2021

COUNSELING, TESTING AND REFERRAL (CTR) SITE Policy and Procedure Manual

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Program Contact Information

The CTR Program is administered by the Division of Sexually Transmitted and Bloodborne Diseases at the North Dakota Department of Health (NDDoH), Section of Disease Control. See below for information on the staff managing the program.

Title*	Phone
HIV.STD.TB.Viral Hepatitis Program Manager	701.328.4555
HIV.STD.Viral Hepatitis Prevention Coordinator	701.328.2366
HIV.STD.Viral Hepatitis Surveillance Coordinator	701.328.1059
Administrative Assistant	701.328.2378

*Current Personnel are listed at www.health.nd.gov/HIV/CTR.

HIV.STI.TB.Viral Hepatitis Program Manager:

- Coordinates contracts and grant applications.
- Processes monthly reimbursement requests.

HIV.STI.Viral Hepatitis Prevention Coordinator:

- Provides training on CTR requirements and expectations.
- Reviews and analyzes Maven data entry for CTR sites.
- Conducts site visits.
- Creation of education materials.

HIV.STI.Viral Hepatitis Surveillance Coordinator:

- Ensure appropriate case follow-up occurs.
- Prepare morbidity reports, including the yearly Epidemiologic Profile.

Administrative Assistant:

- Ordering of supplies and educational materials.

Contact Information for the Division of Sexually Transmitted and Bloodborne Diseases:

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About CTR Program

The NDDOH Division of Sexually Transmitted and Bloodborne Diseases program offers HIV and hepatitis C testing to populations at risk with the counseling, testing and referral (CTR) program. CTR sites aim to inform clients of their HIV and hepatitis C status, provide counseling and support for harm reduction and help to secure needed referrals for treatment and care.

CTR sites are providers who have patients at high risk of HIV and hepatitis C infection. CTR providers may include, but are not limited to local public health units, substance abuse and treatment centers, ND community action organizations, ND family planning sites, pregnancy clinics, correctional institutions, homeless shelters, institutions of higher education, community health centers, sexual health clinics, tribal health, etc. CTR sites offer HIV and/or hepatitis C testing and prevention supplies and counseling. CTR sites may also offer hepatitis vaccination, other STI testing and community education.

Each year, up to 25 agencies are selected via a competitive procurement process to receive contracts to perform services at CTR sites. Additional sites are eligible to receive supplies to offer services without funding and are considered non-contract partners. A list of CTR sites that provide services to the general public is available at www.health.nd.gov/HIV/Testing.

Program Goals for CTR Sites

The HIV and Viral Hepatitis programs of the NDDoH Division of Sexually Transmitted and Bloodborne Diseases aim to reduce the number new HIV and hepatitis C infections, improve access to care and health outcomes for those living with HIV and/or hepatitis C, reduce HIV and hepatitis C related health disparities and health inequities and improve program surveillance and data usage. These goals align with the *HIV National Strategic Plan: A Roadmap to End the Epidemic 2021 - 2025*, *Ending the HIV Epidemic: A Plan for America* initiative and the *Viral Hepatitis National Strategic Plan: A Roadmap to Elimination 2021 – 2025*. The CTR program plays a key role in ending in the HIV and viral hepatitis epidemics in North Dakota. CTR sites provide additional opportunities for healthcare access for those who are at risk, especially for those who are uninsured or underinsured. CTR sites also increase the number of clients' who know their HIV and HCV status, provide risk reduction counseling and harm reduction strategies and provide referrals (i.e. medical, social, prevention and partner services) to clients as needed.

The program is committed to upholding the vision of the HIV National Strategic Plan, which states:

"The United States will be a place where new HIV and viral hepatitis infections are prevented, every person knows their status, and every person with HIV has high-quality care and treatment and lives free from stigma and discrimination.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance."

The program is also committed to upholding the vision of the *Viral Hepatitis National Strategic Plan: A Roadmap to Elimination 2021 – 2025*, which states:

"The United States will be a place where new viral hepatitis infections are prevented, every person knows their status, and every person with viral hepatitis has high-quality health care and treatment and lives free from stigma and discrimination.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance."

In addition to the national strategic and elimination plans, CTR sites should also aim to complete the goals in the ND Integrated HIV and Viral Hepatitis Prevention and Care Plan. This document highlights the objectives, strategies and activities that are the focus of the NDDoH HIV and Viral Hepatitis programs.

The following are core elements that are essential to all CTR sites:

1) Ensure that CTR is a voluntary service that can only be delivered after informed consent is obtained.
2) Provide information and education to the client about HIV and HCV.
3) Provide client-focused HIV/HCV prevention counseling.
4) Use HIV and HCV testing technology approved by the Food and Drug Administration (FDA).
5) Deliver test results in a manner that is supportive and understandable to the client.
6) Assess the need for referrals in support of risk reduction or medical care. Provide appropriate referrals, link clients to referral services and document referrals and their outcomes.

In addition to the required activities associated with the core elements, CTR sites are recommended to provide comprehensive sexual health services, which could include sexually transmitted infection (STI) testing, human papilloma virus (HPV) vaccination and viral hepatitis vaccination at every opportunity. In addition to providing services to incoming clientele, CTR sites, in partnership with the NDDoH), may offer outreach services in the community such as rapid testing at health fairs, community events or stand-alone testing events targeting high-risk individuals. Table 1 below summarizes the required and recommended activities performed at CTR sites.

Table 1. Required and Recommended CTR Activities

Required Activities	Recommended Activities
Obtaining Consent	**Outreach Events**
HIV/Hepatitis C Rapid & Confirmatory Testing	**Community Education**
Ensure Quality of Rapid Test Kits	**STI Testing & Treatment**
Pre- & Post-Test Counseling	**Hepatitis A & B Vaccination**
Risk Reduction	**HPV Vaccination**
Data Submission for All Tests Performed	**Case Management**
Resource Referrals	**Partner Services**
Provide Client Education	**Prescribe PrEP**

CTR Site Required Reporting

The CTR program requires data be reported to the NDDoH by all CTR sites. The following is a summary of the required data:

- **Testing Data:**
  - Patient demographics, including patient name, address, gender identity, assigned sex at birth, race, ethnicity, country of birth, etc.
  - Previous HIV and hepatitis C testing history.
  - Sexual health behaviors.
  - Results of screening and confirmatory testing.
  - Co-infection screenings.
  - Essential support service assessments, needs and referrals.
- **Rapid Test Quality Assurance:**
  - Control and temperature logs.
  - Invalid test reports.
  - Current CLIA waiver.
- **Hepatitis Vaccine**
  - Doses administered.

Testing Data Reporting

For testing data, there is a form available, HIV/HCV Test Form, often referred to as the PEMS form, that has all of the information required to be reported on every individual who is tested for HIV and/or HCV. The paper version of this form is not required to be completed, as the data is required to be entered into the North Dakota Electronic Disease Surveillance System, which is referred to as Maven. The Maven website is: https://apps.nd.gov/maven/login.do. A Required Data Elements and Maven User Guide and Maven tutorial are available on the CTR website.

Site administrators are responsible for requesting Maven access for users and notifying the Division of Sexually Transmitted and Bloodborne Diseases of employees that terminate employment and should no longer have Maven access. These requests and notifications occur via the Maven User and Site Agreement Qualtrics form.

MAVEN Site and User Agreements

All Maven users must sign a Maven Confidentiality Policy and User Agreement annually. This agreement describes policies and procedures related to maintaining confidentiality with the data in Maven. A user's access may be permanently denied for Maven if there is a violation of the agreement.

Rapid Test Quality Assurance and Hepatitis Vaccine

Additional information on reporting requirements for rapid test quality assurance and hepatitis vaccine is detailed in corresponding sections of this manual.

Maven HIV/HCV Test Form

For testing data, there is a form available, HIV/HCV Test Form, often referred to as the PEMS form, that has all of the information required to be reported on every individual who is tested for HIV and/or HCV. A second version of this form is available that is written so that a patient can complete. Sites may choose to modify the HIV/HCV test form as long as the required data elements are completed. Refer to the sections below and the Required Data Elements and Maven User Guide for an explanation and summary of data fields on the HIV/HCV test form.

CTR Site Information

The information required to be entered on the CTR site includes the agency ID, site ID, agency name, site county, site zip code and site type.

Agency ID and Site ID. These fields are obtained from the HIV.STI.Hepatitis Prevention Coordinator. All agencies are provided with an agency ID when becoming a CTR site. Each site within an agency has an ID as well. If an agency has multiple locations or satellite clinics, the agency ID will be the same, but the site ID will vary for various locations or satellite clinics.

Demographic Information

The followings demographic fields are also required to be reported on every individual tested in the CTR program: date of birth, country of birth, client address (State, County & Zip Code), ethnicity, race, current gender identity and assigned sex at birth.

Race and Ethnicity. Individuals of with a similar ethnicity share a common and distinctive culture, religion or language. Individuals of a specified race have common characteristics, share certain distinctive physical traits and have similar biological makeup. Hispanic individuals may not identify as having a race, thus the option Not Specified is an option under race. National original classified as Hispanic or Latino by the United States Census Bureau are the following: Argentine, Cuban, Colombian, Puerto Rican, Spaniards, Dominican, Mexican, Costa Rican, Guatemalan, Honduran, Nicaraguan, Panamanian, Salvadoran, Bolivian, Spanish, Chilean, Ecuadorian, Paraguayan, Peruvian, Uruguayan, and Venezuelan. Below is a chart that describes the region of origin for racial categories.

White	Black or African American	American Indian or Alaska Native	Asian	Native Hawaiian or Other Pacific Islander
Europe Middle East North Africa	Africa	North America South America Central America	Far East Southeast Asia Indian	Hawaii Guam Samoa Pacific Islands

In addition to the above information, the following information is also collected under demographics: client insurance status, billing information for HIV and hepatitis C testing and previous HIV and HCV testing history.

Insurance & Billing. The CTR program is designed to provides services to individuals who do not have insurance. Currently, insured individuals are eligible for screening in the program, but this may not always be available as funding levels change. Individuals who are on the insurance on their parents or another party and choose not to use that insurance should be indicated to not have insurance. The two questions regarding billing pertain to the billing for services to the CTR program. These two questions are 'Was client billed for HIV test?' and 'Was client billed for HCV test?'. If the CTR site asked for reimbursement only from the CTR program, these questions should be answered as no. CTR sites are able to use our product on insured individuals and then bill the insurance company for the counseling fees instead of asking for reimbursement of the CTR program. If only the insurance company or patient paid directly for the counseling reimbursement and no reimbursement was requested from the CTR program, then the above questions should be answered yes. These questions will be used to compare the number of tests on the reimbursement request and the number of CTR events in Maven.

Previous Testing History. All individuals should be assessed for their previous testing history for HIV and hepatitis C. For hepatitis C, there are options for hepatitis C, hepatitis C antibody and hepatitis C RNA test results. These questions will be used to determine if CTR sites are appropriately screening individuals as well as identifying missing opportunities.

HIV and HCV Test Information

The following information is collected on every HIV and HCV test performed: collection date, tester worker, test technology, test result and if the test result was provided. The CTR program does not have requirements to for result delivery. Result delivery can be in-person or over the phone. At outreach events, rapid results can be considered delivered if the policy no news is good news is followed. If the rapid test is positive, information on the confirmatory test (collection date, test result, if the test result was provided and if the CTR sites is providing linkage to care services). Linkage to care services are defined as any service performed by the CTR site to ensure that the patient receives appropriate follow-up care. CTR sites may be reimbursed for HCV linkage to care services. Refer to the linkage-to-care for hepatitis C section of this manual for additional information.

Tests for Co-Infection

All individuals that are tested for HIV and/or HCV should be evaluated for chlamydia, gonorrhea, and syphilis. The following information is required to be reported: if the patient was screened for chlamydia, gonorrhea, and syphilis and if the patient was not screened, what is the reason that the screenings were not provided. Also reported is the specimen source for chlamydia and gonorrhea. The reasons that screenings were not provided include patient refused – unable to pay, patient refused – other reason, not recommended by healthcare provider and not offered by CTR site. CTR sites will be assessed for STI screening rates and potential opportunities for screening among CTR clients. CTR sites are encouraged to integrate STI and HIV testing programs to offer complete sexual health services to their clients.

Hepatitis Vaccine

CTR sites are required to report the following regarding hepatitis vaccine: date vaccine administered, and type of vaccine administered. If no vaccine was administered, CTR sites must report the reason no

vaccine was administered. Only doses given on the date of a HIV and/or HCV test need to be entered into Maven. All doses are also required to be reported in the North Dakota Immunization Information System.

Sexual Health History

The sexual health history section provides a brief overview of the gender identity of a client's sex partners and history of injection drug use. The individual who provides counseling to the client is indicated in the counselor worker ID field. The sexual health history questions provide the counselor with historical risk information. This information is very useful in clients that state they don't have current risks for HIV or HCV. All clients are asked if they have ever and within the last five years have had sex with males, females and transgender individuals. Clients are asked if they have ever or within the last five years injected drugs. Clients are also asked about their history with sharing injection drug equipment.

Current Sexual Health Behaviors & Additional HIV and HCV Risk Factors

The current sexual health behaviors are asked to assess a client's current risk and provide recommendations for STI screening and frequency of STI testing. Clients are asked about the gender identity of current sex partners, number of sex partners, frequency of condom use, types of sex, drug use and anonymous sex partners. Asking clients about the types of sex they are having is important for assessing the need site-specific STI testing (i.e. rectal or pharyngeal swabs). Reviewing these risk factors is an important for healthcare providers to assess for HIV pre-exposure prophylaxis (PrEP) eligibility.

PrEP Awareness, Referrals and Eligibility Screening

One goal of the HIV prevention program is to increase the number of clients that know HIV PrEP is an available HIV prevention tool. All clients are asked if they have heard of PrEP (i.e. they know the purpose of HIV PrEP). Clients are also asked if they are currently on PrEP or if they have had taken PrEP in the previous 12 months. CTR staff then assess the client's risk to determine if they are eligible or recommended for HIV PrEP. Staff are asked to provide referrals and/or navigation services for PrEP services.

Essential Support Services

This section is focused on addressing the social determinants of health and providing services that will improve a client's overall health and well-being. These questions address health benefits navigation and enrollment, risk reduction interventions, behavioral health and social service needs. Counselors and other CTR staff will identify if clients need services and if services are needed, provide referrals and/or services to address their support service needs.

Additional Questions for Persons Diagnosed with HIV

If a client is confirmed to have HIV, there are additional questions that need to be completed. Those diagnosed with HIV are asked about individualized counseling to reduce the further transmission of HIV, their living status, pregnancy status and the support service needs. These questions are utilized to create a care plan for someone newly diagnosed with HIV. This information can be shared with HIV care providers and Ryan White Case Managers.

Screening for HIV and HCV at CTR Sites

Rapid, point-of-care HIV and hepatitis C tests are provided for use at CTR sites. These tests should be prioritized for uninsured or underinsured individuals because HIV and hepatitis C tests are covered by most insurance policies. Individuals who are on a policy of another individual such as youth who utilize their parent's insurance should not be required to process their insurance for HIV and HCV testing.

Testing services at CTR sites is available to individuals considered to be at risk for HIV and/or HCV. Individuals who do not disclose a risk factor or request HIV and hepatitis C testing can be tested with the provider's discretion. Sites shall refer to the quality management performance metrics for the goal of testing among at-risk individuals. Services at CTR sites are considered confidential; anonymous testing is not available.

Individuals do not have to be North Dakota residents to be tested in the CTR program. Individuals can be a resident of any state or country and be tested at CTR sites. Regardless of residency, information from the HIV/HCV test form needs to be reported in Maven on all individuals tested.

Risk Assessment

To determine if individuals are at risk for HIV and/or HCV, they should complete a risk assessment. The HIV/HCV Test Form can be used as a risk assessment form as it has all required questions. An additional risk assessment example for CTR sites to utilize is available. Risk assessment will assist providers in determining the appropriate type of screening needed as well as the frequency of screening recommended for the client. The required risk assessment data elements are described in the document Required Data Elements and MAVEN User Guide. The HIV.STI.Hepatitis Prevention Coordinator can provide assistance to ensure the CTR site is utilizing the optimal tools for their testing program.

HIV Screening

Screening should be provided annually for people who are or have had:

- Men who have sex with men (MSM)
- Sex with people living with HIV (PLWH)
- More than one sex partner since last HIV test
- Injected drugs or shared needles or works with others
- Persons who exchange in sex work
- Persons diagnosed with or sought treatment for tuberculosis (TB), HCV or a STI
- Sex with an injection drug user
- Sex with someone who exchanges in sex work
- Sex with someone whose sexual history is unknown (i.e. anonymous sex partners, usually involves networking apps such as Grindr
- Tattoos or body piercings in unsterile environments

Patients that are considered at high-risk for HIV infection may benefit from being screened every three to six months. Those at high-risk may include:

- Sex partners of PLWH
- Persons who engage in condomless anal sex, especially condomless receptive anal sex
- Persons who use networking apps to meet their partners, i.e. have anonymous sex partners
- Persons who inject drugs (PWID) and their sex partners
- Persons who are or have partners whom exchange in sex work

The above HIV screening recommendations are from CDC as well as informed by the epidemiology of HIV in North Dakota. CDC HIV screening recommendations can be found on www.cdc.gov/hiv.

***Note**: Per CDC, everyone between the ages of 13 and 64 should be screened for HIV at least once in their lifetime without an assessment of risk. This strategy is to be implemented as opt-out screening and is recommended for healthcare facilities. The CTR is unable to support universal and age-based screening programs and should not be implemented in the CTR program.*

HCV Screening

CDC recommends one-time hepatitis C testing regardless of age or setting prevalence among people with recognized conditions or exposures:

- People with HIV
- People who ever injected drugs and shared needles, syringes, or other drug preparation equipment, including those who injected once or a few times many years ago
- People with selected medical conditions, including:
    - people who ever received maintenance hemodialysis
    - people with persistently abnormal ALT levels
- Prior recipients of transfusions or organ transplants, including:
    - people who received clotting factor concentrates produced before 1987
    - people who received a transfusion of blood or blood components before July 1992
    - people who received an organ transplant before July 1992
    - people who were notified that they received blood from a donor who later tested positive for HCV infection
- Healthcare, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood
- Children born to mothers with HCV infection

Routine periodic testing, at least annually or every 3 to 6 months, for people with ongoing risk factors, while risk factors persist:

- People who currently inject drugs and share needles, syringes, or other drug preparation equipment
- People with selected medical conditions, including:
    - people who ever received maintenance hemodialysis
    -

HCV screening may be considered for:

- Men who have sex with men (MSM)

- Intranasal cocaine and other non-injecting illegal drug users
- Sex partners of HCV-positive persons
- Sex partners of persons who inject drugs
- Persons who use illicit drugs, but do not admit to injection drug use, may still be considered for HCV testing due to the potential risk

HCV is not efficiently transmitted through sex, thus heterosexuals or those with multiple sex partners are not recommended for routine HCV screening. Studies of HCV transmission between heterosexual or homosexual couples have yielded mixed results, but generally have found either no or very minimally increased rates of HCV infection in partners of persons with HCV infection compared with those whose partners are not HCV-infected. Data indicate that sexual transmission of HCV can occur, especially among persons with HIV infection. Increasing incidence of acute HCV infection among MSM with HIV infection has been reported in New York City and Boston, along with multiple European cities. These men usually engage in high-risk and traumatic sexual practices and might have concurrent genital ulcerative disease or STI-related proctitis. Other common practices associated with new cases of HCV infection include group sex and use of cocaine and other non-intravenous drugs during sex. Certain studies have revealed that-risk increases commensurate with increasing numbers of sex partners among heterosexual persons with HIV infection and MSM, especially if their partners are also coinfected with HIV.

Individuals that have been successfully treated for HCV or have resolved their infection without treatment, should be screened for HCV at least annually if they have continued risk factors. These individuals are not to be screened with an HCV rapid test as this test will remain positive in those with a history of infection. In order to determine if individuals are currently infected, they should be screened with a HCV RNA test.

Note: *Per CDC, everyone 18 and older should be screened for HCV at least once in their lifetime without an assessment of risk. This strategy is to be implemented as opt-out screening and is recommended for healthcare facilities. The CTR is unable to support universal and age-based screening programs and should not be implemented in the CTR program.*

Screening Services Not Provided

Individuals that are ineligible from receiving CTR testing include those who are seeking testing for employee screening, insurance purchase agreements, travel related purposes, sports' team screening or occupational exposure incidents. The CTR program is also not meant for universal screening of pregnant women. Pregnant women are recommended to have HIV and HCV screening with each pregnancy. ***Note****: HCV rapid tests are not approved for use on pregnant women.*

Screening at Correctional Facilities

Thera are two North Dakota Century Code subsections that describe requirements for HIV and STD screening in correctional facilities. Below are the subsections of the North Dakota Century Code:

- **23-07-07.5. Testing of inmates and convicted individuals for exposure to the human immunodeficiency virus - Reporting - Liability.**

  1. The following individuals must be examined or tested for the presence of antibodies to or antigens of the human immunodeficiency virus:

     a. Every individual convicted of a crime who is imprisoned for fifteen days or more in a grade one or grade two jail, a regional correctional facility, or the state penitentiary;

     b. Every individual, whether imprisoned or not, who is convicted of a sexual offense under chapter 12.1-20, except for those convicted of violating sections 12.1-20-12.1 and 12.1-20-13; and

     c. Every individual, whether imprisoned or not, who is convicted of an offense involving the use of a controlled substance, as defined in chapter 19-03.1, and the offense involved the use of paraphernalia, including any type of syringe or hypodermic needle, that creates an epidemiologically demonstrated risk of transmission of the human immunodeficiency virus.

  2. The results of any positive or reactive test must be reported to the state department of health in the manner prescribed by the department and to the individual tested. Subsection 1 does not require the testing of an individual before sentencing or the testing of an individual held in a jail or correctional facility awaiting transfer to the state penitentiary.

  3. A licensed physician, nurse, technician, or employee of a hospital or clinic who draws blood from any person for the purpose of conducting a test required by this section is not liable in any civil action for damages arising out of such action except for an act or omission that constitutes gross negligence.

- **23-07-08. Persons in prison examined and treated for sexually transmitted diseases. Every person convicted of a crime who is imprisoned fifteen days or more in a state, county, or city prison must be examined for sexually transmitted disease and, if infected, must be treated therefor by the health officer within whose jurisdiction the person is imprisoned.**

Although century code only requires HIV testing of inmates if there were convicted and imprisoned for fifteen days or longer, all inmates regardless of length of imprisonment or conviction status can be tested for HIV and/or HCV in the CTR program. Although STI testing is not included in the CTR program, inmates should also be screened for STIs, including chlamydia, gonorrhea, and syphilis.

Pre-Exposure Prophylaxis (PrEP)

PrEP is short for pre-exposure prophylaxis. It is the use of antiretroviral medication to prevent acquisition of HIV infection. PrEP is used by people without HIV who are at risk of being exposed to HIV through sexual contact or injection drug use. Two medications have been approved for use as PrEP by the FDA. Each consists of two drugs combined in a single oral tablet taken daily:

- Emtricitabine (F) 200 mg in combination with tenofovir disoproxil fumarate (TDF) 300 mg (F/TDF – brand name Truvada®)
- Emtricitabine (F) 200 mg in combination with tenofovir alafenamide (TAF) 25 mg (F/TAF – brand name Descovy®)

These medications are approved to prevent HIV infection in adults and adolescents weighing at least 35 kg (77 lb) as follows:

- Daily oral PrEP with F/TDF is recommended to prevent HIV infection among all persons at risk through sex or injection drug use.
- Daily oral PrEP with F/TAF is recommended to prevent HIV infection among persons at risk through sex, excluding people at risk through receptive vaginal sex. F/TAF has not yet been studied for HIV prevention for receptive vaginal sex.

PrEP should be considered part of a comprehensive prevention plan that includes a discussion about adherence to PrEP, condom use, other sexually transmitted infections (STIs), and other risk reduction methods. Below are CDC and local recommended indications for PrEP use among MSM, heterosexual individuals and persons who inject drugs. Comprehensive guidelines for prescribing PrEP have been published by the Centers for Disease Control and Prevention (CDC) in *A Clinical Practice Guideline* including a *Clinical Providers' Supplement*. Additional information on PrEP baseline testing requirements, recommendations, follow-up and prescription can be found here.

CDC Criteria for PrEP

	MSM	Heterosexual Women and Men	Persons Who Inject Drugs
Substantial Risk of Acquiring HIV Infection	HIV-positive sexual partner Recent (previous 6 months) bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work	HIV-positive sexual partner Recent (previous 6 months) bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work	HIV-positive injecting partner Sharing injection equipment
Notes: Transgender women have high rates of HIV diagnosis. The CDC Clinical Practice Guidelines does not specify recommendations for transgender individuals, but instead states "Although the effectiveness of PrEP for transgender women has not yet been definitively proven in trials, and trials have not been conducted among transgender men, PrEP has been shown to reduce the risk for HIV acquisition during anal sex and penile-vaginal sex. Therefore, its use may be considered in all persons at risk of acquiring HIV sexually."			

Reference: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update, A Clinical Practice Guideline, CDC

Local Criteria for PrEP

Most individuals recommended for PrEP will have a risk based on CDC's criteria. Here are a few examples that may be considered local criteria for PrEP, clients:

- Report always using condoms but report a high number of partners or anonymous sex partners
- Report no substantial risk for HIV but have partners who do have substantial risk for HIV
- Report recreational use of mood-altering substances during sex, including but not limited to alcohol, methamphetamine, cocaine, ecstasy and gamma hydroxybuturate
- Report injecting substances or having sex partners who inject substances, including illicit drugs, hormones, or silicone.
- Self-identify as being at risk without disclosing specific risk behaviors.
- Acknowledge the possibility of or anticipate engaging in risk behaviors in the near future.

CTR sites are encouraged to establish PrEP treatment programs or identify known providers in the community for referrals. Sites interested in creating a PrEP program may reach out to the HIV.STI.Hepatitis Prevention Coordinator for technical assistance (TA). The NDDoH works with the Dakota AIDS Education Training Center (DAETC) to provide TA to healthcare providers about PrEP. This TA would also include information on how to utilize the 340B program for billing.

Post-Exposure Prophylaxis (PEP)

When assessing risk, if there is a concern about a recent exposure, CTR sites should always consider if a referral to a healthcare provider for PEP is needed. Some situations that may require PEP referral include individuals who have been exposed to HIV during sex (ex. If the condom broke), sharing needles or other drug equipment or if clients were sexually assaulted. PEP for HIV is used only in emergency situations and must be started within 72 hours after a possible exposure. There is no PEP available for hepatitis C. CTR sites should determine a good referral source for PEP in their community, oftentimes that would be an emergency room or urgent care clinic. The NDDoH has a PEP Pocket Guide available on body and bodily fluids exposure that CTR sites may use as a reference.

STI Screening

STI screening is not a required component of the CTR program. Screening for STIs, such as chlamydia, gonorrhea, and syphilis, is recommended to be performed by all CTR sites to ensure comprehensive sexual health services are offered to all clients. All individuals at-risk for HIV should be tested STIs and all patients diagnosed with a STI should also be tested for HIV. Refer to the CDC STI Treatment Guidelines for the most complete and current STI screening recommendations. These recommendations also include screening recommendations based on site of exposure, i.e. site-specific STI screening. For example, annual screening for rectal *C. trachomatis* infection should be performed among men who report sexual activity at the rectal site. Healthcare providers should always consider site of exposure for chlamydia and gonorrhea testing. The NDDoH has posters available that explain rectal and pharyngeal specimen self-collection. Order these posters and other supplies here.

For sites that need standing orders for the screening and/or treatment of STIs, they are found at www.health.nd.gov/HIV/CTR. These standing orders have been approved by the North Dakota Board of

Nursing and can be utilized by healthcare agencies to expand the availability of STI screening in their clinic/agency. The CTR program does not regulate the use of these standing orders and questions on these orders should be directed to the North Dakota Board of Nursing.

Although reimbursement for STI screening or treatment is not included in the CTR program, CTR sites are eligible to receive reduced fee STI testing from the NDDoH Division of Microbiology. Please contact the HIV.STI.Hepatitis Prevention Coordinator if you are not receiving reduced fee STI testing. The receipt of this reduced fee testing also qualifies agencies for eligibility for STI designation within the federal 340B pharmacy purchasing program. Agencies have found cost savings through the procurement of medications to treat STIs for their clients. This may include mediations for the treatment of chlamydia, gonorrhea, syphilis, bacterial vaginosis, trichomoniasis as well as antiretroviral medications currently authorized for pre-exposure prophylaxis for HIV infections (HIV PrEP) and hepatitis B and C treatment. For more information on the requirements and instructions on how to register for this designation, contact the HIV.STI.TB.Viral Hepatitis Program Manager.

Counseling at CTR Sites

HIV and HCV prevention counseling is a client-centered exchange designed to support individuals in making behavior changes that will reduce their risk of acquiring or transmitting HIV and/or HCV. At CTR sites, all individuals seeking HIV or HCV testing should be provided counseling. Client-focused counseling techniques should be used to help clients determine their readiness for testing and to provide support systems to access while waiting for and after receiving their test results. Client-focused counseling also assesses the client's ability to cope with a positive test result. At the conclusion of the counseling session, a risk reduction plan should be developed with a client and/or appropriate referrals are made based on results and risks.

There are four goals for every counseling session. These include 1) risk assessment, 2) educate client 3) risk reduction planning and 4) result disclosure. The session is typically described in terms of pre-test and post-test counseling. A summary of activities in the pre and post-test counseling session is provided in Table 2.

Table 2. Pre- and Post-Test Counseling Activities

Pre-Test Counseling	During Waiting Period or Post-Test Counseling
Welcome client and discuss what is going to happen in the session.	Ensure client is ready to receive results. Provide results if client is ready.
Establish rapport.	Describe test and results and clear indicate what those results mean.
Educate client on HIV and hepatitis C.	Awareness of risk. Review risk reduction plan and highlight goals for behavior change.
Assess client's risk and readiness for testing.	Provide referrals as necessary.
Provide information on HIV and HCV testing. Include STI testing if appropriate.	Provide recommendations for continual testing if clients continues to have risky behaviors.
Prepare client to receive result.	Establish the overall knowledge of the disease.
Engage client in risk reduction counseling.	Educating about prevention.

Pre-Test Counseling

The pre-test counseling sessions focus on welcoming the client, establishing rapport, providing education about HIV and HCV, risk assessment and engaging the client in risk reduction counseling. Education provided to the client should at least include the type of testing available, risks and benefits of testing, how to prevent and transmit HIV and hepatitis C, window period for testing and where to obtain more information or other healthcare services.

Post-Test Counseling

The post-test counseling can occur the same day as the pre-test counseling if a rapid test is performed or later if a conventional test is performed. A post-test counseling session includes providing test

results and an explanation of those results. Review HIV and HCV educational material and develop a client specific risk reduction plan and provide appropriate referral services.

Counseling Negative Individuals

Provide test result in a way that is sensitive and appropriate to the client's needs and level of comprehension. Help the client understand the meaning of the test result. Reemphasize staying negative by helping the client understand how to prevent HIV and/or hepatitis C infection and educate client on screening recommendations, i.e. annually or every more frequent screening.

Counseling Newly Identified HIV and/or HCV Confirmed Positive Individuals

Individuals with positive HIV or hepatitis C confirmatory tests, post-test counseling should ideally be offered face-to-face in a confidential setting.

Post-test counseling for positive individuals should include a discussion of:

- The test results and the reliability and significance of the results;
- Partner services for positive HIV cases;
- Facts about HIV or hepatitis C transmission, emphasizing how to protect close contacts;
- Referrals for medical evaluation, care and treatment including healthcare insurance enrollment and information and referrals for support services, including social and emotional support and substance abuse treatment programs, mental health services or other related programs

At the conclusion of the post-test counseling session, providing information to the client that they can take home is very important. Resource packets are available from the NDDoH for individuals testing positive for HIV or hepatitis C. These resource packets include brochures, fact sheets and information on referral services available. These resource packets can be ordered on the supplies order form.

Additional Information

Providers should develop and maintain strong working relationships with other providers and agencies that might be able to provide needed services. Providers who offer HIV/HCV prevention counseling and testing but not a full range of medical and psychosocial support services should develop arrangements with other providers who can offer needed services. When referral resources are not available locally, providers should identify appropriate resources and link clients with them. Coordination and collaboration promotes a shared understanding of the specific medical and psychosocial needs of clients requiring services, current resources available to address these needs, and gaps in resources.

Test Methods Offered at CTR Sites

All tests performed at CTR sites are required to be approved by the FDA. Both rapid and confirmatory HIV and HCV testing are offered to CTR sites. Rapid tests are provided to CTR sites free of charge from the NDDoH. Specimens for confirmatory testing collected at CTR sites should be performed at the NDPHL Division of Laboratory Services. Contracted CTR sites are reimbursed for the expense of confirmatory testing. Non-contracted partners are responsible for the costs associated with confirmatory testing.

Rapid Testing Prerequisites

The HIV and HCV rapid test utilized in the CTR program are CLIA (Clinical Laboratory Improvement Amendments) waived. A CLIA waived test is categorized as "simple laboratory examinations and procedures that have an insignificant risk of erroneous result." Entities performing CLIA waived testing must have a CLIA Certificate of Waiver. A CLIA Certificate of Waiver is issued by the Department of Health and Human Services Centers for Medicare and Medicaid Services. An application is available here and more information about CLIA is available at www.cms.gov/Regulations-and-Guidance/Legislation/CLIA. The CTR program may request a copy of a site's CLIA certificate at any time. Ensuring compliance with CLIA standards is the responsibility of the CTR site.

In North Dakota, CLIA waived tests also need to be approved by the North Dakota Board of Clinical Laboratory Practice (NDBCLP). The NDBCLP decides which tests are consider exempt in North Dakota and requirements for unlicensed personnel performing exempt tests and methods. Section 43-48-03 of the North Dakota Century Code lists individuals whom are exempt from the clinical laboratory licensure law. One exemption that relates to the CTR program reads, "Nurses duly and currently licensed to practice nursing and practicing within the scope of the nursing licenses." It is the responsibility of the CTR site and their staff to ensure that staff have appropriate license and are operating within the scope of that license when performing rapid HIV and HCV testing.

The rapid HIV and HCV tests utilized in the CTR program are listed as exempt tests by the NDBCLP. Because these rapid tests are exempt, individuals without licensure can be perform these tests as long as they are supervised either by an individual licensed by the board, an advanced practice registered nurse or a physician. Requirements for supervision are found within North Dakota Administrative Code section 96-02-10-02. Supervisors are required to complete a form provided by the board, ensure staff are appropriately trained and demonstrate competency and document training and competency assessments. Supervisors shall regularly monitor and be available to consult with the individuals being supervised. The CTR program has examples of rapid testing training materials as well as competency assessments available on www.health.nd.gov/HIV/CTR.

Questions related to the CLIA waiver can be directed to the ND CLIA contact and questions regarding exempt tests and supervision, should be directed to the NDBCLP.

Rapid Testing

To maintain rapid testing, CTR sites must comply will all manufacture instructions and quality assurance measures. Control and temperature logs are necessary to ensure the tests are performing accurately and that operators understand the performance of the rapid test. There are also specifications to consider for each rapid test in the CTR program such as age of eligibility and pregnancy status. Both rapid tests and controls have expiration dates. CTR sites are responsible for ensuring in stock rapid tests do expire. If the rapid test kits at a CTR site are going to be expiring soon, the CTR site should contact the HIV.STI.Hepatitis Prevention Coordinator for assistance in finding a facility that would be able to use the test kits prior to expiration. CTR sites should do this notification at least three months prior to expiration to ensure adequate time to arrange for transfer to another facility. Sites that have wasted test kits may not receive test kits in the future as a CTR site.

Control Logs

For all rapid HIV and HCV tests, controls are required to be performed for quality assurance. Chembio SURE CHECK® HIV 1/2 Assay and HCV OraQuick® rapid tests require controls to be performed for the following circumstances:

1) Each new operator prior to performing tests on patient specimens.
2) When opening a new test kit lot.
3) Whenever a new shipment of test kits is received.
4) If the temperature of the test storage area falls outside:
    a. HIV SURE CHECK®: 8° to 30°C (46° to 86°F)
    b. HCV OraQuick®: 2° to 30°C (36° to 86°F)
5) If the temperature of the testing area falls outside:
    a. HIV SURE CHECK®: 18° to 30°C (64° to 86°F)
    b. HCV OraQuick®: 15° to 37°C (59° to 99°F)
6) At periodic intervals as indicated by facility. ***CTR Program Requirement: 6 Month Interval***

Anytime controls are performed, performance should be documented on a HIV/HCV Rapid Test Control Log. Control logs should be submitted within seven days of control performance.

Although the NDDoH performs controls on all rapid tests when a new shipment is received, CTR sites must also perform controls when a shipment of tests is received. Sites are recommended to label each box of tests with the date controls were performed and the date in which controls are due to be performed next. If sites take tests out of central location or their original packaging and place them in exam rooms, it is important to note on the rapid tests when controls where performed and when controls need to be performed next.

***Note**: HIV controls expire on the date listed on the product. HCV controls expire on the date listed on the product or two months after they are first opened. All HCV controls should be labeled with the date of opening and expiration date. Also note that expired controls and test devices can be used to train new operators.*

Temperature Logs

Controls are required to be stored at refrigerator temperatures. HIV and hepatitis C controls should be stored at temperatures of 2° to 8°C (36° to 46°F). If controls are stored in a refrigerator in which the temperatures are submitted as part of the NDDoH Immunization program, no daily temperatures need to be submitted to the CTR program. Otherwise, daily temperatures need to be recorded on a temperature log, Celsius or Fahrenheit. The temperature log is then submitted at the end of every month. If temperatures fall outside of the acceptable range for the storage of controls, contact the HIV.STI.Hepatitis Prevention Coordinator immediately.

Rapid HIV Test

The rapid HIV test provided to CTR sites is the Chembio SURE CHECK® HIV 1/2 assay. This test is a second-generation HIV test which relies on recombinant HIV proteins or synthetic peptides to detect HIV-1/2 IgG antibodies and the window period is 42 days. **This test is to be used on individuals older than 12 years of age**. The test is approved for use on fingerstick whole blood, venous whole blood, serum or plasma. The results are read between 15 to 20 minutes after test is initiated. This test is very accurate with a sensitivity of 99.7% and a specificity of 99.9%. The window period of the rapid HIV test is 23 to 90 days to reliably detect HIV infection. One requirement for this test is that patients must receive the subject information notice prior to specimen collection and appropriate information when test results are provided.

Per the Chembio Sure Check® HIV 1/2 Assay product insert:

- Read this Product Insert completely before using the product. Follow the instructions carefully when performing the test as not doing so may result in inaccurate test results. Users of this test should follow the CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other blood borne pathogens.

The above requirements for testers are also included in the Staff Development and Training Policy.

Rapid HCV Test

The rapid HCV test provided to CTR sites is the Orasure Oraquick® HCV Rapid Antibody Test. **This test is to be used on individuals older than 14 years and cannot be used on pregnant women**. The approved specimens include fingerstick whole blood or venipuncture whole blood. The test results are interpreted between 20 and 40 minutes following the introduction of the device into the developer solution vial. With a fingerstick sample, the percent positive agreement is 97.9% and the percent negative agreement is 98.5% indicating that results are reliable with greater than 98% accuracy. The window period for anti-HCV screening tests ranges from 4–10 weeks after infection. Anti-HCV can be detected in >97% of people by 6 months after exposure.

Per the Orasure Oraquick® HCV Rapid Antibody Test product insert, testers must:

- Correctly interpret the OraQuick® HCV Visual Reference Panel prior to using the OraQuick® HCV Rapid Antibody Test device.
- Read the package insert completely before using the product.

- Read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.

The above requirements for testers are also included in the Staff Development and Training Policy.

Note: *Rapid tests should not be used for confirmatory testing as rapid tests are not definitive for the diagnosis of HIV or HCV. Individuals who had a positive screening test, such as those testing positive at a plasma center or a blood bank, should be offered a confirmatory test. If patients are not at-risk for HIV or HCV, they should be referred to their primary care provider or other healthcare provider for this confirmatory testing.*

Rapid Test Competency

All CTR sites are required to have an annual competency policy. A sample competency policy is available for CTR sites to modify for their program at www.health.nd.gov/HIV/CTR. Competency policies will be reviewed during site visits. Also available on the above website is a sample competency certificate. CTR sites are recommended to have documentation of competency education for the performance of rapid testing for new testers as well as others for continued professional development.

Confirmatory Testing

All positive rapids tests must be confirmed with a confirmatory test. All CTR sites are recommended to offering confirmatory testing. If CTR sites do not offer confirmatory testing, these sites are required to have a written document that details their plan for ensuring that these clients get the confirmatory testing that they need. In addition to referrals, a process for referral follow-ups should be included in their plan. Sites are encouraged to develop relationships with other CTR sites in their area, if available, to offer referrals for blood draws.

All blood specimens should be spun utilizing a centrifuge prior to sending to a laboratory for confirmatory testing. The CTR program will provide centrifuges as needed to CTR sites if funding is available. Do not centrifuge immediately after drawing blood. Allow the blood to clot in an upright position for at least 30 minutes but not longer than 1 hour before centrifugation. Per NDPHL, blood specimens for HIV and HCV confirmatory testing should be spun at 3 (3,000) RPM for 10 minutes.

Confirmatory testing should be performed at the NDDoH Division of Microbiology. Utilizing this laboratory ensures confirmatory testing fees at a reduced rate. The CTR program will only reimburse sites for confirmatory testing at the rate provided by the Division of Laboratory Services. When submitting specimens for confirmatory testing, ensure that correct procedures are followed. NDPHL Division of Microbiology provides specimen collection procedures and requires submission of completed laboratory request form with each specimen. The laboratory offers a courier service in several communities and healthcare facilities throughout North Dakota. If a CTR agency is not a courier site, they may utilize courier locations in their community. The courier service is free of charge and provides free shipping of specimens to the laboratory.

HIV Confirmatory Testing

The type of HIV confirmatory test performed at Division of Microbiology is a fourth generation HIV-1/2 antigen/antibody combination immunoassay. This fourth-generation test detects the P24 antigen which is produced even before HIV antibodies. The window period for this confirmatory test is 13 to 42 days after infection. If the rapid HIV test is positive and the fourth-generation test is negative, the client is determined to have a false positive rapid HIV test. After a confirmatory antibody test is performed, the client should be referred to a HIV care provider for additional testing, including nucleic acid testing (NAT). The window period for the HIV NAT test is 10 to 33 days after an exposure. Individuals who have suspect acute HIV infection and negative HIV antibody screening test should have a NAT for HIV. It is very important that CTR sites immediately report all rapid reactive HIV tests results to the NDDoH to ensure appropriate confirmatory testing occurs.

HCV Confirmatory Testing

The HCV confirmatory test available is a confirmatory antibody test as well as a quantitative RNA viral load test. Traditionally, all rapid reactive HCV tests would be confirmed with a confirmatory HCV antibody test followed by an HCV RNA test. The CTR program is recommending a non-traditional algorithm for confirmatory HCV testing. In the CTR program, the first confirmatory test ordered should be the HCV RNA. If the HCV RNA test is nonreactive, then a confirmatory HCV antibody test should be ordered. The below diagram illustrates the recommended HCV testing algorithm at CTR sites. The alternative algorithm is utilized to save costs related to unnecessary confirmatory antibody screening tests. All individuals with a positive HCV RNA would have a positive confirmatory antibody test.

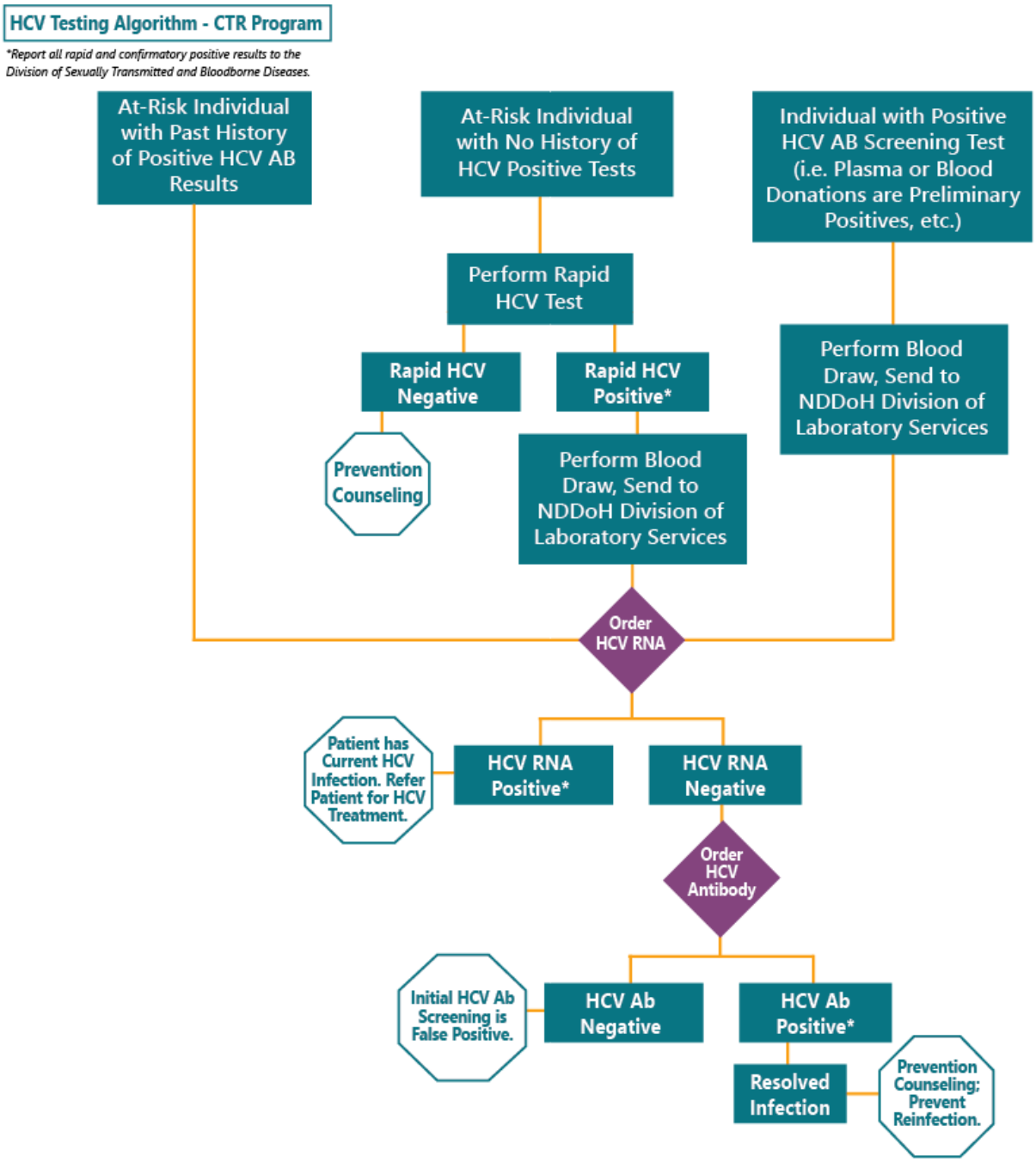
When submitting samples for hepatitis C testing, there are temperature requirements for the performance of the HCV RNA testing. Whole blood or serum stored at ambient temperatures must be to the laboratory within 24 hours of collection and specimens that are refrigerated must be to the laboratory within 48 hours. If the time from collection to arrival at the laboratory will be greater than 48 hours, the sample needs to be frozen at ≥-20°C.

Blood Draw Supplies

CTR sites may order blood draw supplies free-of-charge from the NDDoH. Blood draw supplies that are available include vacutainer tubes, eclipse needles for blood collection 21G x 1 ¼", angel wing collection sets 23G x ¾", one-use vacutainer holders, tourniquets and 2'' x 2" gauze pads. These supplies can be ordered here. These supplies are for blood draws related to confirmatory HIV and HCV testing.

Reporting & Documentation

All testing and screening results need to be reported on every test performed, both rapid and confirmatory tests. These results are entered in Maven. Results should be documented within a client's chart either via a paper form or electronically. The CTR program does not specify which documentation method is used by the site.



If an invalid test result is observed, it must be reported to the HIV.STI.Hepatitis Prevention Coordinator. The invalid test report form is available here. Invalid tests should be reported within seven days of specimen collection.

All HIV rapid and confirmatory positive results must be reported to the NDDoH within one business day. Positive HIV results must be reported by calling the Division of Sexually Transmitted and Bloodborne Diseases at 701.328.2378. When reporting a positive HIV or hepatitis C, staff may speak to anyone in the HIV.STI.TB.Hepatitis Program or they can report to their the local field epidemiologist. All

HCV rapid and confirmatory positive results must be reported to the NDDoH within seven business days. HCV results can be reported by 1) submitting an online disease report card, 2) reporting via phone to the Division of Sexually Transmitted and Bloodborne Diseases or 3) emailing the Maven Event ID to the HIV.STI.Hepatitis Prevention Coordinator. Submitting the information in Maven as a CTR event is not considered reporting a positive test result.

STI Testing & Treatment

STI testing is not a component of the CTR program. However, being a CTR site allows for those agencies to receive certain services from the NDDoH STI Program. CTR sites are eligible to receive reduced fee STI testing from the NDDoH Division of Microbiology. Please contact the HIV.STI.Hepatitis Prevention Coordinator if you are not receiving reduced fee STI testing. Another benefit to the CTR program is that CTR sites are eligible to receive 340B pricing on STI medications. More information on the 340B program is available here: https://www.hrsa.gov/opa/index.html. As a CTR site, the agency is then considered a safety net provider and can receive significantly reduced prices on medications for STI treatment. For more information on the program or how to get registered, please contact the HIV.STI.TB.Hepatitis Program Manager.

Resources and Additional Information

- Hepatitis C Test Interpretation, CDC
- Hepatitis C Testing Algorithm, NDDoH
- Rapid HIV and HCV tests, controls and blood draw supplies ordered online.
- Supplies for STI testing are provided by Division of Microbiology, including swabs for site-specific testing. Contact 701.328.6272.
- Disease reporting forms that are available:
    - STD Reporting Form - Health Care Providers
    - STD Reporting Form – Patient Interview
    - Syphilis Case Report Form
    - HIV Confidential Case Report Form

Policies and Statutes for CTR Programs

Consent

Consent for HIV and HCV testing can be incorporated into general consent for medical care; a separate consent form specific to HIV or hepatitis C is not needed. Consent can be given orally or written as long as it is documented in the client's medical record. Clients shall still have the opportunity to decline testing. Recommendations around consent were described based on the opinion of ND Office of Attorney General. Please contact the HIV.STI.Hepatitis Prevention Coordinator if your facility needs assistance in development of a consent form or policy.

Minor Consent

North Dakota Century Code 14-10-17 states that "*any person of the age of fourteen years or older may contract for and receive examination, care, or treatment for sexually transmitted disease or substance use disorder without permission, authority, or consent of a parent or guardian*". This century code indicates that all adolescents 14 years or older may consent to STI testing (chlamydia, gonorrhea, syphilis, HIV, etc.) without parental consent. Per opinion received by he HIV.STI.TB.Viral Hepatitis Program from the ND Office of Attorney General, hepatitis C testing and HPV vaccination also are applicable under this century code. ***Note**: Rapid hepatitis C testing is only approved for those 15 years and older.*

Record Location and Retention Policy

Location of Records

HIV and HCV records and reports shall be kept in the patient's medical file, if there is one, to ensure health care providers have access to all relevant data when providing patient care. Separate HIV or HCV files shall not be kept. If there is no medical file, records must be kept confidential.

Record Retention Schedule

The NDDoH does not have requirements for record retention at CTR sites. CTR sites are encouraged to establish their own record retention policy. If records are kept electronically, there is no recommendation to keep additional paper records of HIV or HCV records. Data entered into Maven is kept for an indefinite period of time.

Confidentiality

All patient information collected for the CTR program shall be considered protected health information (PHI). All PHI is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule. All CTR sites should ensure that staff are properly trained in maintaining and protecting PHI.

Note: North Dakota Century Code (NDCC 23-07-21) indicates an individual who releases or makes public confidential information may be found guilty of a class C felony. NDCC 23-07-02.2 addresses breaching confidentially of an individual's HIV seropositivity status. According to this NDCC, anyone breaching this confidentiality is guilty of a class C felony (5 years and/or $5,000).

Viral Hepatitis Vaccine

All CTR sites enrolled in the Vaccines for Children (VFC) program through the Immunization Program are eligible to receive adult viral hepatitis vaccine. Twinrix, single antigen hepatitis A and single antigen hepatitis B vaccine are available through the CTR program. The vaccine is available to CTR sites free-of-charge. Contracted CTR sites are also able to request reimbursement for vaccine administration. Current rates of reimbursement are equal to that of the Medicaid administration fee. This fee is located on the reimbursement worksheet in PRS.

All clients at-risk for hepatitis C are recommended to be vaccinated for hepatitis A and B. Thus, all clients whom are tested for hepatitis C should also be screened for a history of hepatitis A and hepatitis B vaccination and/or history of or current infection. If the client has no prior history of hepatitis A or B vaccination and/or history of or current infection, appropriate viral hepatitis vaccine should be offered to the client. CTR sites should strive to ensure that all clients receive a completed vaccine series. To remind patients of subsequent doses required to complete the series, CTR sites could use reminder phone calls, letters, post cards or even utilize incentives when the client comes in for additional doses in the series.

The vaccine in the CTR program is considered 317 vaccine, thus individuals receiving the vaccine must meet the eligibility requirements of the immunization program. Eligible clients include that are one of the following:

1. Medicaid eligible
2. Uninsured
3. American Indian or Alaska Native: As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603)
4. Underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC - eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.

All clients receiving vaccine provided at the CTR sites must be entered in the North Dakota Immunization Information System (NDIIS) along with documentation of the appropriate vaccine lot number and other information required by the NDDoH Immunization Program. Contact the Immunization Program to request NDIIS access information.

All CTR sites that are VFC providers may order adult hepatitis vaccine the same way that other routine VFC vaccines are ordered for your agency. If you are unsure how your agency orders vaccine, please contact the immunization coordinator at your agency. Agencies do not need approval from or notify the CTR program if you are ordering hepatitis vaccine.

CTR sites are responsible for ensuring in stock vaccine does not expire. If the vaccine at a CTR site is going to be expiring soon, the CTR site should contact the HIV.STI.Hepatitis Prevention Coordinator for

assistance in finding a facility that would be able to use the vaccine prior to expiration. CTR sites should do this notification at least three months prior to their vaccine expiring to ensure adequate time to arrange for transfer to another facility. Sites that have wasted doses of vaccine may not receive vaccine in the future as a CTR site.

Although the CTR program does not provide HPV vaccine, all CTR sites are recommended to include the offering of that vaccine as part of their comprehensive sexual health services. CTR sites are excellent locations to vaccinate at risk individuals for HPV that may have been missed in their adolescent years. Contact the Immunization Program at 701.328.2378 for additional information on HPV vaccine and the availability of 317 HPV vaccination.

Staff Development and Training Policy

New Employee Training Requirements

The Division of Sexually Transmitted and Bloodborne Diseases does not certify or license CTR site personnel to be able to perform certain duties needed to execute the activities associated with being a CTR site. CTR sites are responsible for ensuring that their staff have the appropriate licenses and/or credentials for their role in the CTR program. All CTR staff must adhere to the training requirements of the NDDoH. The following are requirements that should be completed within 60 days of hire for CTR staff based on their role within the program:

Required Training	Role Required for This Training
1. Watch online rapid training videos a. OraQuick® Rapid HCV Video: orc.orasure.com/default.aspx?pageid=1995 b. Chembio SURE CHECK ® HIV 1/2 Assay: **SURE CHECK® HIV 1/2 Assay USA – Chembio Diagnostics, Inc.**	**Tester**
2. Read package inserts for HIV and HCV testing devices and controls.	**Tester**
3. For hepatitis C rapid testing, view hepatitis C visual reference panel.	**Tester**
4. Receive training on rapid test performance by qualified individual. ***Note**: Only a new CTR site needs to be trained by the NDDoH; otherwise all new employees can be trained by a qualified (i.e. previously trained) employee.*	**Tester**
5. Read **Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings published by CDC.** *MMWR* 1988; 37(24): 377 to 388.	**Tester**
6. Read CTR manual.	**Tester & Counselor**
7. Watch the following presentations (available at www.health.nd.gov/HIV/CTR) • HIV 101, Viral Hepatitis 101, STD 101, Counseling Overview • 0.5 CEUs are available for each of these ½ hr. presentations.	**Counselor**
8. View *Delivering HIV Rapid Test Results From the Field.* DVDs are available from the HIV.STI.Hepatitis Prevention Coordinator.	**Counselor**
9. View Maven video tutorial and read CTR Maven Manual, both available at www.health.nd.gov/HIV/CTR.	**Maven Data Entry Staff**

Optional: Participate in role playing exercise. Role playing exercises are extremely helpful in practicing asking open vs. closed ended questions. Role playing exercises also provide valuable insight into areas of the counseling and client education that counselors need to prioritize. Nonverbal communication cues can also be observed during role playing exercises. An example of a role play exercise is available at: www.health.nd.gov/HIV/CTR.

Continuing Education

Every two years, it is required that CTR staff complete the following requirements based on their role in the CTR program:

Required Training	Role Required
1. Ensure Test Competency for Rapid HIV and HCV Testing.	**Tester**
2. Review Current CTR Manual.	**Tester & Counselor**
3. View three presentations or attend one conference on HIV, STI or HCV every two years.	**Counselor**
4. Maven data entry review. This training will be periodically conducted by HIV.STI.HCV Prevention Coordinator.	**Maven Data Entry Staff**

The CTR site is responsible for collecting and maintaining records on all staff. Staff training records need to be retained for at least two years as these records will be reviewed by HIV.STI.Hepatitits Prevention Coordinator during the CTR site visit. A staff development and training form is available at www.health.nd.gov/HIV/CTR.

HIV Prevention and Viral Hepatitis Site Visit

All CTR sites will have a site visit conducted by the HIV.STI.Hepatitis Prevention Coordinator once every three years. The goal of these sites visits is to ensure compliance with protocols and policies from the CTR program. These site visits will highlight strengthens and areas of improvement for each CTR site. All site visits will be coordinated at least three weeks in advance with the point of contact indicated for each site.

The following is minimum list of items that will be discussed at each site visit:

1) **Staff Development and Training**
   - Documentation of staff completing training requirements.
   - Note: CTR shall provide a list of employees that were new employees since the previous site visit and a list of employees that were due for continuing education.
2) **CTR Site Staff Assessment**
   - All current staff of the CTR site will need to attend a short presentation and review an assessment to ensure all staff are educated about CTR site policies and procedures.
3) **Testing Data and Submission**
   - Goals for performance standards and metrics.
   - Target population being tested and missed.
   - Timeliness and completeness of data submission.
   - Reporting of positive rapid and confirmatory HIV and HCV test results.
4) **Quality Control**
   - Control and temperature logs.
   - Control and test kit storage and handling.
5) **Testing Protocol**
   - Risk assessment.
   - Documentation of consent.
   - Documentation of test results.
   - CLIA Certificate of Waiver. A copy of current waiver will be requested.
6) **Vaccination**
   - Doses in NDIIS.
   - Completion of series.
7) **Educational Materials**
   - Availability of brochures, safe sex kits, condoms, etc.
8) **Referral Services**
   - Referrals offered by facility to both high-risk negative patients and those diagnosed with HIV or HCV.
9) **Community Outreach**
   - Efforts made or desired by the CTR site to increase community education or awareness.

Quality Management and Quality Improvement

The purpose of the quality management portion of the CTR program is to assess current practices and ensure best practices are being followed to offer high quality sexual health services at CTR sites. Quality management metrics can be used to identify areas for quality improvement, areas in which services may be delivered more efficiently and effectively. Also, CTR sites can request technical assistance to ensure that desired target outcomes are met and there is continued success of the CTR program. A quarterly report will be sent to CTR sites on these quality management metrics.

The following are the goals and performance standards of the CTR program:

Goal	Performance Standard	Measure	Data Source	Target
CTR Services Provide Tests to People At-Risk	Tests are Provided to Individuals At-Risk or are from Disproportionately Affected Populations.	Proportion of Total Tests That Were Performed Among At-Risk Populations.	Data Submissions in Maven	90% of HIV Tests Performed are Among At-Risk Populations.
				90% of HCV Tests Performed are Among At-Risk Populations.
	Individuals Tested More Than Once per Year are at High-risk for HIV or HCV.	Proportion of Total Tested More Than Once per Year That Were Performed Among High-Risk.	Data Submissions in Maven	80% of Repeat HIV Tests are Among High-Risk Populations.
				80% of Repeat HCV Tests are Among High-Risk Populations.
CTR Sites Educate Individuals About PrEP and Provide Referrals	Individuals Tested for HIV Have Heard of PrEP	Proportion of Total Tested for HIV that Have Heard of HIV PrEP	Data Submissions in Maven	75% of Those Tested for HIV Have Heard of HIV PrEP
	Individuals Tested for HIV are Screened for PrEP	Proportion of Total Tested for HIV that are Screened for PrEP Eligibility	Data Submissions in Maven	100% of Those Tested for HIV are Screened for PrEP Eligibility
	Individuals at High-Risk for HIV are Referred to PrEP Services	Proportion of High-Risk Individuals that were Tested for HIV that were Referred to PrEP Services	Data Submissions in Maven	80% of Those at High-Risk for HIV are Referred for PrEP Services

Goal	Performance Standard	Measure	Data Source	Target
CTR Services Identify People Who are HIV and/or HCV Positive and Don't Know Their Status	CTR Sites Maintain a Seropositivity Rate Consistent with CTR Program Standards	Proportion of Total Tests That Had Confirmatory Positive HIV Test Results or Confirmatory HCV Antibody or RNA Positive Test Results.	Data Submissions in Maven	HIV: 0.5% Seropositivity Rate.
				HCV: 5.0% Seropositivity Rate
	Counselors Give Rapid Test Results to Individuals in a Timely Manner.	Proportion of Total Rapid Tests Results Provided to Clients Within 48 Hours of Specimen Collection.	Data Submissions in Maven	95% of All Rapid Test Results are Provided Within 48 Hours.
	Counselors Give Confirmatory Test Results to Individuals in a Timely Manner.	Proportion of Total Rapid Tests Results Provided to Clients Within 3 Days for HIV and 7 Days for HCV Specimen Collection.	Data Submissions in Maven	100% of All Confirmatory Test Results are Provided within 3 Days for HIV and 7 Days for HCV.
Link HIV and HCV Positive Individuals to Care and Services	Individuals Newly Diagnosed with HIV or HCV are Linked to Medical Care.	Proportion of Individuals Confirmatory Positive for HIV or Current HCV Infection that are Linked to Care and Attend a Medical Care Appointment within 90 Days of Result Notification.	Data Submissions in Maven; NDDoH Surveillance System; Health Information Network	90% of Individuals Diagnosed with HIV are Linked to Care and Attends a HIV Medical Care Appt. within 90 Days.
				40% of Individuals Diagnosed with Current HCV Infection are Linked to Care and Attends an HCV Medical Care Appt. within 90 Days
Link HIV and HCV Positive Individuals to Care and Services	Individuals Diagnosed with HIV are Linked to Partner Services within 2 Weeks of Diagnosis.	Proportion of All Confirmatory Positive HIV Patients Linked to Field Epidemiologists for Partner Services	Data Submissions in Maven; NDDoH Surveillance System	100% of Newly Diagnosed HIV Positive Cases are Linked to Partner Services within 2 Weeks of Diagnosis.
	Individuals Diagnosed with HIV are Referred to Medical Case Management within 2 Weeks of Diagnosis.	Proportion of Individuals Diagnosed with HIV that were Referred to Medical Case Management	Data Submissions in Maven Ryan White Program	100% of Newly Diagnosed HIV Cases Referred to Medical Case Management within 2 Weeks of Diagnosis.

Goal	Performance Standard	Measure	Data Source	Target
CTR Counselors will Provide High Quality Services	CTR Staff Accurately Interpret Test Results.	Proportion of Staff Performing Rapid Testing that are Trained and Proficient.	Training Records, Reviewed at Site Visit.	100% of CTR Staff are Appropriately Trained and Maintain Proficiency in Rapid Testing.
	CTR Counselors have Received Training to Deliver Results and Provide Prevention Counseling.	Proportion of Counseling Staff Properly Trained in Delivering Results and Providing Counseling.	Training Records, Reviewed at Site Visit.	100% of Counselors are Appropriately Trained to Deliver HIV and HCV Results and Prevention Counseling.
	Individuals At-Risk for HIV and/or HCV are Tested Appropriately.	Proportion of All Individuals Screened for HIV, HCV and other STIs without Missed Opportunities.	Data Submissions in Maven	90% of Individuals Screened at CTR Sites are not Identified as a Missed Opportunity for HIV, HCV, Chlamydia, Gonorrhea or Syphilis Testing
CTR Sites are Compliant with Contract Requirements	CTR Events are Complete in MAVEN.	Proportion of CTR Events Submitted with all Required Fields Complete.	Data Submissions in Maven	95% of CTR Events have all Required Fields Complete.
	Requests for Reimbursement are Submitted Timely and with Required Documentation.	Proportion of All Reimbursement Requests Submitted Timely and with Appropriate Documentation.	PRS.	80% of all Reimbursement Requests Submitted by the 15th of the Following Month and with Required Documentation.
	CTR Sites Shall Submit all CTR Events in Maven Timely.	Proportion of CTR Events Submitted within 30 Days of Session Date.	Data Submissions in Maven	80% of CTR Events Submitted within 30 Days of Session Date.
	CTR Sites Report Positive Rapid and Confirmatory Results Timely.	Proportion of All CTR Positive Rapid or Confirmatory Results that were Reported Timely.	Data Submissions in Maven; NDDoH Surveillance System	95% of Positive Rapid and Confirmatory Results were Reported Timely, HIV within 24 Hours and HCV within 7 Days, by the CTR Site

Grant Awards & Contracts for CTR Program

Once per year, the HIV.STI.Hepatitis program awards funds to CTR sites. To receive funds, sites must submit an application to participate in the program for the next upcoming calendar year. This grant opportunity is typically made available in November or early December each year. The HIV.STI.Hepatitis Program distributes the grant notice to all current sites and other potential partners as soon as the grant notice is made available. Contracts and funding will be awarded for the time period January 1 - December 31.

In the yearly application, sites are required to submit a project narrative and proposed budget that focuses on accomplishing the goals and scope of the CTR program. The CTR program is designed to screening individuals for HIV and HCV who are at risk for infection and are uninsured and underinsured at no cost to the clients. For clients who are insured and at risk, CTR sites may use the supplies of the CTR program, however the cost of counseling and test administration should be billed to that patient's insurance and not billed to the CTR program. The project narrative may also include supplemental activities of the CTR program include providing viral hepatitis vaccination and linkage-to-care for individuals diagnosed with HCV.

The funding amount awarded to CTR sites is variable from year to year based on federal and state funding. CTR sites are awarded funding based on their submitted application and their capacity to offering screening for HIV and HCV. CTR sites may use their awarded dollar amount for reimbursement of counseling sessions, blood draws, confirmatory testing fees, hepatitis vaccine administration fees, HCV linkage-to-care activities and other related expenses. The current reimbursement rate for these activities is found on the CTR Request for Reimbursement Form.

Items not included in the funding awarded to the CTR site include rapid HIV and HCV test kits and controls, blood draw supplies and viral hepatitis vaccine. These items are available to contract and non-contracted CTR sites free-of-charge at any time if supplies/funding is available.

Non-Contract Partners

Sites may choose to be in the CTR program as a non-contract partner. Non-contract partners do not receive funding from the NDDoH. Thus, these sites are not reimbursed for counseling sessions, blood draws, confirmatory fees, hepatitis vaccine administration fees, HCV linkage-to-care activities or other related expenses.

All non-contract partners are still eligible to receive free rapid HIV and HCV test kits and viral hepatitis vaccine. In return, all policies and procedures must be followed within this manual, including the submission of data on every rapid HIV and/or HCV test performed. All non-contract partners are required to sign a Memorandum of Understanding (MOU) when initiating as a non-contract partner.

Sites may choose to join the CTR program at any time during the year as a non-contract partner. Also any site that submits an application, but is not awarded funds, may still choose to be in the CTR program as a non-contract partner. Non-contract partners are all eligible to apply for grant funds in the next calendar year.

Reimbursement for Services at CTR Sites

All contract partners are eligible to receive reimbursement for certain allowable expenses. Those expenses include:

- Rapid Testing
  - HIV & HCV Rapid Test with Counseling
  - HIV Rapid Test with Counseling
  - HCV Rapid Test with Counseling
- HIV/HCV Confirmatory Testing
  - Blood Draw
  - HIV Laboratory Test
  - HCV Antibody Laboratory Test
  - HCV RNA Laboratory Test
  - Counseling Sessions for Confirmatory Results
- HAV/HBV Vaccination Administration Fee
- Outreach Events
  - Rapid Testing for HIV/HCV.
    - ***Note:*** *Reimbursement is lower for rapid testing at outreach events.*
- Travel
  - Per diem, lodging and mileage are reimbursable for CTR related travel, ex. workshops or conferences
- HCV Linkage-to-Care
  - Hours of time spent on linking-to-care for individuals diagnosed with hepatitis C
- Additional Expenses
  - Supplies, incentives, Facebook advertising, educational materials, etc.
  - Contact the HIV.STI.TB.Hepatitis Program Manager if there are questions on approved additional expenses

To submit reimbursement for the above expenses, CTR sites are required to submit a completed reimbursement form on a monthly basis to the North Dakota Department of Health HIV.STI.TB.Viral Hepatitis Program Manager via the Program Reporting System (PRS). The reimbursement form details the current level of reimbursement for each activity and must be included as an attachment to the request for reimbursement in order for it to be processed. This document serves as the monthly progress report for each site. The reports are due 15 days after the end of the month. If reimbursement is not requested for the month, a report should be submitted showing a zero amount request to ensure consistent requests. The final expenditure report ending December 31st must be received by February 15th.

New users to the PRS system can request a login here. Please contact the HIV.STI.TB.Hepatitis Program Manager for additional instructions on submitting reimbursement expenses in PRS.

Billing for CTR Services

CTR sites are encouraged to bill insurance for HIV and HCV testing and counseling. By billing for services, CTR sites may increase their revenue for these services. Rapid tests can still be used on client's whose insurance is billed for an office sites or counseling session. If grant funds are unavailable or the client is not at risk, CTR sites may charge the client for counseling, confirmatory testing and other expenses as long as clients are not billed for the rapid test. If CTR program rapid testing supplies are used, even if the client is billed for the counseling session, event data must still be reported in Maven.

HIV and HCV Testing at Outreach Events

CTR sites can partner with NDDoH Division of Sexually Transmitted and Bloodborne Diseases to coordinate HIV, STI and hepatitis C testing at various locations across North Dakota such as at health fairs, homeless shelters, veteran's events, etc. Outreach should target at-risk populations. **All outreach events should be submitted for NDDoH approval at least 14 days prior to scheduled event.** Outreach events may not be approved to test populations not at risk, ex. baby boomer screening events for HCV.

Outreach events are a key component in HIV, STI and hepatitis prevention as high-risk individuals may not access testing and education in typical healthcare settings. Awareness days or months are excellent opportunities to host events. Some commonly used awareness events include:

- April: STI Awareness Week
- May: Hepatitis Awareness Month
- May 19: Hepatitis Testing Day
- June 27: National HIV Testing Day
- December 1: World AIDS Day
- Here is a list of additional awareness events.

When planning an outreach or testing event special considerations are needed for ensuring appropriate staff are available, event advertisement, ensuring confidentiality, specimen collection, result delivery, and other logistics concerns. The HIV.STI.Hepatitis Prevention Coordinator can help in organizing and hosting an event. Free STI testing may be available at outreach events, but sites must contact the HIV.STI.Hepatitis Prevention Coordinator prior to the event.

An outreach toolkit is available at www.health.nd.gov/HIV/CTR. This toolkit discusses and provides ideas and considerations for the organization and management of an outreach event. After the outreach event, CTR sites shall report the number tested and positivity for HIV, HCV, chlamydia, gonorrhea or other offered screenings to the HIV.STI.Hepatitis Prevention Coordinator: Please contact the HIV.STI.Hepatitis Prevention Coordinator with any questions regarding outreach testing.

Ordering Prevention and Testing Supplies

All supplies, including condoms, educational materials, rapid tests, controls and other prevention supplies are ordered by submitting an online order form. Orders are typically processed within 1 to 2 weeks. Longer delivery times may be imposed when the weather is too cold or hot. Many prevention supplies, including HIV and hepatitis C rapid tests may not be shipped in extreme cold or hot temperatures.

Note: *The Division of Emergency Preparedness and Response (EPR) is responsible for shipping out condoms and rapid tests and controls. EPR only processes supplies once per week, usually on Tuesdays. The Division of Sexually Transmitted and Bloodborne Diseases will provide confirmation messages for orders of rapid tests and controls as well as confirming those supplies were delivered to ordering agencies.*

CTR Services at Correctional Facilities

Correctional facilities are eligible to be contract and non-contract CTR sites. Contracted CTR sites are also able to provide CTR services at correctional facilities.

Screening

There are two North Dakota Century Code (NDCC) subsections that describe requirements for HIV and STI screening in correctional facilities. Below are the subsections of the North Dakota Century Code:

- **23-07-07.5. Testing of inmates and convicted individuals for exposure to the human immunodeficiency virus - Reporting - Liability.** ***Note: Refer to page 9 of this manual for full text of this subsection.***
- **23-07-08. Persons in prison examined and treated for sexually transmitted diseases. Every person convicted of a crime who is imprisoned fifteen days or more in a state, county, or city prison must be examined for sexually transmitted disease and, if infected, must be treated therefor by the health officer within whose jurisdiction the person is imprisoned.**

Although century code only requires HIV testing of inmates if there were convicted and imprisoned for fifteen days or longer, all inmates regardless of length of imprisonment or conviction status can be tested for HIV and/or HCV in the CTR program. Although STI testing is not included in the CTR program, inmates should also be screened for STIs, including chlamydia, gonorrhea and syphilis.

Counseling

Counseling expectations for inmates are not required for screening in correctional facilities. If inmates are only screened for HIV and/or HCV because of the century code, risk-reduction counseling may not be appropriate. Also, the time available per client may not be available for counseling following screening in the correctional facility. Because of these limitations, the reimbursable amount for counseling/testing in a correctional facility is reduced compared to services in other CTR settings.

The CTR site can determine the length and content of a counseling session in a correctional facility. It is recommended that providing education about disease transmission and prevention and understanding of tests results be prioritized in the counseling session.

Disclosure of HIV & Viral Hepatitis Status of an Inmate

It may be the duty of the counselor to disclose the HIV, HBV or HCV status (protected health information, PHI) of an inmate to medical personnel providing direct care to the individual, the administrator of the correctional facility or as otherwise authorized by law. There should not be any disclosure beyond that, and to the extent there is, disclosure should only be made based on legitimate penological purposes, or as stated in the HIPAA privacy rule. Within the jail, further disclosure is up to the policies of the administrator and should be on a strictly need to know basis.

Except as otherwise provided by NDCC 23-07.5, the results of a HIV or HCV may be disclosed only as follows per the U.S. Department of Health and Human Services HIPAA privacy rule:

To respond to a request for PHI by a correctional institution or a law enforcement official having lawful custody of an inmate or others if they represent such PHI is needed to provide health care to the individual; for the health and safety of the individual, other inmates, officers or employees of or others at a correctional institution or responsible for the transporting or transferring inmates; or for the administration and maintenance of the safety, security, and good order of the correctional facility, including law enforcement on the premises of the facility (45 CFR 164.512(k)(5)).

Linkage-to-Care for Hepatitis C

All CTR sites screening for hepatitis C are encouraged to offer linkage-to-care services for individuals diagnosed with acute or chronic HCV infection. The goal of linkage-to-care services is to ensure the client is receiving appropriate medical care by attending their first medical appointment after their diagnosis. For those diagnosed with HCV, the services that would be considered linkage-to-care include, but are not limited to:

1) Scheduling referral appointments.
2) Following-up with client or referral provider after their appointment.
3) Additional counseling sessions to ensure client is understanding HCV and their diagnosis.
4) Follow-up with client throughout care, i.e. HCV treatment or substance abuse treatment.
5) Assisting clients with overcoming barriers to accessing care, ex. navigation to patient assistance programs or signing up for health insurance.

All time spent on linkage-to-care for hepatitis C must be documented within Maven in order to request reimbursement. Additional information on this required document is found within the Required Data Elements and Maven User's Guide. CTR sites may provide linkage-to-care services for individuals that were diagnosed with HCV at a location other than a CTR site. Even if the client was not tested at the CTR site, an event in Maven should be created to properly document the linkage-to-care activities.

CTR sites are only reimbursed for linkage-to-care services for those diagnosed with HCV. Linkage-to-care services are available to individuals diagnosed with HIV from Ryan White Case Managers and Field Epidemiologists; CTR sites should refer individuals diagnosed with HIV to those providing linkage-to-care.

Reimbursement

The confirmatory counseling is reimbursed at a rate of $30.00 per session. This session is expected to last approximately one hour. Linkage-to-care services would then include any time beyond the one-hour confirmatory counseling session. CTR sites are reimbursed for linkage-to-care services by the hour in a minimum of 15-minute increments. This expense is included on the CTR reimbursement form.

Summary of CTR Responsibilities

The following is a summary of the forms and/or responsibilities within a CTR site:

1. **Program Design.**
    a. Design program to comply with CTR program goals and quality management metrics.
    b. Follow current CTR program policies and procedures.
2. **Risk Assessment.**
    a. Screen all clients for HIV and HCV risk behaviors.
    b. Utilize risk assessment form, HIV/HCV test form or similar form to collect information. Sites may use electronic medical record instead of maintaining a paper record.
    c. Submit all required information into Maven.
3. **Counseling.**
    a. Provide client-centered risk reduction counseling when appropriate.
4. **Rapid Testing.**
    a. Ensure quality assurance on rapid test kits.
        i. Store test kits in approved temperatures.
        ii. Perform controls on test kits when indicated.
        iii. Document and report control performance within 7 days.
        iv. Submit monthly temperature logs for the storage of controls.
        v. Report invalid test results.
        vi. Maintain competency for staff performing rapid HIV and HCV testing.
        vii. Report all positive rapid results to the Division of Disease Control.
5. **Confirmatory Testing.**
    a. Ensure site is following guidelines from the NDDoH Division of Microbiology for proper specimen collection and handling.
    b. Follow CTR designated testing algorithms.
    c. Report all positive confirmatory results to the Division of Sexually Transmitted and Bloodborne Diseases.
    d. If able, provide linkage-to-care for individuals diagnosed with HCV.
6. **Staff Training.**
    a. Complete the Staff Development and Training worksheet for all new employees and employees requiring continuing education.
7. **Hepatitis Vaccination.**
    a. Order vaccine as needed through immunization program.
    b. Ensure vaccine supply does not expire before it is utilized.
    c. Enter doses administered into NDIIS.
8. **Reimbursement.**
    a. Contract sites shall submit monthly reimbursements timely in PRS.
9. **Grant.**
    a. Submit grant application for CTR program in November/December each year.