

A. Program Implementation Plan (Please use this form to describe how you will implement the service components, i.e. Harm Reduction Services, HIV testing, outreach etc. Use as many blank pages as needed):

Services to be Provided (Example, Targeted Outreach, HIV testing, PrEP Navigation, etc.)	Activities (Who, What, Location, and When)	Staff Position(s) Responsible	Expected Outcomes and Measures of Success (# of encounters, referrals/linkages, trainings, list of venues, etc.)	Timetable (Dates)

* The implementation plan form will be used by Contract Managers to monitor programs progress in meeting expected outcomes/measures of success.

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

☐ Initial Application Anticipated Start Date _____
☐ Survey
☐ Change in Certificate Type
☐ Other Changes (Specify) _____
Effective Date _____

CLIA IDENTIFICATION NUMBER

_____ D _____

(If an initial application leave blank, a number will be assigned)

FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS

☐ RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

TELEPHONE NO. *(Include area code)*

FAX NO. *(Include area code)*

FACILITY ADDRESS — ***Physical Location of Laboratory (Building, Floor, Suite if applicable.)*** *Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified*

NUMBER, STREET *(No P.O. Boxes)*

CITY | STATE | ZIP CODE

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*

NUMBER, STREET

CITY | STATE | ZIP CODE

SEND FEE COUPON TO THIS ADDRESS
PICK ONE:
☐ Physical
☐ Mailing
☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS
PICK ONE:
☐ Physical
☐ Mailing
☐ Corporate

CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*

NUMBER, STREET

CITY | STATE | ZIP CODE

NAME OF DIRECTOR *(Last, First, Middle Initial)*

Laboratory Director's Phone Number

CREDENTIALS

FOR OFFICE USE ONLY

Date Received _____

II. TYPE OF CERTIFICATE REQUESTED *(Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)*

☐ Certificate of Waiver *(Complete Sections I – VI and IX – X)*

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

☐ Certificate for Provider Performed Microscopy Procedures (PPM) *(Complete Sections I-VII and IX-X)*

☐ Certificate of Compliance *(Complete Sections I – X)*

☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

☐ The Joint Commission ☐ ACHC ☐ AABB ☐ A2LA

☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 03/31/2024. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact LabExcellence@cms.hhs.gov.

III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

- ☐ 01 Ambulance
- ☐ 02 Ambulatory Surgery Center
- ☐ 03 Ancillary Testing Site in Health Care Facility
- ☐ 04 Assisted Living Facility
- ☐ 05 Blood Bank
- ☐ 06 Community Clinic
- ☐ 07 Comp. Outpatient Rehab Facility
- ☐ 08 End Stage Renal Disease Dialysis Facility
- ☐ 09 Federally Qualified Health Center
- ☐ 10 Health Fair
- ☐ 11 Health Main. Organization
- ☐ 12 Home Health Agency
- ☐ 13 Hospice
- ☐ 14 Hospital
- ☐ 15 Independent
- ☐ 16 Industrial
- ☐ 17 Insurance
- ☐ 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities
- ☐ 19 Mobile Laboratory
- ☐ 20 Pharmacy
- ☐ 21 Physician Office
- ☐ 22 Practitioner Other *(Specify)* _____
- ☐ 23 Prison
- ☐ 24 Public Health Laboratories
- ☐ 25 Rural Health Clinic
- ☐ 26 School/Student Health Service
- ☐ 27 Skilled Nursing Facility/ Nursing Facility
- ☐ 28 Tissue Bank/Repositories
- ☐ 29 Other *(Specify)* _____

IV. HOURS OF LABORATORY TESTING *(List times during which **laboratory testing** is performed in HH:MM format)* *If testing 24/7 Check Here* ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision in 1-3 below)*

Are you applying for a single site CLIA certificate to cover multiple testing locations?

☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?

   ☐ Yes ☐ No

   If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

   ☐ Yes ☐ No

   If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?

   ☐ Yes ☐ No

   If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	

In the next three sections, indicate testing performed and estimated annual test volume.

VI. WAIVED TESTING *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).*

Identify the waived testing (to be) performed by completing the table below. Include each analyte, test system, or device used in the laboratory.

ANALYTE / TEST	TEST NAME	MANUFACTURER
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed _____

☐ Check if no waived tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VII. PPM TESTING *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Listed below are the **only** PPM tests that can be performed by a facility having a Certificate for PPM. Mark the checkbox by each PPM procedure(s) to be performed.

☐ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
☐ Potassium hydroxide (KOH) preparations
☐ Pinworm examinations
☐ Fern tests
☐ Post-coital direct, qualitative examinations of vaginal or cervical mucous
☐ Urine sediment examinations
☐ Nasal smears for granulocytes
☐ Fecal leukocyte examinations
☐ Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed _____

If also performing waived complexity tests, complete Section VI. For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VIII. NON-WAIVED TESTING *(Including PPM testing if applying for a Certificate of Compliance or Certificate of Accreditation) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.*

Identify the non-waived testing (to be) performed by completing the table below. Be as specific as possible. This includes each analyte test system or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity.

ANALYTE / TEST	TEST NAME	MANUFACTURER	M or H
Example: Potassium	Quick Potassium Test	Acme Lab Corporation	M

If additional space is needed, check here ☐ and attach additional information using the same format.

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

If additional space is needed, check here and attach additional information using the same format." Include text box similar to Section VII.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/ subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, ACHC, AABB, A2LA ,CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY 010			**HEMATOLOGY 400**		
☐ Transplant			☐ Hematology		
☐ Nontransplant			**IMMUNOHEMATOLOGY**		
MICROBIOLOGY			☐ ABO Group & Rh Group 510		
☐ Bacteriology 110			☐ Antibody Detection (transfusion) 520		
☐ Mycobacteriology 115			☐ Antibody Detection (nontransfusion) 530		
☐ Mycology 120			☐ Antibody Identification 540		
☐ Parasitology 130			☐ Compatibility Testing 550		
☐ Virology 140			**PATHOLOGY**		
DIAGNOSTIC IMMUNOLOGY			☐ Histopathology 610		
☐ Syphilis Serology 210			☐ Oral Pathology 620		
☐ General Immunology 220			☐ Cytology 630		
CHEMISTRY			**RADIOBIOASSAY 800**		
☐ Routine 310			☐ Radiobioassay		
☐ Urinalysis 320			**CLINICAL CYTOGENETICS 900**		
☐ Endocrinology 330			☐ Clinical Cytogenetics		
☐ Toxicology 340			**TOTAL ESTIMATED ANNUAL TEST VOLUME:**		

IX. TYPE OF CONTROL (CHECK THE ONE MOST DESCRIPTIVE OF OWNERSHIP TYPE)

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT
☐ 01 Religious Affiliation	☐ 04 Proprietary	☐ 05 City
☐ 02 Private Nonprofit		☐ 06 County
☐ 03 Other Nonprofit		☐ 07 State
_____ *(Specify)*		☐ 08 Federal
		☐ 09 Other Government
		_____ *(If 09 is selected, please specify the country or the province.)*

Does this facility have partial or full ownership by a foreign entity or foreign government?

☐ Yes ☐ No

If Yes, what is the country of origin for the foreign entity? _____

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

PRINT NAME OF DIRECTOR OF LABORATORY

PRINT NAME OF OWNER OF LABORATORY

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (***SIGN IN INK OR USE A SECURE ELECTRONIC SIGNATURE***) | DATE

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

INSTRUCTIONS FOR COMPLETION

CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service are not considered laboratories. CLIA does not apply to a facility that only performs forensic testing. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M (42 CFR PART 493) of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application. Information to be submitted with the application include:

- **Verification of State Licensure, as applicable**
- **Documentation of qualifications:**
  - **Education (copy of Diploma, transcript from accredited institution, CMEs),**
  - **Credentials, and**
  - **Laboratory experience.**

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.

I. GENERAL INFORMATION

For an initial applicant, check **"initial application"**. For an initial survey or for a recertification, check **"survey"**. For a request to change the type of certificate, check **"change in certificate type"** and provide the effective date of the change. For all other changes, including change in location, director, lab closure, etc., check **"other changes"** and provide the effective date of the change.

CLIA Identification Number: For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. For all other applicants, enter the 10 digit CLIA identification number already assigned and listed on your CLIA certificate.

Facility Name: Be specific when indicating the name of your facility, particularly when it is a component of a larger entity, e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. NOTE: the information provided is what will appear on your certificate.

Email Address: A valid Email Address will be used for communications between the CLIA program and the laboratory. Selecting the RECEIVE NOTIFICATIONS VIA EMAIL checkbox, requires the laboratory to enter a valid Email Address.

Physical Facility Address: This address is mandatory and must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

If the laboratory has a separate mailing and/or corporate address (from the Facility Address), please complete the appropriate sections on the form.

Mailing Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to an alternate location, such as an accounts payable office. A Post Office box number or Mail Stop number may be used as part of the Mailing Address for this section.

Corporate Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to another location, such as, the main headquarters or home office for the laboratory. A Post Office box number or Mail Stop number may be used as part of the Corporate Address for this section.

Form Mailing: Select the address (Physical, Mailing, Corporate) where the CLIA fee coupon and CLIA certificate are to be mailed.

For Office Use Only: The date received is the date the form is received by the state agency or CMS regional office for processing.

II. TYPE OF CERTIFICATE REQUESTED

Select your certificate type based on the highest level of test complexity performed by your laboratory. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the agency you wish to survey your laboratory.

When completing this section, please remember that a facility holding a:

- **Certificate of Waiver** can only perform tests categorized as waived;*
- **Certificate for Provider Performed Microscopy Procedures** (PPM) can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;*
- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met following a CLIA survey; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization. (If your CMS-approved accreditation organization is not listed, contact your local State Agency for further instructions.)

*A current list of waived and PPM tests may be obtained from your State agency. Specific test system categorizations can also be found on the Internet at: **http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm**.

III. TYPE OF LABORATORY
Select the type that is most descriptive of the location where the laboratory testing is performed.

If selecting 'mobile laboratory' (code 19), a mobile laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment, and records. For record keeping purposes, include, on a separate sheet of paper, the vehicle identification numbers (VINs) of all vehicles used for mobile laboratory testing.

If selecting 'Practitioner Other' (code 22), this type includes practitioners such as, dentists, chiropractors, etc.

IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format and check box marked '24/7' if laboratory testing is performed continuously, e.g., 24 hours a day, 7 days a week. Do not use military time.

V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493. 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3) Hospice and HHA could qualify for an exception.

VI. WAIVED TESTING
Indicate the estimated total annual test volume for all waived tests performed.

VII. PPM TESTING
Indicate the estimated total annual test volume for all PPM tests performed.

VIII. NON-WAIVED TESTING *(INCLUDING PPM)*
The total Estimated Annual Test volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section for test counting information. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

IX. TYPE OF CONTROL
Select the type of ownership or control which most appropriately describes your facility.

X. DIRECTOR OF ADDITIONAL LABORATORIES
List all other facilities for which the director is responsible and that are under different certificates. Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

Reminders - Before submitting the Form CMS-116:

1. Include the current or estimated annual test volume.
2. For Certificate for PPM, Certificate of Compliance, or Certificate of Accreditation, include the laboratory director qualifications.
3. Do not send any money with your application.
4. Send the completed Form CMS-116 to the appropriate State Agency **(https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf)**.

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency. State agency contact information can be found at:
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALITIES

HISTOCOMPATIBILITY (010)
HLA Typing (disease associated antigens)

MICROBIOLOGY

Bacteriology (110)
Gram Stain
Culture
Susceptibility
Strep screen
Antigen assays (H.pylori, Chlamydia, etc.)

Mycobacteriology (115)
Acid Fast Smear
Mycobacterial culture
Mycobacterial susceptibility

Mycology (120)
Fungal Culture
DTM
KOH Preps

Parasitology (130)
Direct Preps
Ova and Parasite Preps
Wet Preps

Virology (140)
RSV (Not including waived kits)
HPV assay
Cell culture

DIAGNOSTIC IMMUNOLOGY

Syphilis Serology (210)
RPR
FTA, MHATP

General Immunology (220)
Allergen testing
ANA
Antistreptolysin O
Antigen/Antibody (hepatitis, herpes, rubella, etc.)
Complement (C3, C4)
Immunoglobulin
HIV
Mononucleosis assay
Rheumatoid factor
Tumor marker (AFP, CA 19-9, CA 15-3, CA 125)*

*Tumor markers can alternatively be listed under Routine Chemistry instead of General Immunology.

HEMATOLOGY (400)
Complete Blood Count (CBC)
WBC count
RBC count
Hemoglobin
Hematocrit (Not including spun micro)
Platelet count
Differential
Activated Clotting Time
Prothrombin time (Not including waived instruments)
Partial thromboplastin time
Fibrinogen
Reticulocyte count
Manual WBC by hemocytometer
Manual platelet by hemocytometer
Manual RBC by hemocytometer
Sperm count

IMMUNOHEMATOLOGY
ABO group (510)
Rh(D) type (510)
Antibody screening
Antibody identification (540)
Compatibility testing (550)

PATHOLOGY
Dermatopathology
Oral Pathology (620)
PAP smear interpretations (630)
Other Cytology tests (630)
Histopathology (610)

RADIOBIOASSAY (800)
Red cell volume
Schilling test

CLINICAL CYTOGENETICS (900)
Fragile X
Buccal smear
Prader-Willi syndrome
FISH studies for: neoplastic disorders, congenital disorders or solid tumors.

CHEMISTRY

Routine Chemistry (310)
Albumin
Ammonia
Alk Phos
ALT/SGPT
AST/SGOT
Amylase
Bilirubin
Blood gas (pH, pO2, pCO2)
BUN
Calcium
Chloride
Cholesterol
Cholesterol, HDL
CK/CK isoenzymes
CO2
Creatinine
Ferritin
Folate
GGT
Glucose (Not fingerstick)
Iron
LDH/LDH isoenzymes
Magnesium
Potassium
Protein, electrophoresis
Protein, total
PSA
Sodium
Triglycerides
Troponin
Uric acid
Vitamin B12

Endocrinology (330)
Cortisol
HCG (serum pregnancy test)
T3
T3 Uptake
T4
T4, free
TSH

Toxicology (340)
Acetaminophen
Blood alcohol
Blood lead (Not waived)
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide
NAPA
Quinidine
Salicylates
Theophylline
Tobramycin
Therapeutic Drug Monitoring

Urinalysis (320)**
Automated Urinalysis (Not including waived instruments)
Microscopic Urinalysis
Urine specific gravity by refractometer
Urine specific gravity by urinometer
Urine protein by sulfosalicylic acid

** Dipstick urinalysis is counted in Section VI. WAIVED TESTING

NOTE: This is not a complete list of tests covered by CLIA. Other non-waived tests and their specialties/ subspecialties can be found at **https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf** and **https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/lccodes.pdf.** You may also call your State agency for further information. State agency contact information can be found at: **https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf**.

GUIDELINES FOR COUNTING TESTS FOR CLIA

- For **chemistry**, each non-calculated analyte is counted separately (e.g., Lipid Panel consisting of a total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides equals 4 tests).
- For **clinical cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests. NOTE: For all other genetic tests, the number of tests is determined by the number of results reported in the final report.
- For manual gynecologic and nongynecologic **cytology**, each slide (not case) is counted as one test.
- For **flow cytometry**, each measured individual analyte (e.g. T cells, B cells, CD4, etc.) that is ordered and reported should be counted separately.
- For **general immunology**, testing for allergens should be counted as one test per individual allergen.
- **Genetics tests** should be placed in the specialty or subspecialty where they fit best, according to the methodology of the test.
- For **hematology**, each **measured** individual analyte of a **complete blood count** or **flow cytometry** test that is ordered **and reported** is counted separately. The **WBC differential** is counted as one test.
- For **histocompatibility**, each HLA typing (including disease associated antigens) is counted as one test, each HLA antibody screen is counted as one test and each HLA cross match is counted as one test. For example, a B-cell, a T-cell, and an auto-crossmatch between the same donor and recipient pair would be counted as 3 tests.
- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per test request from each specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each gram stain or acid-fast bacteria (AFB) smear requested from the primary source is counted as one. For example, if a sputum specimen has a routine bacteriology culture and gram stain, a mycology test, and an AFB smear and culture ordered, this would be counted as five tests. For parasitology, the direct smear and the concentration and prepared slide are counted as one test.
- For **urinalysis**, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **all specialties/subspecialities**, do not count calculations (e.g., A/G ratio, MCH, T7, etc.), quality control, quality assurance, or proficiency testing assays.

If you need additional information concerning counting tests for CLIA, please contact your State agency.