

PROGRAMS TO INCREASE HIV TESTING AND COUNSELING:
THE DOORWAY TO PREVENT AND CONTROL HIV AMONG VULNERABLE
POPULATIONS

by

Bridget Leyland

BS, Biology, Pennsylvania State University, 2006

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This essay is submitted

by

Bridget Leyland

on

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and approved by

Essay Advisor:

Simon M. Barratt-Boyes, BVSc, PhD _____

Professor

Department of Infectious Diseases and Microbiology

Graduate School of Public Health

University of Pittsburgh

Essay Reader:

Linda Rose Frank, PhD, MSN, ACRN, FAAN _____

Associate Professor of Public Health, Medicine, and Nursing

Department of Infectious Diseases & Microbiology

Graduate School of Public Health

University of Pittsburgh

Essay Reader:

Mark S. Friedman, PhD, MSW, MPA _____

Assistant Professor

Department of Behavioral and Community Health Sciences

Graduate School of Public Health

University of Pittsburgh

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Simon M. Barratt-Boyes, BVSc, PhD

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ABSTRACT

Human immunodeficiency virus (HIV) is a preventable cause of disease that infects approximately 50,000 individuals annually in the United States. Not all individuals are impacted equally and health disparities exist among racial, ethnic, and sexual minorities. Routine screening for HIV has been effective in certain populations, but widespread testing has been limited. National guidelines call for routine HIV screening among individuals aged 13-64 years seeking healthcare; however, implementation has been hindered due to barriers at the individual, health system, and societal level. HIV prevention counseling is also recommended for high risk individuals, but not required as part of routine testing because of time and staffing restraints. A number of HIV testing program interventions have sought to streamline testing and counseling procedures to combat such barriers. This review aims to summarize HIV testing and counseling programs in the U.S., the effect on individual and public health, and offer directives for future use of HIV screening. The public health importance for increasing knowledge of HIV status will benefit HIV positive individuals by promoting early entry into care and faster time to treatment. Both HIV positive and negative individuals may benefit from HIV prevention education to reduce their risk for transmitting or acquiring HIV, thus control the spread of infection.

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PREFACE

I would like to acknowledge the Pittsburgh AIDS Task Force (PATF) for allowing me the opportunity to gain experience in HIV testing and counseling practice in a public health setting, Dr. Frank and Dr. Friedman for their invaluable feedback and contribution to this work, Dr. Barratt-Boyes for his guidance and mentoring, and the Department of Infectious Disease & Microbiology, Graduate School of Public Health for the opportunity to study, practice, and present public health.

1.0 INTRODUCTION

In the United States an estimated 15.8% of individuals living with human immunodeficiency virus (HIV) infection are unaware of their status and many continue to propagate the HIV epidemic by unknowingly spreading the virus to others.^{1,2} In 2009, 32% of individuals newly diagnosed with HIV infection progressed to acquired immunodeficiency syndrome (AIDS) within one year, suggesting these individuals have been living with HIV for years and gone undiagnosed.^{3,4} Identifying and diagnosing HIV positive individuals at the earliest stage possible is crucial to not only benefit the individual by getting them into care, but to benefit public health by controlling HIV transmission by those unaware they are positive. Broadening and increasing HIV testing to identify HIV positive individuals promotes early entry into care and faster time to highly active anti-retroviral treatment (HAART) to improve health outcomes. Knowledge of one's HIV positive status has been shown to significantly reduce high risk behavior lowering the likelihood of transmitting HIV, thus controlling the spread of infection.⁵ In addition, HIV negative individuals can benefit from HIV prevention education to practice risk reduction or to avoid acquiring HIV infection. Currently there is no cure for HIV and AIDS. Vaccines and microbicides offer hope, yet none exist to date that effectively prevent infection.

Prevention of HIV relies heavily on identifying at risk individuals and confirming their HIV status to implement behavioral changes that can lead to healthier lives and prevent HIV transmission, which begins with HIV testing. This review aims to summarize HIV testing and counseling as a mechanism to prevent and control HIV among vulnerable populations in the U.S.

and to provide an example of a coordinated care approach at the Pittsburgh AIDS Task Force in Pittsburgh, PA.

1.1 HIV/AIDS TRENDS IN THE UNITED STATES

In the U.S., approximately 1.1 million people aged 13 and older are living with HIV and nearly 50,000 new infections occur each year.⁶ In 2011, the Centers for Disease Control and Prevention (CDC) estimated 49,273 incident HIV infections.⁷ Mortality due to HIV progression to AIDS has declined dramatically since the initiation of HAART;^{8,9,10,11} however AIDS-related deaths still occurred in over 15,000 individuals in 2010.⁷ The cumulative estimation for total AIDS-related deaths in the U.S. reaches over 635,000.⁷ Southern U.S. has the highest percentage (48%) of total AIDS-related deaths. When factoring in population size, the Northeastern region of the U.S. accounted for the highest rates of individuals living with AIDS and AIDS-related deaths.¹² HIV tends to localize to urban areas, with most cases in metropolitan areas defined as greater than or equal to 500,000 people. In 2011, California, Florida, Texas, and New York had the greatest number of cases with HIV infection diagnosis. The District of Columbia, Louisiana, Maryland, and Florida had the highest rates of new HIV diagnosis.¹³

Racial and ethnic groups differ with respect to the impact from the HIV epidemic (Figure 1). African Americans account for the highest number of new HIV diagnosis followed by whites, Hispanic and Latino, Asian, Multiple Race, American Indian and Alaska Native, and Native Hawaiian and Other Pacific Islander.⁷ This view changes with respect to the rates of HIV infection diagnosis for each racial or ethnic group's representation of the U.S. population.³ African Americans remain the most affected by HIV, especially young men who have sex with men (MSM). Hispanic and Latinos are disproportionately affected by HIV infection and account

for approximately 21% of all new infections.^{3,7} Native Hawaiians and Other Pacific Islanders account for a small percent of the overall population, though have a higher estimated rate of individuals unaware of their HIV positive status and the highest proportion of late HIV diagnosis, defined as progression to AIDS within one year. American Indians and Alaska Natives have the second highest proportion of late HIV diagnosis. Whites and Asians have the lowest rates of new HIV infection and late diagnosis when their representation of the U.S. population is factored.^{3,7}

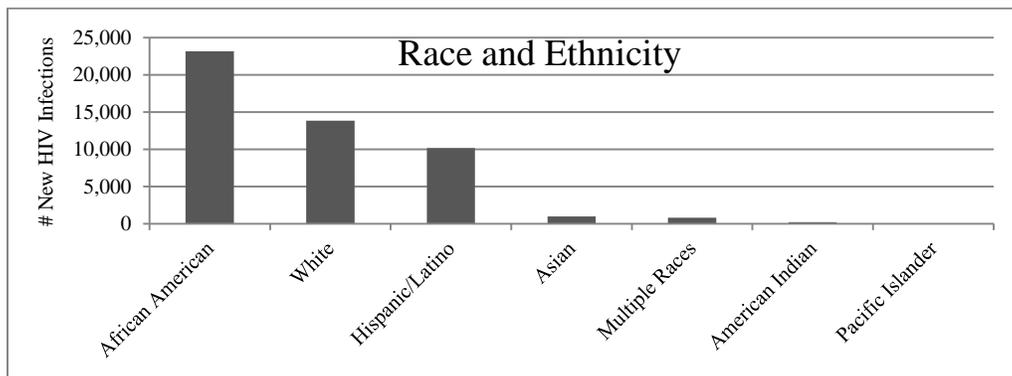


Figure 1. Estimated HIV diagnoses among adults and adolescents by race and ethnicity⁷

Transmission of HIV occurs through infected blood, semen, vaginal and cervical fluid, and breast milk. The major modes of transmission are unprotected anal and vaginal sex or use of HIV contaminated shared needles for injection drug use (IDU). Transmission categories can be defined as male to male transmission, high risk heterosexual contact, and IDU of shared needles, as shown in Figure 2. Other modes of transmission include perinatal exposure or blood transfusion with HIV infected blood. HIV transmission has been significantly reduced in the U.S. due to universal HIV screening of all blood donations. The availability of antiretroviral treatment

for HIV positive pregnant women has significantly decreased cases of perinatal acquired HIV infection.^{14,15}

Overall, men account for a higher proportion of HIV incidence and prevalence than women. In 2010, males represented 76% of individuals living with HIV and 69% considered themselves gay, bisexual, or MSM, representing the most significantly affected group by the HIV epidemic in the U.S. Sexual activity between men is the primary route of transmission (78% of new HIV infection in men, 63% of total new HIV infections).⁷ Approximately 1 in 4 individuals living with HIV are female and high risk heterosexual contact is the primary route of transmission (84% of new HIV infections in women). High risk heterosexual contact includes unprotected sex, sex with multiple partners, sex with a person who is HIV positive or highly at risk for HIV infection.

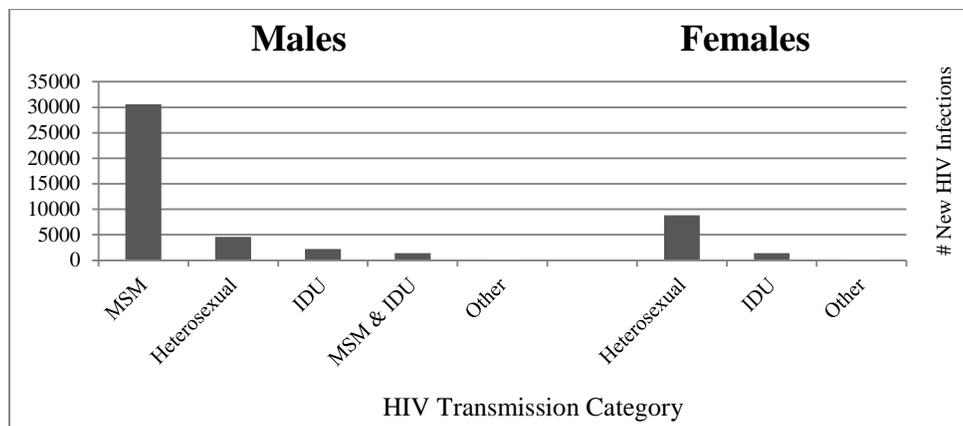


Figure 2. Estimated HIV diagnoses among adults and adolescents by transmission⁷

In most cases, the risk for acquiring and transmitting HIV begins at the onset of high risk sexual activity or IDU and continues as long as such behavior continues. The impact of HIV diagnosis on different age groups is varied (Figure 3), but estimates show younger individuals

aged 13-29 are at an increased risk for new infection, especially young African American and Hispanic/Latino MSM. In 2009, MSM aged 13-29 represented 69% of incident HIV infections among MSM and 27% of all new HIV infections.⁷ Children less than 13 years of age mainly acquired HIV via mother-to-child transmission, and in 2011 an estimated 127 children acquired HIV.⁷ In the U.S., perinatal transmission has been greatly reduced by screening pregnant women for HIV and treating HIV positive pregnant women with HAART to reduce viral load to undetectable levels.^{15,16} HIV positive pregnant mothers often deliver through caesarean section to reduce HIV transmission and do not breast feed.^{17,18}

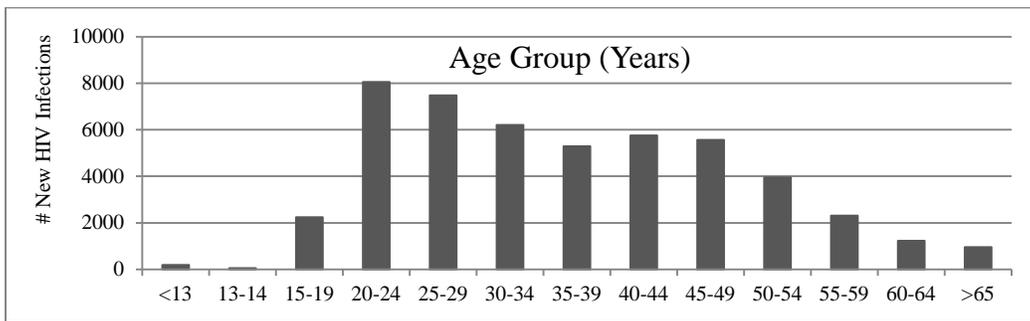


Figure 3. Estimated HIV diagnoses among adults and adolescents by age⁷

1.2 DISPARITIES IN PREVENTION AND CONTROL OF HIV

HIV incidence among subpopulations in the U.S. based on gender, race/ethnicity, and transmission category are shown in Figure 4. The impact of HIV on certain subpopulations is disproportionate to their representation of the U.S. population. These vulnerable groups represent small portions of the population, yet over represent the burden of HIV infection. Disparities in HIV infection among subpopulations can be viewed by race/ethnicity and sexual orientation,

though there is overlap among groups. Vulnerable populations highly susceptible to contracting and spreading HIV present a unique challenge to HIV testing efforts.^{19,20}

Racial and ethnic minorities are highly impacted by HIV/AIDS. African Americans, who represent 12% of the U.S. population, account for 44% of Americans living with HIV/AIDS, 44% of new HIV infections, and 40% of total HIV-related deaths.^{3,7} Racial disparities exist in the percent estimated lifetime risk of becoming HIV-infected where 1 in 70 white Americans compared to 1 in 22 African Americans will become infected with HIV.²¹ African American males are 6 times more likely to acquire HIV than white males and African American females are 16 times more likely than white females.²¹ MSM transmission is the number one cause of new HIV infection in African American males (73%) and heterosexual contact is the most common cause of new infection in females (85%).⁶ African Americans are most affected by HIV/AIDS compared to other races with 475,000 cumulatively diagnosed with AIDS, an estimated 20,000 will be diagnosed with HIV, and 16,000 will be newly diagnosed with AIDS.^{3,6} Among youths aged 13-24, HIV disparately affects African Americans where 20% of new HIV infections occur in all youths, 65% of youth HIV diagnosis occurs in African Americans with an increased risk in youth MSM.⁶ Hispanics and Latinos are also disproportionately affected by HIV, representing 17% of the U.S. populations, but accounting for 21% of all new HIV infections and 19% of persons living with HIV/AIDS.^{3,6,22}

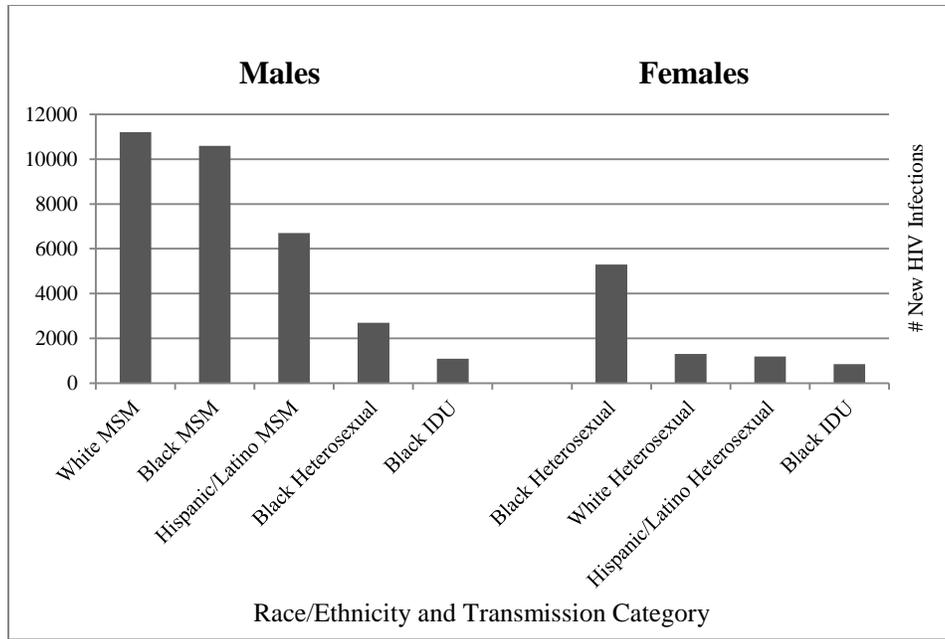


Figure 4. HIV infection estimates for most affected subpopulations in the U.S.³

An investigation of 91,307 HIV-related deaths in individuals aged 25-64 from 1993-2007 assessed HIV mortality trends among racial and ethnic minorities by gender and education level.²³ This study defined socioeconomic status by least education (≤ 12 years high school), some education (13-15 years some college), and most education (> 16 years graduate or postgraduate). HIV caused mortality was highest in least educated African American males (53 per 100,000 black men compared to 5 per 100,000 white men). HIV caused mortality rates in least educated African American women were 30 per 100,000 pre-HAART compared to 27 per 100,000 post-HAART.²³ Higher mortality rates were observed in African Americans, especially with low income and less education. The study found no improvement in HIV mortality rates among African American women despite the advent of antiretroviral therapy.^{23,24,25}

Based on sexual orientation, MSM remain the number one most vulnerable population affected by HIV in the U.S., and HIV infection among this population has significantly increased

12% from 2008 to 2010.⁷ The CDC estimates MSM represent only 4% of the male population, yet account for 63% of all new HIV infections.²⁶ HIV infection increased 22% among MSM 13-24 years old, with African Americans disproportionately affected. From 2008 to 2010, HIV infections among young African American MSM increased by 20%.^{3,7} Among MSM, Hispanics and Latinos accounted for 22% of new HIV infections, with 39% of new infections occurring in young MSM aged 25-34. While not disproportionately affected, white MSM are greatly impacted by HIV accounting for 38% of new HIV infections, of which 29% of new infections were seen in MSM aged 25-34. Long-term data are lacking about the HIV impact on male to female transgender women and female to male transgender men; however, recent statistics suggest male to female transgender women are at an increased risk for new HIV infection.^{27,28} Even less data exist on the impact of HIV infection on transgender men, though focus is increasing. There are many factors contributing to disparities in HIV infection among vulnerable populations, as summarized in Table 1.

Table 1. Common factors associated with HIV infection disparities^{23,29-39}

HIV Disparity Causes	Individual and Societal Factors
Socioeconomic status	Lack of permanent housing and homelessness
	Intravenous drug use or active substance abuse
	Incarceration
	Limited education
Limited access to healthcare	Gaps in employment with medical coverage
	Limited access to mental and behavioral health care
	Language barriers
	Lack of permanent housing and homelessness
	Incarceration
	Foster care
	Welfare system
Differences in infection rates	Tendency to have sex partners within the same race
	Higher rates of STIs in minorities that increase risk
	Possible unknown genetic mechanism
Lack of physician awareness	Not practicing routine testing

Table 1 Continued

of high risk groups	Overwhelmed workload
	Avoidance of uncomfortable topics (e.g. sex, LGBT, drug use)
	Cultural incompetence for minority familial and relationship values, community influence, and historical perspectives
	Cultural incompetence for minority and gender risk behaviors (e.g. sexual abuse, physical abuse, violence)
	Lack of racial and ethnic minority investigators
Social stigma and marginalization	Historical impact
	Social, economic, and political inequality
	Fear, discrimination, homophobia still exist
	Magnified in LGBTQI and IDU populations
Lack of HIV prevention knowledge	Cultural, religious, or philosophical beliefs do not support open sex or risk behavior discussion
	Lack of risk reduction education
	Institutional and historical barriers
Unknown testing status	Not-routinely offered in health care settings
	Fear of health insurance or job loss
	Stigma and social issues
	Privacy concerns
	Distrust of practitioners
	Fear of disclosure
Delays in diagnosis and length of time to begin HAART	HIV testing is not routinely offered in health care settings
	Lack of focus directed on high risk individuals
	Misconceptions surrounding medical insurance coverage
	Poor treatment from health care professionals
	Substance abuse, mental health conditions, or homelessness
Poor adherence to medications	Fear of health care settings and social stigma
	Medication side-effects
	Substance abuse, homelessness, psychological issues
	Other needs trump own medical needs
	Lack of social and peer support systems
Comorbid conditions	Symptoms mask HIV symptoms and lead to misdiagnosis
	Patients with co-conditions not being routinely HIV tested

1.3 CURRENT TESTING TRENDS FOR HIV

HIV testing is conducted at a variety of settings.⁴⁰ Healthcare settings include hospital, emergency room, private doctor, outpatient clinic, public health department clinic, drug

treatment facility, correctional facility, family planning clinic, prenatal clinic, sexually transmitted disease (STD) clinic, or community health clinic. Non-healthcare settings include AIDS counseling and testing site, employer or insurance company clinic, military service site, immigration site, home, and other non-clinical setting such as bars, community organizations, or mobile testing sites. Both healthcare and non-healthcare settings can be publicly funded and include public health departments, drug treatment facilities, family planning centers, prenatal clinics, STD clinics, community health clinics, AIDS testing and counseling sites, while hospitals and emergency rooms are primarily privately funded.

Over the past decade, HIV testing trends in the U.S. were assessed for ever been tested or been tested in the last 12 months.⁴¹ Results varied depending on the data source. Primarily, trends for gender, race and ethnicity showed significant increases or no change in HIV testing ever or in the last 12 months; however significant decreases were observed for tested in the last 12 months for white race and other race/ethnicity. Increased testing or no change was also seen in all age groups except for young adults 18-24 years of age. Trends for HIV infection are high for individuals aged 13-29, yet younger persons were less likely to have been HIV tested. Data from National Health and Nutrition Examination Survey (NHANES) found a significant decrease in ever been tested for this age group. The National Health Interview Survey (NHIS) reported significant decreases for ever been tested and tested in the last 12 months in non-healthcare settings.

Cost analyses have found overall, HIV testing in both healthcare and non-healthcare settings is cost effective.^{42,43,44} The *Assessment of 2010 CDC-funded Health Department HIV Testing Spending and Outcomes* found testing in non-healthcare settings required more cost than healthcare settings; however, non-healthcare settings diagnosed more HIV positive individuals.⁴⁵

In non-healthcare settings, costs were 9 times higher per testing event and 5 times higher per newly identified confirmed HIV positive diagnosis. Costs were higher due to infrastructure expenses and recruitment costs associated with reaching high risk populations who do not regularly seek clinical care. Non-healthcare settings cast a wider net than healthcare settings, which is crucial for reaching populations who do not actively seek out providers to identify HIV positive individuals and link them to care.

In healthcare settings, the CDC recommends HIV screening for patients aged 13-64 given the patient is notified testing will be performed and given the option to decline or opt-out.⁴⁶ HIV screening should be incorporated into general consent for medical care and separate written consent is not recommended. Prevention counseling as part of HIV testing programs in healthcare settings is also not recommended; however, jurisdiction over consent, pre-test and post-test counseling is regulated at the state level and not all states have adopted opt-out HIV screening.

In July of 2010, the White House released the National HIV/AIDS Strategy (NHAS), the first U.S. comprehensive and coordinated HIV/AIDS roadmap with measurable goals to be achieved by 2015.⁴⁷ The CDC supports efforts to implement the NHAS, which include action steps to reduce new HIV infection, increase access to care and improve health outcomes for people living with HIV, reduce HIV related disparities and health inequities, and achieve a more coordinated national response to the HIV epidemic. One of the measurable goals is to increase the number of individuals living with HIV who are aware of their status from 79% to 90%. Another strategy is to improve monitoring, reporting, and coordination of HIV programs across and between the federal, state, tribal, and local governments and agencies.⁴⁷

1.4 KNOWLEDGE OF HIV TESTING STATUS

It is estimated that 15.8% of individuals living with HIV are unaware of their HIV positive status.¹ The likelihood these individuals continue to unknowingly transmit the virus to others resulting in the spread of infection is high. HIV positive individual with unknown testing status are unlikely to reduce high risk behaviors such unprotected sex, sex with multiple partners, or IDU needle sharing.^{48,49,50} Knowledge of HIV status has been linked to behavioral changes that decrease risky behavior practice and promote harm reduction to reduce transmission to sexual or needle-sharing partners.^{2,51,52,53,54,55,56,57} Primary HIV infection is the time after infection before an individual's immune system has generated HIV specific antibodies to combat the virus.⁵⁸ Individuals in this acute stage of HIV infection are highly infectious and at an even higher risk of transmitting HIV.^{59,60}

Over time, lack of HIV testing status awareness can lead to increased morbidity and mortality in HIV positive individuals. The majority of AIDS-related deaths occur from opportunistic infections that thrive due to the individuals weakened immune system. Treatment with antiretroviral therapy, primarily HAART, lowers HIV viral load by suppressing viral replication and increasing CD4+ T-lymphocytes thereby improving immune function to significantly delay progression to AIDS.^{8,9,10,11} By maintaining the immune system, HAART has dramatically reduced the number of opportunistic infections and improved survival rates for persons living with HIV. Viral load suppression also offers protection for sex partner, prevents mother-to-child transmission, and improves the quality of life for the person with HIV. Faster time to treatment results in better control of the HIV virus and better health outcomes; however,

to be able to take advantage of highly effective HIV therapy individuals must know their testing status first.⁶¹

To increase awareness of HIV status the CDC established the *Expanded Testing Initiative (ETI)*, which included *PS07-768: Expanded and Integrated HIV Testing for Populations Disproportionately Affected by HIV, Primarily African American* (2007-2010), followed by *PS10-10138: Expanded HIV Testing for Disproportionately Affected Populations* (2010-2011), and currently *PS12-1201: Comprehensive HIV Prevention Programs for Health Departments* (2012-2017).⁶² The purpose of the ETI is to significantly increase the number of individuals tested in regions with high rates of HIV among disproportionately affected populations and to support implementation of the CDC recommendations for HIV testing in healthcare settings. Through PS07-768, the CDC funded jurisdictions in high HIV burdened areas to increase HIV testing, linkage to medical care, and prevention services. Over a 3 year period, 2,786,739 HIV tests were conducted and 18,432 (0.7%) were newly identified confirmed HIV positive, of which 74.3% were linked to HIV medical care.⁶² PS10-10138 and PS12-1201 were designed to continue the progress made under PS07-768 and expand routine HIV testing services for other high risk populations, including Hispanic men and women, MSM and IDU by funding more jurisdictions.

2.0 SECOND CHAPTER: HIV TESTING AND COUNSELING

HIV testing was first introduced in 1985 to screen blood donors and reduce transmission via blood transfusions. By 1987 the implications of testing HIV positive became apparent and the first set of guidelines were established by the U.S. Public Health Service (USPHS) calling for routine testing and counseling among high risk individuals seeking STD treatment.⁶³ Six years later, the CDC extended recommendations for voluntary HIV testing and counseling to hospitals, acute care settings, and emergency departments. Dependent on HIV/AIDS rates, hospitals were encouraged, not required, to routinely offer voluntary counseling and HIV testing to all patients 15-54 years of age. Voluntary and confidential testing, documented informed consent, and explanation of testing was recommended.⁶⁴ Client-centered counseling to assess high risk behaviors, develop tailored prevention plans, and safer goal strategies was introduced in 1994.⁶⁵

Voluntary HIV testing and counseling was recommended in all pregnant women in 1995 by the USPHS after treatment with anti-retroviral medication resulted in significant reduction in perinatal HIV transmission.^{66,67} To reduce barriers of HIV testing in pregnant women, the CDC modified these recommendations in 2001 simplifying counseling and the consent process.⁶⁸ Health-care settings were expanded to include private and publicly funded clinics to improve access of HIV testing. The 2001 guidelines also suggested testing be routinely offered to all patients in high HIV prevalent settings, and targeted HIV testing by doing risk assessment be implemented in areas with low HIV prevalence.⁶⁹

Providers and patients found that discomfort discussing sensitive topics, time restrictions, and written informed consent presented as barriers to HIV testing.^{70,71} To combat this issue, the CDC created a new initiative in 2003 called *Advancing HIV Prevention: New Strategies for a*

Changing Epidemic, to make routine voluntary HIV testing part of medical care at the same level as other diagnostic and screening tests, implement new models for diagnosing HIV outside medical settings, focus prevention on HIV-infected persons and their partners, and decrease perinatal HIV transmission by universal rapid testing of all pregnant women, prenatally, during labor and delivery, or postpartum.⁷² HIV prevention counseling was considered desirable for high risk individuals, but not always feasible.⁷³

The CDC *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, 2006*, are in circulation today.⁷⁴ From 2004-2006, the CDC utilized a multi-disciplinary approach and solicited the aid of health-care providers, professionals, local health officials, public health agencies, researchers, clinicians, community organizations, HIV specific care givers and persons living with HIV to provide feedback on how broaden and increase HIV testing, especially for those at high risk. The final recommendations were produced in response to evidence that feasibility of increased HIV testing would improve by simplifying the process, which would also lower costs. Of note, the CDC does not recommend prevention counseling with HIV testing in healthcare settings because it is seen as a barrier to testing; however, prevention counseling is recommended for persons at high risk for HIV and in non-medical settings. The CDC also recommended utilization of opt-out HIV testing, where the individual is notified the HIV test will be performed and consent is inferred unless the individual declines. Opt-in HIV testing requires an individual explicitly consents in writing to receive an HIV test.

The 2010 CDC *Sexually Transmitted Disease Treatment Guidelines* recommendations for *Detection of HIV Infection: Screening and Establishing a Diagnosis* include opt-out HIV screening part of routine healthcare for all individuals aged 13-64 years.⁴⁶ The CDC also calls for

routing screening for all individuals seeking STD evaluation regardless of specific HIV risk behavior and re-screening high risk individuals every 3-6 months. The guidelines suggest routinizing HIV testing in combination with other tests, such as blood pressure and cholesterol, will aid in identifying and diagnosing HIV positive individuals and help reduce stigma that may present as a barrier to testing. The U.S. Preventive Services Task Force (USPSTF) recommends routine HIV screening for everyone aged 15-65 years and targeting screening in those aged less than 15 and greater than 65 years who are at high risk for HIV infection.

In the U.S., mandates and laws regarding HIV testing and counseling are governed by laws enacted at the state level.⁷⁵ Although the federal government does not have jurisdiction over state mandates regarding HIV testing, 90.2% of states adopted or revised testing laws considered compatible with the 2006 CDC recommendations.⁷⁶ Variations among HIV testing laws occur from state to state for opt-in versus opt-out informed consent, HIV pre- and post-test counseling, availability of anonymous testing, required partner notification, implementation of routine HIV testing, rapid and confirmatory testing, and provisions regarding minor and adolescent testing.⁷⁷ Mandates around HIV testing also vary between states for different settings such as healthcare facilities, correctional institutions, substance abuse or mental health treatment centers.

2.1 CURRENT HIV TESTS AND PROCEDURES

Advances in HIV testing have improved the simplicity, reliability, and safety of conducting testing in healthcare and non-healthcare settings. There are two different modes of detection for HIV tests: HIV antibody production and HIV viral load. Conventional antibody tests are enzyme immunoassays (EIA) or enzyme-linked immunosorbent assays (ELISA) and

can be performed on blood or oral fluid in a laboratory. Test results are usually available between 2-14 days. Rapid antibody tests are point-of-care tests that can also be performed on blood by finger prick or oral fluid with a result turnaround time of 20-40 minutes and are highly sensitive.^{78,79} Antibody tests can be classified as 1st, 2nd, 3rd, and 4th generation based on the antibodies they detect: 2nd generation detects IgG antibodies; 3rd generation detects IgM and IgG antibodies; and 4th generation detects HIV antibodies and the HIV viral p24 antigen.⁷⁸

Antibody test negative results indicate the test did not detect HIV antibodies and are considered definitive for no HIV infection given the time point of exposure. The window period, which is the time it takes for HIV antibodies to develop after infection, can take up to 3 months after exposure to HIV.^{80,81} This is critical for a HIV antibody tests to be definitive. Individuals seeking antibody testing, should be made aware of the window period and advised to retest 3 months after the point of known or possible exposure, such as unprotected sex or shared needle IDU. Antibody test positive results are considered preliminary positive for detection of HIV antibodies and require confirmatory testing. HIV confirmatory testing should also be conducted for inconclusive antibody test results.

Confirmatory tests are typically Western blot, HIV viral load test, or an antibody test of a different brand.⁸² HIV antibody tests tend to be highly sensitive and less specific, which means they can produce false-positive results. A Western blot, the most common confirmatory test, is a highly specific antibody test that has a lower likelihood of yielding a false-positive result. HIV viral load tests detect viral RNA by polymerase chain reaction (PCR) and measure the level of HIV in blood, which is also commonly performed to monitor viral suppression in HIV positive individuals on anti-retroviral medication. If Western blot or HIV viral load tests are not feasible, a second antibody test from a different manufacturer can be performed.

2.2 HIV COUNSELING FUNDAMENTALS

HIV counseling arms individuals with tools to reduce their risk of acquiring or transmitting HIV. Counseling provides an opportunity to confront myths about HIV and empower individuals with facts surrounding transmission, infection, and treatment. Individuals also have the opportunity to bring up concerns and ask questions. The current CDC guidelines do not recommend HIV prevention counseling in healthcare settings due to lack of evidence for effectiveness.⁴⁶ While the CDC provides national recommendations, requirements for HIV testing, consent, and counseling vary under state law and some states require pre- and post-test counseling. Non-healthcare settings may be more likely to use risk reduction counseling targeted at high risk individuals who do not regularly seek medical care. Both healthcare and non-healthcare settings may benefit from having staff trained in HIV prevention counseling to ensure they give information and answer questions correctly. The procedure for HIV prevention counseling using a client centered approach is outlined below.^{65,69,74}

Pre-test Procedure

1. Offer the test
2. Explain the test, how it is used and its limitations
3. Explain how the results are interpreted
4. HIV prevention, exposure, and treatment information must be available
5. Obtained written consent, which can be part of a general medical consent

Post-test Procedure

1. Provide results for both positive and negative individuals
2. Explain what the results mean
3. For test positive patients, a second confirmatory test is necessary and they should avoid behavior that could put others at risk (i.e. use condoms during sex or refrain from sex altogether)
4. Provide information about preventing transmission
5. Explain the benefits of contact tracing or partner services
6. For test positive individuals:

- a. Provide referrals for proper health care providers and services
- b. Provide referrals for community and case management services
- c. Provide information regarding HIV
- d. Test results are confidential; however, confirmatory test positive results are reported to the health department

Consent: First and foremost, counselors should address with the individual seeking testing that all information will remain confidential under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and will not be disclosed to any employment or insurance agencies under the Confidentiality of HIV-Related Information Act.^{83,84} Second, they should explain that some of the discussion to follow will surround personal information and sensitive topics may be uncomfortable, and that no judgment or assumptions will be made. The goal is to inform about the facts on HIV and create a plan to eliminate or reduce HIV risk so they remain healthy. If required under state laws, counselors should inform the individual seeking testing that in order to perform the HIV test and disclose the results; the individual must sign a consent form. This form may contain demographic information useful not only for reporting, but so the counselor may gather information such as age, race/ethnicity, and gender useful for assessing risk. Counselors should urge the individual to interrupt at any time he or she may feel uncomfortable and reassure that information will remain confidential and used to provide the best outcome for the individual.

Assessing risk: Clients may not be aware of their own behaviors that put them at risk for HIV infection. By asking open ended questions, such as “What brings you to get testing today?,” allows the individual to direct the discussion to suit their needs. Common reasons an individual may seek HIV testing include an unprotected sex act, drug use with shared needles, or a healthcare professional accidental needle stick. If the individual is hesitant to offer information readily, use a combination of open ended questions or direct yes or no questions to gather

information on sexual orientation or IDU. The next series of open ended questions should focus on the individuals' circumstance that brought them to seek HIV testing. Circumstances may include current and past sexual practices including number of sex partners, gender of each partner, condom usage, ever had unprotected sex, forms of birth control, past pregnancy, any chance of pregnancy, STI history, substance abuse including tobacco and alcohol use/quantity, illegal or prescribed drugs for recreational purposes, and were they injectable or needles were used or shared.

Identify safer goal behaviors: Counselors should help the client understand how a specific behavioral change directly links to their risk behavior. For example, always using condoms, abstaining from sex acts, always using clean syringes during IDU, or abstaining from IDU virtually eliminates the risk of HIV infection. The goal behavior must be attainable and the client must be willing to adopt. This may not always be sufficient to eliminate risk for HIV infection. If the client is unwilling to completely eliminate a risk factor, identification of alternate goals will reduce HIV risk such as reducing the number of sex partners or keeping clean works for IDU. Counselors should also discuss previous successes and barriers.

Create client centered risk elimination or harm reduction plan: Together the counselor and client design a specific plan with incremental steps the client can carry out to help adopt safer goal behaviors based on the *Transtheoretical Model*.⁸⁵ In this model, behavior modification occurs through progression of 5 stages: pre-contemplation, contemplation, preparation, action, and maintenance. Ideally individuals reach termination and eliminate the unhealthy behavior or they may relapse and cycle through the stages several times before termination. At first it may seem obvious to simply summarize the safer goal behaviors and tell the client to implement them; however, creating a realistic, achievable plan must take into account other circumstances.

Clients may have other needs that take prioritization over their own health and risk reduction behavior including domestic violence, alcohol and substance abuse, lack of housing, lack of transportation, need for childcare, unemployment, mental illness, and incarceration. If warranted, referrals should be provided to help guide clients to the proper sources specific for the challenges they are facing. Ancillary services are an important link for entry into and retention in HIV care including case management, mental health support, substance abuse treatment, transportation, childcare, or housing assistance.^{86,87} Such services aid in efforts to improve the client’s quality of life, thus assist in their HIV care and prevention.

2.3 COORDINATED, COMPREHENSIVE, CARE NETWORKS

The most successful HIV prevention networks offer programs that are coordinated, comprehensive, and care-focused.^{88,89,90,91} Coordination involves effective communication among many disciplines including providers, researchers, counselors, case management, community organizations, referral services, insurance agencies, and the client. A comprehensive approach includes a wide-range of care services that covers a majority of needs to reach as many individuals as possible. The patient or client care should be held to the utmost professional standard, making sure resources are reliable, making appropriate and adequate recommendations, and integrating the needs of the individual seeking care into the services provided.

Table 2. Characteristics of a successful HIV care network

A comprehensive and coordinated HIV care program should include:	
Dedicated and experienced team of professionals	<ul style="list-style-type: none"> · HIV care coordinators · Physician (an HIV expert clinician is ideal) · Nurses

Table 2 Continued

	<ul style="list-style-type: none"> · Pharmacist · Counselors trained in HIV prevention · Case-manager · Administrative staff
Cover all aspects of HIV care	<ul style="list-style-type: none"> · Offer HIV testing, prevention and education counseling · HIV diagnosis confirmation · Promote early entry into care and fast time to treatment · Focus on follow-up and retention in care · Implement and adhere to current HIV prevention and treatment guidelines and recommendations
Patient confidentiality	<ul style="list-style-type: none"> · Implement and adhere to HIPAA guidelines · No breach of confidentiality will be tolerated · Legal repercussions and expulsion will be dealt · Teach standards and guidelines to reduce opportunities for patient information leaks · Utilize electronic medical records to eliminate paper charts · Explain how patient trust is imperative to successful HIV care · Constant measures to assess in-house care by evaluation and quality improvement
Cultural competence	<ul style="list-style-type: none"> · Culture differences among minority and ethnic groups · LGBTQI community · Women’s issues · Self-cultural view · Increase awareness of cultural values and ethics · Increase communication skills across cultures · Multi-lingual staff to overcome language barriers · Culture friendly waiting and exam rooms
Strong referral and linkage system to alternate medical and support service providers	<ul style="list-style-type: none"> · Mental health services · Ob-Gyn providers · Family planning · Substance abuse treatment · Homeless services

Clinicians, supervisors, and care coordinators should lead their team and develop workplace policies to improve the quality of care based on the *U.S. Department of Health and Human Services: Health Resources and Services Administration (HRSA)* guidelines for HIV/AIDS clinical care and the *National Institutes of Health HIV/AIDS* related medical practice guidelines.^{92,93} Policies should implement guidelines for cultural competence and patient

confidentiality practices for no tolerance work zones and enforce strict repercussions in the event of a confidentiality breach. Clinic staff should be educated on addressing different cultures or backgrounds without using judgment. In regions with high immigration, hire or make available as needed bi-lingual or multi-lingual staff members specific for that demographic. Programs should enforce HIPAA guidelines and confidentiality practices. Focus should be placed on the imperative role that the patient-clinic relationship factors in HIV care and affects not only the patient, but the community including the staff themselves. Evaluation measures should be in place to monitor quality of care such as annual completion of competence and confidentiality modules, tracking patient follow-up data for improvements, and obtaining patient feedback.

2.4 PITTSBURGH AIDS TASK FORCE HIV TESTING PROGRAM

The Pittsburgh AIDS Task Force (PATF) is a not-for-profit 501(c) (3) organization with a mission *dedicated to supporting and empowering all individuals living with HIV/AIDS and preventing the spread of infection.*⁹⁴ The PATF excels as a HIV/AIDS prevention agency that incorporates in house free and confidential HIV testing and counseling with community prevention and education outreach. The PATF serves as a model for coordinated and comprehensive care from the first stop for individuals seeking HIV testing, case management, linkage to care, and discounted pharmaceuticals for HIV positive individuals who qualify under the Ryan White CARE Act.⁹⁵ Ancillary to HIV specific care and treatment, the PATF provides comprehensive services including a food pantry, transportation and emergency fund assistance, transitional and permanent housing, pro bono legal services, support groups, and advocacy.

The PATF conducts free and anonymous HIV testing Sunday through Friday at a location accessible to public transportation and at various offsite locations commonly frequented by high risk groups.^{83,84} They perform approximately 2,000 HIV tests annually and provide medical case management for over 650 HIV positive individuals. The case management program is critical to provide medication assistance and ensure adherence among vulnerable populations who may not seek healthcare otherwise. In addition, the PATF has provided housing for 50 individuals living with HIV/AIDS. Of those seeking HIV care services, 57% identified as gay, lesbian, or bisexual and the majority live below the poverty line.

In addition to walk-in HIV testing, the PATF has developed a strong network in the community and continuously works to expand outreach and opportunities to provide HIV testing and prevention education throughout. The PATF targets outreach and recruitment efforts at populations who are high risk and underserved in the Greater Pittsburgh Area and Western Pennsylvania. HIV transmission rates are highest in men who have sex with men (MSM, 53.9%), followed by high risk heterosexual transmission (21.1%), and intravenous drug users (IDU, 11.6%), with minorities over representing persons living with HIV/AIDS.⁹⁶

HIV/AIDS in Allegheny County, Pennsylvania, 2010⁹⁶

- Incidence: 12.51 per 100,000
- New Diagnosis: 98 HIV & 55 AIDS cases
- Persons living with HIV/AIDS: 2344 individuals (78% of Western PA)
 - 80.7% Male, 19.3% Female
 - 51.5% White, 39.1% Black, 3.6% Hispanic

To intervene in these vulnerable yet differing populations, the PATF coordinates HIV prevention programs including GirlTalk aimed at adolescent females 13-18 years of age, GirlFriends aimed at adult females, and the M2M project to reach those at highest risk for HIV transmission in the MSM population. The GirlTalk and GirlFriends programs center on

empowering women to make healthy and safe lifestyle choices. These projects create a safe and fun environment for teen or adult women to come together and discuss health education topics including sexual health, HIV, STI's, substance abuse, peer pressure for teens, domestic violence and basic prevention knowledge in a small group setting. HIV knowledge is assessed and before and after education interventions using questionnaires. The GirlTalk program recently increased efforts to reach out and recruit girls who are less feminine or more masculine, a vulnerable population that has previously gone under the radar with respect to HIV prevention efforts. The M2M 1st Wednesday and 4th Tuesday outreach projects offered a safe haven for lesbian, gay, bisexual, transgender, queer or questioning, and intersex (LGBTQI) individuals to feel comfortable to discuss topics around HIV and sexual orientation while having fun. Workshops were designed to aid individuals with employment resources, resume building, interview practice, career development, and other topics deemed relevant by the participants.

All outreach projects aimed to educate high risk individuals and offer free and confidential HIV testing. HIV testing is performed using the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test and results are available in 20 minutes for detection of HIV-1 and HIV-2 antibodies with 99.3% sensitivity (CI=98.4-99.7%) and 99.8% specificity (CI=99.6-99.9%).⁹⁷ The OraSure® HIV-1 Oral Specimen Collection Device is conducted as a follow-up confirmatory test for reactive or invalid OraQuick® Rapid test. This confirmatory test also uses an oral fluid sample that is sent out for a laboratory-based enzyme immunoassay (EIA) screening test and Western Blot, the current gold standard for HIV testing.⁹⁸

HIV prevention often deals with sensitive topics that can be uncomfortable to some. Social stigma and stereotyping associated with HIV have marked this disease with shame masking efforts to promote prevention and testing. The PATF utilizes a variety of approaches to

overcome social fear to engage communities and marginalization to target populations difficult to reach. Much of HIV prevention and care is centered on the clients' needs. Just as no one individual is the same, no one program exists to encompass all individuals at risk for HIV, and the PATF is constantly evaluating and re-evaluating their programs to capture individuals who are underserved.

3.0 THIRD CHAPTER: INCREASING HIV TESTING EFFORTS

National guidelines and policies call for improving early HIV diagnosis by increasing the number of HIV positive individuals unaware of their status that were offered testing and subsequent HIV care and prevention services.⁹⁹ Healthcare settings are encouraged to implement routine HIV testing; however, widespread implementation has been slow.^{99,100,101,102,103,104} Rarely does an individual walk into a healthcare provider visit and is offered an HIV test. Barriers to increase testing efforts in healthcare settings include cost reimbursement, overwhelming provider schedules, lack of time to conduct risk assessment and counseling, and lack of HIV trained healthcare staff.^{44,102,105,106,107} Non-healthcare settings are better suited to provide targeted HIV prevention counseling and disseminate HIV education, though counseling is not required. Non-healthcare organizations can dedicate more time to each individual seeking HIV testing or education, yet there remains a population who do not utilize these services. Targeted testing programs in both healthcare and non-healthcare settings have been beneficial and acceptable by patients and clients, but still face time and follow-up barriers to identify HIV positive individuals.^{103,107,108,109}

There are a number of evidence based interventions that aim to reduce high risk behavior and HIV infection, and some directly measure HIV testing rates. Most studies report reduced high risk behavior from brief patient centered risk reduction counseling; however evidence has shown mixed effects from risk reduction counseling on reducing HIV and other STI acquisition. Tailored interventions were shown to be effective among high risk populations such as MSM and African American or Latino minorities. Onsite rapid HIV testing was shown to be very well accepted and effective at increasing receipt of HIV test and results. A program designed to notify

sex and needle sharing partners of HIV positive individuals that they are at risk for transmission was also very effective in targeting and increasing HIV testing at high risk individuals and identifying HIV infection in individuals who were unaware. Evidence based HIV testing and counseling interventions are summarized in Table 3.

Table 3. Evidence based HIV testing and counseling programs

Study Name	Intervention	Outcome(s)
The AWARE Randomized Clinical Trial ¹¹⁰	5012 HIV negative patients aged >18 were randomized to 2 study arms to assess the effect of brief risk reduction counseling on STI acquisition: 1. Rapid HIV test with brief patient-centered HIV risk reduction counseling 2. Rapid HIV test with standard testing information only	HIV & other STIs measured at 6 months: Significant findings for intervention: • No difference in 6 month STI incidence between study arms • Suggests no added benefit from brief patient centered risk reduction counseling in reducing STI incidence
Project RESPECT Randomized Clinical Trial ¹¹¹	5758 HIV negative, heterosexual patients aged >14 were randomized to 4 study arms to assess 2 counseling interventions on STI acquisition and risk behavior: 1. 4 enhanced interactive theory based sessions 2. 2 brief interactive risk reduction sessions 3. 2 brief didactic HIV test information only sessions 4. 2 brief didactic HIV test information only sessions with no follow up	STIs measured at 6 and 12 months: Significant findings for interventions: <i>Enhanced Counseling</i> • Lower rate of STI incidence • Greater reported condom use, no unprotected vaginal sex, ≤ 1 sex partner <i>Brief Counseling</i> • Lower rate of STI incidence • Greater reported no unprotected vaginal sex, ≤ 1 sex partner, no causal or new partners • Suggests brief counseling effectively lowered STI incidence and had better retention rates than enhanced counseling
Project RESPECT-2 Randomized Clinical Trial ¹¹²	3,297 HIV negative patients aged 15-39 were randomized to 2 study arms to assess the effect of a booster counseling intervention on STI acquisition and risk behavior: 1. 2 brief interactive risk reduction sessions plus a 3 rd booster session at 6 months 2. 2 brief interactive risk reduction sessions 3. Participants were randomized to receive a rapid or standard HIV test	STIs measured at 3, 6, 9, 12 months: Significant findings for intervention: • Less reported ≥ 2 sex partners or unprotected sex with non-primary partner • No difference for incident STI • Type of HIV test, rapid versus standard, did not modify the intervention effects • Suggests brief counseling+ booster was not more effective at preventing incident STI, but did reduce sexual risk behavior compared to brief counseling only

Table 3 Continued

<p>National Drug Abuse Treatment Clinical Trials Network: HIV Rapid Testing and Counseling Study (CTN 0032)¹¹³</p>	<p>1281 HIV negative participants from community based drug treatment programs were randomized to 3 study arms to assess HIV testing and risk behaviors:</p> <ol style="list-style-type: none"> 1. Onsite rapid HIV testing with HIV risk reduction counseling 2. Onsite rapid HIV testing with testing information only 3. Referral for offsite HIV testing 	<p>Receipt of HIV test and results were measured at 1 month and risk behaviors at 6 months.</p> <p>HIV rapid test & confirmed positive cases:</p> <ul style="list-style-type: none"> • 2 onsite with counseling • 1 onsite with information only <p>Significant findings for interventions:</p> <ul style="list-style-type: none"> • Greater receipt of HIV test and results in onsite HIV testing groups than offsite • No difference in receipt of HIV test and results between onsite counseling and onsite information only groups • No difference in unprotected sex • Suggest onsite rapid HIV testing increased receipt of test and results and identified HIV infection in drug treatment centers
<p>The EXPLORE Randomized Controlled Study¹¹⁴</p>	<p>4295 HIV negative MSM age ≥ 16 were randomized to 2 study arms to assess a behavioral intervention on HIV acquisition and risk behavior:</p> <ol style="list-style-type: none"> 1. 10 core counselling sessions every 4-6 months followed by 7 booster sessions every 3 months 2. 2 bi-annual brief counseling sessions using RESPECT model 3. Participants received HIV test every 6 months 	<p>HIV infection and risk behavior were measured every 6 months.</p> <p>HIV acquisition:</p> <ul style="list-style-type: none"> - 15.7% lower rate in intervention group when adjusted for baseline covariates <p>Significant findings for intervention:</p> <ul style="list-style-type: none"> • Less reported any unprotected anal sex, serodiscordant unprotected anal sex • Drug and alcohol use was associated with unprotected anal sex • Suggests tailored behavioral intervention was feasible to reduce HIV infection in MSM; need for interventions to address serodiscordant partner, drug and alcohol risk
<p>Men Maintaining Wellbeing and Healthy Relationships (HoMBReS)¹¹⁵</p>	<p>30 soccer teams comprised of 222 Latino men aged ≥ 18 were randomized to 2 study arms to assess a lay health advisor (LHA) intervention on HIV testing and condom use:</p> <ol style="list-style-type: none"> 1. 15 soccer teams elected and trained LHAs work with teammates 2. 15 soccer teams served as the control group with no LHA 	<p>HIV infection and condom use were measured every 3 months.</p> <p>Significant findings for intervention:</p> <ul style="list-style-type: none"> • More reported HIV testing at 18 months • More reported consistent condom use with all partners at 3 months • Suggests LHA intervention was feasible to increase HIV testing and condom use among Latino men
<p>Many Men, Many Voices (3MV)¹¹⁶</p>	<p>338 HIV negative African American MSM ages ≥ 18 were randomized to 2 study arms to assess a small group intervention on HIV testing and risk behavior:</p> <ol style="list-style-type: none"> 1. 6 consecutive 2-3 hour MSM tailored HIV/STI prevention sessions at a weekend retreat 2. Waitlist control group 	<p>HIV, STI, and risk behavior measured at 3, 6 months.</p> <p>Significant findings for intervention:</p> <ul style="list-style-type: none"> • Less reported any unprotected anal sex with casual partners • Greater reported HIV testing • Suggests tailored prevention intervention was feasible to increase HIV testing and reduce sex risk behavior among MSM

Table 3 Continued

<p>Strength Through Youth Livin' Empowered (STYLE)¹¹⁷</p>	<p>81 young MSM of color (mean age=21) were enrolled into a social marketing campaign intervention to assess HIV acquisition:</p> <ol style="list-style-type: none"> 1. Social marketing campaign, targeted outreach and HIV testing, and a strongly linked medical and social support network 	<p>HIV diagnosis for intervention group:</p> <ul style="list-style-type: none"> • 2/3 newly diagnosed • 1/3 diagnosed during the acute stage • Suggests a social network campaign is a feasible intervention to increase HIV diagnosis among young MSM of color
<p>Partner Counseling and Referral Services (PCRS)¹¹⁸</p>	<p>Systematic review of 9 studies to assess partner notification, HIV testing and acquisition:</p> <ul style="list-style-type: none"> • Provider referral-HIV positive patient voluntarily discloses partner information and provider notifies • Patient referral-HIV positive patient notifies partners • Contact referral-HIV positive patient voluntarily discloses partner information and agrees to notify partners; provider notifies partners if not completed within time period 	<p>Partner notification results:</p> <ul style="list-style-type: none"> • 67% partners located and notified • 63% partners were HIV tested • 20% partners tested HIV positive <p>PCRS delivery results:</p> <ul style="list-style-type: none"> • Little difference among 3 partner notification delivery methods • Few studies assessed patient or contact referral • Suggest provider referral PCRS effectively increased HIV testing and diagnosis among
<p>Rapid HIV Testing in Community-based Organizations (CBO)¹¹⁹</p>	<p>23,900 rapid HIV antibody tests were administered to high risk individuals:</p> <ul style="list-style-type: none"> • Trained CBO staff offered counseling and rapid HIV testing to clients either in mobile testing units or inside venues that included parks, shelters, hotels, clubs, health fairs, syringe-exchange sites, and community clinics. 	<p>HIV testing status</p> <ul style="list-style-type: none"> • 30% never been tested • 43% not tested in past year <p>Rapid HIV antibody test results:</p> <ul style="list-style-type: none"> • 331 (1%) preliminary positive • 286 (86%) received confirmatory test • 267 (93%) confirmed HIV positive • 17 (6%) confirmed HIV negative • 94% positive predictive value • Suggests rapid HIV testing conducted by CBOs effectively identified HIV infection among high risk populations
<p>Rapid HIV Test Distribution (RTDP)¹²⁰</p>	<p>372,960 rapid HIV antibody tests were administered at 230 organizations by 107 coordinators:</p> <ul style="list-style-type: none"> • 121 state and local health departments • 101 medical centers and community-based organizations • 8 correctional facilities • 48 coordinators were interviewed 	<p>Rapid HIV antibody test results:</p> <ul style="list-style-type: none"> • 5,385 (1.4%) preliminary positive • 4,650 (1.2%) confirmed HIV positive • 79.1% confirmed results were provided to clients <p>90% coordinators interviewed reported increased HIV screening was due to:</p> <ul style="list-style-type: none"> • RTDP providing additional tests (81%) • Clients did not have to return for a second visit to receive results (79%) • Suggests rapid HIV testing increased client acceptance and staff availability to conduct more testing

Emergency departments offer a healthcare setting to implement non-targeted routine HIV testing and identify high risk individuals, yet the fast pace, urgent nature of this setting has hindered utilization. A survey of emergency department providers showed they rarely encourage patients seeking STD treatment to receive an HIV test during their visit. Slightly more providers (35%) referred patients to seek HIV testing at outside sources; however, lack of follow-up services and poor compliance of patients render referrals less effective.^{104,121} Alternately, an analysis found emergency department testing identified more HIV infection than STD clinics and publicly funded sites.¹²² Providing HIV counseling in fast pace healthcare settings is less clear. HIV prevention counseling has been shown effective to reduce risk behavior in HIV positive individuals; but some studies have shown little effect of counseling on HIV negative individuals.^{109,123} Two randomized controlled trials assessing prevention counseling found the nature and duration of prevention counseling might influence its effectiveness.^{111,114} Routine testing in emergency departments may also help lift stigma and fear by normalizing HIV testing.^{124,125,126,127}

3.1 INDIVIDUAL EFFECTS: BENEFITS AND HARMS

Knowledge of HIV status by receiving testing is important for both HIV positive and HIV negative individuals. Prompt entry into care and time to treatment is critical for HIV positive individuals to promote better health outcomes, and getting HIV tested is the first step to identify and guide these individuals to the appropriate resources. HIV positive persons who are unaware of their diagnosis are a missed opportunity to intervene in HIV progression to AIDS, which results in increased susceptibility to opportunistic infections and cancers that cause severe

disease and death. The sooner an HIV positive person receives treatment with HAART increases their likelihood for survival. HIV testing has the potential to diagnose individuals at an early stage before symptoms develop with routine testing programs. Studies have shown many HIV positive individuals seen in healthcare settings while they are unaware of infection were not tested or diagnosed.^{103,108} Survival benefits for screening HIV positive patients and linking them to care has been shown to outweigh the substantial costs associated with HIV care.^{44,105,128}

Counseling and support groups help individuals cope with their HIV diagnosis. Becoming newly diagnosed with HIV can elicit many emotions such as fear, anger, sadness and concerns of death and stigma. Community organizations and peer groups for HIV support are excellent resources to alleviate individuals' fear and enlighten them on the positive steps they can take to embrace their diagnosis and lead a healthy fulfilling life. Prevention counseling arms individuals with the knowledge and resources to go back into the community and practice safe goal behaviors. Knowing HIV status is a tool that can promote healthy behaviors to reduce HIV acquisition among HIV negative individuals, though studies on prevention counseling among persons who are HIV negative have mixed results on the adoption of risk reduction behaviors.^{103,104,111,114,123} Regardless of HIV status, individuals who seek testing and counseling may take the HIV health education knowledge gained back to their partner, friends, family, or community thus spreading positive promotion to get tested and practice harm reduction.

3.2 OVERALL EFFECT ON PUBLIC HEALTH

The benefit of early HIV diagnosis by testing is important for public health prevention efforts to reduce transmission to sex and needle sharing partners.¹²⁹ Knowledge of HIV status

has been shown to greatly promote risk reduction among HIV positive individuals, which aids in the prevention of transmission because persons who are aware of their HIV-positive status take precautions to avoid infecting others.² Data have shown HIV positive individuals significantly reduce their risk of transmitting HIV infection to others.^{2,51,52,53,54,55,56,57} Identifying HIV infected individuals at the earliest stage possible serves as an opportunity to intervene and control the in the spread of HIV infection even further. Expanding HIV testing can also help reduce stigma that still exists and prohibits individuals from seeking HIV testing.^{124,125,126} Increasing providers and healthcare professionals who practice routine HIV testing can increase acceptability among patients and normalize HIV testing.¹⁰⁴

The public health impact of universally screening the donated blood supply for HIV and screening and treating HIV positive pregnant women has been successful in significantly reducing blood donor recipient and perinatal transmission.¹³⁰ Among pregnant women, screening has proven substantially more effective than risk-based testing for detecting unsuspected maternal HIV infection and preventing perinatal transmission.^{131,132,133} Public health interventions to reduce risk behaviors such as needle exchange programs have also had success among IDU; however reducing high risk sexual behavior, such as condom use, has not proven as effective.^{134,135,136,137,138} The public health impact of HAART treatment as prevention of HIV transmission rests on the identification of HIV infected at risk for transmitting and partners of HIV positive individuals at risk for acquisition.

4.0 FOURTH CHAPTER: FUTURE DIRECTIONS OF HIV TESTING

Programs to increase HIV testing should identify high risk individuals, promote entry and retention into care, and retain follow up for continuing treatment. Comprehensive HIV programs, such as the Pittsburgh AIDS Task Force, include testing, prevention and education counseling, case management, and referral services for diagnosis and treatment of HIV, treatment of co-infections, follow-up and retention in care. Despite the effectiveness of such programs, many HIV positive individuals remain unaware they are infected. These individuals may benefit from non-targeted routine testing programs in healthcare settings such as emergency departments and urgent care providers. Studies have shown testing in emergency departments increase the number of early diagnosed HIV infection.^{139,140} Hospital emergency departments and urgent care centers offer an alternative setting to test a large number of individuals for HIV infection who normally would not seek testing.^{141,142,143} However, time restraints, lack of funding, and limited staff have hindered uptake of HIV testing in emergency departments.¹⁴⁰ Another major concern is linkage and subsequent follow up to ensure the patient enters into HIV care. Strategies need to be in place to collect or update correct contact information, establish provider-patient trust, and allocate staff effort to formulate linkage to care relationships with the patient and HIV specific provider.¹⁴³ A cost-analysis found non-targeted HIV testing in an emergency department was less cost-effective, but identifies more HIV infection previously undiagnosed.¹³⁹ Improvements to reduce costs associated with HIV testing in emergency departments are needed.

National recommendations have called for increased efforts to diagnose early HIV infection. The CDC recently released an algorithm shown to accurately detect HIV before antibodies have developed using 4th generation antibody tests that measure the HIV p24-antigen

directly and confirming with HIV-1/HIV-2 differentiation tests.^{144,145} Studies demonstrated this algorithm performed better than the western blot at identifying acute phase HIV-1 infection and differentiating between HIV-1 and HIV-2 infection.^{146,147} The CDC reported results from two HIV screening programs evaluating this diagnostic algorithm.¹⁴⁵ Among patients aged 18-64 seen at an emergency department in Phoenix, Arizona, the CDC testing algorithm identified 37 undiagnosed HIV infections and 12 (34%) acute phase HIV infections. The *Screening Targeted Populations to Interrupt On-going Chains of HIV Transmission with Enhanced Partner Notification (STOP)* study program identified 654 (1.7%) of 37,876 patients aged 12 or older reactive for the 4th generation immune assay and further differentiated for HIV-1 (n=554; 84.7%) and for both HIV-1 and HIV-2 (n=1; 0.2%). Of the remaining 99 patients with a negative or indeterminate differentiation test result, confirmatory testing found HIV-1 RNA present in 55 patients who were 4th generation immune assay positive. Both screening programs conducted 4th generation HIV testing with the Architect HIV Ag/Ab Combo Assay (Abbott Diagnostics) and HIV-1/HIV-2 antibody differentiation with the Multispot HIV-1/HIV-2 Rapid Test (Bio-Rad Laboratories). Analysis from these studies found this HIV testing algorithm reduced missed diagnoses in 32% of the HIV positive patients at the Phoenix, Arizona emergency department program and 9% of patients in the STOP programs. These findings suggest non-targeted HIV testing with a 4th generation immune assay in emergency departments and acute care settings can improve diagnosis of acute HIV infection.

Home HIV rapid tests are now available for purchase and can be conducted in the privacy of one's own home with the hopes of attracting individuals at risk for HIV who would not normally seek testing.^{148,149} Studies have shown untrained participants were able to easily perform the test, accurately interpret the results, and understood the need for confirmatory

testing.^{150,151,152} One study reporting the use of home tests in HIV discordant MSM couples found regular testing with at home HIV rapid tests reduced risky behavior practices.¹⁵³ The marketing of home HIV tests aims to breakthrough certain barriers that prevented uptake of testing at clinics such as confidentiality and stigma fears; however issues surround the affordability of the test. The likelihood that high risk individuals will be able to afford the cost of the test is low and there is concern of disproportionate testing among healthy individuals at low risk for HIV infection.¹⁵⁴ There are some concerns about an individuals' reaction to a positive result in the absence of a trained counselor; however experts believe the wealth of resources available for HIV rapid test positive individuals are sufficient.¹⁵⁵ Lack of an HIV professional also limits the opportunity to accurately explain the window period. Data and trends for uptake of home tests are not yet available, and mixed view of optimism and skepticism surround the potential impact on diagnosing more individuals to help combat the HIV epidemic in the U.S.

Public health interventions to reduce the spread of HIV have been effective, but not sufficient. New approaches to prevention are needed to halt the HIV epidemic. Increasing the acceptability and utilization of HIV testing by both healthcare professionals and individuals requires a comprehensive and coordinated approach. In addition to maintaining non-healthcare programs that target vulnerable and underserved population, routine non-targeted HIV testing in healthcare settings, mainly emergency departments, and home testing offer promise to identify new HIV diagnosis.

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