CAHAN San Diego
California HEALTH ALERT NETWORK

Date: March 25, 2019
To: CAHAN San Diego Participants
From: Health and Human Services Agency

HIV Testing Recommended in All Healthcare Settings

The County of San Diego recommends that all persons receive testing for the human immunodeficiency virus (HIV), regardless of risk factors. All healthcare systems, including, but not limited to, primary care settings, emergency departments, and inpatient facilities, should test patients except where the prevalence of undiagnosed HIV infection is known to be 0.1% or less (i.e., ≤1 person in 1,000 is HIV-positive).

Key Points

- Approximately 1,446 San Diego County residents are living with HIV infection but are unaware of it.
- People living with HIV who are unaware of their status account for around 40% of new transmissions.
- Current HIV treatment options are highly effective at preventing complications of HIV infection and onward transmission.
- Identification of people living with HIV who are unaware of their status is a priority of the County of San Diego's Getting to Zero initiative to end the HIV epidemic in the region.
- Local surveillance data indicate significant delays in HIV diagnosis in San Diego County, particularly for persons ≥50 years of age.
- The Centers for Disease Control and Prevention and the United States Preventive Services Task Force recommend a routine opt-out approach to HIV testing.

Situation

San Diego

Approximately 1,446 San Diego County residents are living with HIV infection but are unaware of their status. People living with HIV (PLWH) who are unaware of their status cause approximately 40% of the new HIV transmissions in the United States. Therefore, identifying these individuals is critical, not only to ensure that all PLWH know their status and access the health benefits of antiretroviral therapy (ART), but also to prevent new infections.

Tools to Help End the HIV Epidemic

Biomedical tools are available that can effectively end the HIV epidemic. Specifically, PLWH who are taking combination ART and have undetectable levels of the virus in the blood for at least 6 months cannot transmit HIV to others through sexual intercourse. This concept is known as "treatment as prevention" or TasP.

Daily use of antiretroviral medication by HIV-negative individuals who are at high risk of becoming infected with HIV has been shown to reduce the risk of HIV infection by over 90%. This strategy is known as pre-exposure prophylaxis, or

PrEP. The United States Food and Drug Administration has approved a fixed-dose combination of emtricitabine and tenofovir disoproxyl fumarate (Truvada®, Gilead Sciences) for use by adults and adolescents as PrEP. Other agents are currently under investigation.

Recommendations for Routine Testing

On March 1, 2016, the San Diego County Board of Supervisors unanimously approved the Getting to Zero initiative to end the HIV epidemic in San Diego County. Expansion of PrEP use and identification of all PLWH through routine testing are two core components of this initiative. These approaches are aligned with the Centers for Disease Control and Prevention (CDC) strategy to end the HIV epidemic. Routine, rather than focused or risk-based, HIV testing is consistent with long-standing recommendations by the United States Preventive Services Task Force (USPSTF) and CDC.

Routine testing removes barriers to HIV testing, such as fear, stigma, and inaccurate risk perception by patients and/or providers, and removes the requirement for people to actively seek testing. It also provides the opportunity to diagnose people earlier after infection. Local and national surveillance data indicate that current testing practices, which have focused primarily on those at high risk of HIV infection, have resulted in missed opportunities for early diagnosis of HIV and initiation of ART. Of new cases of HIV infection diagnosed from 2012 through 2016, 489 (20%) received a diagnosis of acquired immune deficiency syndrome (AIDS) within 30 days of being diagnosed with HIV infection (i.e., simultaneous diagnoses). Persons aged 50 years and older were more likely to have simultaneous diagnoses than other age cohorts. Also, CDC reported that the median delay between HIV infection and HIV diagnosis at the national level was 3.0 years (interquartile range 0.7-7.8 years) in 2015, and at-risk heterosexuals were less likely to receive an HIV test than other at-risk groups such as men who have sex with men (MSM) and persons who inject drugs (PWID). Furthermore, at least two thirds of at-risk persons who were not tested in the previous 12 months had seen a healthcare provider in the last year.

Progress since Getting to Zero Implemented

San Diego County is making significant progress in the effort to end the HIV epidemic. In 2017, the number of new cases of HIV infection reported in the county decreased by 21% (from 499 cases in 2016 to 392 cases in 2017). Eliminating new infections will require a multipronged approach that includes identifying all PLWH and linking them to ART and providing all at-risk HIV-negative persons with PrEP. HIV testing is the first step to ensure that those who need ART for treatment or prevention purposes receive it.

Recommendations for Healthcare Systems and Providers

- Offer routine HIV testing to all adolescent and adult patients, except for patients who:
  - are known to have HIV infection; or
  - have a documented previous negative HIV test result and no ongoing risk factors for HIV infection.
- Routine HIV testing should be voluntary. Providers should inform patients that an HIV test will be performed, provide information about HIV infection and the meaning of positive and negative test results, allow patients to ask questions, and give patients the opportunity to decline testing.
- For persons who have negative baseline HIV testing, offer at least annual testing to those who are at increased risk of acquiring HIV, including:
  - MSM
  - PWID
  - Persons who have acquired or required testing for other sexually transmitted infections (STIs)
  - Persons who have unprotected vaginal or anal intercourse with someone who is HIV-positive or of unknown HIV serostatus
  - Persons with sexual partners who are MSM or PWID
  - Persons who exchange sex for drugs or money
- Providers should regularly obtain sexual histories from patients and obtain information about substance use, including injection drug use, as patients may not feel comfortable bringing up these subjects themselves.

- Healthcare systems should develop processes for follow-up of HIV test results, disclosure of positive test results, and timely linkage of newly-diagnosed individuals to HIV primary care. Collaboration across specialties and dedicated multidisciplinary teams to handle new HIV diagnoses will maximize the likelihood of success.
- Be aware that the HIV, STD, and Hepatitis Branch (HSHB) of Public Health Services can be a resource in a number of areas, including technical assistance with positive HIV test disclosures, HIV partner services, and linkage to HIV primary care and treatment. Please call **(619) 692-8501** for assistance.

Attachments

Number	Document Title	Brief Description
1	Dear Colleague Letter	Letter from County of San Diego STD Controller about recommendation for routine HIV testing in healthcare settings
1a	County of San Diego Statement-Routine HIV Testing in Healthcare Settings	Detailed statement that includes: 1) national recommendations for routine HIV testing in healthcare settings; 2) a brief overview of California state laws regarding HIV testing; 3) the most current available data regarding new HIV diagnoses in San Diego County, and potential missed opportunities for HIV screening; 4) information about the County of San Diego Getting to Zero initiative; and 5) specific recommendations for routine HIV testing in local healthcare systems
1b	Frequently Asked Questions about Routine HIV Testing	A brief document with commonly asked questions regarding the County recommendation for routine HIV testing in question-and-answer format
1c	HIV Testing Fact Sheet	A brief document that describes: 1) the benefits of HIV testing; 2) HIV testing recommendations; 3) HIV testing strategies and results disclosure; 4) delayed HIV diagnoses; 5) HIV testing challenges and opportunities; and 6) additional resources.
1d	Rationale for Routine HIV Testing of Adults and Adolescents in Healthcare Settings	Description of the County rationale for recommending routine HIV testing in local healthcare settings, with reference to national recommendations and the limitations of focused, or risk-based, HIV testing strategies

Thank you for your continued participation.

CAHAN San Diego
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WILMA J. WOOTEN, M.D., M.P.H.
PUBLIC HEALTH OFFICER

March 25, 2019

Dear Colleague:

The County of San Diego strongly recommends that local healthcare systems offer routine testing for the human immunodeficiency virus (HIV), regardless of risk factors, in order to identify persons living with HIV who are unaware of their status. This recommendation is based on recommendations made by the Centers for Disease Control and Prevention (CDC) and the United States Preventive Services Task Force (USPSTF) in 2006 and 2013, respectively. ***A significant proportion of HIV transmissions are attributable to HIV-infected individuals who are unaware of their status.*** Engaging local healthcare systems to identify these individuals and link them to antiretroviral therapy (ART) is one of the primary strategies of the County of San Diego Board of Supervisors Getting to Zero initiative to end the HIV epidemic in the region. It also is aligned with the *Live Well San Diego* vision of healthy, safe, and thriving communities in the region.

The attached County of San Diego Statement: Routine HIV Testing in Healthcare Settings (Appendix #1a) includes: 1) specific recommendations for routine HIV testing in local healthcare systems; 2) national recommendations for routine HIV testing in healthcare settings; 3) a brief overview of California state laws regarding HIV testing; 4) the most current available data regarding new HIV diagnoses in San Diego County, and potential missed opportunities for HIV screening; and 5) information about the County of San Diego Getting to Zero initiative.

Also attached are: Frequently Asked Questions about Routine HIV Testing (Appendix #1b), HIV Testing Fact Sheet (Appendix #1c), and Rationale for Routine HIV Testing of Adults and Adolescents in Healthcare Settings (Appendix #1d).

If you have any questions about the County of San Diego's Getting to Zero initiative, the above recommendation, or the appendices, please do not hesitate to contact me (Winston.Tilghman@sdcounty.ca.gov).

Sincerely,

Myres Winston Tilghman, MD
Medical Director and STD Controller
HIV, STD, and Hepatitis Branch

County of San Diego Statement
Routine HIV Testing in Healthcare Settings

Recommendations for Healthcare Systems

- Offer routine human immunodeficiency virus (HIV) testing to all adolescent and adult patients, except for those who:
  - are known to have HIV infection; or
  - have a documented previous negative HIV test result and no ongoing risk factors for HIV infection.
- Routine HIV testing should be voluntary. Providers should inform patients that an HIV test will be performed, provide information about HIV infection and the meaning of positive and negative test results, allow patients to ask questions, and give patients the opportunity to decline testing.
- For persons who have negative baseline HIV testing, offer at least annual testing to those who are at increased risk of acquiring HIV, including:
  - Men who have sex with men (MSM)
  - Persons who inject drugs (PWID)
  - Persons who have acquired or required testing for other sexually transmitted infections (STIs)
  - Persons who have unprotected vaginal or anal intercourse with someone who is HIV-positive or of unknown HIV serostatus
  - Persons with sexual partners who are MSM or PWID
  - Persons who exchange sex for drugs or money
- Providers should regularly obtain sexual histories from patients and obtain information about substance use, including injection drug use, as patients may not feel comfortable bringing up these subjects themselves.
- Healthcare systems should develop processes for follow-up of HIV test results, disclosure of positive test results, and timely linkage of newly-diagnosed individuals to HIV primary care. Collaboration across specialties and dedicated multidisciplinary teams to handle new HIV diagnoses will maximize the likelihood of success.
- Be aware that the HIV, STD, and Hepatitis Branch (HSHB) of Public Health Services can be a resource in a number of areas, including technical assistance with positive HIV test disclosures, HIV partner services, and linkage to HIV primary care and treatment. Please call **(619) 692-8501** for assistance.

National Recommendations for Routine HIV Testing

On July 2, 2013, the United States Preventive Services Task Force (USPSTF) issued a Grade A recommendation for clinicians to screen for HIV infection in adolescents and adults aged 15 to 65 years, including those without known risk factors for HIV infection. This represented an expansion of previous USPSTF recommendations for HIV testing in persons at increased risk for HIV infection and pregnant women. The updated recommendation was based on evidence demonstrating the benefits of antiretroviral therapy (ART) in persons with higher CD4+ T-lymphocyte counts (i.e., HIV-positive

persons who were likely to be asymptomatic and more likely to be detected by screening than by clinical presentation), including reduction in acquired immune deficiency syndrome (AIDS)-related events and reduced risk of transmitting HIV to others. The full recommendation statement can be found here.

The USPSTF endorsed a previous recommendation by the Centers for Disease Control and Prevention (CDC) that HIV screening should be voluntary and done only with the patient's knowledge and understanding. Patients should be informed that HIV testing will occur unless they decline the test (i.e., "opt-out" testing) and, prior to the test, should receive an explanation of HIV infection and the meaning of positive and negative HIV test results. They should be offered the opportunity to ask questions and to decline testing.

Although the USPSTF did not recommend a specific testing frequency for adults aged 15 to 65 years, a suggested approach included a one-time screening of patients in this age cohort, with repeated screening for those with risk factors or in communities or geographic locations with an HIV seroprevalence of at least 1%. Routine testing is not recommended for settings with extremely low prevalence (i.e., ≤0.1%). HIV seroprevalence can be determined by screening approximately 4,000 patients. If no HIV-infected patients are identified, a risk-based, rather than a routine, HIV screening approach could be adopted.

California HIV Testing Laws

Consistent with the USPSTF recommendation for HIV screening, the California Health and Safety Code (HSC) provides guidance regarding routine opt-out HIV testing in primary care settings.

Section 120990 of the HSC requires providers who perform routine opt-out HIV testing to:

1) Inform the patient that an HIV test is planned;
2) Provide information about the test;
3) Inform the patient that there are numerous options available for HIV treatment;
4) Advise the patient that persons who test negative for HIV should continue to be routinely tested; and
5) Inform the patient that he/she may opt out of testing.

Section 120991 of the HSC states that each patient who has blood drawn at a primary care clinic and has consented to an HIV test pursuant to Section 120990 of the HSC shall be offered an HIV test.

Section 120992 of the HSC calls for pilot testing of routine HIV testing based on USPSTF recommendations in four designated emergency departments in California. Pilot testing was projected to end on February 28, 2019, and results of pilot testing will be reported to the California State Legislature by December 1, 2019.

Potential Missed Opportunities for HIV Testing

Despite the fact that the USPSTF and CDC recommendations have been in place for several years, local HIV surveillance data indicate potential missed opportunities to detect HIV infection. Of the new cases of HIV infection diagnosed from 2012 through 2016, 489 (20%) received simultaneous diagnoses (i.e. received a diagnosis of AIDS within 30 days of HIV diagnosis), indicating that they had HIV infection for several years prior to receiving an HIV test. Persons older 50 years of age, who make up an increasing proportion of new reported HIV cases, were more likely to have a simultaneous diagnosis than other age cohorts.

Delays in HIV diagnosis are supported by a recent CDC publication that reported a median delay between HIV infection and HIV diagnosis of 3.0 years (interquartile range 0.7-7.8 years) among the 39,720 persons diagnosed with HIV infection nationwide in 2015. CDC analyzed data from the National HIV Behavioral Surveillance (NHBS) survey and determined the percentage of individuals in different risk groups (i.e., MSM, PWID, and at-risk heterosexuals) who had received an HIV test in the previous 12 months. Among those interviewed for NHBS, 71% of MSM, 58% of PWID, and 41% of at-risk heterosexuals reported having received an HIV test in the previous 12 months. At least two thirds of those who were not tested had seen a health care provider in the past year.

The CDC estimates that 15% of persons living with HIV infection in 2015 were unaware of their diagnosis. It is estimated that there are 1,446 persons living with HIV in San Diego County who are unaware that they have HIV. Approximately 40% of HIV transmissions in the United States are attributed to HIV-positive persons who are unaware of their status. People who are unaware of their HIV status do not receive the health benefits of ART and may engage in behaviors that could result in transmission of HIV to others. Therefore, increasing the number of people living with HIV infection who are aware of their status is critical, not only to improve health outcomes for those who are infected, but also to prevent new infections from occurring in the community.

Getting to Zero

“Getting to Zero” was the title of the Joint United Nations Programme on AIDS (UNAIDS) Strategic Plan for 2011-2015 and was based on the vision of a world with zero new HIV infections, zero AIDS-related deaths, and zero discrimination. It was firmly grounded in science, thanks to significant advances in HIV prevention, HIV testing, and access to highly effective treatment. In 2014, Chairman Ron Roberts and Supervisor Dave Roberts called for the formation of an Ad Hoc Task Force of the HIV Services Planning Group to review the state of HIV in San Diego County and formulate recommendations for improving outcomes related to HIV. These recommendations were adopted by the Board of Supervisors on March 1, 2016, as the Getting to Zero initiative.

The Task Force outlined six general recommendations, which include:

1) Promoting awareness of HIV as a major public health concern;
2) Engaging public and private healthcare systems in Getting to Zero;
3) Implementing pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) to reduce new HIV infections;
4) Using HIV and STI surveillance data to improve health outcomes for persons living with HIV, as well as identify individuals at high risk for HIV infection;
5) Developing specific strategies to reduce disproportionalities among key populations; and
6) Pursuing policies that will help achieve Getting to Zero. In order to implement the second recommendation, the County of San Diego convened a Medical Advisory Committee that consists of representatives from inpatient and outpatient healthcare facilities from throughout the County as well as the Hospital Association of San Diego and Imperial Counties (HASDIC). Expanding routine HIV testing in healthcare settings is the main focal point of this committee. The full Getting to Zero Implementation Plan is available here.

Frequently Asked Questions about Routine HIV Testing

What is the County's recommendation regarding routine HIV testing in health care settings?

- The County of San Diego Health and Human Services Agency (HHSA) recommends that **all persons receive testing for the human immunodeficiency virus (HIV), *regardless of risk factors***.
- Patients should be advised verbally or in writing that an HIV test will be performed as a routine part of the visit and that they may opt out of the test. They also should receive education on the meaning of positive and negative test results and the fact that HIV treatment is available.

Why is the County recommending routine HIV testing?

- Approximately **1,446** people living with HIV (PLWH) in San Diego County and 161,200 PLWH nationwide are **unaware of their infection** and therefore are not able to experience the health benefits of antiretroviral treatment (ART).
- People who have HIV, but don't know it, may unknowingly transmit the virus to others. The Centers for Disease Control and Prevention (CDC) estimates that **about 40% of new HIV infections are from PLWH who are unaware of their status**.
- Routine testing provides the opportunity to diagnose people earlier after infection, particularly those who are otherwise unlikely to seek or be offered HIV testing. According to CDC, the median time between HIV infection and diagnosis in 2015 was 3 years overall and 5 years for at-risk heterosexuals.
- There are multiple missed opportunities for HIV testing in healthcare settings. A recent analysis by CDC showed that, among individuals at high risk for HIV infection who had not been tested for HIV in the past 12 months, at least two thirds of them had seen a health care provider in the past year.
- People may not talk to their providers about HIV risk or seek/request an HIV test due to fear of stigma or a lack of awareness of their risk. Normalizing HIV testing as a routine part of medical care removes these barriers to testing.
- CDC issued a recommendation for routine opt-out HIV testing in 2006, and several years later the United States Preventive Services Task Force endorsed this approach based on available evidence. This opt-out approach is allowed under California state law.

How does this fit into the County Getting to Zero initiative to end the HIV epidemic?

- Highly effective ART has changed the face of HIV prevention and made ending the HIV epidemic possible.
    - ART allows PLWH to live long and healthy lives if it is started early enough after infection, but it may be less effective for those who have advanced infection by the time they are diagnosed with HIV.
    - PLWH who are on ART and have undetectable levels of the virus in the blood for at least 6 months have no risk of transmitting HIV to others through sexual intercourse.

    - Daily use of an ART medication by HIV-negative individuals at high risk of becoming infected can reduce the risk of getting HIV by as much as 99%. This is called pre-exposure prophylaxis or PrEP.
- People can only benefit from ART as treatment or prevention by knowing their HIV status. That is why testing is so important.

What resources are available to assist providers who have a patient who tests positive for HIV?

- The HIV, STD, and Hepatitis Branch, Division of Public Health Services in HHSA can assist with disclosure of positive HIV test results and link newly-diagnosed PLWH to HIV primary care and treatment. They also can provide technical assistance regarding HIV testing practices. Call **(619) 692-8501** for more information!
- A number of resources are available through CDC, including HIV screening recommendations that are based on the most current testing technologies and best practices.
- Additional training and resources are available through the Pacific AIDS Education Training Center (http://paetc.org) and the University of Washington (https://www.hiv.uw.edu).

HIV Testing Fact Sheet

In 2006, the Centers for Disease Control and Prevention (CDC) issued a recommendation for opt-out testing for the human immunodeficiency virus (HIV) of all persons aged 13-64 years as a routine part of clinical care in all healthcare settings, regardless of risk factors. In 2013, the United States Preventive Services Task Force (USPSTF) issued a Grade A recommendation for routine opt-out HIV testing of all persons aged 15-65 years. These were major departures from previous guidelines that limited HIV testing to those who had known risk factors for infection.

Benefits of HIV Testing

HIV testing is recommended for all adults and adolescents due to its individual and public health benefits.

For people who are not aware that they have HIV, testing and subsequent knowledge of their status enables them to access HIV care and treatment. If started early enough, HIV treatment lowers the amount of HIV circulating in the blood to levels below those which can be detected by commercially available viral load tests (i.e., undetectable viral loads). Achievement of sustained (i.e., ≥ 6 months) undetectable viral loads results in improved health and quality of life and longer life expectancy by decreasing the virus's effect on the immune system. It also *eliminates* the risk of sexual transmission of HIV to others, thereby decreasing new infections in the community.

For people who do not have HIV, but are at risk for HIV infection, the knowledge of their status enables them to take steps to remain HIV-negative. One of the medications used to treat HIV infection is also approved for use by HIV-negative adults and adolescents to prevent HIV infection from occurring (i.e., pre-exposure prophylaxis or PrEP). In addition to behavioral changes, such as condom use with sexual activity and limiting the number of sexual partners, PrEP can reduce the risk of acquiring HIV by up to 99%, if taken as directed.

HIV Testing Recommendations

CDC recommends that all adults and adolescents aged 13 to 64 years get tested at least once for HIV as a routine part of their medical care, regardless of risk factors. Gay, bisexual, and other men who have sex with men and others with risk factors for HIV infection should be tested more frequently.

CDC recommends "opt-out" screening for HIV, meaning that a patient is informed orally or in writing that an HIV test will be done and is given the opportunity to opt out of the test. The patient also should receive information about HIV, the meaning of positive and negative test results, and the availability of HIV treatment and should be given the opportunity to ask questions about the test. If the patient accepts the test, a separate written informed consent is not required, as the voluntary opt-out HIV test would be covered by the general consent for medical care. This approach to HIV testing is allowable under California law (Health and Safety Code Sections 120990 and 120991).

HIV Testing Strategies and Results Disclosure

HIV testing technology has improved substantially over time. If an initial test for HIV is positive, a second test is always done to confirm the result.

HIV antibody tests detect the presence of antibodies against HIV, which typically develop within two to eight weeks after exposure, and can be performed on a blood or oral fluid sample. Since it takes time for antibodies to develop, testing for antibodies alone may miss recent infections.

Combination antigen-antibody tests detect both antibody against HIV and a protein that is part of the virus (p24 antigen). Since p24 antigen can be detected within four to seven days before HIV antibodies appear, these tests will miss fewer recent infections than antibody tests but still may miss some.

HIV Ribonucleic Acid (RNA) tests detect the actual presence of the virus in the blood and can detect infection soon after exposure, typically within 10-15 days of exposure.

Recommended HIV testing algorithms start with an HIV antibody test or combination antigen-antibody test. HIV RNA testing may be performed if there are discordant initial and confirmatory test results (i.e., the first test is positive, but the confirmatory test is negative) and/or if recent or acute HIV infection is suspected.

Receiving an HIV diagnosis can be a stressful time, but the good news is that current HIV treatment options are highly effective and allow people to live long and healthy lives. Also, newer HIV medications have much better side effect profiles than older HIV medications.

It is important to know the resources available for HIV care and treatment when informing someone that he/she has tested positive for HIV. Most HIV primary care clinics are set up to take new patients within days of diagnosis or even on the same day, and treatment is available to everyone, even those without health insurance. The local health department can provide assistance in disclosing positive HIV test results and linking newly-diagnosed HIV-positive persons to care. Please call **(619) 692-8501** to learn more or to request assistance.

Delayed HIV Diagnoses

In 2016, a total of 15,132 people were estimated to be living with HIV in San Diego County. Of these, 13,686 (90%) were aware of their status. Approximately 1,446 people, or 10% of the total number of people living with HIV in San Diego, are thought to have HIV infection but not know it. According to CDC, about 40% of HIV transmissions are attributed to people living with HIV who are unaware of their status. Therefore, identifying the unaware through testing is critical, so that they can take measures to improve their own health and avoid transmitting the virus to others.

Local and national data indicate that there are significant delays between HIV infection and diagnosis. The median delay between HIV infection and HIV diagnosis at the national level is three years. In San Diego, of the new cases of HIV infection that were reported from 2012 through 2016, 489 (20%) received a diagnosis of the acquired immune deficiency syndrome

(AIDS) within 30 days of HIV diagnosis, indicating that they had HIV infection for several years prior to testing. Persons aged 50 years and older, who account for an increasing proportion of new reported HIV cases (16.4% of cases diagnosed from 2012 to 2016), were more likely than other age cohorts to receive a diagnosis of AIDS within 30 days of HIV diagnosis.

HIV Testing Challenges and Opportunities

People may not seek HIV testing due to fear, stigma, or lack of awareness of their risk for HIV infection. However, many people who have HIV or are at risk of getting it may have contact with the healthcare system in places such as primary care clinics, urgent care facilities, and emergency departments. Routine testing in healthcare settings removes these barriers to HIV testing and presents an opportunity to identify the unaware, get them the treatment they need, and prevent new HIV infections.

Additional Resources

Centers for Disease Control and Prevention: https://www.cdc.gov/hiv/testing/clinical/index.html

Pacific AIDS Education and Training Center: http://paetc.org/resources/

RATIONALE FOR ROUTINE HIV TESTING OF ADULTS AND ADOLESCENTS IN HEALTHCARE SETTINGS

In 2013, the United States Preventive Services Task Force (USPSTF) issued a Grade A recommendation for routine testing of adolescents and adults aged 15 to 65 years for HIV infection, regardless of known risk factors for infection. This expansion of previous recommendations, which were limited to those at increased risk of infection, was based on the significant proportion of people living with HIV (PLWH) who are unaware of their infection or diagnosed at a late stage of infection, the effectiveness and safety of antiretroviral therapy (ART), and the demonstrated benefits of early diagnosis and treatment of HIV infection. These include both individual and population-level benefits due to improved health outcomes for those on treatment and reduced risk of onward transmission.

***Hundreds of new HIV infections continue to occur in San Diego County each year, despite advances in treatment and prevention*.**

In 2017, a total of 392 new cases of HIV infection were reported in San Diego County, representing a 21% decrease from 499 new cases reported in 2016 and the lowest number of new cases since the beginning of the HIV epidemic.[1] While this decline in new HIV infections is encouraging, hundreds of people continue to become infected with HIV each year in San Diego County. Furthermore, local surveillance data indicate that significant delays in HIV diagnosis, which can lead to poor health outcomes for individual PLWH and increase the risk of onward transmission in the community, continue to occur. In 2015, 22% of new cases of HIV infection in San Diego County also received a diagnosis of acquired immune deficiency syndrome (AIDS) within the first year of HIV diagnosis.[1] Furthermore, a total of 20% of individuals diagnosed with HIV infection between 2012 and 2016 received "simultaneous diagnoses" (i.e., were diagnosed with AIDS within 30 days of HIV diagnosis).[1] Persons aged 50 years and older were more likely to have simultaneous diagnoses than other age cohorts (30.2% versus 8.0% , 14.6%, and 20.4% of newly diagnosed persons aged 20-29 years, 30-39 years, and 40-49 years respectively). These data indicate that a significant proportion of recently-diagnosed PLWH in San Diego County had HIV infection for several years prior to being diagnosed. These cases represent missed opportunities for early diagnosis of HIV infection, initiation of life-saving treatment, and prevention of onward transmission of HIV in the region.

Throughout much of the HIV epidemic, screening efforts have focused on those with known risk factors for HIV infection and/or those who actively seek HIV testing. While these focused testing strategies have resulted in the identification of many PLWH, an estimated 1,446 PLWH in San Diego County are unaware that they have HIV infection. Therefore, not everyone living with HIV is being identified through focused testing. Fear and stigma can prompt patients to provide inaccurate sexual histories to their providers (i.e., tell them what they want to hear), to withhold information about sexual activities, and to not seek HIV testing.[2] Also, people who are considered to be at low risk of infection (e.g., heterosexuals who do not inject drugs) may not be aware of factors that may place them at risk of HIV infection and may not be offered an HIV test

by their provider. It is estimated that around 40% of HIV transmissions in the United States (U.S.) are from PLWH who are unaware of their infection[3]. Therefore, focused HIV testing alone is not enough to end the HIV epidemic and prevent new infections from occurring.

Currently available treatment improves health outcomes and decreases transmission to others, especially when started early after infection is acquired.

The availability of highly effective combination ART has resulted in improved health outcomes for PLWH, including decreased risk of progression to AIDS, decreases in AIDS-related complications and deaths, and longer life expectancy. HIV treatment limits the effect of the virus on the host immune system by reducing viral replication (i.e., preventing the virus from copying itself) and reducing the amount of virus circulating in the blood and capable of infecting target cells. The goal of ART is to achieve a sustained undetectable viral load, which means that levels of HIV in the blood are so low that they cannot be detected by commercially available viral load tests. While the benefits of treating people with advanced HIV infection or AIDS, reflected by a CD4+ T-lymphocyte count (or CD4 count) less than 200 cells/mm^3, have been known for a very long time, more recent clinical trials have demonstrated health benefits of treating people with higher CD4 counts (i.e., 200 to 500 cells/mm^3).[4-5] These benefits include decreased risk of HIV-related complications and death.

Recent studies also have demonstrated that treatment of HIV infection prevents transmission to uninfected sexual partners. A growing body of evidence has shown that PLWH who are started on combination ART and have sustained undetectable viral load do not transmit the virus to others through sexual activity[6-8]. Therefore, ART not only benefits individuals who have HIV infection but also benefits the population as a whole by decreasing the potential for onward transmission. This concept has been termed “Treatment as Prevention,” or TasP, and also has resulted in “Undetectable = Untransmittable” (U=U) campaigns throughout the U.S. Early diagnosis and early initiation of ART are essential to achieve undetectable viral loads as quickly as possible and to minimize the period of time during which onward transmission can occur.

Current HIV treatment guidelines recommend initiation of ART in all PLWH, regardless of the stage of infection or CD4 count[9]. This is based on the effectiveness of currently-available ART to control HIV infection, improve health outcomes in PLWH, and prevent transmission of HIV to others. Also, newer antiretroviral medications have more favorable safety profiles, less adverse effects, and lower pill burdens than older agents. Furthermore, several combination ART regimens are available as a single daily pill. In other words, higher benefits and lower risks of ART have tipped the scale clearly in favor of treatment for everyone, rather than reserving it for those who have advanced HIV infection and/or have already experienced complications of the disease.

In addition to the benefits of ART for PLWH, daily use of a single antiretroviral medication by uninfected people who are at risk for acquiring HIV has been demonstrated to significantly reduce the risk of HIV infection. This concept has been termed HIV pre-exposure prophylaxis or PrEP. Currently, one medication, which is a fixed-dose combination of emtricitabine and

tenofovir disoproxyl fumarate (Truvada®, Gilead Sciences) has been approved by the U.S. Food and Drug Administration for use as PrEP. When taken as directed, this medication can reduce the risk of HIV infection by over 90%[10]. The effectiveness of other antiretroviral medications, including long-acting agents, currently is being evaluated in research studies, making it likely that even more options for PrEP will be available in the future.

Routine HIV testing is critical to ensure that everyone who would benefit from ART, as either treatment or prevention, receives it and to end the HIV epidemic in San Diego County.

Being aware of one's HIV status is the first step to maintaining personal health and protecting others from HIV. People with HIV infection can receive treatment to improve their health and allow them to have healthy relationships, and people without HIV infection who are at risk of acquiring it can benefit from PrEP and other prevention strategies. Even in the absence of treatment, when people know that they are HIV-positive, they are less likely to engage in behaviors that are associated with risk of transmission (i.e., unprotected anal and/or vaginal intercourse) than are HIV-positive persons who are unaware that they have the virus.[11] Identifying the unaware is essential to end the HIV epidemic.

However, focused HIV testing strategies alone are not enough to identify the unaware and to end the HIV epidemic. According to a report released by the Centers for Disease Control and Prevention (CDC), approximately 15% of PLWH in 2015 were unaware of their status.[12] Not everyone who would benefit from HIV testing and/or is at risk for acquiring HIV infection receives testing. In particular, heterosexuals are more likely to be diagnosed with HIV later in the course of the infection and are less likely to be offered HIV testing by health care providers, even if they have risk factors.

Among persons who were diagnosed with HIV infection in 2015, the median interval from the time of infection to the time of diagnosis was three years (interquartile range 0.7-7.8 years) overall and even longer (4.9 years) in heterosexual males. Among persons interviewed through CDC's National HIV Behavioral Surveillance, 71% of gay, bisexual, and other men who have sex with men (MSM), 58% of persons who inject drugs, and 41% of heterosexuals who were at increased risk of acquiring HIV reported having been tested in the previous 12 months. About two thirds of persons in each risk group who had not been tested for HIV in the last year reported having seen a health care provider in the past year. Of those who were not tested for HIV in the past 12 months but had seen a provider during the same time frame, three fourths reported not being offered the test at any of their visits.[12] These data indicate that focused testing strategies fail to accurately identify all people who are at risk for HIV infection and highlight the need for a new testing strategy to identify the unaware.

Routine HIV testing, using an opt-out model, decreases the stigma associated with HIV testing, addresses the issue of inaccurate perception of risk by both providers and patients, and reduces the time and effort required to conduct HIV testing in busy clinical settings.

Routine HIV testing, regardless of risk factors, is not a new concept. In fact, in 2006 CDC issued a recommendation that all persons aged 13 to 64 get tested for HIV at least once in life as a part of routine healthcare, regardless of risk factors. CDC also recommended opt-out testing, which means that providers advise patients that HIV testing will be done as a part of their routine healthcare, unless he or she opts out of the test.[13] This is in contrast to traditional HIV testing practices, which required pre-test counseling and a separate written informed consent prior to testing for HIV. Although these requirements were important during the earlier years of the HIV epidemic, when effective treatment was not available and an HIV diagnosis could result in the loss of family, friends, housing, and/or employment, they resulted in exceptionalism of HIV testing. Routine opt-out testing removes this exceptionalism that can be a barrier to HIV testing, particularly in busy clinical settings where dedicated staff for HIV counseling and testing may not be available. In its most recent HIV screening guidelines, the USPSTF endorsed this opt-out model for routine HIV testing.[14] California state law provides a framework for providers who conduct routine opt-out HIV testing in Section 120990 of the Health and Safety Code.

Routine opt-out testing decreases stigma and fear surrounding HIV testing by normalizing HIV testing as a routine part of healthcare, equating HIV testing to other routine tests, and not requiring any acknowledgement of stigmatized behaviors that are associated with increased risk of HIV infection. It also addresses the problems with inaccurate perception of risk by both providers and patients that may result in failure to perform HIV testing of persons who actually have risk factors for HIV. Providers may not be aware of a patient's actual risk for HIV if they do not routinely take a sexual history from patients or if patients do not feel comfortable providing accurate information regarding behaviors that increase the risk of HIV acquisition. Also, patients are not always aware of their own risk, as they may be unaware of partner behaviors that put them at risk of acquiring HIV.

Many people living with or at risk for HIV do not seek HIV testing or present to HIV testing centers but present to other healthcare settings.

These settings include, but are not limited to, primary care settings, urgent care centers, and hospital emergency departments. Performance of routine opt-out testing in these settings is an opportunity to reach people who otherwise are unlikely to seek or be offered testing and to identify the unaware. This decreases the time between HIV infection and diagnosis, which is associated with better health outcomes and a decrease in the period of time during which onward transmission may occur. In other words, identifying the unaware improves the efficacy of ART, reduces complications of HIV infection, and reduces the number of new HIV infections. All of these translate into reduced costs to the healthcare system in the long term and a healthier population.

While follow-up of HIV test results and management of people who test positive for HIV may be a concern, there are numerous resources available to PLWH in San Diego County. HIV treatment is available to anyone who has a diagnosis of HIV infection, regardless of insurance, ability to pay, or documentation status. HIV care and treatment are available in most major

healthcare systems and in multiple public and private clinics throughout San Diego County. The County of San Diego can provide assistance with disclosure of positive HIV test results and assistance with linkage to HIV care and treatment. For more information, visit http://getting2zerosd.com/get-treatment/ or call **(619) 692-8501**.

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