2012

Colorado Comprehensive HIV Testing Plan

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Executive Summary

For the first time in the past three decades of the HIV epidemic, the White House formulated the National HIV/AIDS Strategy (NHAS) released in July 2010. The NHAS provides a comprehensive roadmap to reduce and control the impact of HIV infection and care in the United States. In addition to clear priority targets for HIV prevention, the NHAS calls for close cooperation between government agencies, and public and private partners to combine efforts toward a common purpose.

The core principles of the strategy include ambitious objectives for HIV prevention in the U.S. for the next 5 years:

- To lower the annual number of new infections by 25 percent.
- To increase the number of people living with HIV who know of their infection from 79 to 90 percent.
- To reduce the HIV transmission rate, a measure of annual transmissions in relation to the number of people living with HIV, by 30 percent.
- To increase the percentage of newly diagnosed people linked to care within 3 months from 65 to 85 percent. The NHAS emphasizes the connection between prevention, care, and treatment in reducing new infections and improving the health and survival of people living with HIV.
- To increase the proportion of HIV-diagnosed gay and bisexual men, African Americans, and Latinos with undetectable viral load by 20 percent.

In order to strengthen the impact of HIV prevention efforts in reducing new infections, the NHAS promotes the prioritization of HIV prevention efforts in the communities where HIV is most heavily concentrated; the expanded and targeted use of effective combinations of evidence-based HIV prevention approaches and the renewed effort to educate all Americans about the threat of HIV and how to prevent it. Towards that end, the NHAS recognizes the critical importance of reducing disparities in HIV prevention and care and in reducing the stigma and discrimination associated with HIV.

CDPHE has begun the process of aligning its prevention efforts to better support the goals of the NHAS. HIV prevention is modeled after the test and treat approach designed to reduce and ultimately control the epidemic. While sharing many characteristics with the rest of the nation, the profile of the HIV epidemic in Colorado is distinct. Although the State subscribes to the principles of the NHAS, it recognizes that the implementation of the national strategy requires unique tailoring to geographic variability and social realities of the State. In pursuit of a test and treat formula adapted to Colorado, the CDPHE contracted with John Snow Inc. (JSI) to facilitate the work of a panel of experts to inform this Colorado Comprehensive HIV Testing Plan and Guidance. A stakeholder process comprised of leaders in the field of HIV around the State was convened in March 2012 to advise on the optimal approaches to conduct the test and treat strategy to stem the HIV epidemic. The HIV Testing Plan and Guidance sponsored by the Colorado Department of Public Health and Environment (CDPHE) is conceived to be a dynamic document that will provide a coordinated roadmap to public and private stakeholders engaged in healthcare delivery and HIV prevention services. It is anticipated that knowledge gained from the test and treat experience in Colorado will be instrumental to further refine the plan to contribute to the achievement of the stated vision of the NHAS:

"***The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination."***[1]

The Colorado Comprehensive HIV Testing Plan

The 2012 Colorado Comprehensive HIV Testing Plan (hereafter referred to as the HIV Testing Plan) has been developed to ensure that, as the State continues to respond to the HIV epidemic, it does so in a coordinated fashion across all service providers, ensuring the most effective and efficient use of available resources. It is intended to be a living document, and is supported by the Colorado Comprehensive HIV Testing Guidance (hereafter referred to as the HIV Testing Guidance) which provides context to the HIV epidemic in Colorado and to the recommendations in this plan.

The HIV epidemic is constantly evolving, as is the nation's response to it. On both national and local levels, efforts to reduce HIV-related health disparities, reduce the rate of new infections, increase the number of persons aware of their HIV status (positive or negative), and increase the number of persons linked to and retained in care, will continue to adapt to changing environments, both political and social.

In light of evolving national leadership from the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the Office of the President of the United States, Colorado will continue to work within a coordinated national response while advancing policies in the best interest of local providers and residents. The HIV Testing Plan is intended to provide key guidance to all agencies providing HIV testing services throughout Colorado, on how HIV testing efforts could be managed throughout the State - in rural, urban, and reservation-based settings, and in both clinical and non-clinical settings - regardless of the manner in which those testing services are funded.

Staff at the Colorado Department of Public Health and Environment (CDPHE) worked closely with seventeen local HIV experts (listed in the Acknowledgements) to develop this plan and guidance, which reflects both national guidelines and guidelines specific to Colorado. In addition, this document is supported by the goals and objectives set forth by the CDPHE's annual HIV Prevention Operational Plan. The Operational Plan can be accessed at http://www.cdphe.state.co.us/dc/HIVandSTD. The CDPHE will conduct an annual evaluation of the plan based on these operational targets.

This HIV Testing Plan is organized into the following sections:

1. A tiered approach to testing
2. Universal guidelines for all settings
3. Additional guidelines for HIV testing in clinical/healthcare settings
4. Additional guidelines for HIV testing in non-clinical/non-healthcare settings
5. Guidelines for laboratories
6. Special considerations for rural settings

Section 1. A tiered approach to testing

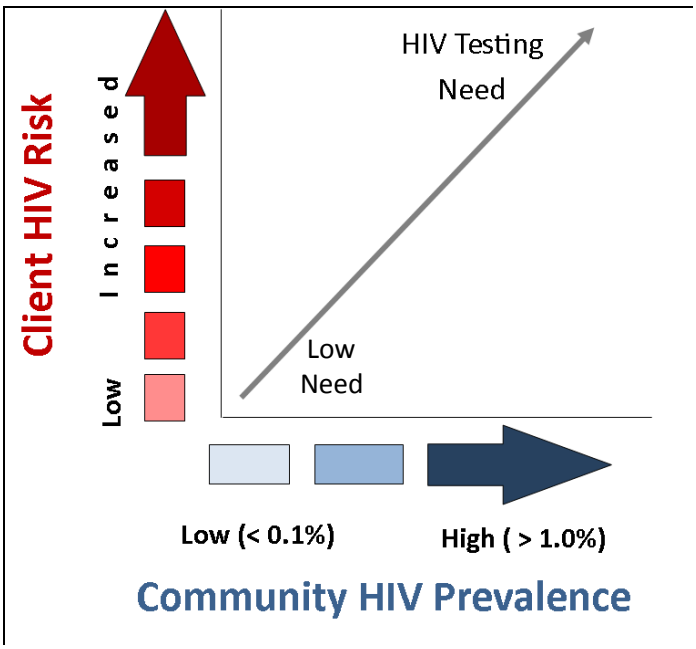
These guidelines acknowledge that:

- Every agency serves a unique client base;
- Every agency is situated in a unique setting, be that rural, urban, or reservation-based; and
- Every agency has a unique funding structure with varying degrees of resources.

Every institution/agency (hereafter referred to as agency), clinical or non-clinical, is encouraged to develop a unique HIV testing strategy to best suit the needs of their communities. While individual strategies may vary based on resource constraints, such as funding, staff expertise, staff time, the

volume of HIV tests available, etc., adherence to the Universal Guidelines for HIV Testing described in the section below is recommended.

As agencies develop HIV testing strategies to align with local resource constraints, the provision of testing services may be targeted in order to maximize limited resources. Testing services may be targeted based on, a) community prevalence and b) risk factors. These indicators, however, are not mutually exclusive. As individual risks or HIV prevalence in the community increases, so does the need to provide HIV testing services.



Described below are possible HIV testing strategies. To determine the best agency strategy(ies), given available resources, agency setting and communities being served, also below are tiered approaches broken down by HIV prevalence and HIV risk. These recommendations were guided by input from the panel of experts convened to help create this plan, and aim to provide a tailored approach to needs and resources in Colorado, which at times differ with the more general guidelines provided by the CDC.

- HIV Testing Strategies - [2,3]

HIV testing strategies guide how the agency or the person conducting the test decides who will be tested. Testing strategies include HIV screening/universal testing, which is population-based; and targeted testing, which is based on a person's characteristics.

HIV Screening
A testing strategy that involves testing persons regardless of whether they have a recognized behavioral risk or presence of signs or symptoms of HIV infection. This might be accomplished by testing all persons in a defined population or by selecting persons with specific population-level characteristics (e.g., demographic, geographic area).

Note:
- HIV screening is different from a **risk screen**, which is a brief evaluation of behavioral HIV risk factors used to decide who should be recommended for HIV testing, interventions, or other services.
- HIV screening is most likely conducted in health-care settings.

Targeted testing
A testing strategy that involves testing persons based on characteristics that increase their likelihood of being infected with HIV, as defined by local and/or state data. These characteristics can include the presence of sexually transmitted infections, behavioral risks, pregnancy or attendance at venues frequented by high-risk persons.

Note:
- To assess a person's risk, a risk screen or a risk assessment may be necessary.

Risk-based targeted testing
Using a risk scale or risk assessment to limit the number of tests administered by identifying and testing only those at greatest risk for HIV infection.

Diagnostic testing
Testing that is initiated for a person with clinical signs or symptoms consistent with HIV infection.

– Ascertaining Prevalence –

Prevalence Based on Geographic Data:
All agencies involved in the provision of HIV testing services are encouraged to obtain the geographic distribution of HIV prevalence data of the local communities served. Local HIV prevalence data is available from the CDPHE or the local health department. An example of localized data would be zip code or city-level data. Generalized data would be state-level data. Agencies are encouraged to defer to the most localized and high quality data available when making decisions regarding who and when to test for HIV based on prevalence.

Within geographic boundaries, it is recommended that prevalence be further catalogued, where possible, according to the following parameters:
- Specific, high risk populations (i.e., MSM and IDUs)
- Gender
- Race/ethnicity
- Poverty level
- Housing status

Prevalence Based on Agency-level data:
All agencies are encouraged to retrospectively analyze or prospectively research the HIV prevalence of the patient/client population served by the agency in the following manner:

- Step 1: Conduct HIV screening or randomized, non-targeted HIV testing until ideally 1,000 clients/patients are tested for HIV. If resources do not allow HIV prevalence to be measured with 1,000 clients/patients, the minimum number of tests recommended is 100.

- Step 2: Determine HIV prevalence in the agency
  - IF the agency finds nine or less positive HIV test results among the 1,000 clients/patients tested, agency-level HIV prevalence rate is below 1.0 percent - zero positive HIV test results for the 100 client/patient base.
  - IF the agency finds ten or more positive HIV test results among the 1,000 clients/patients tested, agency-level HIV prevalence is ≥ 1.0 percent. Among the 100 client/patient base, one or more positive HIV test results would represent an HIV prevalence of ≥ 1.0 percent.
- Step 3: Determine appropriate HIV testing strategy related to prevalence-based testing standards, described below.
- Step 4: Repeat this process every few years or as population served significantly increases or changes.

Recommended Prevalence-Based HIV Testing Standards	
Level 1	Test all persons (ages 13-64) for HIV at agencies with a 1.0% prevalence rate or higher regardless of risk. At agencies with less than 1.0% prevalence, testing decisions are encouraged to be based on risk factors and available resources.
Level 2	Test all persons (ages 13-64) for HIV at agencies with a 0.1% prevalence rate or higher,[4] regardless of risk.
Level 3	All persons (ages 13-64) are tested for HIV, regardless of community prevalence.

For all levels[5]:

- Conduct repeat testing for patients at high risk for HIV at least twice annually (every six months) if accessibility to patients/clients permits it.
- Repeat testing of persons not likely to be at high risk for HIV should be performed on the basis of clinical judgment.

– Ascertaining Risk –

It is recommended that agencies devise a methodology by which to risk screen patients/clients for HIV-related risk factors. Two possible options to ascertain risk for all patients/clients are described below:

Option 1: Using a Basic HIV Risk Screen[6]

- Patients/clients are asked to respond to the following seven questions with 'yes' or 'no' responses:

Since patient/client last got tested for HIV, or 'ever' if s/he was never tested for HIV:

1. Are you a male who has had unprotected sex with other males?
2. Have you had more than one sexual partner at the same time and not used protection?
3. Have you injected drugs or shared injection equipment with others?
4. Have you been in jail or prison?
5. Have you been diagnosed or treated for a sexually transmitted infection, hepatitis or tuberculosis?

6. Have you had unprotected sex with someone you think might be at risk for or infected with HIV? For example, a partner who injected drugs, has been diagnosed or treated for an STI or hepatitis, has had multiple or anonymous sex partners, who is male and has had sex with other men, or has exchanged sex for drugs or money.
7. Have you had non-consensual, unprotected sexual encounter(s)? For example, sexual assault or forced to provide commercial sex services.

- Any person providing an affirmative ('yes') response to *any* of these questions is considered at increased-risk for HIV.
- Refusal to provide a response to any of these questions should be documented. It is encouraged to offer HIV testing to patients/clients who refuse to disclose behavioral risks.
- Mandatory reporting to appropriate authorities is required when a child is subjected to unlawful sexual behavior[7], including sexual contact of a child <15 years old by someone 4 or more years older or a child 15 or 16 years of age by someone 10 or more years older ("consensual" or not). Cases of adult sexual assault/domestic violence are reportable if there are children less 18 years of age present during the act.[8]

Option 2: Using a Behavioral Risk Screening Tool

- A behavioral risk screening tool is an assessment questionnaire with a demonstrated capacity to accurately identify individuals at high risk for HIV according to specific variables.[9]
- One such risk screening tool is the Denver HIV Risk Score, which is currently used at Denver Health and Hospital Authority. For more information about the Denver HIV Risk Score, please refer to the cited article. [10]
- A behavioral risk screening tool should address factors such as age, gender, race/ethnicity, sexual activity (including sex with a male, vaginal intercourse, and receptive anal intercourse), injection drug use, and previous HIV testing.
- Behavioral risk screening results should be documented in the patient/client's medical record or intake form.
- Patients/clients have the right to refuse to participate in the behavioral risk screening. Such refusal should be upheld and documented in the medical record or intake form. It is encouraged to offer HIV testing to patients/clients who refuse to disclose behavioral risks.

Risk-Based HIV Testing Standards	
Level 1	It is recommended that all clients deemed at increased risk for HIV (based on a risk assessment, described above) be tested for HIV. • An annual assessment of increased risk is encouraged, if accessibility to patients/clients permits it.
Level 2	It is recommended that sub-populations known to be at increased risk for HIV, including men who have sex with men (MSM), Black/African American and Hispanic/Latino men and women, and injecting drug users (IDU), be tested for HIV at least every 12 months, if accessibility to patients/clients permits it.
Level 3	It is recommended that all persons between the ages of 13 and 64 be tested for HIV, regardless of risk.[11] ▪ Conduct repeat testing for patients at high risk for HIV at least every six months if accessibility to patients/clients permits it. ▪ Repeat testing of persons not likely to be at high risk for HIV should be performed on the basis of clinical judgment.

Section 2. Universal guidelines for all settings

Some principles of HIV testing should be considered universally applicable to all sites, regardless of funding source, community resources, or on-site service capabilities.

These universal guidelines serve to ensure that there is no difference in the quality of HIV testing and prevention services throughout Colorado, regardless of agency type or location.

The following guidelines are recommended across all settings: rural, urban, reservation-based, clinical and non-clinical.

Minimum HIV testing standards

- An HIV test should be available to all persons seeking a test.
- All persons at increased risk for HIV should be tested at least once every six months.
- All persons between the ages of 13 and 64, being served at agencies with an HIV prevalence rate above 1.0 percent should be tested for HIV.
- All persons attending STI clinics and those seeking treatment for STIs in other clinical settings should be tested for HIV.
- All pregnant women should be tested for HIV.
- Agencies providing HIV testing, should be aware of resources for Hepatitis C testing as well as vaccinating for Hepatitis A and B, especially for populations at increased risk such as injecting drug users (IDU).
- When uncertain about necessity to provide an HIV test, it is recommended that agencies always err on the side of caution: **provide an HIV test!**

HIV testing consent

- The persons receiving an HIV test must: 1) have decision making and emotional capacity, 2) be aware of the testing prior to it being performed, and 3) have the right and opportunity to decline testing. Specific language should be made available to staff providing HIV testing services for general consent that is standardized and meets legal requirements.
- Either verbal or written consent can be used. When using written consent, wording could be as simple as having the patient/client sign after the statement, "I consent to be tested for HIV" or more extensive as that used in the sample *HIV Antibody Test Consent Form* for rapid testing, included in *Appendix A*.

HIV testing technology

- It is recommended that all agencies providing HIV testing services use rapid testing technologies when appropriate, as well as third and fourth generation tests that are more accurate and can diagnose persons within days of HIV exposure, if resources permit.
- HIV testing agencies should ensure proper storage for rapid tests and address staff training.
- It is recommended that agencies using non-rapid conventional testing ensure HIV test results are communicated to patients/clients. Potential methods include:
  - The test site schedules a follow-up appointment with the patient/client to provide test results.
  - The test site provides the patient/client with a telephone number to call to receive the HIV test result.

  - The test site provides incentives to the patient/client to follow-up.
  - The test site provides reminders to the patient/client should contact information be available.
  - If applicable, the test site delivers the test results during a subsequent appointment for other services.

- Whether HIV testing is conducted through conventional or rapid testing technologies, agencies can select from a number of approved testing algorithms included in *Appendix B*.
- An HIV test should be considered positive only after screening and confirmatory tests are reactive. A confirmed positive test result indicates that a person has been infected with HIV.
- The Food and Drug Administration (FDA) approved Home Access HIV-1 tests and OraQuick In-Home HIV tests are a good alternative for persons who would otherwise not get tested. These tests allow consumers to purchase a test kit, collect a sample in private, and either get the result within 20 to 40 minutes with the OraQuick test, or send the sample to a lab for analysis, and call a toll-free number to get the test result with the Home Access HIV-1 test. It is recommended that agencies be aware of FDA approved home HIV testing in order to provide guidance to their patients/clients. In addition, agencies are encouraged to establish a process to ensure confirmatory testing for those persons testing positive, and to link HIV positive persons to care.

Utilization of confidential vs. anonymous testing

- Confidential testing - in which basic client information is documented but kept strictly confidential - is encouraged over anonymous testing.
- Anonymous testing, in which no client information is documented, is only recommended when not providing the HIV test would present a barrier for the person to access HIV testing.
- It is encouraged that the agencies inform all persons seeking an anonymous test that identifying information will be requested in the event of a positive test result, in order to link that person into care.
- Agencies must report all positive tests indicative of HIV infection, including HIV-1 and HIV-2 EIA, Western Blot, Rapid HIV, CD4 and Viral Load tests, to either the state or local health department within seven days of diagnosis. See *Confidential HIV Test Reporting Form* included in *Appendix C*.

Recommended Policies and Procedures

- Agencies providing HIV testing services are encouraged to implement and maintain relevant quality assurance policies and procedures to ensure quality of test results and counseling services, including, but not limited to:
  - Mandatory staff training for those administering HIV testing services
  - Mandatory reporting procedures (communicable diseases and sexual-related crimes)
  - Lab and point-of-care testing protocols
  - Privacy and confidentiality protocols
  - Informed consent
  - Language assistance services
  - Counseling services
  - Communication of HIV test results
  - Referrals to care and other services
  - Record keeping
  - Staff safety

It is important to note that for non-clinical agencies this recommendation applies if the agency is interested in obtaining a Clinical Laboratory Improvement Amendments (CLIA) waiver. All clinical agencies providing HIV testing are required by law to adhere to CLIA regulations.[12]

- Defining and documenting localized linkage to care resources, staff, and processes is recommended in order to ensure seamless linkages to care.

Inclusion of HIV positive persons and at-risk populations

Agencies are encouraged to involve HIV positive patients/clients, as well as relevant negative or unknown serostatus persons from at-risk populations (IDU, MSM, etc.) in the planning, implementation and evaluation of proposed HIV testing programming.

Section 3. Specific guidelines for HIV testing in clinical/healthcare settings

Specific guidelines may be tailored according to either the type of agency providing services or to the needs of the individual communities within which services are offered. An HIV testing strategy should be developed within each agency that is responsive to the needs of the community while respectful of funding and resource constraints, including staff time and expertise.

Guidelines

- An electronic medical record reminder system is recommended to remind providers to ask questions pertaining to behavioral risks and to provide an HIV test as appropriate.
- A separate consent form for HIV testing is not recommended for clinical settings. Consent for HIV testing can be incorporated into the patient's general informed consent for medical care on the same basis as are other screening or diagnostic tests.
- It is recommended that staff providing HIV testing services use standardized language that meets legal requirements to secure general consent, in the client's native language or that oral interpretation be provided.
- Recommendations for HIV testing of pregnant women:
  - It is recommended that all licensed healthcare providers include HIV testing in the routine panel of prenatal screening tests for all pregnant women.
  - It is recommended that refusals to test for HIV be documented in the patient's medical record.
  - It is recommended that pregnant women be tested as early as possible during pregnancy.
  - It is recommended that HIV screening be repeated in the third trimester for women residing in communities with HIV positivity rates ≥ 0.1 percent. Repeat screening in the third trimester is also encouraged for women known to be at high risk for acquiring HIV, specifically:
    - Injecting drug users (IDU),
    - IDU sex partners,
    - Women who exchange sex for money or drugs,
    - Women who are sex partners of HIV-infected persons,

- Women who have had a new or more than one sex partner during the pregnancy, or
- Women who have signs or symptoms consistent with acute HIV infection.

- It is recommended to provide oral or written information on HIV in the patient/client's native language (or orally interpreted), interventions that can reduce HIV transmission from mother to infant, and the meaning of positive and negative test results, are recommended.
- Rapid HIV testing is recommended for all women in labor who do not have documentation of HIV test results.

Additional Considerations

- Patient flow: It is important to consider patient flow in clinical settings to determine where and when HIV testing can be conducted in a confidential and secure fashion.
- Linkage to care: It is recommended that clinical agencies provide seamless linkage to care for people testing HIV positive.
- Partner counseling and referral services (PCRS): Resources and referral networks are encouraged to systematically reach out to the partners of persons newly diagnosed as HIV positive. More information on PCRS can be found in the HIV Testing Guidance.
- Cultural and linguistic responsiveness: It is recommended that staff providing HIV testing services in clinical settings receive yearly training on providing culturally and linguistically sensitive services to address barriers/challenges to testing

Section 4. Specific guidelines for HIV testing in non-clinical/non-healthcare settings

Guidelines

- It is recommended that access to an HIV test be available to any client/patient seeking a test. If an HIV test is unavailable at a particular agency, it is recommended that the client be promptly referred to an agency capable of providing such a test.
- All non-clinical HIV agencies are encouraged to implement and manage an active referral process to facilitate access to HIV care. It is recommended that this process be evaluated and updated annually. See the HIV Testing Guidance for additional information.
- Non-clinical agencies are encouraged to establish relationships with clinical settings in order to provide timely, efficient and active referral services for medical care.
- It is recommended that written protocols for providing HIV testing services also include the following:
  - Privacy and confidentiality: Suggested strategies may include the use of a separated area in a mobile van, utilizing rooms with locking doors, marking a specific room with a 'do not disturb' sign, finding areas that allow for privacy, or providing services in the client's home, among others.
  - Counseling: It is recommended that staff be trained to use risk screening strategies to determine whether or not HIV testing or prevention counseling is appropriate.
  - Testing: Because field conditions can affect HIV test specimens, it is recommended that efforts be devoted to ensure that the selection of HIV testing technology be based on

logistical considerations such as field conditions, transportation and storage of specimen, and the means for clients to receive HIV test results.

- Record keeping: All providers of HIV counseling, testing and referral (CTR) services are advised to develop clear, written protocols for record keeping that address the transportation of client records to and from the outreach site. Developing procedures to ensure that client anonymity is maintained when sought by the client are also recommended.
- Staff safety: Appropriate training is recommended to minimize risks to staff safety.
- Mandatory reporting procedures (communicable diseases and sexual-related crimes): If you learn that a child is subjected to unlawful sexual behavior,[13] including sexual contact of a child < 15 years old by someone 4 or more years older or a child 15 or 16 years of age by someone 10 or more years older ("consensual" or not). Cases of adult sexual assault/ domestic violence are reportable if there are children less than 18 years of age present during the act.[14]

- All non-clinical agencies are encouraged to meet quality standards for the provision of HIV testing services. These quality standards should encompass - at a minimum - administration of the test, storing of the test, reporting of test results, confidentiality, the provision of positive and negative test results, and linkage to HIV care services for HIV positive persons.
- It is recommended that resources for persons testing negative for HIV be identified and provided to person. Such resources include, but may not be limited to:
  - Community-based resources;
  - HIV and STI prevention services;
  - Substance abuse and mental health services;
  - Language assistance and translation services; and
  - Sexual assault recovery sites.
- It is recommended that prevention counseling include discussions of risk, risk reduction strategies and the provision of additional health-related information and resources.
- Approved agencies are encouraged to consider ways in which to confidentially share information surrounding who is in need of linkage to care services in order to collaboratively address barriers to care.
- Cultural and linguistic responsiveness: All staff providing HIV counseling, testing and referral (CTR) in non-clinical settings is advised to receive yearly training on providing culturally and linguistically sensitive services to address barriers/challenges to testing.

Section 5. Guidelines for laboratories[15,16]

- Consistent with Colorado Board of Health rules, all laboratories or persons performing laboratory tests for HIV shall report to the CDPHE or appropriate local department of health, on the appropriate form and within a time period designated by the state department of public health and environment, the name, date of birth, sex, and address of any individual whose specimen submitted for examination tests positive for HIV as defined by the state board of health. Such report shall include the test results and the name and address of the attending physician and any other person or agency referring such positive specimen for testing. An HIV case reporting form is included in *Appendix C*.

- Laboratories shall report every test result that is diagnostic for or highly correlated with or indicates HIV infection, including, but not limited to, any undetectable HIV viral load and HIV genotype testing. The report shall include the name, date of birth, sex and address of the individual from whom the specimen was submitted. Such test results shall be reported by all in-state laboratories and by out-of-state laboratories that maintain an office or collection facility in Colorado or arrange for collection of specimens in Colorado. Results must be reported by the laboratory which performs the test, but an in-state laboratory which sends specimens to an out-of-state referral laboratory is also responsible for reporting the results. The laboratory shall also report the name and address of the attending physician and any other person or agency referring such specimen for testing.
- Report of test results by a laboratory does not relieve the attending physician of his/her obligation to report the case or diagnosis, nor does report by the physician relieve the laboratory of its obligation.

Section 6. Special considerations for rural settings

- Agencies or persons providing HIV testing services in rural settings are encouraged to identify and define unique barriers to care for newly diagnosed HIV positive persons or for individuals at increased risk for whom additional HIV prevention counseling, behavioral counseling, or other services may be appropriate.
- Agencies or persons providing HIV testing services in rural settings are encouraged to ensure that identified barriers are addressed through community based partnerships. Specific focus should be placed on, a) addressing transportation barriers, and b) developing formal linkages with community partners, providing key referral services such as primary care or mental health counseling.
- Linkage to care in rural settings may not happen as seamlessly as it might in urban settings. As such, defining and documenting localized linkage to care resources, staff, and processes is recommended in order to ensure seamless linkages to care.

The Colorado Comprehensive HIV Testing Guidance

Executive Summary

The Colorado Comprehensive HIV Testing Guidance supports and expands on the information presented in the HIV Testing Plan. Information presented in this guidance and the HIV Testing Plan has been compiled from feedback provided by the panel of experts convened for the creation of this plan and guidance (members listed in the Acknowledgements), Colorado Statutes and Regulations, Colorado Department of Public Health and Environment (CDPHE) STI/HIV surveillance data, Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA) guidelines, and the National HIV/AIDS Strategy, among other resources (for a full listing see References).

The Expert Panel developed a set of Core Principles to guide HIV testing in Colorado. These principles are recommended by the panelists and the CDPHE. Though they represent important aspects of HIV testing, they are by no means exhaustive.

Core Principles

Access

- An HIV test should be available and accessible to anyone who wants one.

Addressing barriers

- All efforts should be made to remove barriers to HIV testing. Cost or ability to pay should not be a barrier to receiving an HIV test. In such cases where cost is a barrier from the prospective client's perspective, HIV testing services should be provided for free.

  Additional potential barriers to address include, but are not limited to:

  a. Stigma
  b. Fear of results
  c. Low HIV knowledge
  d. Language, cultural and social differences
  e. Religious beliefs
  f. Mental health/substance use issues
  g. Lack of transportation
  h. Lack of confidentiality

Normalization

- HIV testing needs to become normalized in order to make receiving an HIV test widely acceptable. To accomplish this, stigma must be addressed and reduced through education and awareness.
- Institutions/agencies (hereafter referred to as agencies) should develop outreach and marketing materials appropriate to their target population in a culturally and linguistically appropriate fashion.

Addressing Disparities

- Specific populations should be targeted for HIV testing outreach efforts in order to reduce persistent HIV-related health disparities, including:
  - Men who have sex with men (MSM)
  - Men of color who have sex with men
  - MSM who do not identify as gay or bisexual

- Female partners of MSM
- Women of color
- Youth of color
- Injecting Drug Users (IDU)
- Any other disparate populations

Linkage to Care

- HIV testing agencies should strive to seamlessly transition persons testing positive into comprehensive systems of care.

Partner Services

- A comprehensive system should be in place to ensure that the partners of persons testing positive receive an HIV test and are also linked to care in a timely fashion.

Cultural Responsiveness

- All agencies should ensure the provision of respectful, linguistically and culturally responsive care for all persons seeking testing. Language assistance services should be provided, at no cost to the client, and should NOT include family members or friends.[17]

HIV Testing Consent

- The persons receiving an HIV test must: 1) have decision making capacity, 2) be aware of the testing prior to it being performed, and 3) have the right and opportunity to decline testing.

Testing Technology

- All sites providing HIV testing services are encouraged to use rapid testing technologies when appropriate.

Utilization of Confidential vs. Anonymous Testing[18]

- The CDPHE is required to conduct an anonymous counseling and testing program for persons considered to be at high risk for infection with HIV.
- The provision of confidential counseling and testing for HIV, in which basic client information is documented but kept strictly confidential, is the preferred screening service for detection of HIV infection.
- Agencies are encouraged to have and adhere to an HIV record retention policy that includes how to address the availability of anonymous testing.[19]

Policies and Procedures

- Every agency providing HIV testing services should implement and maintain quality assurance policies, procedures and protocols to ensure quality of test results and counseling services.

The HIV Testing Guidance is divided in six main sections that expand on and provide context to the information in the HIV Testing Plan. These are:

A. Overview of National and State Trends
B. Epidemiology of HIV in Colorado
C. Resources and Required Network to Implement Comprehensive HIV Testing
D. HIV Testing Counselors - Competency Standards
E. Data Collection and Reporting Processes

In addition to these sections, the HIV Testing Guidance includes a list of commonly used terms and their definitions, special acknowledgements, and references.

Section A. Overview of National and State Trends

As national leadership continues to impact the manner in which HIV prevention efforts occur at the state- and local-level, Colorado must work to ensure that HIV prevention is carried out in a manner consistent with local priorities and responsive to local needs. The following provides an overview of national trends and state priorities.

A.1 National Guidance

The Centers for Disease Control and Prevention (CDC) estimate that 1.2 million persons are currently living with HIV in the United States. In addition, it is estimated that 50,000 new infections occur each year and that one in five (20%) HIV positive persons are unaware of their HIV positive status.[20] The CDC has recognized that learning one's HIV status reduces engagement in risk behavior and that routine testing carries substantial potential to reduce new infections, increase time to care for those newly infected, and reduce the stigma associated with receiving an HIV test. In fact, studies have shown that transmission rates among HIV positive persons unaware of their status may be as high as 3.5 times greater than among HIV positive persons aware of their status.[21]

The National HIV/AIDS Strategy (NHAS) issued by the White House Office of National AIDS Policy in July of 2010, put forth three primary goals:

1. Reduce the number of people who become infected with HIV,
2. Increase access to care and improve health outcomes for people living with HIV, and
3. Reduce HIV-related health disparities.

The NHAS further called for a coordinated national response to the HIV epidemic in order to accomplish those goals, acknowledging that the successful realization of those goals will require "the commitment of governments at all levels, businesses, faith communities, philanthropy, the scientific and medical communities, educational institutions, people living with HIV, and others."[22]

Within those overarching goals, a number of clear objectives were also set forth. In fact, the strategy has set targets for the reduction of new, annual infections by 25 percent by the year 2015 and the reduction of HIV transmission rates by 30 percent. In order to do so, the NHAS calls for the scaling up of HIV prevention efforts in highly affected communities and within geographic areas in consistent with the epidemic. Specifically, the strategy calls for governments at all levels to utilize epidemiological data to target high prevalence populations and communities.

The NHAS also recognizes that advancements in HIV therapies have allowed HIV positive persons to live longer, healthier lives. As such, the NHAS calls on both the public and private health sector to ensure that "all people living with HIV are well supported in a regular system of care." In order to do so, the strategy further calls for the establishment of seamless systems to link people to care upon an HIV diagnosis, efforts to increase the number and diversity of high quality clinical care providers for HIV positive persons, and the provision of additional support for persons living with HIV with co-occurring health conditions. Specific objectives for the nation include the following:

- Increasing from 65 percent to 85 percent the proportion of newly diagnosed patients linked to clinical care within three months of their HIV diagnosis.
- Increasing from 73 percent to 80 percent the proportion of Ryan White HIV/AIDS Program clients who are in continuous care.

- Increasing from 82 percent to 86 percent the percentage of Ryan White HIV/AIDS Program clients with permanent housing

The NHAS also calls upon the health care sector to address and reduce HIV-related health disparities resulting from stigma or discrimination. The NHAS recognizes that the most vulnerable segments of society are often the hardest hit by the epidemic due to a lack of access to prevention and treatment services, resulting in poorer health outcomes. In order to address such challenges, the NHAS calls for 1) the reduction of HIV-related mortality in high risk communities, 2) the adoption of community-level approaches to reduce HIV infection in high-risk communities, and 3) the reduction of stigma and discrimination against HIV positive persons. Specific objectives include:

- Increasing by 20 percent the proportion of HIV diagnosed gay and bisexual men with undetectable viral load.
- Increasing by 20 percent the proportion of HIV diagnosed Blacks with undetectable viral load.
- Increasing by 20 percent the proportion of HIV diagnosed Latinos with undetectable viral load.

These directives carry significant implications for the manner in which states appropriate funding and orient their HIV prevention strategies. In Colorado, it means finding an appropriate balance between directing HIV prevention funds to areas in which the bulk of new diagnoses occurs - metropolitan areas - and ensuring that resources remain available in low prevalence, rural settings in order to ensure HIV prevalence in those areas remains low and that HIV positive persons residing in those areas have access to high quality care. It also means utilizing a reliable epidemiologic profile to target activities toward the populations and communities in which new HIV diagnoses are most likely to occur or in which significant health disparities exist. Finally, it means that all agents involved in the system of HIV-related care in Colorado must work collaboratively to ensure seamless linkages to care for newly diagnosed persons while also ensuring that persons linked to care remain in care and are supported for the rest of their lives.

In alignment with the NHAS, and in light of limited federal HIV prevention funds, CDC has emphasized its focus on HIV prevention efforts that focus on identifying HIV status and linking HIV positive persons to care. As such, the CDC has adopted a new funding approach, termed *High Impact Prevention*, featuring the, "better geographic targeting of resources and a stronger focus on supporting the highest impact prevention strategies."[23] Specifically, CDC funded efforts will include routine opt-out testing of patients between the ages of 13 and 64 within healthcare settings, the targeted testing of persons in non-healthcare settings, routine screening of pregnant women, and the screening for other STDs in conjunction with HIV testing. Activities will also incorporate social marketing/media techniques in efforts to "educate and inform high-risk populations, healthcare providers and other relevant audiences about HIV."[24] The new approach will also fund the expansion of HIV testing efforts for disproportionately affected populations, specifically African American and Hispanic persons,[25] and increase efforts to "improve treatment, care, and support for persons living with HIV/AIDS."[26]

A.2 State Objectives

Achieving the goals set forth in the NHAS requires that every state work in a targeted fashion to reduce new infections among high risk communities, address HIV-related disparities, and ensure seamless linkages to care. With a moderate prevalence and largely rural state, Colorado must balance national objectives with local needs. It must do so collaboratively across a wide range of stakeholders, responsible for the development of HIV and STI health policy, the administration of funding, the provision of medical and non-medical care, as well as social support. This guidance document represents

a key step towards achieving a standardized, statewide system of HIV prevention and care designed to 1) reduce new HIV infections, 2) identify and diagnose HIV positive persons unaware of their status, and 3) link and retain HIV positive persons into high quality systems of care and support.

In Colorado two specific sets of regulatory documents guide the provision of HIV testing:

First, the Colorado Revised Statutes (CRS), Title 25, Article 4, Sections 1401 et seq., known as the Colorado comprehensive public health AIDS/HIV control law, outlines several provisions pertaining to insurance regulations, testing inside and outside of the criminal justice system, the mandatory distribution of information, informed consent, counseling requirements, anonymous testing, reporting regulations, testing of pregnant women, testing of minors and adolescents, and the training and education of health care providers, among others.

Second, the Colorado Rules and Regulations, Series 1009-9.0 et seq., provides additional detail and clarification to the CRS. These regulations detail additional responsibilities for the Colorado Department of Public Health and Environment, Physicians, Health Care Providers, Hospitals, Laboratories and other HIV/AIDS service providers surrounding reporting requirements, confidentiality standards, and testing operational standards, among other provisions.

The Colorado Compendium of State HIV Testing Laws, compiled by the National HIV/AIDS Clinicians' Consultation Center (NCCC) and published in April, 2011, provides an in-depth overview of both sets of regulatory documents. This compendium can be found at http://www.nccc.ucsf.edu/docs/Colorado.pdf.

Comprehensive testing and linkage to care
Comprehensive HIV testing comprises the whole continuum of care: from providing access to testing services to linking and retaining HIV positive persons into care. HRSA's *Engagement in Care Continuum* below helps to illustrate steps within the continuum.

Not in Care — In Care

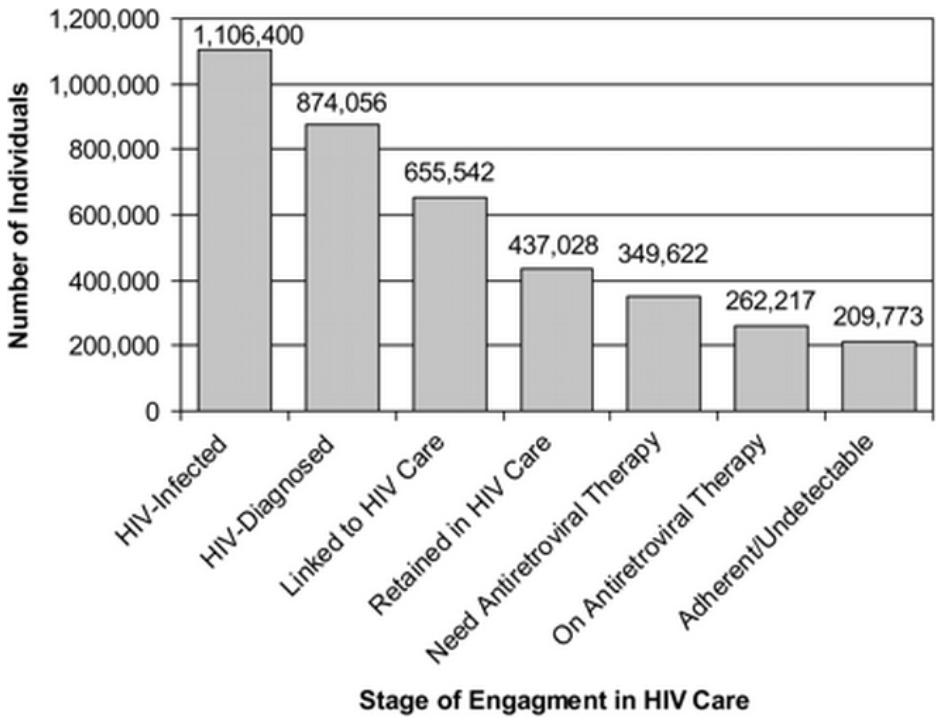
Unaware of HIV Status (not tested or never received results)	Know HIV Status (not referred to care or didn't keep referral)	May Be Receiving Other Medical Care But Not HIV Care	Entered HIV Primary Medical Care But Dropped Out (lost to follow-up)	In and Out of HIV Care or Infrequent User	Fully Engaged in HIV Primary Medical Care

HIV testing is particularly critical to HIV prevention. While Colorado's service providers, health departments, hospitals, community-based organizations (CBOs), clinics and health workers have all contributed to making substantial progress in testing for HIV in Colorado, as mentioned previously, CDC estimates that 20 percent of all HIV positive persons nationwide are unaware of their status.[27]

Developing data driven HIV testing policies which address critical referral and linkage to care networks will contribute to HIV prevention efforts throughout Colorado in two important fashions:

1. Sustainable HIV testing efforts ensure that many previously unaware HIV positive persons will have the opportunity to learn their status, enter into care and suppress their viral load status to undetectable levels. This relationship is best depicted in the graph below, developed by Edward Gardner et al. and published in the journal, *Clinical Infectious Diseases*:

Figure 1. The National HIV Cascade



Source: Gardner, Edward M. Margaret P. McLees, John F. Steiner, Carlos del Rio, and William J. Burman. 2011. "The Spectrum of Engagement in HIV Care and its Relevance to Test-and-Treat Strategies for Prevention of HIV Infection. *Clinical Infectious Diseases* 52(6): 793-800

The HIV Cascade provides a clear picture of the impacts of barriers to reducing the viral load of all HIV positive persons to an undetectable level. As can be seen from Graph 1, only 79 percent of all HIV positive persons nationally are diagnosed with the disease. In turn, only 75 percent of those persons are linked to care, and 67 percent of those that are linked to care are retained in care. Of those persons in care about 80 percent need Antiretroviral Therapy (ART), of which 75 percent are on it. And finally, from those on ART, 80 percent are adherent to their therapy with undetectable viral load levels. Gardner et al. used this relationship to determine that only about 19 percent of all HIV positive persons in the United States have an undetectable viral load.[28]

The role of HIV testing and linkage to care are both critically important to reducing the pattern of HIV transmission and acquisition in Colorado.

2. The CDC has recognized that learning one's HIV status generally reduces engagement in risk behavior and that routine testing carries substantial potential to reduce new infections, increase time to care for those newly infected, and reduce the stigma associated with receiving an HIV test.[29] In fact, studies have shown that transmission rates among HIV positive persons unaware of their status may be as high as 3.5 times greater than HIV positive persons aware of their status.[30]

3. The term 'sustainable HIV testing' refers to finding or providing ongoing resources to support this effort. Sustainable HIV testing also refers to the alignment of state and local objectives with national goals, such as targeting resources to areas with the highest prevalence and to populations with the greatest HIV-related health disparities. In Colorado, this means targeting metropolitan areas and populations with high HIV prevalence rates or disproportionate HIV incidence rates, such as men who have sex with men (MSM), African American and Latino/Hispanic men and women, and injecting drug users (IDU).

Section B. Epidemiology of HIV in Colorado

The following provides an overview of the HIV epidemic in Colorado according to HIV prevalence, incidence and concurrent diagnoses.

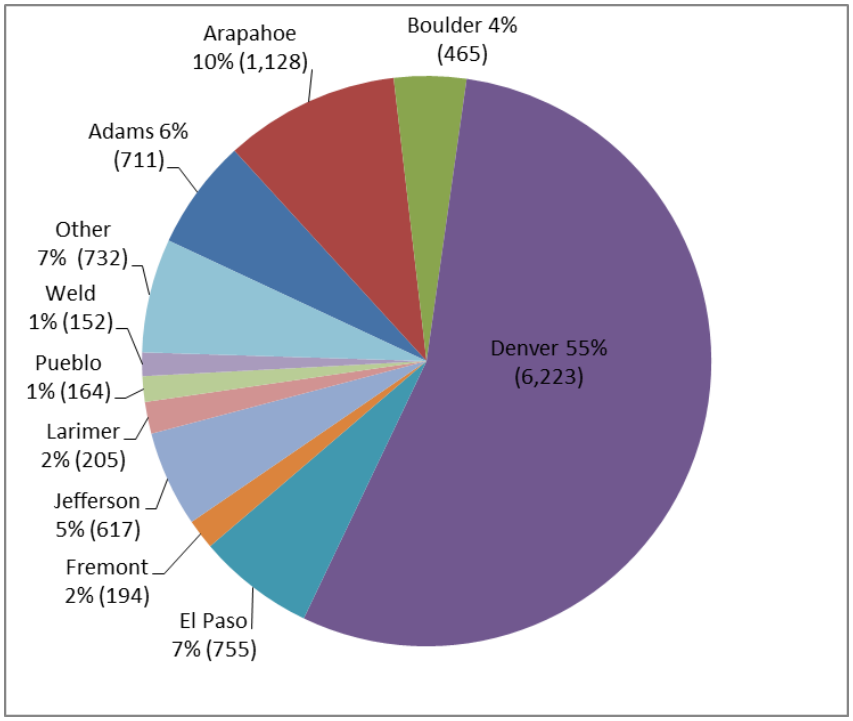
B.1 HIV Prevalence

Geographic prevalence

The majority of HIV positive persons in Colorado have historically been diagnosed in metropolitan areas. Since the beginning of the epidemic through December 31, 2011, 16,897 persons have been diagnosed with HIV in Colorado. Among those persons, over 94 percent (15,906) of all diagnoses occurred in a metropolitan area.[31,32]

As of December 31, 2011, 11,346 persons are presumed living with HIV/AIDS in Colorado. Figure 2 below presents the top 10 counties by HIV/AIDS positive case counts. Nine of the top 10 counties are considered metropolitan: Denver, Arapahoe, El Paso, Adams, Jefferson, Boulder, Larimer, Pueblo, and Weld.[33,34]

Figure 2. Top 10 Counties by HIV/AIDS Diagnoses as of 12/31/2011 (percent of total cases, volume)



Source: Colorado Department of Public Health and Environment. Colorado HIV Surveillance Report, 4th Quarter 2011. Available at http://www.cdphe.state.co.us/dc/HIVandSTD/stats/HIV%20Surveillance%20Report%203rd%20Q%202011.pdf
The term presumed living is utilized because the case counts are calculated from available data at the time.

Population-based prevalence

The demographic makeup of the 11,346 persons presumed living with HIV/AIDS in Colorado is described in the table below.

Figure 3. People Living with HIV/AIDS as of December 31, 2011

All cases of HIV/AIDS			
	N^	% (rounded)	Rate (per 100,000 population)
Total	11,346	100	221.7
Gender			
Male	10,053	89	392.0
Female	1,281	11	50.3
Transgender	12	0.1	--
Age*			
Under 13 years	31	0.3	3.5
13-19	29	0.3	6.1
20-29	648	6	87.7
30-39	1,673	15	234.7
40-49	3,892	34	544.7
50-59	3,594	32	503.3
60 years and over	1,479	13	171.0
Race and Hispanic Origin			
White, non-Hispanic	7,271	64	203.8
Black, non-Hispanic	1,643	14	838.7
Hispanic (All Races)	2,122	19	198.2
Asian/Pacific Islander	109	1	73.8
American Indian/Alaska Native	91	1	277.4
Multiple Race/Unknown	110	1	--
Exposure Category			
MSM	7,310	64	--
IDU	848	8	--
MSM & IDU	954	8	--
Heterosexual contact	1,107	10	--
Pediatric**	67	0.6	--
Transfusion/hemophiliac	39	0.4	--
No Identified Risk/Other	1,021	9	--

Source: Adapted from the CDPHE Colorado HIV Surveillance Report, 4th Quarter 2011.

^ All HIV/AIDS surveillance data reported to the CDPHE as of December 31, 2011.

* Age as of December 31, 2011

** Diagnosed with HIV/AIDS between the ages of 0 and 13; includes perinatal exposure.

As can be determined from the above table, the majority of persons living with HIV/AIDS in Colorado are primarily comprised of the following demographic groups and exposure category:

- Males
- Persons between the ages of 40 and 59
- White non-Hispanic persons
- MSM

In fact, approximately 80 percent of all persons living with HIV/AIDS in Colorado as of December 2011 acquired it through MSM, Injecting Drug Users (IDU), or MSM & IDU exposure.

HIV prevalence, however, is a poor indicator of HIV-related health disparities, or the degree to which certain populations are impacted by HIV disease. To better understand HIV-related disparities, one must control for the size of individual populations using HIV prevalence *rates*, or the number of cases of HIV in a given population among every 100,000 persons within that population, as shown on the right hand side column of Figure 3 above.

Taking into consideration HIV prevalence rates, while African American persons comprise a smaller proportion of the total number of HIV positive persons in Colorado, they are nonetheless disproportionately impacted by the disease. In fact, African American persons are impacted by HIV at a rate over four times that of non-Hispanic Whites or Hispanics of any race. Black females in particular face severe HIV-related disparities. While the HIV rate per 100,000 persons among Black males in Colorado in 2010 was over four times greater than that of White males (52.9 compared to 12.2 respectively), the rate per 100,000 among Black females in 2010 was 35 times that of White females (31.6 compared to 0.9 respectively).[35]

B.2 HIV Incidence

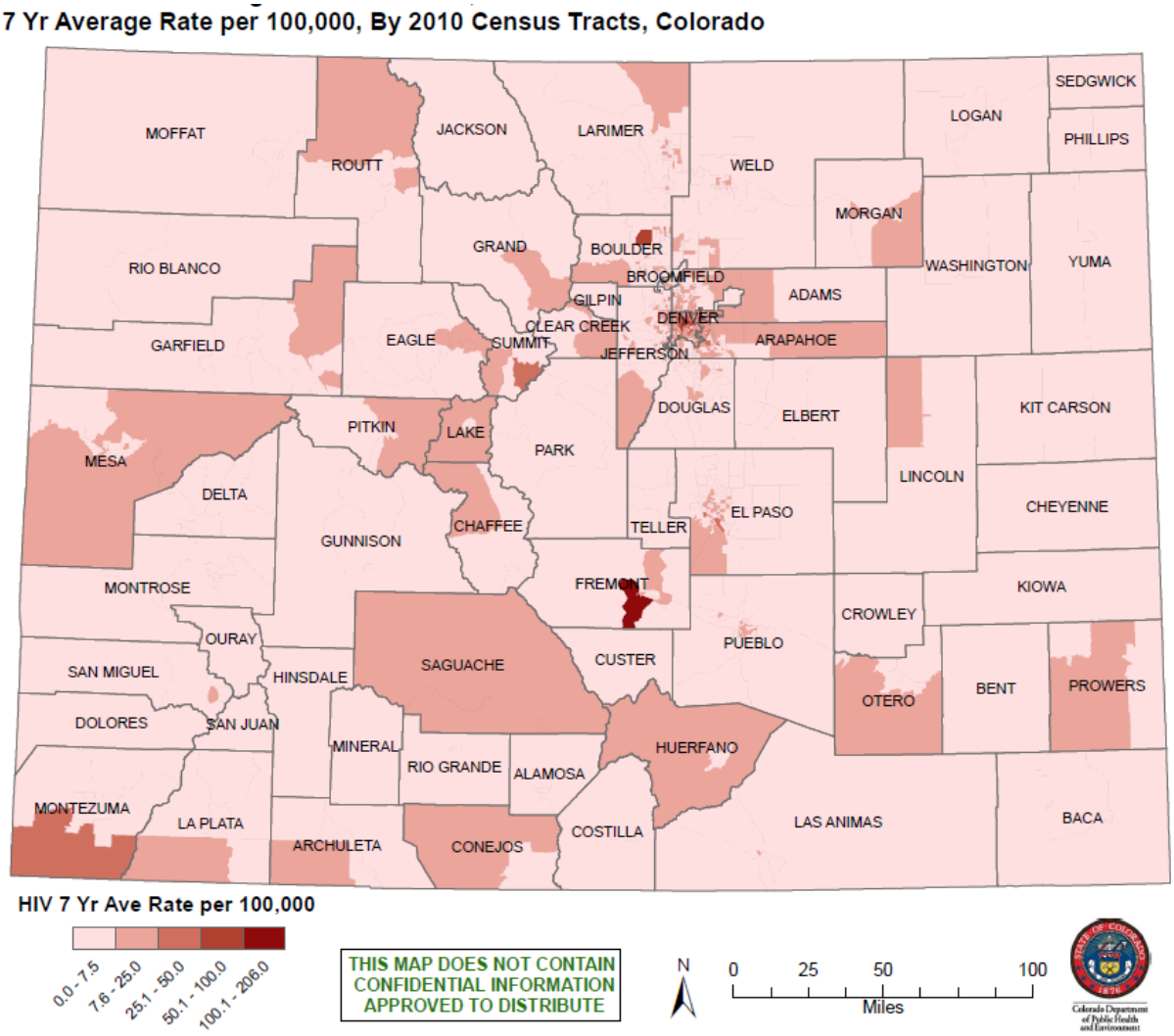
Between 2006 and 2010, the average number of annual, newly diagnosed cases of HIV was about 430, about a four percent annual increase.[36]

Geographic Incidence

Between January 1, 2007 and September 30, 2011, there were 807 new cases of HIV diagnosed in Denver County, representing 41 percent of all new diagnoses in the State. Arapahoe County reported 290 cases, representing 15 percent of all new HIV diagnoses and Adams County identified 282 new cases, representing 14 percent. These three counties combined, represent almost 70 percent of all new HIV diagnoses in Colorado.

Other counties are also impacted by new HIV diagnoses. As can be seen by Figure 4, below, pockets of increased HIV incidence rates (above 25 cases per 100,000) appear in Fremont County, Boulder County, Summit County, Montezuma County, Arapahoe County, and El Paso County.

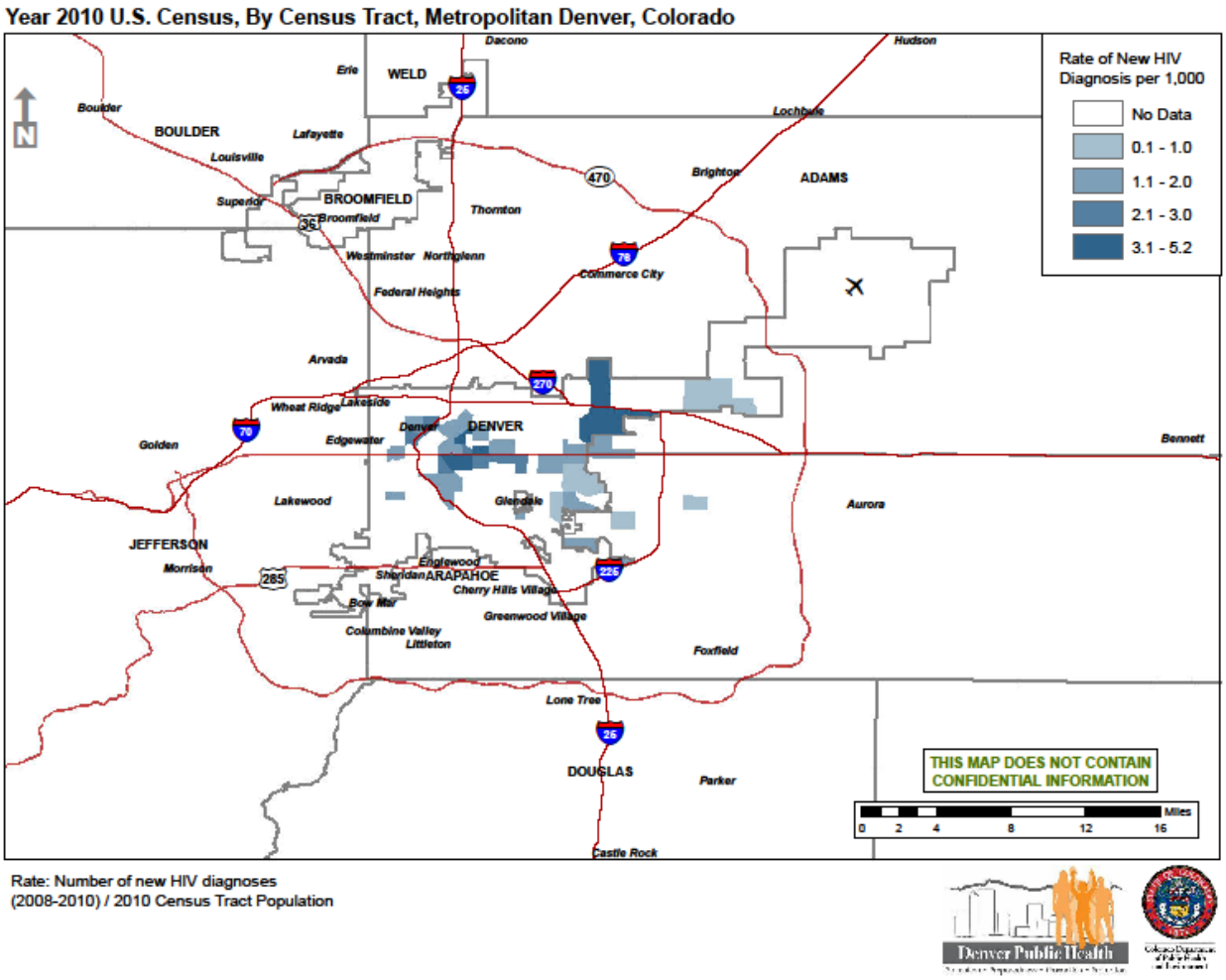
Figure 4. New HIV Disease Diagnoses in Colorado between 2005 and 2011[37]



Source: Colorado Department of Public Health and Environment STI/HIV Surveillance Program

Within and directly surrounding Denver County increased rates of new HIV diagnoses, see Figure 5 below, can be seen west of Interstate 25, north of Interstate 225, and south of Interstate 270. There were however, pockets of increased rates of new diagnoses in the northeast part of Denver City, and to the northeast and northwest of the intersection of interstate 270 and 225.

Figure 5. New HIV Diagnoses in Denver County, 2008 – 2010[38]



Source: Colorado Department of Public Health and Environment STI/HIV Surveillance Program

Population-based Incidence[39]

Between 2006 and 2010, there were a total of 2,151 new diagnoses of HIV in Colorado. The majority of these occurred among males, specifically MSM. As with HIV positive persons living in the State, MSM, IDU, and MSM/IDU comprised over 70 percent of all new HIV diagnoses in Colorado between 2006 and 2010. While White populations comprise the largest percentage of new diagnoses, Hispanic/Latino populations comprise almost 26 percent of these. In addition, persons between the ages of 25 and 29 comprise the largest percentage of new diagnoses per five year age group.

B.3 Concurrent Diagnoses

Population based rates of concurrent HIV/AIDS diagnoses (HIV cases that progressed to AIDS within one year of diagnosis) from 2006 to 2010 provide additional information as to which populations may face prolonged gaps between the time of their HIV infection and the time of their receiving an HIV diagnosis. Understanding this gap is particularly important because populations with disproportionate rates of concurrent HIV/AIDS diagnoses may face additional barriers to both receiving an HIV test and linkage into care.

Figure 6. Percent of all Coloradans Diagnosed (Dx) with Concurrent HIV/AIDS Diagnoses between 2006 and 2010, by Demographic, Risk, and Geographic Groups*

	Concurrent HIV/AIDS Dx		Non-concurrent Cases		Total
	N	%	N	%	N
All	754	35	1,397	65	2,151
Sex at Birth					
Male	653	36	1,183	64	1,836
Female	101	32	214	68	315
Age at HIV Diagnosis					
<25	68	20	265	80	333
25 – 34	194	28	488	72	682
35 – 44	246	40	365	60	611
45 – 64	228	47	261	53	489
65 and Over	18	50	18	50	36
Race/Ethnicity by Birth Origin					
White - US Born	358	31	780	69	1,138
Latino - US Born	140	37	239	63	379
Black - US Born	78	33	159	67	237
American Indian/Alaska Native - US Born	7	37	12	63	19
Asian/Pacific Islander - US Born	7	35	13	65	20
Multi Race - US Born	2	20	8	80	10
Latino - Non-US Born	100	56	77	44	177
Black - Non-US Born	48	37	82	63	130
Other - Non-US Born	14	34	27	66	41
Documented Transmission Category					
MSM	446	33	889	67	1,335
IDU	40	41	58	59	98
MSM & IDU	36	30	84	70	120
Male Heterosexual	54	49	57	51	111
- **US Born**	19	40	29	60	48
- **Non-US Born**	35	56	28	44	63
Female Heterosexual	64	32	137	68	201
Other	2	10	18	90	20
Unknown	112	42	154	58	266
County Type of Residence					
Denver Metro	558	34	1,065	66	1,623
Non-Denver	196	37	332	63	528

Source: Colorado Department of Public Health and Environment STI/HIV Surveillance Program
* All percentages have been rounded to the nearest whole percent and may not equal 100%

As can be seen from Figure 6, above, certain populations are more likely to receive a concurrent HIV/AIDS diagnosis than are others. Specifically:

Age	**HIV positive persons above the age of 45 are: more likely to receive a concurrent diagnosis than any other age group**	
	2.7 times more likely than	persons under the age of 25
	1.9 times more likely than	persons between the ages of 25 and 34
	1.3 times more likely than	persons between the ages of 35 and 44

Race and Birth Origin	**HIV positive Latino – Non-US born (foreign born) persons are: more likely to receive a concurrent HIV/AIDS diagnosis than any other race/ethnicity by birth origin**	
	1.8 times more likely than	White - US born persons Black - US born persons
	1.5 times more likely than	Latino - US born persons Black - Non-US Born persons

Risk Category	**HIV positive Male Heterosexuals are: more likely to receive a concurrent HIV/AIDS diagnosis than any other population by documented transmission category**	
	1.6 times more likely than	Female heterosexuals MSM & IDU
	1.4 times more likely than	MSM
	1.2 times more likely than	IDU

B.4 Other Sexually Transmitted Infections (STIs)

Behavioral risk factors for HIV are similar to those of other STIs. For example, engaging in sexual activity without the use of a condom also places one at risk for syphilis, chlamydia, or gonorrhea along with HIV. For that reason, it is important to understand the link between HIV and other STIs.

Preliminary analysis conducted by the CDPHE on persons determined to be recently infected (not diagnosed) with HIV, indicates that 25 percent of these had a gonorrhea diagnosis in the previous 24 months.

Also according to data made available by the CDPHE, **nearly 60 percent of all persons known to be infected with syphilis in 2011 were co-infected with HIV**. In 2010, there were 138 new cases of syphilis reported in Colorado, a 100 percent increase over the number of cases reported in 2006 (69 cases). The majority of reported syphilis cases in 2010 occurred in:

- Males (99%, 136 out of 138 cases)
- White, Non-Hispanic persons (69%, 95 out of 138 cases)
- Persons between the ages of 45 and 54 (24%, 33 out of the 138 cases)

Section C. Resources and Required Network to Implement Comprehensive HIV Testing

Comprehensive HIV testing refers to a "test and treat" strategy that promotes routine HIV testing for persons 13 to 64 as an effort to encourage everyone to know their HIV status; and the critical step to link HIV positive persons to care in a timely and seamless fashion. It is the responsibility of every agency, whether public or private, that provides medical or social services to persons infected with HIV, to ensure adequate referral and support to access life-saving medical care and treatment, in order to reduce related morbidity and mortality, as well as the risk of transmitting HIV.

Colorado's Early Identification of Individuals with HIV/AIDS (EIIHA) strategy aligns with NHAS goals and summarizes a comprehensive approach to reaching Colorado's HIV prevention goals. The EIIHA strategy is contained in *Appendix D*.

Following are recommendations that help support a comprehensive network for HIV Testing:

Linkage to Care

- HIV testing agencies are recommended to seamlessly transition persons testing positive into comprehensive systems of care.
- Essential services for HIV positive persons include, access to clinical care, medical case management, HIV prevention counseling, and support services.
- In order to link HIV positive persons into care and retain them in care, it is recommended that agencies explore ways to share information about who is in need of care. To accomplish this, agencies need data sharing agreements and ways to ensure security of shared data across sites. This may include both the physical and digital security of confidential information and ongoing staff training.
- Though linkage to care may not occur as seamlessly as it might in clinical or urban settings, non-clinical agencies and agencies located in rural settings are encouraged to take necessary steps to ensure that linkage to care occurs in a seamless fashion. This includes, but is not limited to:
  - Developing written referral protocols,
  - Requiring training on such protocols on an annual or bi-annual basis,
  - Conducting active referrals,
  - Developing formal relationships (i.e., through a memorandum of agreement) with clinical facilities/providers,
  - Development of strong case management programs,
  - Ensuring access to free language assistance services at no cost to the client (a requirement for all agencies who receive any type of federal funding[40]), and
  - Development of transportation resources and procedures on how to access these services.

Comprehensive care

Comprehensive care does not solely encompass traditional medical care. Instead, comprehensive care involves the full range of services that may be needed in order to adequately support HIV positive persons. These services may include:

- culturally responsive care
- medication assistance
- adherence support
- health insurance assistance
- linguistic services
- home health care
- housing
- mental health care

- oral health care
- culturally responsive medical case management
- partner notification
- culturally responsive health education
- medical nutrition
- substance abuse
- food security
- transportation
- child care
- legal services

Awareness of HIV status

It is important to identify HIV positive persons who are unaware of their HIV status. This may be accomplished through:

- Targeted testing of persons identified as high risk for HIV
- Screening/universal testing of persons living in high prevalence areas or seeking services at an agency with high prevalence for HIV
- Outreach via networks of HIV positive persons already engaged in care

Reaching out to HIV positive persons not in care

Agencies are highly encouraged to conduct active follow-up with HIV positive patients/clients who failed to present to care for a period of 12 months or greater. If an agency is unable to contact a patient/client after three attempts over a period of 12 months or more, that agency is encouraged to contact the State Health Department and, if needed and possible, other providers who are known to have provided care to the patient/client, such as mental health providers, AIDS service organizations, etc., in order to re-engage that client in care or confirm the client's status as linked to care through another service provider, moved out of state, or deceased.

Partner Services

A comprehensive system should be in place to ensure that the partners of persons testing positive receive an HIV test and are also linked to care in a timely fashion. A good resource is the Partner Counseling and Referral Services (PCRS) offered by the CDPHE.

In order to implement these recommendations and the *Core Principles* determined by the CDPHE and the panel of experts convened to help create the HIV Testing Plan and Guidance (members listed in the Acknowledgments), agencies providing HIV testing services are recommended to have specific protocols in place to appropriately address the medical, mental health, substance abuse and risk reduction needs of both a) persons newly diagnosed with HIV, and b) HIV negative persons at increased risk of contracting HIV. This may be accomplished through either direct service provision or through active referral processes. *Active* referral (described in greater detail below in the "Linked Referral" standards) entails taking a proactive approach to link a person into care.

In Colorado, all agencies providing HIV testing services are encouraged to have active referral guidelines and mechanisms for follow-up to effectively address the needs of newly diagnosed HIV positive persons. This is known as comprehensive linkage-to-care (LTC). LTC networks ensure that seamless (i.e., timely) transitions occur from the point of positive diagnosis to entry into systems of care.

Appropriate systems of care include not only medical care, but also substance abuse, mental health care, and case management:

Required networks for:	
HIV positive persons	**High risk, HIV negative persons**
Outpatient medical care: Primary care providers and infectious disease physicians with a specialization in HIV.	Primary care services
Case management: ▪ Emergency financial assistance ▪ Housing assistance ▪ Health care enrollment assistance (private or public) ▪ AIDS Drug Assistance Program (ADAP) enrollment	Mental health services
Mental health services	Substance abuse services
Substance abuse treatment services	HIV behavioral risk reduction counseling
HIV behavioral risk reduction counseling	Social and emotional support and programs
Partner services	
Social and emotional support	

It is the responsibility of the individual agency conducting HIV testing services to provide the above services directly or to identify and collaborate with an appropriate network capable of providing such services. A brief overview of federal and state-based resources and organizations involved in ensuring the availability of these services in Colorado is described below. Technical assistance to agencies is available free of charge through CDPHE, local health departments, the AIDS Education and Training Centers (AETCs), and/or the Prevention Training Centers (PTCs).

C.1 Resources

The Ryan White HIV/AIDS program, funded through the Health Resources and Services Administration (HRSA), provides funding for the majority of HIV-related care services throughout Colorado. Part A funding, distributed to Eligible Metropolitan Areas (EMAs) and Transitional Grant Areas (TGAs), is managed by the Denver City and County Mayor's office and is responsible for providing a range of services, including outpatient/ambulatory services, case management, mental health, and housing services, among others.[41] For the first time in 2010 Ryan White Part A funds were also distributed for Early Intervention Services (EIS).[42] EIS encompasses linking to primary care HIV infected persons who are unaware of their status as well as those who have previously been diagnosed and are not in care.

Part B funding is administered through the CDPHE's STI/HIV Section. This Part B Care and Treatment program is divided into four parts:

- The AIDS Drug Assistance Program (ADAP)
- Medicare Part D
- The Health Insurance Assistance Program
- HIV Care and Case Management

Through those programs, the CDPHE provides funding to empower local agencies to provide outpatient medical care, medication assistance, health insurance assistance, substance abuse treatment, mental health therapy, case management, housing services, and transportation services, among others. The CDPHE also employs trained linkage to care coordinators who proactively reach out to HIV positive persons newly diagnosed or who have potentially dropped from care.[43]

Colorado as a whole receives funding for Ryan White Part C (Early Intervention Services), Part D (Women, Infants, Youth, and Families), Part F (Oral Health Programs, AETCs, and Special Projects of National Significance (SPNS)), and Minority AIDS Initiatives (MAI). For more information about each of these programs, visit the HRSA Ryan White HIV/AIDS Program website at http://hab.hrsa.gov/abouthab/aboutprogram.html.

The CDC's Division of HIV/AIDS Prevention (DHAP) also provides funding to Colorado to conduct key HIV prevention and care activities. In Fiscal Year 2011, Colorado received over 8 million dollars through DHAP, the majority of which was directed to HIV/AIDS Surveillance activities and HIV prevention projects through CDPHE.

All such funds are distributed to local agencies and health departments to reduce the spread of HIV in local communities and to provide support to HIV positive persons throughout the state. A comprehensive guide to local resources throughout Colorado can be found at the AIDS Coalition for Education (ACE) website: http://www.acecolorado.org/.

C.2 Linkage to Care[44]:

Linkage to Care (LTC) refers to the process by which newly diagnosed HIV positive persons are actively referred into systems of care. It is recommended that the LTC process be conducted by the agency providing the HIV test result, the CDPHE or another qualified person/agency. In this section, the person conducting the LTC process is referred to as the LTC counselor. Depending on the setting or funding mechanism, the LTC counselor is known as a medical case manager, social worker, care coordinator, etc. It is recommended that the LTC counselor be responsible for the completion of the following four phases:

1. Intake
2. Assessment
3. Linked Referral
4. Follow-Up, Transition and Case Closure

Each phase is described below. Guidelines are for both clinical and non-clinical settings, unless specified.

Intake

An initial, face-to-face interview between a newly diagnosed HIV positive person and an LTC counselor. The intake process is a time to build trust and establish rapport with the client in order to help assure that the client will remain engaged for future visits. Motivational interviewing skills are helpful in this process.

Purpose

To assess client's emotional state and support system.

To acquaint client with LTC process.

To collect or verify demographic, contact, financial, housing, insurance, and other information.

To acquaint the client with 'next steps', such as referral processes, EIS, Ryan White services, etc.

To help client determine a client-centered plan of action for his or her care.

Timeframe

It is recommended that the intake process take place following the initial HIV positive diagnosis or ***within two business days*** of a confirmed diagnosis.

Specific activities

It is recommended that the intake process include the collection of needed demographic and other data.

Data collected from clients should be accurate and complete.

It is recommended that data collected include copies of:

- *Identifying documents*, including state identification (such as a driver's license), and
- *Health care related documents*, if available, such as the Colorado Indigent Care Program (CICP) cards, Medicaid cards, or private health insurance cards.

Additional guidance for non-clinical settings

Connection to intake personnel is recommended directly following the patient/client's session with the testing counselor who informed the initial HIV positive diagnosis. Although the client will be impacted by having just received a preliminary HIV diagnosis, it is important for them to meet and bond with the person who may become their linkage to care contact after confirmatory test results.

Assessment

An in-depth interview process in which the client's full range of need is assessed and an LTC plan developed to engage client in the full continuum of care (with assistance of a trained interpreter, if needed). It is recommended that the LTC plan be based on client need, community resources, and real or perceived barriers to care.

Purpose

To evaluate the client's medical and psychosocial needs, strengths, resources, limitations and projected barriers to future services.

To obtain information necessary for the development of an LTC plan.

To assist in the coordination of a continuum of care that provides:

1. Timely access to medically-appropriate levels of health and support services;
2. An ongoing assessment of the client's and other family members' needs and person support systems; and

3. A coordinated effort with other agencies and facilitators (i.e., hospitals, CBOs, case management facilities, etc.).

To identify appropriate organizations capable of providing necessary support services identified in the assessment.

Timeframe

Simultaneously with intake, or within one week of intake.

Specific activities

Comprehensive assessments: LTC counseling should be based on a comprehensive understanding of the client's current situation, including their health insurance status, their housing status, their transportation concerns, their food security concerns, their family resources, etc.

Accurate and reliable information: Clients should base their health care decisions on accurate, understandable information about their healthcare options. It is the responsibility of the LTC counselor to provide such information, specifically pertaining to the following:

- Private health insurance options
- Public health programs
- The Colorado AIDS Drug Assistance Program, including both Medication Assistance and Insurance Assistance
- Once healthcare options are assessed, the LTC counselor needs to assess if a Financial Screening Appointment may be needed prior to client's medical appointment

Case management: To address clients' needs, it is recommended that the LTC counselor share with clients, services available through case management providers at intake and the referral if requested by the client at the assessment session. Agencies offering LTC services are encouraged to have a list of organizations providing case management.

Assessment and counseling: It is recommended that clients be supported in addressing physical or behavioral barriers to care, including:

- Substance abuse issues that may pose a barrier to care
  - Assessment should include an evidence-based screening for substance abuse issues, such as Screening, Brief Intervention, and Referral to Treatment (SBIRT), or the Substance Abuse and Mental Illness Symptoms Screener (SAMISS).
  - Clients may be referred to agencies which provide substance abuse counseling and/or groups funded by Ryan White, if eligible.

- Mental health issues that may pose a barrier to care
  - Assessment should include an evidence-based screening for mental health issues.
  - Clients may be referred to agencies which provide mental health counseling and/or groups funded by Ryan White, if eligible.
  - It is recommended that the LTC counselor follow-up with clients regularly to determine whether they are having difficulty accessing mental health treatment prescriptions or medication and to help them access their medication, if needed and within the scope of the LTC counselor.
  - The LTC counselor may also call clients regularly to 'remind' them to take their medication(s), if the client has indicated difficulty with maintaining adherence to mental health medications.

- HIV behavioral issues
  - Assessment should include screening for HIV risk behaviors and brief HIV risk reduction counseling, when appropriate.
  - Ideally, such services will occur within the organization where the client is receiving linkage to care services, or within a short distance convenient to client.
  - It is recommended that agencies providing LTC services have information regarding organizations which provide HIV risk reduction services pertinent to their client's needs.

Additional guidance for non-clinical settings

It is recommended that LTC be coordinated with local federally qualified health centers (FQHCs), infectious disease clinics, hospitals or physicians' offices, based upon the eligibility of the client, the reputation and knowledge of the medical facility surrounding treatment of HIV, cultural and linguistic competency of the medical facility, and the preference of the client.

Linked Referral

The process by which newly diagnosed HIV positive persons are referred into systems of care in a proactive fashion. Linked Referral is comprised of eight key components:

1. Referral to a named agency with information regarding language(s) spoken by the client;
2. Providing to the client the name of a contact person at the referral agency;
3. Providing to the client an exact address;
4. Assisting clients with making and keeping appointments;
5. Assisting clients with accessing transportation services to appointments;
6. Identifying referral agency eligibility requirements;
7. Assisting client to gather required documents to bring to the appointment; and
8. Obtaining releases of information in order to follow-up on client's participation in the appointment and/or barriers encountered that prevented the client to keep appointment.

Purpose

To actively link clients to care in a timely and seamless fashion.

To address real or perceived barriers to care in order to ensure linked referrals. Barriers could include, but may not be limited to:

- Lack of transportation
- Cost
- Social stigma
- Lack of health insurance
- Citizenship status
- Lack of stable housing
- Religious beliefs
- Language and cultural differences

Timeframe
It is recommended that clients be referred into medical care as soon as possible.
If deemed necessary by the LTC counselor, and the client agrees, it is recommended that clients be linked to medical care within one week of initial intake, regardless of setting.
Linkages to all other services should occur as soon as possible or on an ongoing basis.
Specific activities
Initial laboratory work: The LTC counselor is encouraged to ensure the direct provision or linked referral to initial laboratory work (viral load, CD4 count) that is consistent with Public Health Service Guidelines. Clients should have the option to initiate HIV-care-related laboratory testing in a timely manner.
The LTC counselor is expected to initiate referrals that were agreed upon by the client and identified through the assessment process.
All referrals need to be appropriate to client situation and need. The cultural responsiveness - with regards to sexual orientation, gender identity, or racial/ethnic status - of the agency to which the client is being referred should be taken into consideration.
Taking into consideration agency eligibility requirements (such as geographic service boundaries or insurance requirements) should be a routine part of the referral process.
Referring clients with health insurance back to their health insurance provider is necessary but NOT sufficient linkage to care.
Referring organizations should obtain a release of information from the client to ensure that the client is receiving services and to follow-up if the client becomes unable to attend appointments. Releases of Information may also be used to obtain additional information about the client's needs.
The LTC counselor is encouraged to identify and resolve any barriers clients may have in following through with their LTC plan.
Clients should receive prompt follow-up to identify and eliminate barriers to accessing HIV care.
Agencies conducting LTC are encouraged to utilize a tracking mechanism to monitor completion of all LTC referrals.
It is recommended that the LTC counselor document when a client refuses to follow through with a referral.
During LTC, clients should be linked to medical case management support, which should include financial and housing assistance, among other services, with client's consent.
Additional guidance for non-clinical settings
If possible, the LTC counselor is encouraged to accompany clients to their first medical appointment, with client's consent.

Follow-Up, Transition and Case Closure
Follow-up, transition and case closure are defined as the processes by which LTC counselors ensure that linked referral mechanisms were successful and that clients are actively engaged in care on an ongoing basis.
Purpose
To ensure that HIV positive persons are linked to care in a timely, appropriate and comprehensive manner.
Timeframe
Ongoing
Specific activities
Each client receiving LTC services should be connected to medical care and experience a seamless transition to case management services.
The LTC counselor is encouraged to create a mechanism by which to verify completion of HIV care appointments, CD4 testing, viral load testing, and case management referrals.
The LTC counselor is encouraged to document when a client refuses to follow through on a referral or refuses to continue medical care.
During the follow-up period, it is recommended that the LTC counselor monitor key quality indicators to ensure clients continue to access medical care and case management services (see below).
Recommended key quality indicators
At least 80% of LTC clients should demonstrate successful linkage to care (verified by completion of HIV care appointments, CD4 testing, viral load testing, and case management referrals) within 90 days of HIV/AIDS diagnosis.
At least 80% of LTC clients who demonstrate the need for long-term care should be linked successfully to long-term case management.
In at least 80% of cases where clients require and request laboratory testing, such testing should occur within 10 business days following intake.

Section D. HIV Testing Counselors - Competency Standards

This section provides a brief overview of the core competencies expected in all counseling and testing sites (CTS). CTS are CDPHE designated sites which screen individuals for HIV infection without providing on-going health care services.[45] These competencies also serve as guidance to other agencies providing HIV counseling and/or testing.

D.1 HIV pre and posttest prevention and risk reduction baseline counseling standards

The following applies to all persons providing HIV pre- and post-test prevention and risk reduction counseling at CTS.

Required coursework objective standards

- Completion of the HIV Serologic Test Counseling course or an equivalent of not less than 16 hours of training, approved by the CDPHE STI/ HIV Section, Prevention Program.
- A minimum of eight hours of relevant HIV/STI or allied health services continuing education annually, approved by the CDPHE STI/ HIV Prevention Program.[46]

Operational standards

All persons providing HIV pre- and post-test prevention and risk reduction counseling at CTS provide:

- HIV pretest prevention and risk reduction counseling
  - Conduct a risk assessment (a fundamental part of a client-centered HIV prevention counseling session in which the client is encouraged to identify, acknowledge, and discuss in detail his or her personal risk for acquiring or transmitting HIV)
  - Discuss and develop a risk-reduction plan
  - Fully and legibly complete the HIV 1 Serology lab slip
- HIV posttest prevention and risk reduction counseling
  - Inform clients in person of test results
  - Explain the significance of both positive and negative test results
  - Discuss and/or modify the risk-reduction plan
  - Refer clients who test positive for follow-up medical and counseling services
- Consent
  - Need to obtain consent from clients/patients
- Testing Parameters
  - MAY NOT provide anonymous testing to any person 12 years of age or younger
  - MAY defer testing if the counselor judges that a client is unable to give informed consent, and does not understand either counseling or testing process
- Written Results
  - MAY NOT provide written results to any person testing anonymously
  - MAY provide written results to person testing confidentially. To receive written results, the CTS must be presented with photo identification from the person requesting written results at the time of post-test.
- Confidentiality and record maintenance
  - Contracting agencies MUST have and adhere to an HIV record retention policy[47]

Additional baseline standards

- Protection of Limited English Proficient (LEP) Individuals under Title VI of the Civil Rights Act of 1964
- Mandatory Reporting Requirements
  - Children who are victims of sexual abuse/witnesses to assault
  - Communicable disease reporting
- Linkage to Care
  - Counselors must be aware of and offer Linkage to Care services
- Partner Notification
  - All persons providing partner notification interviews must complete necessary coursework in compliance with 6 CCR-1009-9.6: Objective Standards. Specifically, that person should have completed courses concerning introduction to sexually transmitted disease interviewing and partner notification, as specified by the CDPHE.
- Consent
  - All coursework approved by CDPHE pertaining to HIV pre- and post-test prevention and risk counseling should include detailed information pertaining to informed consent and with specific regards to the provision of HIV testing opt-out consent, opt-in consent, and the testing of minors and pregnant women.
- Confidentiality:
  - Counselors should take measures to protect the confidentiality of youth receiving HIV testing services
  - All youth presenting at a testing site should be provided information about testing and screened for appropriateness of testing

Provision of HIV test results

- All positive test results should be delivered *in-person* by an individual trained in HIV pre- and post-test prevention and risk reduction counseling according to the first recommendation above.
- Negative test results should be delivered in-person or via another secure method by an individual trained in HIV pre- and post-test prevention and risk reduction counseling according to the recommendation above.

Evaluation of counseling services

- Written protocols surrounding the periodic evaluation of HIV counseling services should be developed within clinical and non-clinical settings providing counseling services. This may be accomplished through supervisor observation, client satisfaction surveys, or other tools appropriate to the individual agency.

D.2 Advanced HIV pre- and post-test prevention and risk reduction counseling standards

Counselors may also benefit from formal training on:

- Transmission and prevention of HIV and other sexually transmitted and blood-borne diseases
- The natural history of HIV
- Recognition and treatment of opportunistic infections
- New therapeutic agents used to treat HIV and AIDS
- Prevention case management
- Other HIV prevention and support services available in the community
  - services related to substance abuse assessment
  - cultural competence
  - adolescent concerns
  - domestic abuse
  - health concerns of LGBTQ clients
- Additional training in specific counseling skills (e.g., training on how to facilitate groups for counselors conducting group sessions)

Section E. Data Collection and Reporting Processes

This section outlines standards pertaining to the flow of information between the CDPHE and individual agencies providing HIV testing services.

E.1 Core standards

Standardization:

Data collection processes and variables need to be standardized across all agencies within the state in order to allow for comparisons across testing sites, geographic locations, and populations.

Digitization:

Data collection processes should ideally be electronic.

Central repository:

There should be one central data repository managed by the CDPHE to allow different systems to enter data in a confidential and coordinated fashion so that data can be accessed and evaluated by multiple parties.

Data collection:

Data should be collected for:

a. Everyone who receives an HIV test
b. Everyone who tests positive for HIV upon receiving an HIV test

Reporting Timeline[48]

Agency	Item to report	Timeline	To whom
Healthcare providers	HIV or AIDS diagnosis	7 days	State or local health department
Healthcare facilities	HIV or AIDS diagnosis	7 days	State or local health department
Laboratories	• CD4 count <500/mm or CD4% <29% • Any HIV viral load • HIV genotype testing	7 days	State health department
Local Health Departments	HIV and AIDS diagnosis	7 days	State health department

Funded and non-funded sites:

Relationships should be developed with all HIV testing sites to ensure that standardized data is collected regardless of funding source.

E.2 CDPHE Reporting

CDPHE will report HIV/AIDS related data with all agencies and providers conducting HIV testing across the state to assist them in evaluating their testing, linkage to care, and care programs.

Data reported by CDPHE should include:

Testing data:

- Report all HIV tests
  - Total tests given (both positive and negative results)
  - Total positive test results
  - Location where test was performed
  - Barriers encountered (if any)
- Positivity prevalence by site and type of site
- Report all testing methods used with all positive and negative test results
  - Rapid tests
  - Conventional lab testing
- Surveillance data for HIV positive persons, including zip code, demographics, risk behaviors, socio-economic status, language(s) spoken and if victims of sexual assault
- Historical data (data from the previous 5 years) should be reported in order to track changes over time
- HIV persons recently tested and positive that are already in the surveillance system or records

Linkage to Care Data:

- Was the patient/client successfully linked to the following:
  - HIV care appointments
  - CD4 testing
  - Viral load testing
  - Case management, if appropriate
- To which organizations was the patient/client linked
- Barriers encountered
- Timeframe to first medical appointment
- Timeframe to first case management appointment, if appropriate
- Timeframe to first mental health or substance abuse appointment (if applicable)

Care data:

- CD4 count
  - Actual count
  - When first CD4 count was completed
- Viral load
  - Actual viral load
  - When first viral load was completed
  - Time to undetectable viral load
- Patient/client satisfaction

In addition, best practices for testing, linkage to care and care should be shared across the state.

CDPHE reporting timeline:

- CDPHE will report data quarterly to all agencies and providers conducting HIV testing across the state

CDPHE reporting format:

- CDPHE will post quarterly reports on a secure website.

E.3 Core reporting variables for agencies

It is recommended that all agencies or providers conducting HIV testing track the core variables below for all patients/clients that receive a test. This data should then be reported, either directly or indirectly, to the central repository or the tracking mechanism being used across the state. Direct or indirect reporting is determined by ability to access the tracking mechanism.

VARIABLES	
Agency	
Session Date (mm/dd/yyyy)	Intervention ID
Unique Agency ID Number	Funder
Site ID	Funding/Program Announcement Number
Site Type	
Client	
Client ID	Ethnicity
Date of Birth (mm/dd/yyyy)	Hispanic or Latino
Zip Code	Not Hispanic or Latino
County	Don't know
Country of Birth	Declined
Date of Immigration to US if non-US born (mm/dd/yyyy)	Race
Previous HIV Test	American Indian/Alaska Native
Yes (If yes, date of last HIV test)	Asian
No	Black/African American
Don't know	Native Hawaiian/Pacific Islander
Declined	White
Not asked	Don't know
Self-Reported Result of previous test	Declined
Positive	Current Gender
Negative	Male
Preliminary Positive	Female
Indeterminate	Transgender Male to Female
Don't know	Transgender Female to Male
Declined	Transgender Unspecified
Not asked	Declined
If not tested before, identify barriers	Additional
Risk Factors	
Females only: In past 12 months, has client identified having vaginal intercourse with the following:	Male and Female: In the past 12 months, has client identified having anal sex with the following:
Male (M)	Male (M)
Transgender (T)	Female (F)
M/T while not using a condom	Transgender (T)
A person who is an IDU	M/F/T while not using a condom
A person who is HIV positive	A person who is an IDU
An MSM	A person who is HIV positive
Receptive or insertive anal sex	An MSM
In the past 12 months has the client had oral sex?	
In the past 12 months has the client used injection drugs?	
If yes, did client share drug injection equipment?	

HIV Test Information	
Sample Date (mm/dd/yyyy)	Test Result
Worker ID	Positive/Reactive
Test Election	Negative
Tested anonymously	Indeterminate
Tested confidentially	Invalid
Declined testing	No result
Test not offered	Result Provided
Test Technology	Yes
Non-rapid conventional	No
Rapid	Yes, client obtained result from another agency
NAA/RNA testing	If results not provided, why?
Other	Declined notification
Specimen type	Did not return/could not locate
Serum	Other (Specify)
Plasma	
If HIV positive:	
Viral load	
CD4 count	
Incidence Information (for clients/patients with a preliminary or confirmed positive HIV test)	
Date client reported information (mm/dd/yyyy)	Has client used or is client currently using antiretroviral medication (ARV)?
Has the client ever had a previous positive test?	Yes
Yes (If yes, date of first positive HIV test)	No
No	Don't know
Don't know	Declined
Declined	Is yes, specify:
Has the client ever had a negative test?	2-digit code for ARV
Yes (If yes, date of last negative HIV test)	Date ARV began (mm/dd/yyyy)
No	Date of last ARV used (mm/dd/yyyy)
Don't know	
Declined	
Number of negative HIV tests within 24 months before the current (or first positive)	
Referrals (for clients/patients with a preliminary or confirmed positive HIV test)	
Was client referred to medical care?	If client was referred to/contacted by partner services, was client interviewed by Partner Services?
Yes	Yes
No	No
If yes, did client attend the first appointment	Don't know
Yes	If yes, was the client interview within 30 days of receiving their result?
No	Yes
Don't know	No
If yes, was the first appointment within 90 days of the HIV test?	Don't know
Yes	Was client referred to HIV prevention services?
No	Yes
Don't know	No

If no, why?	If yes, did client receive HIV prevention services?
Client already in HIV medical care	Yes
Client declined HIV medical care	No
Other	Don't know
Was client referred to/contacted by Partner Services?	Identify any barriers to receiving care
Yes	
No	
Referrals for pregnant clients	
If female, is client pregnant?	If yes, in prenatal care?
Yes	Yes
No	No
Don't know	Don’t know
Declined	Declined
	Not asked

HIV Testing Nomenclature and Definitions

General

- *AIDS*: Acquired immunodeficiency syndrome.
- *HIV*: Human immunodeficiency virus.
- *Prevalence*: The total number of persons living with a disease or condition at a given time. HIV prevalence data are generally presented as "persons living with HIV disease."[49]
- *Incidence*: The number of new cases of a disease that occur in a population during a certain time period, usually a year.[50]
- *Risk factors*: Any characteristic, condition or behavior that increases the possibility of HIV infection.
- *MSM*: Men who have sex with other men.
- *IDU*: Injecting drug user.

Signs and symptoms of HIV infection[51]

- *Acute Primary Infection* (within one to two months after initial infection)
  - Fever
  - Muscle soreness
  - Rash
  - Headache
  - Sore throat
  - Mouth or genital ulcers
  - Swollen lymph glands, mainly on the neck
  - Joint pain
  - Night sweats
  - Diarrhea
  - Anorexia
- *Clinical latent infection* (typically lasts 8 to 10 years)
  - No specific signs or symptoms,
  - Persistent swelling of lymph nodes does occur
- *Early symptomatic HIV infection*
  - Fever
  - Fatigue
  - Swollen Lymph nodes
  - Diarrhea
  - Weight loss
  - Cough and shortness of breath
- *Progression to AIDS*
  - Soaking night sweats
  - Shaking chills or fever higher than 100F (38C) for several weeks
  - Cough and shortness of breat0068
  - Chronic diarrhea
  - Persistent white spots or unusual lesions on the tongue or mouth
  - Headaches

  - Persistent, unexplained fatigue
  - Blurred and distorted vision
  - Weight loss
  - Skin rashes or bumps

- *Opportunistic infections*: Infections which occur as a result of a weakened immune system. Such infections may include the following:
  - Candidiasis (oral, pharyngeal, vaginal)
  - Pneumocystis pneumonia (PCP)
  - Mycobacterium Avium Complex (MAC)
  - Tuberculosis (TB)
  - Salmonellosis
  - Cytomegalovirus (CMV)
  - Cryptococcal meningitis
  - Toxoplasmosis
  - Cryposporidiosis[52]

Setting

- *Clinical*: Any agency involved in patient treatment or providing direct patient care. Also referred to as healthcare setting. May include hospital EDs, urgent-care clinics, inpatient services, STD clinics or other venues offering clinical STD services, tuberculosis (TB) clinics, substance abuse treatment clinics, other public health clinics, community clinics, correctional health-care facilities, and primary care settings.
- *STI Clinic*: Clinic devoted specifically to the diagnosis and treatment of sexually transmitted infections (STIs).
- *Non-Clinical*: Any agency providing services other than patient treatment or direct patient care. Also referred to as non-healthcare setting.
- *Testing site*: Any location in which an HIV test is provided.
- *Outreach site*: A site in a neighborhood location, business or agency, such as a homeless shelter or bar, in which an HIV test is provided.
- *Metropolitan area*: An area with a total population of at least 100,000 inhabitants and at least one urbanized area of at least 50,000 inhabitants.[53]

Consent approach

- The method by which the recommendation for an HIV test is presented to a person. In one method, the HIV test is offered and the person decides if he or she wants to be tested for HIV (opt-in testing approach). In the other method, the person is tested for HIV unless the person declines (opt-out testing approach).

Patient/client indication of willingness to be tested[54]

- *Verbal:* The person receiving an HIV test indicates his or her assent (or absence of refusal) by verbal (or absence of verbal) comment. This does not refer to what consent information is given, or the format in which it is transmitted.

- *Signed:* The person receiving an HIV test indicates his or her consent (or absence of refusal) by his/her signature or mark. This does not refer to what consent information is given, or whether that information is written.

Post-consent program methods

Testing and Assay[55]

- *Rapid assay:* Results expected to be available during the encounter.
- *Conventional assay:* Results not expected to be available until after the encounter.
- *Additional test*: Any repeat, confirmatory, or other testing during or after initial test, further categorized by assay type, timing, and location where performed.
- *Anonymous testing*: Personal identifiers are not recorded, nor associated with the result.
- *Confidential testing*: The person being tested for HIV provides his or her name and other identifying information.

Pre-result Communication[56]

- *Testing process information:* Basic information about HIV and AIDS, and the testing assay. May also include related information such as the epidemiology of HIV infection, current public health recommendations, or other testing options. Minimally intensive and not individualized.
- *Education:* General information about HIV specific to transmission and risk reduction intended to increase health literacy. May not be highly individualized, and falls short of the requirements for prevention counseling or motivation for behavior change.
- *Prevention counseling:* An interactive process of assessing risk, recognizing specific behaviors that increase the risk of HIV acquisition or transmission, and to plan specific steps to reduce those risks. Highly individualized and expected to motivate behavior change.

Post-result Communication and Methods[57]

- *Post-result information:* Basic information about HIV, the illness caused by HIV, and any other information needed to understand the individual test result.
- *Referral:* Appointments made or referrals given, positive/negative, and intended service or provider/agency.
- *Active referral:* Actively working to ensure that persons receiving an HIV test receive care subsequent to their visit, such as making an appointment for them and/or attempted remediation of failed referral or linkage to care.

Outcome measures

Patient/Client Characteristics

- *Risk profile:* Factors known about the person receiving an HIV test that are pertinent to likelihood of HIV infection. This may include factors recognized before or after the test was made available, such as race/ethnicity, geographic area, risk behaviors, etc.[58]
- *Risk Screening:* A brief evaluation of HIV risk factors, both behavioral and clinical, used for decisions about who should be recommended HIV counseling and testing.[59]
- *Behavioral risk*: Engagement in activities which place a person at increased risk for acquiring HIV. Such activities include engagement in unprotected sexual intercourse or injection drug use.

Result Notification and Linkage[60,61]

- *Successful notification:* Result notification within 14 days (conventional testing) or during visit (rapid testing).
- *Delayed notification:* Result notification more than 14 days (conventional testing) or after ED visit, whether hospitalized or discharged (rapid testing).
- *Unsuccessful notification:* No indication that the person receiving an HIV test was notified of his or her test result.
- *Linkage to Care (LTC):* The process by which newly diagnosed HIV positive persons are actively referred into systems of care.
- *Continuous care*: at least two visits for routine HIV medical care in 12 months at least three months apart.

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