

# Literature Resources For the NYSDOH Task Force



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## Subjects:

### Identifying undiagnosed individuals and HIV testing

### Linkage, engagement, and retention in care

### Pre-exposure prophylaxis

- A. Clinical trials
- B. Guidelines
- C. Implementation studies
- D. Opinion

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## Identifying undiagnosed individuals and HIV testing:

Arbelaez C, Wright EA, Losina E, et al. Emergency provider attitudes and barriers to universal HIV testing in the emergency department. [\*The Journal of Emergency Medicine\*](#). 2012;42(1):7-14.

**Background:** The Centers for Disease Control and Prevention (CDC) recently published recommendations for routine, voluntary human immunodeficiency virus (HIV) testing of adults in all health care settings, including the emergency department (ED).

**Study Objective:** The objective of this study was to examine the willingness of ED providers to offer HIV testing, as well as their perceived barriers to implementation of these guidelines.

**Methods:** Before the establishment of a routine HIV testing program in the ED, a 21-item survey was used to assess ED providers' knowledge, attitudes, and perceived challenges to HIV testing. Six months after program initiation, the identical survey was re-administered to determine whether HIV testing program experience altered providers' perceptions.

**Results:** There were 108 of 146 (74%) providers who completed both the pre- and post-implementation surveys. Although the majority of emergency providers at 6 months were supportive of an ED-based HIV testing program (59/108 [55%]), only 38% (41/108) were willing to offer the HIV test most or all of the time. At 6 months, the most frequently cited barriers to offering a test were: inadequate time (67/108 [62%]), inadequate resources (65/108 [60%]), and concerns regarding provision of follow-up care (64/108 [59%]).

**Conclusions:** After the implementation of a large-scale HIV testing program in an ED, the majority of emergency providers were supportive of routine HIV testing. Nevertheless, 6 months after program initiation, providers were still reluctant to offer the test due to persistent barriers. Further studies are needed to identify feasible implementation strategies that minimize barriers to routine HIV testing in the ED.

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**Aronson ID, Marsch LA, Rajan S, et al. Computer-based video to increase HIV testing among emergency department patients who decline. *AIDS and Behavior*. 2014 Jul. 17 [Epub. ahead of print].**

The Centers for Disease Control and Prevention recommend routine HIV screening in clinical settings, including emergency departments (EDs), because earlier diagnosis enables treatment before symptoms develop and delivery of interventions to reduce continued transmission. However, patients frequently decline testing. This study delivered a 16-min video-based intervention to 160 patients who declined HIV tests in a high volume, urban ED. One third of participants (n= 53) accepted an HIV test post-intervention. Interviews with a subset of participants (n = 40) show that before the video, many were unaware HIV testing could be conducted without drawing blood, or that results could be delivered in 20 min.

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**Berg LJ, Delgado MK, Ginde AA, et al. Characteristics of US emergency departments that offer routine human immunodeficiency virus screening. *Academic Emergency Medicine*. 2012;19(8):894-900.**

**Objectives:** The association between emergency department (ED) characteristics, ED director's perceptions of preventive services, and the availability of human immunodeficiency virus (HIV) screening are unknown. The authors hypothesized that, after adjusting for ED operational and demographic characteristics, teaching hospital status would be associated with increased availability, and ED crowding and ED director agreement with barriers to screening would be associated with decreased availability.

**Methods:** This was a secondary, cross-sectional analysis on previously collected data from 2008 to 2009 regarding availability of ED preventive services. Data were obtained from a random sample of 277 EDs in which ED directors provided information on ED characteristics and availability of HIV screening and rated five barriers to providing preventive services. The association between the availability of HIV screening and teaching hospital and crowding status, ED volume, urban-rural location, ownership, geographic region, patient demographics, state HIV testing consent laws, and ED director opinions on barriers to providing preventive services were determined in univariate analyses and a multivariate logistic regression model.

**Results:** Nineteen percent of the sampled EDs offer HIV screening. Teaching hospitals offer HIV screening more frequently than nonteaching hospitals (38% vs. 18%; p = 0.03), but after

adjusting for other characteristics in a multivariate model, this association was not significant (relative risk ratio [RR] = 2.07, 95% confidence interval [CI] = 0.91 to 3.59). ED crowding also was not significantly associated with screening availability (RR = 0.66, 95% CI = 0.34 to 1.21). However, public ownership (RR = 2.13, 95% CI = 1.28 to 3.14), 24-hour social work (RR = 1.87, 95% CI = 1.02 to 2.99), uninsured population  $\geq 35\%$  (RR = 2.48, 95% CI = 1.39 to 3.69), increased local nonwhite minority population percentage (RR = 1.14 per 10%, 95% CI = 1.02 to 1.26), and state laws allowing opt-out consent for testing (RR = 1.76, 95% CI = 1.01 to 2.74) were associated with increased availability of screening in multivariable analysis. EDs whose directors were concerned about added costs were associated with decreased availability of screening (RR = 0.45, 95% CI = 0.23 to 0.85).

**Conclusions:** After adjusting for other ED operational and demographic characteristics, ED crowding and teaching hospital affiliation were not independently associated with the availability of HIV screening. EDs whose directors were concerned about the cost of preventive services were less likely to provide routine HIV screening. Addressing ED director's concerns about the added costs of ED preventive services, increasing social work availability, and implementing testing laws consistent with Centers for Disease Control and Prevention (CDC) recommendations may facilitate increased adoption of ED HIV screening.

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**Boyer CB, Robles-Schrader GM, Li SX, et al. A comparison of network-based strategies for screening at-risk Hispanic/Latino adolescents and young adults for undiagnosed asymptomatic HIV infection. *Journal of Adolescent Health*. 2014 Sep. 13 [Epub. ahead of print].**

**Purpose:** Hispanic/Latino adolescents and young adults are disproportionately impacted by the HIV/AIDS epidemic; yet little is known about the best strategies to increase HIV testing in this group. Network-based approaches are feasible and acceptable means for screening at-risk adults for HIV infection, but it is unknown whether these approaches are appropriate for at-risk young Hispanics/Latinos. Thus, we compared an alternative venue-based testing (AVT) strategy with a social and sexual network-based interviewing and HIV testing (SSNIT) strategy.

**Methods:** All participants were Hispanics/Latinos aged 13-24 years with self-reported HIV risk; they were recruited from 11 cities in the United States and Puerto Rico and completed an audio computer-assisted self-interview and underwent HIV screening.

**Results:** A total of 1,596 participants (94.5% of those approached) were enrolled: 784 (49.1%) through AVT and 812 (50.9%) through SSNIT. HIV infection was identified in three SSNIT (.37%) and four AVT (.51%) participants ( $p = .7213$ ).

**Conclusions:** Despite high levels of HIV risk, a low prevalence of HIV infection was identified with no differences by recruitment strategy. We found overwhelming support for the acceptability and feasibility of AVT and SSNIT for engaging and screening at-risk young Hispanics/Latinos. Further research is needed to better understand how to strategically implement such strategies to improve identification of undiagnosed HIV infection.

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**Centers for Disease Control and Prevention. [State HIV prevention progress report, 2014.](#)**

Over the past 30 years, tremendous progress has been made in the prevention and treatment of HIV infection. Not all Americans have benefited equally from this progress, however. The burden of HIV infection, the reach of HIV testing, and the health of people living with HIV vary widely across the United States. Understanding the current status of HIV prevention and care outcomes in states informs our efforts to achieve our nation's HIV prevention goals and safeguard the health of all people who are at-risk of, or living with, HIV in each state. The purpose of the State HIV Prevention Progress Report (SPR) is to provide state-level data that show how states are doing in relation to key national goals.

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**Chin T, Hicks C, Samsa G, et al. Diagnosing HIV infection in primary care settings: Missed opportunities. [AIDS Patient Care and STDs.](#) 2014;27(7):392-397.**

In the United States, 20% of HIV-infected persons are unaware of their diagnosis. Improved application of HIV screening recommendations in healthcare settings may facilitate diagnosis. Clinical patient data and previous healthcare visits were reviewed from medical records of newly diagnosed HIV-infected persons in Durham County, North Carolina, who initiated HIV care at Duke University Medical Center in 2008-2011. Comparisons were made to similar data from 2002-2004 using the Pearson's chi-square test and logistic regression. 101 consecutive newly diagnosed patients were identified: 67 males; 73 black, 20 white, and 8 Hispanic/Latino. Mean age was 39 years (range, 17-69), and 73 had health insurance. Median baseline CD4 count was 313 cells/ $\mu$ L (range, 4-1302), and HIV-1 viral load was 45,700 copies/mL (range, 165-10,000,000). One-third had a baseline CD4 count  $<50$  cells/ $\mu$ L, and 15% presented with opportunistic infections. Compared to patients newly diagnosed in 2002-2004, significantly greater proportions were black and less immunocompromised in 2008-2011. Most had been seen at least once by a healthcare provider in the year prior to HIV diagnosis: 72 had  $\geq 1$  prior visits, and 47 had  $\geq 2$  visits. Among those with prior visits, 37/72 (51%) were seen in an emergency department on the first or second visit. Men were three times more likely than women to be diagnosed at their first healthcare encounter ( $p=0.03$ ,  $OR=3.2$ ). Despite CDC recommendations for widespread HIV screening in healthcare settings, HIV diagnosis remains delayed, even among those with frequent healthcare encounters. Educating providers and removing barriers to HIV screening may improve this problem.

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**Christopoulos KA, Kaplan B, Dowdy D, et al. Testing and linkage to care outcomes for a clinician-initiated rapid HIV testing program in an urban emergency department. [AIDS Patient Care and STDs.](#) 2011;25(7):439-444.**

The urban emergency department is an important site for the detection of HIV infection. Current research has focused on strategies to increase HIV testing in the emergency department. As more

emergency department HIV cases are identified, there need to be well-defined systems for linkage to care. We conducted a retrospective study of rapid HIV testing in an urban public emergency department and level I trauma center from June 1, 2008, to March 31, 2010. The objectives of this study were to evaluate the increase in the number of tests and new HIV diagnoses resulting from the addition of targeted testing to clinician-initiated diagnostic testing, describe the demographic and clinical characteristics of patients with newly diagnosed HIV infection, and assess the effectiveness of an HIV clinic based linkage to care team. Of 96,711 emergency department visits, there were 5340 (5.5%) rapid HIV tests performed, representing 4827 (91.3%) unique testers, of whom 62.4% were male and 60.8% were from racial/ethnic minority groups. After the change in testing strategy, the median number of tests per month increased from 114 to 273 (  $p = 0.004$ ), and the median number of new diagnoses per month increased from 1.5 to 4 (  $p = 0.01$ ). From all tests conducted, there were 65 new diagnoses of HIV infection (1.2%, 95% confidence interval [CI] 0.9%, 1.5%). The linkage team connected over 90% of newly diagnosed and out-of-care HIV-infected patients to care. In summary, the addition of targeted testing to diagnostic testing increased new HIV case identification, and an HIV clinic-based team was effective at linkage to care.

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**Egan DJ, Cowan E, Fitzpatrick L, et al. Legislated human immunodeficiency virus testing in New York State emergency departments: reported experience from emergency department providers. *AIDS Patient Care and STDS*. 2014;28(2):91-97.**

In 2010, New York (NY) passed new legislation mandating Emergency Departments (EDs) to offer HIV tests to patients 13-64 presenting for care. We evaluated the requirement's implementation and determined differences based on HIV prevalence or site-specific designated AIDS centers (DACs). We also evaluated policies for linkage to care of new HIV positive patients. An electronic survey on testing practices and linkage to care was administered to all NY EDs, excluding VA hospitals. Basic descriptive statistics were used for analysis. The response rate was 96% (184/191). All respondents knew of the legislation and 86% offered testing, but only 65% (159/184) to all patients required by the law. EDs in NYC, high prevalence areas, and DACs were more likely to offer HIV testing. Most facilities (104/159, 65%) used separate written consent despite elimination of this requirement. Most EDs (67%) used rapid testing: oral point-of-care ED testing and rapid laboratory testing. Only 61% of EDs provided results to patients while in the ED. Most (94%) had a linkage-to-care protocol. However, only 29% confirm linkage. We provide the first report of NY ED HIV testing practices since the mandatory testing law. Most EDs offer HIV testing but challenges still exist. Linkage-to-care plans are in place, but few EDs confirm it occurs.

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**Ellman TM, Sexton ME, Warshafsky D, et al. A forgotten population: older adults with newly diagnosed HIV. [AIDS Patient Care and STDS](#). 2014 Sep. 11 [Epub. ahead of print].**

Limited data are available regarding adults age  $\geq 50$  at initial HIV diagnosis. Improved understanding of this group is critical in designing interventions to facilitate earlier diagnosis and linkage to HIV care. We characterize individuals newly diagnosed with HIV, particularly those  $\geq 50$  years old, and examine the relationship between age and late diagnosis defined as concurrent HIV and AIDS diagnoses. This is a retrospective study of individuals newly diagnosed with HIV from 2006-2011 at an academic medical center in New York City. Multivariable logistic regression was performed to evaluate the effect of age, gender, race/ethnicity, risk factor, and prior medical visits on late diagnosis. Adults age  $\geq 50$  comprised 21.3% of all newly diagnosed individuals. Among these older adults, 70.0% were diagnosed as inpatients and 68.9% concurrent with AIDS, compared to 41.7% and 38.9% of younger adults, respectively. On adjusted analyses, age  $\geq 50$  (OR 3.13, 95% CI 1.63, 5.98) and injection drug use (OR 4.4, 95% CI 1.31, 14.75) were positively associated with late diagnosis, whereas female gender was negatively associated with late diagnosis (OR 0.52, 95% CI 0.28, 0.98). Our data suggest that HIV testing efforts targeting older adults are essential to address the unmet needs of this population, including implementation of HIV screening guidelines in primary care settings.

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**Gilman G, Hidalgo J, Thomas C, et al. Linkages to care for newly diagnosed individuals who test HIV positive in nonprimary care settings. [AIDS Patient Care and and STDs](#). 2012;26(3):132-140.**

Linkage services are an increasingly important component of the continuum of care for people living with HIV, particularly for individuals diagnosed in nonprimary care settings who are less likely than those identified in primary care settings to have a usual source of care. This study examines successful models used by hospital emergency departments, health department outpatient clinics, and other nonprimary care providers for testing, linking, and engaging newly diagnosed HIV-positive racial and ethnic minorities into medical care. Based on studies of five mature linkage-to-care (LTC) programs implemented in geographically and institutionally diverse settings, we identify five key characteristics that make them viable. Effective linkage programs are low cost, intensive, time limited, unique, and flexible. We also identify four core components of successful LTC protocols: directly employed linkage workers, active referral to medical care, person-centered linkage case management, and cultural and linguistic concordance. Finally, we develop a set of operational strategies to help providers address barriers at all levels of the health care system to help promote the effective linkage of newly diagnosed patients to care. We organize the strategies around four key areas: adherence to LTC protocols, selection of linkage workers, execution of linkage programs, and sustainability of linkage programs. The findings presented in this study provide a practical and operational guide for developing and implementing policies and procedures for linking newly diagnosed individuals who test HIV positive in nonprimary care settings into ongoing care for HIV infection.

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**Gruber D, Campos P, Dutcher M. Linking recently diagnosed HIV-positive persons to medical care: Perspectives of referring providers. *AIDS Care*. 2011;23(1):16-24.**

**Background.** Quantitative results from clients participating in the Antiretroviral Treatment Access Studies–II (ARTAS-II) intervention have previously been published. The current report provides qualitative data from providers (agency staff who referred clients to ARTAS-II) concerning how the introduction of ARTAS-II case managers affected referrals to HIV care.

**Methods.** Referring providers from agencies that conducted HIV counseling and testing (community organizations, health care clinics, hospitals, and public health agencies) that had been asked to refer recently diagnosed HIV-positive individuals to ARTAS-II participated. Five ARTAS-II sites interviewed a total of 18 providers using a survey instrument of 11 open-ended questions. The questions covered interviewee characteristics (e.g., how long have you been in this position, job title) and questions related to the ARTAS-II project (e.g., before ARTAS-II, how did you link clients? what benefits have come from being part of the ARTAS-II program?)

**Results.** Prior to the ARTAS-II project, the referring providers described the referral process as ranging from uncertain to disorganized and chaotic. Referring providers reported the process improved dramatically following implementation of the project, with the transition from HIV testing to medical care becoming less complicated and less prone to delays. Recommendations from the providers for further improvement included increasing the number of ARTAS-II case managers, having the program staff use direct, face-to-face communication with staff at referring agencies, and increasing system integration by having ARTAS-II program staff be co-located in clinic settings.

**Conclusion.** The introduction of ARTAS-II case managers to receive referrals from HIV counseling and testing programs was widely viewed as a success by referring providers. ARTAS-II case managers were reported to fill a much needed role that strengthened the HIV service delivery system.

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**Hack CM, Scarfi CA, Sivitz AB, et al. Implementing routine HIV screening in an urban pediatric emergency department. *Pediatric Emergency Care*. 2013;29(3):319-323.**

**Objective:** In 2006, the Centers for Disease Control and Prevention recommended that all outpatient health care settings offer routine, opt-out HIV screening for patients aged 13 to 64 years, except where the prevalence of undiagnosed HIV infection is known to be less than 0.1%. Most emergency departments (EDs) lack routine HIV screening. The objective of this investigation was to describe the results of the implementation of routine, non-targeted opt-in HIV screening for patients aged 13 to 20 years in an urban pediatric ED (PED) in a city in which 1 of 30 residents has HIV/AIDS.

**Methods:** This was a retrospective chart review from an urban, academic PED. The implementation of routine HIV screening in the ED was funded by the New Jersey Department of Health and Senior Services and planned independently of the study investigator. Patients aged 13 to 64 years were offered HIV screening by nursing staff, physicians, and/or HIV counselors.

Patients who accepted were screened with rapid HIV fingerstick testing performed via Clear view HIV 1/2 STAT-PAK by HIV counselors as per the New Jersey Department of Health and Senior Services protocol. Data collected by the study investigator were done by chart review from October through December 2009, the first 3 months after implementation of routine HIV screening. Data were collected from patients aged 13 to 20 years presenting to the PED. Primary outcomes measured included the proportion of patients offered and accepted screening, newly diagnosed HIV cases, and the rate of linking newly diagnosed HIV patients to treatment. Demographic data collected included patient age, sex, and ethnicity. Results from the first 3 months of routine, non-targeted screening were compared with the HIV screening results of October through December 2008, during which time rapid HIV screening was provided to patients in the ED based on clinical indication. Patients who were not offered testing or who refused testing were measured by forms that were placed in every chart and collected by physicians. Emergency department census data were queried to identify the total number of patients seen in the ED within age range and time frame studied.

**Results:** Three hundred (11%) of the 2645 patients aged 13 to 20 years were offered routine HIV screening in the PED from October through December 2009. Two hundred twenty-four patients (74%) accepted HIV testing. No new cases of HIV were identified. There was an increase in acceptance of HIV testing that correlated with increasing age ( $P < 0.05$ ). There was no significant difference between male and female acceptance rates ( $P < 0.05$ ). Eleven (4.9%) of the patients accepting testing did not have testing performed because of unavailability of the counselor and/or the patient could not wait. Review of HIV testing performed in the PED from October through December 2008 showed 39 patients aged 13 to 20 years were tested. Routine testing increased the number of patients tested by 446%.

**Conclusions:** Pediatric patients in this urban setting are very accepting of HIV testing. HIV screening is increased when routine screening is offered.

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**Haukoos JS, White DA, Lyons MS, et al. Operational methods of HIV testing in emergency departments: a systematic review. *Annals of Emergency Medicine*. 2011;58(Suppl. 1):S96-S103.**

**Objectives:** Casual review of existing literature reveals a multitude of individualized approaches to emergency department (ED) HIV testing. Cataloging the operational options of each approach could assist translation by disseminating existing knowledge, endorsing variability as a means to address testing barriers, and laying a foundation for future work in the area of operational models and outcomes investigation. The objective of this study is to provide a detailed account of the various models and operational constructs that have been described for performing HIV testing in EDs.

**Methods:** Systematic review of PUBMED, EMBASE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Web of Science through February 6, 2009 was performed. Three investigators independently reviewed all potential abstracts and identified all studies that met the following criteria for inclusion: original research, performance of HIV testing in an ED in the United States, description of operational methods, and reporting of specific testing



outcomes. Each study was independently assessed and data from each were abstracted with standardized instruments. Summary and pooled descriptive statistics were reported by using recently published nomenclature and definitions for ED HIV testing.

**Results:** The primary search yielded 947 potential studies, of which 25 (3%) were included in the final analysis. Of the 25 included studies, 13 (52%) reported results using nontargeted screening as the only patient selection method. Most programs reported using voluntary, opt-in consent and separate, signed consent forms. A variety of assays and communication methods were used, but relatively limited outcomes data were reported.

**Conclusion:** Currently, limited evidence exists to inform HIV testing practices in EDs. There appears to be recent progression toward the use of rapid assays and nontargeted patient selection methods, with the rate at which reports are published in the peer-reviewed literature increasing. Additional research will be required, including controlled clinical trials, more structured program evaluation, and a focus on an expanded profile of outcome measures, to further improve our understanding of which HIV testing methods are most effective in the ED.

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**Hudepohl NJ, Lindsell CJ, Hart KW, et al. Effect of an emergency department HIV testing program on the proportion of emergency department patients who have been tested. *Annals of Emergency Medicine*. 2011;58(Suppl. 1):S140-S144.**

**Objective:** The lack of well-described population-level outcome measures for emergency department (ED) HIV testing is one barrier to translation of screening into practice. We demonstrate the impact of an ED diagnostic testing and targeted screening program on the proportion of ED patients ever tested for HIV and explore cumulative effects on testing rates over time.

**Methods:** Data were extracted from electronic HIV testing program records and administrative hospital databases for January 2003 to December 2008 to obtain the monthly number of ED visits and HIV tests. We calculated the proportions of (1) patients tested in the program who reported a previous HIV test or had been previously tested in the program, and (2) the cumulative number of unique ED patients who were tested in our program.

**Results:** During the study period, 165,665 unique patients made 491,552 ED visits and the program provided 13,509 tests to 11,503 unique patients. From 2003 to 2008, tested patients who reported a history of an HIV test increased by 0.085% per month (95% confidence interval [CI] 0.037% to 0.133%), from 67.7% to 74.4%; the percentage of tested patients who had previous testing in the program increased by 0.277% per month (95% CI 0.245% to 0.308%), from 3.2% to 21.2%; and the percentage of unique ED patients previously tested in the program increased by 0.100% per month (95% CI 0.096% to 0.105%), reaching a cumulative proportion of 6.9%.

**Conclusion:** Our HIV testing program increased the proportion of ED patients who have been tested for HIV at least once and repeatedly tested a subset of individuals. HIV screening, even during a minority of ED visits, can have important cumulative effects over time.

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**Kyle TL, Horigian VE, Tross S, et al. Uptake of HIV testing in substance use disorder treatment programs that offer on-site testing. *AIDS and Behavior*. 2014 Jul. 30 [Epub. ahead of print].**

Increasing rates of HIV testing within substance use disorder (SUD) treatment clients is an important public health strategy for reducing HIV transmission rates. The present study examined uptake of HIV testing among 1,224 clients in five SUD treatment units that offered on-site testing in Florida, New York, and California. Nearly one-third (30 %) of the participants, who had not previously tested positive, reported not having been tested for HIV within the past 12 months. Women, African Americans, and injection drug users had a higher likelihood of having been tested within the past 12 months. The SUD treatment program was the most frequently identified location of participants' last HIV test. Despite the availability of free, on-site testing, a substantial proportion of clients were not tested, suggesting that strategies to increase uptake of testing should include addressing barriers not limited to location and cost.

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**Mannheimer SB, Wang L, Wilton L, et al. Infrequent HIV testing and late HIV diagnosis are common among a cohort of black men who have sex with men (BMSM) in six cities. *Journal of Acquired Immune Deficiency Syndromes*. 2014 Sep. 5 [Epub. ahead of print].**

**Objective:** US guidelines recommend at least annual HIV testing for those at risk. This analysis assessed frequency and correlates of infrequent HIV testing and late diagnosis among black men who have sex with men (BMSM).

**Methods:** HIV testing history was collected at enrollment from participants in HPTN 061, an HIV prevention trial for at-risk US BMSM. Two definitions of late HIV diagnosis were assessed: CD4 cell count <200 cells/mm<sup>3</sup> or <350 cells/mm<sup>3</sup> at diagnosis.

**Results:** HPTN 061 enrolled 1553 BMSM. HIV testing questions were completed at enrollment by 1284 (98.7%) of 1301 participants with no prior HIV diagnosis; 272 (21.2%) reported no HIV test in prior 12 months (infrequent testing); 155 of whom (12.1% of the 1284 with testing data) reported never testing. Infrequent HIV testing was associated with: not seeing a medical provider in the prior 6 months (relative risk [RR]: 1.08, 95% confidence intervals [CI]: 1.03-1.13), being unemployed (RR 1.04, CI: 1.01-1.07), and having high internalized HIV stigma (RR: 1.03, CI: 1.0-1.05). New HIV diagnoses were more likely among infrequent testers compared to men tested in the prior year (18.4% vs. 4.4%; OR: 4.8, 95% CI: 3.2-7.4). Among men with newly diagnosed HIV, 33 (39.3%) had a CD4 cell count <350 cells/mm<sup>3</sup> including 17 (20.2%) with CD4 <200 cells/mm<sup>3</sup>.

**Conclusions:** Infrequent HIV testing, undiagnosed infection, and late diagnosis were common among BMSM in this study. New HIV diagnoses were more common among infrequent testers, underscoring the need for additional HIV testing and prevention efforts among US BMSM.

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McNairy ML, El-Sadr WM. A paradigm shift: focus on the HIV prevention continuum. [\*Clinical Infectious Diseases\*. 2014;59\(Suppl. 1\):S12-S15.](#)

The human immunodeficiency virus (HIV) prevention continuum is a framework that illustrates the interconnectedness of each step in the spectrum of prevention services, while emphasizing that all steps are needed to decrease HIV acquisition and transmission. This continuum, similar to the HIV care continuum, begins with HIV testing followed by linkage of HIV-uninfected persons to prevention services, retention in such services, and adherence to prevention interventions with repeated HIV testing to monitor for HIV acquisition. To advance the global goal of zero new HIV infections, individuals must receive the entire continuum of prevention services, and no partial credit can be given to achievement of one step in isolation of all steps in the continuum.

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Nakao JH, Wiener DE, Newman DH, et al. Falling through the cracks? Missed opportunities for earlier HIV diagnosis in a New York City hospital. [\*International Journal of STD and AIDS\*. 2014 Feb. 17 \[Epub. ahead of print\].](#)

Newly diagnosed HIV-positive patients have frequent health care encounters prior to diagnosis representing missed opportunities for diagnosis. This study determines the proportion of patients with new HIV diagnoses with encounters in the 3 years prior to diagnosis. We describe the characteristics of newly diagnosed patients and of "late testers" (CD4 <200 cells/mm<sup>3</sup> at the time of diagnosis). We identified all newly diagnosed with HIV in emergency department, inpatient, and outpatient settings between May 1, 2006, and December 31, 2009. Data abstractors searched hospital records to identify all emergency department, inpatient, and outpatient visits for the 3 years prior to diagnosis. In all, 23,271 HIV tests were performed and 253 persons were newly diagnosed (1.1%); 152 new positives (60.1%) made at least one prior visit. Of patients with CD4 counts available, 104/175 (59.4%) had CD4 <200 cells/mm<sup>3</sup>. Patients with at least one prior visit had a median of three. There was no difference in numbers of visits between late testers and non-late testers, although late testers were more likely to have ED visits. Most newly diagnosed HIV-positive patients had multiple encounters prior to diagnosis. Many of these patients presented with CD4 counts below 200 cells/mm<sup>3</sup>, indicating true missed opportunities for earlier diagnosis.

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Richey LE, Carpenter EJ, Barbeau JM, et al. Rapid HIV testing in a New Orleans emergency department is effective in identifying new HIV diagnoses and in linking patients to care. [\*The Journal of the Louisiana State Medical Society\*. 2014;166\(1\):28-33.](#)

A retrospective chart review of patients who agreed to a rapid HIV test in the emergency department in the initial year of institution of the rapid test was conducted. Out of 8,204 patients, 99 were newly diagnosed with HIV in the first year of the institution of the rapid HIV test (1.2%). Eighty-five (86%) had a documented referral to the infectious disease clinic, and 59 (60%) were

linked to care within one year of diagnosis. The majority (58%) of the patients with a new diagnosis of HIV had been seen in the Interim Louisiana State University Public Hospital (ILPH) healthcare system in the five years prior to their diagnosis. Forty-nine percent of the patients met diagnostic criteria of AIDS at diagnosis. Rapid HIV testing in the emergency department is an effective way to find previously undiagnosed patients and link them to subspecialty care.

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**Rothman RE, Kelen GD, Harvey L, et al. Factors associated with no or delayed linkage to care in newly diagnosed human immunodeficiency virus (HIV)-1–Infected patients identified by emergency department–based rapid HIV screening programs in two urban EDs. *Academic Emergency Medicine*. 2012;19(5):497-503.**

The objective was to describe the proportions of successful linkage to care (LTC) and identify factors associated with LTC among newly diagnosed human immunodeficiency virus (HIV)-positive patients, from two urban emergency department (ED) rapid HIV screening programs.

This was a retrospective analysis of programmatic data from two established urban ED rapid HIV screening programs between November 2005 and October 2009. Trained HIV program assistants interviewed all patients tested to gather risk behavior data using a structured data collection instrument. Reactive results were confirmed by Western blot testing. Patients were provided with scheduled appointments at HIV specialty clinics at the institutions where they tested positive within 30 days of their ED visit. "Successful" LTC was defined as attendance at the HIV outpatient clinic within 30 days after HIV diagnosis, in accordance with the ED National HIV Testing Consortium metric. "Any" LTC was defined as attendance at the outpatient HIV clinic within 1 year of initial HIV diagnosis. Multivariate logistic regression was performed to determine factors associated with any LTC or successful LTC.

Of the 15,640 tests administered, 108 (0.7%) were newly identified HIV-positive cases. Nearly half (47.2%) of the patients had been previously tested for HIV. Successful LTC occurred in 54% of cases; any LTC occurred in 83% of cases. In multivariate analysis, having public medical insurance and being self-pay were negatively associated with successful LTC (odds ratio [OR] = 0.33, 95% confidence interval [CI] = 0.12 to 0.96; OR = 0.34, 95% CI = 0.13 to 0.89, respectively); being female and having previously tested for HIV was negatively associated with any LTC (OR = 0.30, 95% CI = 0.10 to 0.93; OR = 0.23, 95% CI = 0.07 to 0.77, respectively).

In spite of dedicated resources for arranging LTC in the ED HIV testing programs, nearly 50% of patients did not have successful LTC (i.e., LTC occurred at >30 days), although >80% of patients were LTC within 1 year of initial diagnosis. Further evaluation of the barriers associated with successful LTC for those with public insurance and self-pay is warranted.

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**Schnall R, Clark S, Olender S, et al. Providers' perceptions of the factors influencing the implementation of the New York State mandatory HIV testing law in two urban academic emergency departments. [Academic Emergency Medicine](#). 2013;20(3):279-286.**

**Objectives:** Of the 1.1 million people in the United States infected with human immunodeficiency virus (HIV), more than 20% are unaware of their infection. To increase early diagnosis and treatment, New York State recently passed legislation mandating that HIV testing be offered to all patients, ages 13 to 64 years, receiving health care services. Implementation of this legislation is complex, especially in the emergency department (ED). This study explores ED providers' perceptions of the factors affecting the implementation of the law.

**Methods:** The authors conducted six focus group sessions and three in-depth interviews with ED health care providers from two New York City teaching hospitals. Sessions were audiotaped and transcribed. Data were coded and summarized thematically through an iterative process after each session.

**Results:** A total of 49 providers participated and data saturation was achieved. Six factors were identified that predispose a provider to offer an HIV test: 1) self-efficacy, 2) behavioral intention, 3) the testing process, 4) provider knowledge of the legislation, 5) type of HIV test, and 6) follow-up procedures. Five factors were identified that enable providers to offer an HIV test: 1) resources related to time, 2) space, 3) staff, 4) type of test, and 5) timing of the offer. Improving access to HIV testing, linkage to care, and public health were all key factors in reinforcing providers' desire to offer HIV tests. Concerns regarding overall cost saving and coverage for the test were indicated as barriers that needed to be resolved to reinforce the providers to offer an HIV test.

**Conclusions:** Understanding the factors influencing the practice of ED providers charged with carrying out this mandate is critical. Despite earlier research that indicated that offering HIV testing to ED patients is largely influenced by cost, this study found additional factors that are important to consider to effectively implementing HIV testing in the ED.

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**Usher D, Frye V, Shinnick J, et al. Recruitment by a geospatial networking application for research and practice: The New York City experience. [Journal of Acquired Immune Deficiency Syndromes](#). 2014 Sep. 20 [Epub. ahead of print].**

Social networking using mobile phone-based applications ("apps") has become widespread, with 89% of Americans ages 18-29 reporting that they use social networking sites. Men who have sex with men (MSM) utilize social networking sites at high rates, in part because they are able to form private, anonymous and relatively safe communities on these sites. A variety of niche sites like Grindr, Manhunt, Adam4Adam and Scruff have web pages and mobile phone-based applications for use by MSM, with a large proportion of MSM using such applications to find sex partners. Several studies have documented the success of using social networking for HIV prevention and recruitment for HIV prevention research. Recently, researchers have reported the use of mobile phone applications for education and as a tool to recruit MSM for research studies.

Here we describe our experience using a geospatial social networking application (Grindr) for recruitment into three different HIV prevention projects, including an HIV testing program, a social epidemiological survey (NYCM2M) and an HIV vaccine trial (HIV Vaccine Trials Network 505 (HVTN 505)). The HIV testing program was part of a national testing initiative with the goal of identifying undiagnosed HIV-infected MSM, with a specific focus on Latino and black men.

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**Weidle PJ, Lecher S, Botts LW, et al. HIV testing in community pharmacies and retail clinics: a model to expand access to screening for HIV infection. *Journal of the American Pharmacists Association*. 2014;54:486-492.**

**Objective:** To test the feasibility of offering rapid point-of-care human immunodeficiency virus (HIV) testing at community pharmacies and retail clinics.

**Design:** Pilot program to determine how to implement confidential HIV testing services in community pharmacies and retail clinics.

**Setting:** 21 community pharmacies and retail clinics serving urban and rural patients in the United States, from August 2011 to July 2013.

**Participants:** 106 community pharmacy and retail clinic staff members.

**Intervention:** A model was developed to implement confidential HIV counseling and testing services using community pharmacy and retail clinic staff as certified testing providers, or through collaborations with organizations that provide HIV testing. Training materials were developed and sites selected that serve patients from urban and rural areas to pilot test the model. Each site established a relationship with its local health department for HIV testing policies, developed referral lists for confirmatory HIV testing/care, secured a CLIA Certificate of Waiver, and advertised the service. Staff were trained to perform a rapid point-of-care HIV test on oral fluid, and provide patients with confidential test results and information on HIV. Patients with a preliminary positive result were referred to a physician or health department for confirmatory testing and, if needed, HIV clinical care.

**Main outcome measures:** Number of HIV tests completed and amount of time required to conduct testing.

**Results:** The 21 participating sites administered 1,540 HIV tests, with 1,087 conducted onsite by staff during regular working hours and 453 conducted at 37 different HIV testing events (e.g., local health fairs). The median amount of time required for pretest counseling/consent, waiting for test results, and posttest counseling was 4, 23, and 3 minutes, respectively. A majority of the sites (17) said they planned to continue HIV testing after the project period ended and would seek assistance or support from the local health department, a community-based organization, or an AIDS service organization.

**Conclusion:** This pilot project established HIV testing in several community pharmacies and retail clinics to be a feasible model for offering rapid, point-of-care HIV testing. It also demonstrated the willingness and ability of staff at community pharmacies and retail clinics to provide confidential HIV testing to patients. Expanding this model to additional sites and evaluating its feasibility and effectiveness may serve unmet needs in urban and rural settings.

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**Xia Q, Kobrak P, Wiewel EW, et al. The high proportion of late HIV diagnoses in the USA is likely to stay: findings from a mathematical model. *AIDS Care*. 2014 Sep 22 [Epub. ahead of print].**

A static model of undiagnosed and diagnosed HIV infections by year of infection and year of diagnosis was constructed to examine the impact of changes in HIV case-finding and HIV incidence on the proportion of late diagnoses. With no changes in HIV case-finding or incidence, the proportion of late diagnoses in the USA would remain stable at the 2010 level, 32.0%; with a 10% increase in HIV case-finding and no changes in HIV incidence, the estimated proportion of late diagnoses would steadily decrease to 28.1% in 2019; with a 5% annual increase in HIV incidence and no changes in case-finding, the proportion would decrease to 25.2% in 2019; with a 5% annual decrease in HIV incidence and no change in case-finding, the proportion would steadily increase to 33.2% in 2019; with a 10% increase in HIV case-finding, accompanied by a 5% annual decrease in HIV incidence, the proportion would decrease from 32.0% to 30.3% in 2011, and then steadily increase to 35.2% in 2019. In all five scenarios, the proportion of late diagnoses would remain stable after 2019. The stability of the proportion is explained by the definition of the measure itself, as both the numerator and denominator are affected by HIV case-finding making the measure less sensitive. For this reason, we should cautiously interpret the proportion of late diagnoses as a marker of the success or failure of expanding HIV testing programs.

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**Linkage, engagement, and retention in care:**

**Centers for Disease Control and Prevention. Behavioral and clinical characteristics of persons receiving medical care for HIV infection — Medical monitoring project, United States, 2009. *Morbidity and Mortality Weekly Report*. 2014;63(5):1-23.**

**Problem:** As of December 31, 2009, an estimated 864,748 persons were living with human immunodeficiency virus (HIV) infection in the 50 U.S. states, the District of Columbia, and six U.S.-dependent areas. Whereas HIV surveillance programs in the United States collect information about persons with a diagnosis of HIV infection, supplemental surveillance systems collect in-depth information about the behavioral and clinical characteristics of persons receiving outpatient medical care for HIV infection. These data are needed to reduce HIV-related morbidity and mortality and HIV transmission.

**Reporting Period Covered:** Data were collected during June 2009–May 2010 for patients receiving medical care at least once during January–April 2009.

**Description of the System:** The Medical Monitoring Project (MMP) is an ongoing surveillance system that assesses behaviors and clinical characteristics of HIV-infected persons who have received outpatient medical care. For the 2009 data collection cycle, participants must have been aged ≥18 years and have received medical care during January–April 2009 at sampled facilities that provide HIV medical care within participating MMP project areas. Behavioral and selected

clinical data were collected using an in-person interview, and most clinical data were collected using medical record abstraction. A total of 23 project areas in 16 states and Puerto Rico were funded to collect data during the 2009 data collection cycle. The data were weighted for probability of selection and nonresponse to be representative of adults receiving outpatient medical care for HIV infection in the United States and Puerto Rico. Prevalence estimates are presented as weighted percentages. The period of reference is the 12 months before the patient interview unless otherwise noted.

**Results:** The patients in MMP represent 421,186 adults who received outpatient medical care for HIV infection in the United States and Puerto Rico during January–April 2009. Of adults who received medical care for HIV infection, an estimated 71.2% were male, 27.2% were female, and 1.6% were transgender. An estimated 41.4% were black or African American, 34.6% were white, and 19.1% were Hispanic or Latino. The largest proportion (23.1%) were aged 45–49 years. Most patients (81.1%) had medical coverage; 40.3% had Medicaid, 30.6% had private health insurance, and 25.7% had Medicare.

An estimated 69.6% of patients had three or more documented CD4+ T-lymphocyte cell (CD4+) or HIV viral load tests. Most patients (88.7%) were prescribed antiretroviral therapy (ART), and 71.6% had a documented viral load that was undetectable or  $\leq 200$  copies/mL at their most recent test. Among sexually active patients, 55.0% had documentation in the medical record of being tested for syphilis, 23.2% for gonorrhea, and 23.9% for chlamydia.

Noninjection drugs were used for nonmedical purposes by an estimated 27.1% of patients, whereas injection drugs were used for nonmedical purposes by 2.1% of patients. Overall, 12.9% of patients engaged in unprotected sex with a partner of negative or unknown HIV status.

Unmet supportive service needs were prevalent, with an estimated 22.8% in need of dental care and 12.0% in need of public benefits, including Social Security Income or Social Security Disability Insurance. Fewer than half of patients (44.8%) reported receiving HIV and sexually transmitted disease prevention counseling from a health-care provider.

**Interpretation:** The findings in this report indicate that most adults living with HIV who received medical care in 2009 were taking ART, had CD4+ and HIV viral load testing at regular intervals, and had health insurance or other coverage. However, some patients did not receive clinical services and treatment in accordance with guidelines. Some patients engaged in behaviors, such as unprotected sex, that increase the risk for transmitting HIV to sex partners, and some used noninjection or injection drugs or both.

**Public Health Actions:** Local and state health departments and federal agencies can use MMP data for program planning to determine allocation of services and resources, guide prevention planning, assess unmet medical and supportive service needs, inform health-care providers, and help focus intervention programs and health policies at the local, state, and national levels.

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**Cohen SM, HU X, Sweeney P, et al. HIV viral suppression among persons with varying levels of engagement in HIV medical care, 19 jurisdictions. [Journal of Acquired Immune Deficiency Syndromes](#). 2014 Sep. 18 [Epub. ahead of print].**

**Background:** Ongoing HIV medical care is vital to achieving and maintaining viral suppression. We examined viral suppression applying retention in care definitions used by various federal agencies.

**Methods:** Using National HIV Surveillance System data from 19 U.S. jurisdictions with complete CD4 and viral load reporting, we determined viral suppression among persons who met the National HIV/AIDS Strategy retention in care definition ( $\geq 2$  visits  $\geq 3$  months apart; "retained in continuous care") and among those who had evidence of care but did not meet the definition ("engaged in care"). We also examined viral suppression among persons who met the Health and Human Services Core Indicator definition for retention.

**Results:** Of 338,959 persons living with diagnosed HIV infection in 19 areas in 2010, 63.7% received any care; of these, 19.7% were "engaged in care" and 80.3% were "retained in continuous care". Of those "engaged in care," 47.7% achieved viral suppression, compared to 73.6% of persons "retained in continuous care." Significant differences were evident for all subpopulations within each care category; younger persons and blacks/African Americans had lower levels of viral suppression than their counterparts. Persons "engaged in care", regardless of sex, age, race/ethnicity, and transmission category, had significantly lower percentages of viral suppression than persons "retained in continuous care." Similar patterns of viral suppression were found for persons meeting the Health and Human Services definition compared to persons "retained in continuous care."

**Conclusion:** Higher levels of engagement in care, including more frequent monitoring of CD4 and viral load, were associated with viral suppression.

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**Crawford TN, Sanderson WT, Thornton A. Impact of poor retention in HIV medical care on time to viral load suppression. [Journal of the International Association of Providers of AIDS Care](#). 2014;13(3):242-249.**

**Objective:** The purpose of this study was to evaluate how poor retention in HIV care impacts time to viral suppression after initiating highly active antiretroviral therapy.

**Methods:** A retrospective cohort study design, employing a medical chart review, was conducted at an academic infectious disease clinic at the University of Kentucky. Patients seeking care between 2003 and 2011 were included in the study. A log-normal model was employed to determine the factors associated with time to viral suppression.

**Results:** Of the 532 patients in the study, 426 (80.1%) patients were virally suppressed. Controlling for insurance status, race, baseline CD4 counts, and viral loads, the expected time to viral suppression for non-optimal retainers was longer compared to optimal retainers (100% retained in care; time ratio: 2.04; 95% confidence interval: 1.40-2.90).

**Conclusion:** Researchers should continue to study the impact of retention on clinical outcomes and strategies to improve retention and reengage those lost to follow-up back into care.

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**Cunningham CO, Buck J, Shaw FM, et al. Factors associated with returning to HIV care after a gap in care in New York State. *Journal of Acquired Immune Deficiency Syndromes*. 2014;66(4):419-427.**

**Background:** Retention in HIV care has important implications. Few studies examining retention include comprehensive and heterogeneous populations, and few examine factors associated with returning to care after gaps in care. We identified reasons for gaps in care and factors associated with returning to care.

**Methods:** We extracted medical record and state-wide reporting data from 1865 patients with 1 HIV visit to a New York facility in 2008 and subsequent 6-month gap in care. Using mixed effect logistic regression, we examined sociodemographic, clinical, and facility characteristics associated with returning to care.

**Results:** Most patients were men (63.2%), black (51.4%), had Medicaid (53.9%). Many had CD4 counts >500 cells per cubic millimeter (34.4%) and undetectable viral loads (45.0%). Most (55.9%) had unknown reasons for gaps in care; of those with known reasons, reasons varied considerably. After a gap, 54.6% returned to care. Patients who did (vs. did not) return to care were more likely to have stable housing, longer duration of HIV, high CD4 count, suppressed viral load, antiretroviral medications, and had facilities attempt to contact them. Those who returned to care were less likely to be uninsured and have mental health problems or substance use histories.

**Conclusion:** Over half of our sample of patients in New York with 1 HIV visit and subsequent 6-month gap in care returned to care; no major reasons for gaps emerged. Nevertheless, our findings emphasize that stabilizing patients' psychosocial factors and contacting patients after a gap in care are key strategies to retain HIV-positive patients in care in New York.

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**Doshi RK, Isenberg D, Matthews T, et al. High rates of retention and viral suppression in United States HIV safety net system: HIV care continuum in the Ryan White HIV/AIDS program, 2011. *Clinical Infectious Diseases*. 2014 Sep. 15 [Epub. ahead of print].**

**Background:** In the HIV care continuum, retention in HIV medical care and viral suppression are key goals to improve individual health outcomes and reduce HIV transmission. National data from clinical providers is lacking.

**Methods:** HIV providers funded by the Ryan White HIV/AIDS Program (RWHAP) annually report demographic, service, and clinical data using encrypted unique client identifiers, and data are processed and de-duplicated to create a single record for each client. We calculated retention and viral suppression for clients who received RWHAP-funded HIV medical care in 2011. We conducted multivariate logistic regression to identify factors associated with these outcomes.

**Results:** In 2011, an estimated 512,911 HIV-infected clients received at least one RWHAP-funded non-ADAP service. Of these, 317,458 (61.8%) were seen for at least 1 HIV medical care visit. Of these, 82.2% were retained in HIV medical care, and 72.6% achieved viral suppression. Viral suppression was higher among retained clients (77.7%) versus clients who were not retained (58.3%). The lowest levels of retention and viral suppression were among individuals between ages 13 and 34 years.

**Conclusions:** The RWHAP provides HIV medical care and support services for over one half million poor and underinsured individuals living with HIV in the United States. Rates of retention and viral suppression are relatively high compared to other national estimates but demonstrate room for improvement, especially among youth and racial minorities. Additional improvements in retention and viral suppression will contribute to achieving the goals of the National HIV/AIDS Strategy and improve individual and public health.

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**Gardner EM, McLees MP, Steiner JF, et al. The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. [Clinical Infectious Diseases](#). 2011;52(6):793-800.**

For individuals with human immunodeficiency virus (HIV) infection to fully benefit from potent combination antiretroviral therapy, they need to know that they are HIV infected, be engaged in regular HIV care, and receive and adhere to effective antiretroviral therapy. Test-and-treat strategies for HIV prevention posit that expanded testing and earlier treatment of HIV infection could markedly decrease ongoing HIV transmission, stemming the HIV epidemic. However, poor engagement in care for HIV-infected individuals will substantially limit the effectiveness of test-and-treat strategies. We review the spectrum of engagement in care for HIV infected individuals in the United States and apply this information to help understand the magnitude of the challenges that poor engagement in care will pose to test-and-treat strategies for HIV prevention.

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**Gardner LI, Girodano TP, Marks G, et al. Enhanced personal contact with HIV patients improves retention in primary care: a randomized trial in 6 US HIV clinics. [Clinical Infectious Diseases](#). 2014;59(5):725-734.**

**Background:** The aim of the study was to determine whether enhanced personal contact with human immunodeficiency virus (HIV)-infected patients across time improves retention in care compared with existing standard of care (SOC) practices, and whether brief skills training improves retention beyond enhanced contact.

**Methods:** The study, conducted at 6 HIV clinics in the United States, included 1838 patients with a recent history of inconsistent clinic attendance, and new patients. Each clinic randomized participants to 1 of 3 arms and continued to provide SOC practices to all enrollees: enhanced contact with interventionist (EC) (brief face-to-face meeting upon returning for care visit, interim

visit call, appointment reminder calls, missed visit call); EC + skills (organization, problem solving, and communication skills); or SOC only. The intervention was delivered by project staff for 12 months following randomization. The outcomes during that 12-month period were (1) percentage of participants attending at least 1 primary care visit in 3 consecutive 4-month intervals (visit constancy), and (2) proportion of kept/scheduled primary care visits (visit adherence).

**Results:** Log-binomial risk ratios comparing intervention arms against the SOC arm demonstrated better outcomes in both the EC and EC + skills arms (visit constancy: risk ratio [RR], 1.22 [95% confidence interval {CI}, 1.09–1.36] and 1.22 [95% CI, 1.09–1.36], respectively; visit adherence: RR, 1.08 [95% CI, 1.05–1.11] and 1.06 [95% CI, 1.02–1.09], respectively; all Ps < .01). Intervention effects were observed in numerous patient subgroups, although they were lower in patients reporting unmet needs or illicit drug use.

**Conclusions:** Enhanced contact with patients improved retention in HIV primary care compared with existing SOC practices. A brief patient skill-building component did not improve retention further. Additional intervention elements may be needed for patients reporting illicit drug use or who have unmet needs.

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**Giordano TP, Gifford AL, White AC, et al. Retention in care: a challenge to survival with HIV infection. *Clinical Infectious Diseases*. 2007;44(11):1493-1499.**

**Background:** Patients with human immunodeficiency virus (HIV) infection need lifelong medical care, but many do not remain in care. The effect of poor retention in care on survival is not known, and we sought to quantify that relationship.

**Methods:** We conducted a retrospective cohort study involving persons newly identified as having HIV infection during 1997-1998 at any United States Department of Veterans Affairs hospital or clinic who started antiretroviral therapy after 1 January 1997. To be included in the study, patients had to have seen a clinician at least once after receiving their first antiretroviral prescription and to have survived for at least 1 year. Patients were divided into 4 groups on the basis of the number of quarters in that year during which they had at least 1 HIV primary care visit. Survival was measured through 2002. Because data were available for only a small number of women, female patients were excluded from the study.

**Results:** A total of 2619 men were followed up for a mean of >4 years each. The median baseline CD4(+) cell count and median log(10) plasma HIV concentration were 228x10(6) cells/L and 4.58 copies/mL, respectively. Thirty-six percent of the patients had visits in <4 quarters, and 16% died during follow-up. In Cox multivariate regression analysis, compared with persons with visits in all 4 quarters during the first year, the adjusted hazard ratio of death was 1.42 (95% confidence interval, 1.11-1.83; P<.01), 1.67 (95% confidence interval, 1.24-2.25; P<.001), and 1.95 (95% confidence interval, 1.37-2.78; P<.001) for persons with visits in 3 quarters, 2 quarters, and 1 quarter, respectively.

**Conclusions:** Even in a system with few financial barriers to care, a substantial portion of HIV-infected patients have poor retention in care. Poor retention in care predicts poorer survival with HIV infection. Retaining persons in care may improve survival, and optimal methods to retain patients need to be defined.

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**Gwadz M, Applegate E, Cleland C, et al. HIV-infected individuals who delay, decline, or discontinue antiretroviral therapy: Comparing clinic-and peer-recruited cohorts. *Frontiers in Public Health*. 2014;16(2):doi 10.3389.**

A substantial proportion of persons living with HIV/AIDS (PLHA) delay, decline, or discontinue antiretroviral therapy (ART) when it is medically indicated (40-45%), largely African-Americans and Latinos/Hispanics. This study explores the feasibility of locating PLHA, who are not on ART (PLHA-NOA) through clinics and peer-referral; compares the two cohorts on multi-level barriers to ART; and examines readiness to initiate/reinitiate ART, a predictor of treatment outcomes. We recruited adult HIV-infected African-American and Latino/Hispanic PLHA-NOA through HIV hospital clinics and peer-referral in 2012-2013. Participants were engaged in structured 1-h assessments with reliable/valid measures on barriers to ART. We found that recruitment through peers (63.2%, 60/95) was more feasible than in clinics (36.8%, 35/90). Participants were 48.0 years old and had lived with HIV for 14.7 years on average, and 56.8% had taken ART previously. Most (61.1%) were male and African-American (76.8%), and 23.2% were Latino/Hispanic. Peer-recruited participants were older, had lived with HIV longer, were less engaged in HIV care, and were more likely to have taken ART previously. The cohorts differed in reasons for discontinuing ART. Levels of ART knowledge were comparable between cohorts (68.5% correct), and there were no differences in attitudes toward ART (e.g., mistrust), which were in the neutral range. In bivariate linear regression, readiness for ART was negatively associated with physician mistrust ( $B = -10.4$ ) and positively associated with self-efficacy ( $B = 5.5$ ), positive outcome expectancies ( $B = 6.3$ ), beliefs about personal necessity of ART ( $B = 17.5$ ), and positive internal norms ( $B = 7.9$ ). This study demonstrates the feasibility of engaging this vulnerable population through peer-referral. Peer-recruited PLHA evidence particularly high rates of risk factors compared to those in hospital clinics. Interventions to support ART initiation and continuation are sorely needed for both subgroups.

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**Hightow-Weidman LB, Johnes K, Wohl AR, et al. Early linkage and retention in care: Findings from the outreach, linkage, and retention in care initiative among young men of color who have sex with men. *AIDS Patient Care and STDs*. 2011;25(Suppl. 1):S31-S38.**

Early linkage and retention in HIV clinical care is essential for optimal disease management, promotion of health, and receipt of secondary prevention messages to decrease onward transmission of HIV. Youth, specifically racial/ethnic minority young men who have sex with men (YMSM), continue to acquire new HIV infections and have been shown to be less likely to engage in regular HIV care and adhere to scheduled medical visits. The goal of the current study was to evaluate the characteristics of participants and program delivery that were associated with early linkage and retention in HIV care among HIV-infected YMSM of color enrolled in an outreach, linkage, and retention study. Of the 334 patients included in the linkage analysis, 72% were linked

to care within 30 days of diagnosis, 81% within 60 days, and 87% within 90 days. While no patient-level characteristics were associated with early linkage, having the person who provided the positive HIV test result refer the patient to HIV care ( $p=0.048$ ), specifically calling to make the appointment ( $p=0.009$ ), was associated with earlier linkage. Retention of Latino participants (96.2%) was significantly higher than for the African-American (79.9%) youth ( $p=0.006$ ). Overall, 221 participants had at least 1 year of possible follow-up and 82.8% of these participants were retained at 1 year. While unique challenges exist in the care of adolescents infected with HIV from identification to engagement and retention in clinical care, programs that are responsive and dedicated to the needs of these youth can be successful in retaining them in care.

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**Holtgrave DR, Kim JJ, Adkins C, et al. Unmet HIV service needs among black men who have sex with men in the United States. *AIDS and Behavior*. 2014;18(1):36-40.**

The National HIV/AIDS Strategy (NHAS) clearly emphasized the need to provide services to black men who have sex with men (MSM). However, there are no estimates of the unmet HIV-related service delivery needs among black MSM. We estimate that of 195,313 black MSM living with HIV in the US, 50,196 were not yet diagnosed, and 145,118 were aware of their seropositivity (of whom 67,625 were not linked to care and 77,493 were linked to care). Also, of those already diagnosed, ~43,390 had undetectable viral load and 101,728 had detectable viral load. Approximately 19,545 of diagnosed black MSM engage in unprotected risk behavior in serostatus-discordant partnerships. The cost of delivering services needed to meet the NHAS goals is ~\$2.475 billion in 2011 U.S. dollars. Mathematical modeling suggests that provisions of these services would avert 6213 HIV infections at an economically favorable cost of \$20,032 per quality-adjusted life year saved.

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**Magnus M, Franks J, Griffith S, et al. Engaging, recruiting, and retaining black men who have sex with men in research studies: Don't underestimated the importance of staffing—Lessons learned from HPTN 061, the BROTHERS study. *Journal of Public Health Management and Practice*. 2014;20(6):E1-E9.**

**Context:** HIV/AIDS in the United States continues to primarily impact men who have sex with men (MSM), with disproportionately high rates among black MSM.

**Objective:** The purpose of this study was to identify factors that may influence engagement and retention of black MSM in HIV research.

**Design and Participants:** This was a qualitative evaluation of study implementation within a multisite, prospective, observational study (HIV Prevention Trials Network 061, BROTHERS) that enrolled 1553 black MSM in 6 cities throughout the United States. Data collection for this evaluation included a written, structured survey collected from each of the sites describing site characteristics including staff and organizational structure, reviews of site standard operating

procedures, and work plans; semistructured key informant interviews were conducted with site coordinators to characterize staffing, site-level factors facilitating or impeding effective community engagement, study recruitment, and retention. Data from completed surveys and site standard operating procedures were collated, and notes from key informant interviews were thematically coded for content by 2 independent reviewers.

**Results:** Several key themes emerged from the data, including the importance of inclusion of members of the community being studied as staff, institutional hiring practices that support inclusive staffing, cultivating a supportive working environment for study implementation, and ongoing relationships between research institutions and community.

**Conclusions:** This study underscores the importance of staffing in implementing research with black MSM. Investigators should consider how staffing and organizational structures affect implementation during study design and when preparing to initiate study activities. Ongoing monitoring of community engagement can inform and improve methods for engagement and ensure cultural relevance while removing barriers for participation.

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**Mugavero MJ, Westfall AO, Zinski A, et al. Measuring retention in HIV care: the elusive gold standard. *Journal of Acquired Immune Deficiency Syndromes*. 2012;61(5):574-580.**

**Background:** Measuring retention in HIV primary care is complex, as care includes multiple visits scheduled at varying intervals over time. We evaluated 6 commonly used retention measures in predicting viral load (VL) suppression and the correlation among measures.

**Methods:** Clinic-wide patient-level data from 6 academic HIV clinics were used for 12 months preceding implementation of the Centers for Disease Control and Prevention/Health Resources and Services Administration (CDC/HRSA) retention in care intervention. Six retention measures were calculated for each patient based on scheduled primary HIV provider visits: count and dichotomous missed visits, visit adherence, 6-month gap, 4-month visit constancy, and the HRSA HIV/AIDS Bureau (HRSA HAB) retention measure. Spearman correlation coefficients and separate unadjusted logistic regression models compared retention measures with one another and with 12-month VL suppression, respectively. The discriminatory capacity of each measure was assessed with the c-statistic.

**Results:** Among 10,053 patients, 8235 (82%) had 12-month VL measures, with 6304 (77%) achieving suppression (VL <400 copies/mL). All 6 retention measures were significantly associated ( $P < 0.0001$ ) with VL suppression (odds ratio; 95% CI, c-statistic): missed visit count (0.73; 0.71 to 0.75, 0.67), missed visit dichotomous (3.2; 2.8 to 3.6, 0.62), visit adherence (3.9; 3.5 to 4.3, 0.69), gap (3.0; 2.6 to 3.3, 0.61), visit constancy (2.8; 2.5 to 3.0, 0.63), and HRSA HAB (3.8; 3.3 to 4.4, 0.59). Measures incorporating "no-show" visits were highly correlated (Spearman coefficient = 0.83-0.85), as were measures based solely on kept visits (Spearman coefficient = 0.72-0.77). Correlation coefficients were lower across these 2 groups of measures (range = 0.16-0.57).

**Conclusions:** Six retention measures displayed a wide range of correlation with one another, yet each measure had significant association and modest discrimination for VL suppression. These

data suggest there is no clear gold standard and that selection of a retention measure may be tailored to context.

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**Nachega JB, Uthman OA, del Rio C, et al. Addressing the Achilles' heel in the HIV care continuum for the success of a test-and treat strategy to achieve an AIDS-free generation. *Clinical Infectious Diseases*. 2014;59(Suppl. 1):S21-S27.**

Mathematical models and recent data from ecological, observational, and experimental studies show that antiretroviral therapy (ART) is effective for both treatment and prevention of HIV, validating the treatment as prevention (TasP) approach. Data from a variety of settings, including resource-rich and -limited sites, show that patient attrition occurs at each stage of the human immunodeficiency virus (HIV) treatment cascade, starting with the percent unaware of their HIV infection in a population and linkage to care after diagnosis, assessment of ART readiness, receipt of ART, and finally long-term virologic suppression. Therefore, in order to implement TasP, we must first define practical and effective linkage to care, acceptability of treatment, and adherence and retention monitoring strategies, as well as the cost-effectiveness of such strategies. Ending this pandemic will require the combination of political will, resources, and novel effective interventions that are not only feasible and cost effective but also likely to be used in combination across successive steps on the HIV treatment cascade.

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**Philbin MM, Tanner AE, DuVal A, et al. Factors affecting linkage to care and engagement in care for newly diagnosed HIV-positive adolescents within fifteen adolescent medicine clinics in the United States. *AIDS and Behavior*. 2014;18(8):1501-1510.**

Early linkage to care and engagement in care are critical for initiation of medical interventions. However, over 50 % of newly diagnosed persons do not receive HIV-related care within 6 months of diagnosis. We evaluated a linkage to care and engagement in care initiative for HIV-positive adolescents in 15 U.S.-based clinics. Structural and client-level factors (e.g. demographic and behavioral characteristics, clinic staff and location) were evaluated as predictors of successful linkage and engagement. Within 32 months, 1,172/1,679 (69.8 %) of adolescents were linked to care of which 1,043/1,172 (89 %) were engaged in care. Only 62.1 % (1,043/1,679) of adolescents were linked and engaged in care. Linkage to care failure was attributed to adolescent, provider, and clinic-specific factors. Many adolescents provided incomplete data during the linkage process or failed to attend appointments, both associated with failure to linkage to care. Additional improvements in HIV care will require creative approaches to coordinated data sharing, as well as continued outreach services to support newly diagnosed adolescents.

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**Rowan SE, Burman WJ, Johnson SC, et al. Engagement-in-care during the first 5 years after diagnosis: Data from a cohort of newly HIV-diagnosed individuals in a large US city. [AIDS Patient Care and STDS](#). 2014;28(9):475-482.**

Initial descriptions of the HIV engagement continuum are limited by short-term follow-up and incomplete data. We evaluated engagement in a newly HIV-diagnosed cohort. Our goals were to assess long-term engagement-in care, evaluate the effects of out-of-state migration on engagement estimates, and determine whether engagement has improved in more recently diagnosed individuals. This is a retrospective cohort study of individuals newly HIV-diagnosed at two large HIV care centers in the Denver metropolitan area from 2005 to 2009. Clinical data were obtained from three public HIV providers and two clinical trial groups. For statewide evaluation, we used mandated laboratory reporting databases for CD4 lymphocyte counts and HIV-1 RNA levels. From 2005 to 2009, 615 individuals were diagnosed with HIV. By 18 months after HIV diagnosis, 84% of the cohort had linked to care, 73% were retained in care, 49% were prescribed antiretroviral therapy, and 36% had viral suppression. By 5 years after HIV diagnosis, 55% of the cohort were retained in care, 37% had viral suppression, 15% had moved out of state, and 3% were deceased. When censoring for outmigration and death, 66% of the cohort were retained in care and 45% of the cohort had viral suppression 5 years after HIV diagnosis. Engagement-in-care 18 months after diagnosis was better in individuals diagnosed more recently. Retention in care declined while viral suppression increased over time after HIV diagnosis. Accounting for outmigration and death significantly increased estimates of engagement-in-care. Performance in the engagement continuum 18 months after diagnosis improved significantly in individuals more recently diagnosed with HIV.

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**Sabharwal CJ, Braunstein SL, Robbins RS, et al. Optimizing the use of surveillance data for monitoring the care status of persons recently diagnosed with HIV in NYC. [Journal of Acquired Immune Deficiency Syndromes](#). 2014;65(5):571-578.**

**Background:** Comprehensive laboratory reporting of CD4 and viral load (VL) tests to surveillance has been used to assess HIV care-related outcomes at the population level, but their validity for this purpose has not been comprehensively evaluated.

**Objective:** Assess performance characteristics and validity of surveillance-based measures of linkage to and establishment of HIV primary care among HIV-infected persons in the first 12 months after diagnosis using medical record (MR) data on outpatient HIV primary care visits as the gold standard.

**Methods:** All patients diagnosed with HIV in 2009 at 24 New York City high-volume, HIV diagnostic and treatment facilities who linked to care within 12 months at the same site as defined by the presence of  $\geq 1$  CD4/VL report received by surveillance were selected for MR review to confirm linkage to outpatient HIV primary care within the first year. All HIV care visit dates were abstracted and considered associated with a surveillance laboratory report, if within 14 days of a care visit. The proportion linking to care according to the MR was compared with the proportion linking per CD4/VL tests reported to surveillance. Four measures of the establishment of outpatient HIV primary care in the first year were assessed: (1) sustained care (first visit within

3 months; second visit, 3-9 months later), (2) continuous care (2 visits at least 90 days apart), (3) trimester visits (visit in each 4-month period), and (4) visit constancy (visit in each 3-month period). The validity of surveillance data for measuring this outcome was assessed by comparing results for each of the 4 measures calculated using surveillance data to those calculated using MR data.

**Results:** Of the 782 patients selected, 20% (N = 157) of patients did not link to outpatient HIV primary care at the co-located care facility within 12 months of diagnosis. Half (48.5%) of patients' care visits after linkage did not have an associated CD4/VL reported to surveillance. Of the 4 establishment measures, sustained and continuous care had the highest agreement with MR (86.6% and 88.8%, respectively) as compared with the trimester visits and visit constancy (77.8% and 72.8%, respectively).

**Conclusions:** Surveillance data overestimated linkage rates but underestimated the frequency of HIV care in the first year after HIV diagnosis. Of the 4 measures of establishment of HIV care evaluated, "sustained care" is best suited for measurement using surveillance data because of its high level of agreement with MR data and close alignment with national standards for timely linkage and flexible follow-up.

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**Tedaldi EM, Richardson JT, Debes R, et al. Retention in care within 1 year of initial HIV care visit in a multisite US cohort: who's in and who's out? [Journal of the International Association of Providers of AIDS Care](#). 2014;13(3):232-241.**

Biannual attendance at medical visits is an established measure of retention in HIV care. We examined factors associated with attending at least 2 clinic visits at least 90 days apart among HIV-infected, antiretroviral therapy (ART)-naive HIV Outpatient Study participants entering care during 2000 to 2011. Of 1441 patients, 85% were retained in care during the first year of observation. Starting ART during the year was the strongest correlate of retention (adjusted odds ratio [aOR] 6.4, 95% confidence interval [CI] 4.4-9.4). After adjusting for starting ART, publicly insured patients (aOR 0.6, 95% CI 0.4-1.0), and patients with baseline CD4 counts <200 cells/mm<sup>3</sup> (aOR 0.5, 95% CI 0.3-0.9) or missing CD4 counts (aOR 0.3, 95% CI 0.2-0.6) were less likely to be retained in care. Although most patients had recommended biannual care visits, some ART-naive individuals may require additional interventions to remain in care. Promptly initiating ART may facilitate engagement in care.

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**Thompson ML, Mugavero MJ, Amico KR, et al. Guidelines for improving entry into and retention in care and antiretroviral adherence for persons with HIV: evidence-based recommendations from an International Association of Physicians in AIDS Care panel. [Annals of Internal Medicine](#). 2012;156(11):817-833.**

**Description:** After HIV diagnosis, timely entry into HIV medical care and retention in that care are essential to the provision of effective antiretroviral therapy (ART). Adherence to ART is among

the key determinants of successful HIV treatment outcome and is essential to minimize the emergence of drug resistance. The International Association of Physicians in AIDS Care convened a panel to develop evidence-based recommendations to optimize entry into and retention in care and ART adherence for people with HIV.

**Methods:** A systematic literature search was conducted to produce an evidence base restricted to randomized, controlled trials and observational studies with comparators that had at least 1 measured biological or behavioral end point. A total of 325 studies met the criteria. Two reviewers independently extracted and coded data from each study using a standardized data extraction form. Panel members drafted recommendations based on the body of evidence for each method or intervention and then graded the overall quality of the body of evidence and the strength for each recommendation.

**Recommendations:** Recommendations are provided for monitoring entry into and retention in care, interventions to improve entry and retention, and monitoring of and interventions to improve ART adherence. Recommendations cover ART strategies, adherence tools, education and counseling, and health system and service delivery interventions. In addition, they cover specific issues pertaining to pregnant women, incarcerated individuals, homeless and marginally housed individuals, and children and adolescents, as well as substance use and mental health disorders. Recommendations for future research in all areas are also provided.

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**Yehia BR, French B, Fleishman JA, et al. Retention in care is more strongly associated with viral suppression in HIV-infected patients with lower versus higher CD4 counts. *Journal of Acquired Immune Deficiency Syndromes*. 2014;65(3):333-339.**

Retention in care is important for all HIV-infected patients, but may be more important for people with advanced HIV disease. We evaluated whether the association between retention in care and viral suppression differed by HIV disease severity.

A repeated cross-sectional analysis (2006-2011) involving 35,433 adults at 18 US HIV clinics. Multivariable logistic regression models examined associations between retention measures [Health Resources and Services Administration (HRSA) retention measure, 6-month gap, and 3-month visit constancy] and viral suppression (HIV-1 RNA  $\leq$  400 copies/mL) for HIV disease severity groups defined by CD4 counts:  $\leq$  200, 201-350, 351-500, and  $>$ 500 cells per cubic millimeter.

Overall, patients met the HRSA measure in 84% of person-years, did not have a 6-month gap in 76%, and had visits in all 4 quarters in 37%; patients achieved viral suppression in 72% of person-years. The association between retention in care and viral suppression differed by disease severity, and was strongest for patients with lower CD4 counts:  $\leq$  200 [adjusted odds ratio (AOR) = 2.33, 95% confidence interval (CI): 2.16 to 2.51], 201-350 (AOR = 1.96, CI: 1.81 to 2.12), 351-500 (AOR = 1.65, CI: 1.53 to 1.78), and  $>$ 500 cells per cubic millimeter (AOR = 1.22, CI: 1.14 to 1.30) using the HRSA retention measure as a representative example.

This is one of the first studies to report the impact of HIV disease severity on retention in care and viral suppression, demonstrating that retention in care is more strongly associated with viral suppression in patients with lower CD4 counts. These results have important implications for

improving the health of patients with advanced HIV disease and for test and treat approaches to HIV prevention.

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### **Pre-exposure prophylaxis:**

#### **A. Clinical trials:**

**Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. [New England Journal of Medicine](#). 2012;367(5):399-410.**

**Background:** Antiretroviral preexposure prophylaxis is a promising approach for preventing human immunodeficiency virus type 1 (HIV-1) infection in heterosexual populations.

**Methods:** We conducted a randomized trial of oral antiretroviral therapy for use as preexposure prophylaxis among HIV-1-serodiscordant heterosexual couples from Kenya and Uganda. The HIV-1-seronegative partner in each couple was randomly assigned to one of three study regimens--once-daily tenofovir (TDF), combination tenofovir-emtricitabine (TDF-FTC), or matching placebo--and followed monthly for up to 36 months. At enrollment, the HIV-1-seropositive partners were not eligible for antiretroviral therapy, according to national guidelines. All couples received standard HIV-1 treatment and prevention services.

**Results:** We enrolled 4758 couples, of whom 4747 were followed: 1584 randomly assigned to TDF, 1579 to TDF-FTC, and 1584 to placebo. For 62% of the couples followed, the HIV-1-seronegative partner was male. Among HIV-1-seropositive participants, the median CD4 count was 495 cells per cubic millimeter (interquartile range, 375 to 662). A total of 82 HIV-1 infections occurred in seronegative participants during the study, 17 in the TDF group (incidence, 0.65 per 100 person-years), 13 in the TDF-FTC group (incidence, 0.50 per 100 person-years), and 52 in the placebo group (incidence, 1.99 per 100 person-years), indicating a relative reduction of 67% in the incidence of HIV-1 with TDF (95% confidence interval [CI], 44 to 81;  $P < 0.001$ ) and of 75% with TDF-FTC (95% CI, 55 to 87;  $P < 0.001$ ). Protective effects of TDF-FTC and TDF alone against HIV-1 were not significantly different ( $P = 0.23$ ), and both study medications significantly reduced the HIV-1 incidence among both men and women. The rate of serious adverse events was similar across the study groups. Eight participants receiving active treatment were found to have been infected with HIV-1 at baseline, and among these eight, antiretroviral resistance developed in two during the study.

**Conclusions:** Oral TDF and TDF-FTC both protect against HIV-1 infection in heterosexual men and women.

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**Buchbinder SP, Liu A. Pre-exposure prophylaxis and the promise of combination prevention approaches. [AIDS and Behavior](#). 2011; Suppl 1:S72-9.**

Pre-exposure prophylaxis (PrEP) for HIV prevention is a promising experimental approach currently being tested globally. A number of PrEP trials are evaluating the safety and

effectiveness of PrEP in men who have sex with men (MSM) and other populations at risk for HIV, and results will be available from this first generation of efficacy trials over the next few years. Here we review the rationale for orally-administered antiretrovirals for prevention, and outline issues the first generation trials will address as well as questions that may be addressed in future studies. We also describe the rationale for combination prevention approaches that may combine PrEP with other prevention modalities as part of a larger prevention package.

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**Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *The Lancet*. 2013;381(9983):2083-2090.**

**Background:** Antiretroviral pre-exposure prophylaxis reduces sexual transmission of HIV. We assessed whether daily oral use of tenofovir disoproxil fumarate (tenofovir), an antiretroviral, can reduce HIV transmission in injecting drug users.

**Methods:** In this randomised, double-blind, placebo-controlled trial, we enrolled volunteers from 17 drug-treatment clinics in Bangkok, Thailand. Participants were eligible if they were aged 20-60 years, were HIV-negative, and reported injecting drugs during the previous year. We randomly assigned participants (1:1; blocks of four) to either tenofovir or placebo using a computer-generated randomisation sequence. Participants chose either daily directly observed treatment or monthly visits and could switch at monthly visits. Participants received monthly HIV testing and individualised risk-reduction and adherence counselling, blood safety assessments every 3 months, and were offered condoms and methadone treatment. The primary efficacy endpoint was HIV infection, analysed by modified intention-to-treat analysis. This trial is registered with ClinicalTrials.gov, number NCT00119106.

**Findings:** Between June 9, 2005, and July 22, 2010, we enrolled 2413 participants, assigning 1204 to tenofovir and 1209 to placebo. Two participants had HIV at enrolment and 50 became infected during follow-up: 17 in the tenofovir group (an incidence of 0.35 per 100 person-years) and 33 in the placebo group (0.68 per 100 person-years), indicating a 48.9% reduction in HIV incidence (95% CI 9.6-72.2;  $p=0.01$ ). The occurrence of serious adverse events was much the same between the two groups ( $p=0.35$ ). Nausea was more common in participants in the tenofovir group than in the placebo group ( $p=0.002$ ).

**Interpretation:** In this study, daily oral tenofovir reduced the risk of HIV infection in people who inject drugs. Pre-exposure prophylaxis with tenofovir can now be considered for use as part of an HIV prevention package for people who inject drugs.

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**Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. [New England Journal of Medicine](#). 2010;363(27):2587-2599.**

**Background:** Antiretroviral chemoprophylaxis before exposure is a promising approach for the prevention of human immunodeficiency virus (HIV) acquisition.

**Methods:** We randomly assigned 2499 HIV-seronegative men or transgender women who have sex with men to receive a combination of two oral antiretroviral drugs, emtricitabine and tenofovir disoproxil fumarate (FTC-TDF), or placebo once daily. All subjects received HIV testing, risk-reduction counseling, condoms, and management of sexually transmitted infections.

**Results:** The study subjects were followed for 3324 person-years (median, 1.2 years; maximum, 2.8 years). Of these subjects, 10 were found to have been infected with HIV at enrollment, and 100 became infected during follow-up (36 in the FTC-TDF group and 64 in the placebo group), indicating a 44% reduction in the incidence of HIV (95% confidence interval, 15 to 63;  $P=0.005$ ). In the FTC-TDF group, the study drug was detected in 22 of 43 of seronegative subjects (51%) and in 3 of 34 HIV-infected subjects (9%) ( $P<0.001$ ). Nausea was reported more frequently during the first 4 weeks in the FTC-TDF group than in the placebo group ( $P<0.001$ ). The two groups had similar rates of serious adverse events ( $P=0.57$ ).

**Conclusions:** Oral FTC-TDF provided protection against the acquisition of HIV infection among the subjects. Detectable blood levels strongly correlated with the prophylactic effect.

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**Grohskopf LA, Chillag KL, Gyetadze R, et al. Randomized trial of clinical safety of daily oral tenofovir disoproxil fumarate among HIV-uninfected men who have sex with men in the United States. [Journal of the Acquired Immune Deficiency Syndromes](#). 2013;64(1):79-86.**

**Objectives:** To evaluate the clinical safety of daily tenofovir disoproxil fumarate (TDF) among HIV-negative men who have sex with men.

**Design:** Randomized, double-blind, placebo-controlled trial. Participants were randomized 1:1:1:1 to immediate or delayed study drug (TDF, 300 mg orally per day, or placebo).

**Methods:** Four hundred healthy HIV-uninfected men who have sex with men reporting anal sex with another man within the previous 12 months enrolled in Atlanta, Boston, and San Francisco. HIV serostatus, clinical and laboratory adverse events (AEs), adherence (pill count, Medication Event Monitoring System, and self-report), and sexual and other sociobehavioral data were assessed at 3-month intervals for 24 months. Primary outcomes were clinical safety, assessed by incidence of AEs and laboratory abnormalities.

**Results:** Study drug was initiated by 373 (93%) participants (186 TDF and 187 placebo), of whom 325 (87%) completed the final study visit. Of 2428 AEs reported among 334 (90%) participants, 2366 (97%) were mild or moderate in severity. Frequencies of commonly reported AEs did not differ significantly between TDF and placebo arms. In multivariable analyses, back pain was more likely among TDF recipients ( $P = 0.04$ ); these reports were not associated with documented fractures or other objective findings. There were no grade  $\geq 3$  creatinine elevations; grades 1 and

2 creatinine increases were not associated with TDF receipt. Estimated percentage of study drug doses taken was 92% by pill count and 77% by Medication Event Monitoring System. Seven seroconversions occurred: 4 on placebo and 3 among delayed arm participants not yet on study drug.

**Conclusions:** Daily oral TDF was well tolerated, with reasonable adherence. No significant renal concerns were identified.

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**Haire B. It's time: The case for PrEP as an active comparator in HIV biomedical prevention trials. *Bioethical Inquiry*. 2014 Jul 20 [Epub. ahead of print].**

In July 2012, based on evidence from two major trials, the United States Food and Drug Administration approved the use of combined oral tenofovir/emtricitabine as pre-exposure prophylaxis (PrEP) for people at high risk of HIV acquisition. PrEP effectiveness is marred by poor adherence, however, even in trial populations, thus it is not a magic bullet for HIV prevention. It is, however, the most effective biomedical HIV prevention intervention available for people at high risk of HIV, particularly those who have receptive sex and lack the power to negotiate condom use. Accordingly, there are compelling reasons to compare future experimental HIV prevention interventions against PrEP. The interests both of trial participants and of science are served by using PrEP as comparator: Not only would HIV incidence be reduced, but also the question of whether new interventions were superior to best proven interventions, in a given setting, would be answered comprehensively.

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**Liu AY, Vittinghoff E, Chilaq K, et al. Sexual risk behavior among HIV-uninfected men who have sex with men participating in a tenofovir preexposure prophylaxis randomized trial in the United States. *Journal of Acquired Immune Deficiency Syndromes*. 2013;64(1):87-94.**

**Objective:** To evaluate for changes in sexual behaviors associated with daily pill use among men who have sex with men (MSM) participating in a preexposure prophylaxis trial.

**Design:** Randomized, double-blind, placebo-controlled trial. Participants were randomized 1:1:1:1 to receive tenofovir disoproxil fumarate or placebo at enrollment or after a 9-month delay and followed for 24 months.

**Methods:** Four hundred HIV-negative MSM reporting anal sex with a man in the past 12 months and meeting other eligibility criteria enrolled in San Francisco, Atlanta, and Boston. Sexual risk was assessed at baseline and quarterly visits using Audio Computer-Assisted Self-Interview. The association of pill taking with sexual behavior was evaluated using logistic and negative-binomial regressions for repeated measures.

**Results:** Overall indices of behavioral risk declined or remained stable during follow-up. Mean number of partners and proportion reporting unprotected anal sex declined during follow-up ( $P < 0.05$ ), and mean unprotected anal sex episodes remained stable. During the initial 9 months, changes in risk practices were similar in the group that began pills immediately vs. those in the

delayed arm. These indices of risk did not differ significantly after initiation of pill use in the delayed arm or continuation of study medication in the immediate arm. Use of poppers, amphetamines, and sexual performance-enhancing drugs were independently associated with one or more indices of sexual risk.

**Conclusions:** There was no evidence of risk compensation among HIV-uninfected MSM in this clinical trial. Monitoring for risk compensation should continue now that preexposure prophylaxis has been shown to be efficacious in MSM and other populations and will be provided in open-label trials and other contexts.

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**Mugo NR, Hong T, Celum C, et al. Pregnancy incidence and outcomes among women receiving pre-exposure prophylaxis for HIV prevention: A randomized clinical trial. *Journal of the American Medical Association*. 2014;312(4):362-371.**

Antiretroviral preexposure prophylaxis (PrEP), using tenofovir disoproxil fumarate (TDF) and combination emtricitabine/tenofovir disoproxil fumarate (FTC+TDF), is efficacious for prevention of human immunodeficiency virus (HIV) acquisition. PrEP could reduce periconception HIV risk, but the effect on pregnancy outcomes is not well defined.

**Objective:** To assess pregnancy incidence and outcomes among women using PrEP during the periconception period.

**Design, setting, and participants:** Randomized trial among 1785 HIV-serodiscordant heterosexual couples (the Partners PrEP Study) in which the female partner was HIV uninfected that demonstrated that PrEP was efficacious for HIV prevention, conducted between July 2008 and June 2013 at 9 sites in Kenya and Uganda.

**Interventions:** Daily oral TDF (n = 598), combination FTC+TDF (n = 566), or placebo (n = 621) through July 2011, when PrEP demonstrated efficacy for HIV prevention. Thereafter, participants continued receiving active PrEP without placebo. Pregnancy testing occurred monthly and study medication was discontinued when pregnancy was detected.

**Main outcomes and measures:** Pregnancy incidence, birth outcomes (live births, pregnancy loss, preterm birth, congenital anomalies), and infant growth.

**Results:** A total of 431 pregnancies occurred. Pregnancy incidence was 10.0 per 100 person-years among women assigned placebo, 11.9 among those assigned TDF (incidence difference, 1.9; 95% CI, -1.1 to 4.9 [P = .22 vs placebo]), and 8.8 among those assigned FTC+TDF (incidence difference, -1.3; 95% CI, -4.1 to 1.5 [P = .39 vs placebo]). Before discontinuation of the placebo treatment group in July 2011, the occurrence of pregnancy loss (96 of 288 pregnancies) was 42.5% for women receiving FTC+TDF compared with 32.3% for those receiving placebo (difference for FTC+TDF vs placebo, 10.2%; 95% CI, -5.3% to 25.7%; P = .16) and was 27.7% for those receiving TDF alone (difference vs placebo, -4.6%; 95% CI, -18.1% to 8.9%; P = .46). After July 2011, the frequency of pregnancy loss (52 of 143 pregnancies) was 37.5% for FTC+TDF and 36.7% for TDF alone (difference, 0.8%; 95% CI, -16.8% to 18.5%; P = .92). Occurrence of preterm birth, congenital anomalies, and growth throughout the first year of life did not differ significantly for infants born to women who received PrEP vs placebo.



**Conclusions and relevance:** Among HIV-serodiscordant heterosexual African couples, differences in pregnancy incidence, birth outcomes, and infant growth were not statistically different for women receiving PrEP with TDF alone or combination FTC+TDF compared with placebo at conception. Given that PrEP was discontinued when pregnancy was detected and that CIs for the birth outcomes were wide, definitive statements about the safety of PrEP in the periconception period cannot be made. These results should be discussed with HIV-uninfected women receiving PrEP who are considering becoming pregnant.

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**Murnane PM, Celum C, Mugo N, et al. Efficacy of pre-exposure prophylaxis for HIV-1 prevention among high-risk heterosexuals: Subgroup analyses from a randomized trial. *AIDS*. 2013;27(13):2155-2160.**

**Background:** Daily oral antiretroviral pre-exposure prophylaxis (PrEP) is a promising strategy for prevention of HIV-1 acquisition. Three clinical trials demonstrated PrEP efficacy; however, two PrEP trials among women did not find protection against HIV-1. One hypothesis proposed for these divergent results is that PrEP efficacy may be reduced in populations with higher HIV-1 incidence.

**Methods:** Using data from the Partners PrEP Study, a randomized, placebo-controlled trial of daily oral tenofovir (TDF) and emtricitabine/tenofovir (FTC/TDF) PrEP among heterosexual HIV-1 serodiscordant couples from Kenya and Uganda, we assessed PrEP efficacy among subgroups at higher risk for HIV-1 acquisition, including subgroups of women with high HIV-1 incidence.

**Results:** The overall placebo arm HIV-1 incidence was 2.0 per 100 person-years. Among higher risk subgroups, placebo arm HIV-1 incidence ranged from 3.9 to 6.6 per 100 person-years. In all subgroups, PrEP was protective against HIV-1 acquisition, with efficacy point estimates ranging from 64 to 84%. Among subgroups of women with placebo-arm HIV-1 incidence more than 5.0, efficacy estimates ranged from 64 to 84%. Monthly visit attendance for PrEP refills and tenofovir detection in plasma were high.

**Conclusion:** Among higher-risk subgroups in the Partners PrEP Study, including groups solely of higher-risk women, both TDF alone and combined FTC/TDF PrEP had consistently high efficacy for HIV-1 protection. PrEP, when used with high adherence, is a highly effective prevention strategy for higher risk heterosexuals. Prioritizing PrEP for persons at high risk of HIV-1 will maximize its prevention impact.

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**Peterson L, Taylor D, Roddy R, et al. Tenofovir disoproxil fumarate for prevention of HIV infection in women: a phase 2, double-blind, randomized, placebo-controlled trial. *PLOS Clinical Trials*. 2007;25(5)e27.**

**Objectives:** The objective of this trial was to investigate the safety and preliminary effectiveness of a daily dose of 300 mg of tenofovir disoproxil fumarate (TDF) versus placebo in preventing HIV infection in women.

**Design:** This was a phase 2, randomized, double-blind, placebo-controlled trial.

**Setting:** The study was conducted between June 2004 and March 2006 in Tema, Ghana; Douala, Cameroon; and Ibadan, Nigeria.

**Participants:** We enrolled 936 HIV-negative women at high risk of HIV infection into this study.

**Intervention:** Participants were randomized 1:1 to once daily use of 300 mg of TDF or placebo.

**Outcome measures:** The primary safety endpoints were grade 2 or higher serum creatinine elevations (>2.0 mg/dl) for renal function, grade 3 or 4 aspartate aminotransferase or alanine aminotransferase elevations (>170 U/l) for hepatic function, and grade 3 or 4 phosphorus abnormalities (<1.5 mg/dl). The effectiveness endpoint was infection with HIV-1 or HIV-2.

**Results:** Study participants contributed 428 person-years of laboratory testing to the primary safety analysis. No significant differences emerged between treatment groups in clinical or laboratory safety outcomes. Study participants contributed 476 person-years of HIV testing to the primary effectiveness analysis, during which time eight seroconversions occurred. Two were diagnosed in participants randomized to TDF (0.86 per 100 person-years) and six in participants receiving placebo (2.48 per 100 person-years), yielding a rate ratio of 0.35 (95% confidence interval = 0.03-1.93), which did not achieve statistical significance. Owing to premature closures of the Cameroon and Nigeria study sites, the planned person-years of follow-up and study power could not be achieved.

**Conclusion:** Daily oral use of TDF in HIV-uninfected women was not associated with increased clinical or laboratory adverse events. Effectiveness could not be conclusively evaluated because of the small number of HIV infections observed during the study.

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**Sweeney P, Garnder LI, Buchacz K, et al. Shifting the paradigm: Using HIV surveillance data as a foundation for improving HIV care and preventing HIV infection. *The Millbank Quarterly*. 2013;91(3):558-603.**

**Context:** Reducing HIV incidence in the United States and improving health outcomes for people living with HIV hinge on improving access to highly effective treatment and overcoming barriers to continuous treatment. Using laboratory tests routinely reported for HIV surveillance to monitor individuals' receipt of HIV care and contacting them to facilitate optimal care could help achieve these objectives. Historically, surveillance-based public health intervention with individuals for HIV control has been controversial because of concerns that risks to privacy and autonomy could outweigh benefits. But with the availability of lifesaving, transmission-interrupting treatment for HIV infection, some health departments have begun surveillance-based outreach to facilitate HIV medical care.

**Methods:** Guided by ethics frameworks, we explored the ethical arguments for changing the uses of HIV surveillance data. To identify ethical, procedural, and strategic considerations, we reviewed the activities of health departments that are using HIV surveillance data to contact persons identified as needing assistance with initiating or returning to care.

**Findings:** Although privacy concerns surrounding the uses of HIV surveillance data still exist, there are ethical concerns associated with not using HIV surveillance to maximize the benefits from HIV medical care and treatment. Early efforts to use surveillance data to facilitate optimal

HIV medical care illustrate how the ethical burdens may vary depending on the local context and the specifics of implementation. Health departments laid the foundation for these activities by engaging stakeholders to gain their trust in sharing sensitive information; establishing or strengthening legal, policy and governance infrastructure; and developing communication and follow-up protocols that protect privacy.

**Conclusions:** We describe a shift toward using HIV surveillance to facilitate optimal HIV care. Health departments should review the considerations outlined before implementing new uses of HIV surveillance data, and they should commit to an ongoing review of activities with the objective of balancing beneficence, respect for persons, and justice.

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**Thigpen MC, Kebaabetswe PM, Paxton LA, et al. Antiretroviral pre-exposure prophylaxis for heterosexual HIV transmission in Botswana. *New England Journal of Medicine*. 2012;367(5):423-434.**

**Background:** Preexposure prophylaxis with antiretroviral agents has been shown to reduce the transmission of human immunodeficiency virus (HIV) among men who have sex with men; however, the efficacy among heterosexuals is uncertain.

**Methods:** We randomly assigned HIV-seronegative men and women to receive either tenofovir disoproxil fumarate and emtricitabine (TDF-FTC) or matching placebo once daily. Monthly study visits were scheduled, and participants received a comprehensive package of prevention services, including HIV testing, counseling on adherence to medication, management of sexually transmitted infections, monitoring for adverse events, and individualized counseling on risk reduction; bone mineral density testing was performed semiannually in a subgroup of participants.

**Results:** A total of 1219 men and women underwent randomization (45.7% women) and were followed for 1563 person-years (median, 1.1 years; maximum, 3.7 years). Because of low retention and logistic limitations, we concluded the study early and followed enrolled participants through an orderly study closure rather than expanding enrollment. The TDF-FTC group had higher rates of nausea (18.5% vs. 7.1%,  $P<0.001$ ), vomiting (11.3% vs. 7.1%,  $P=0.008$ ), and dizziness (15.1% vs. 11.0%,  $P=0.03$ ) than the placebo group, but the rates of serious adverse events were similar ( $P=0.90$ ). Participants who received TDF-FTC, as compared with those who received placebo, had a significant decline in bone mineral density. K65R, M184V, and A62V resistance mutations developed in 1 participant in the TDF-FTC group who had had an unrecognized acute HIV infection at enrollment. In a modified intention-to-treat analysis that included the 33 participants who became infected during the study (9 in the TDF-FTC group and 24 in the placebo group; 1.2 and 3.1 infections per 100 person-years, respectively), the efficacy of TDF-FTC was 62.2% (95% confidence interval, 21.5 to 83.4;  $P=0.03$ ).

**Conclusions:** Daily TDF-FTC prophylaxis prevented HIV infection in sexually active heterosexual adults. The long-term safety of daily TDF-FTC prophylaxis, including the effect on bone mineral density, remains unknown.

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**Van Damme L, Corneli A, Ahmed K, et al. Pre-exposure prophylaxis for HIV infection among African women. [New England Journal of Medicine](#). 2012;367(5):411-422.**

**Background:** Pre-exposure prophylaxis with antiretroviral drugs has been effective in the prevention of human immunodeficiency virus (HIV) infection in some trials but not in others.

**Methods:** In this randomized, double-blind, placebo-controlled trial, we assigned 2120 HIV-negative women in Kenya, South Africa, and Tanzania to receive either a combination of tenofovir disoproxil fumarate and emtricitabine (TDF-FTC) or placebo once daily. The primary objective was to assess the effectiveness of TDF-FTC in preventing HIV acquisition and to evaluate safety.

**Results:** HIV infections occurred in 33 women in the TDF-FTC group (incidence rate, 4.7 per 100 person-years) and in 35 in the placebo group (incidence rate, 5.0 per 100 person-years), for an estimated hazard ratio in the TDF-FTC group of 0.94 (95% confidence interval, 0.59 to 1.52; P=0.81). The proportions of women with nausea, vomiting, or elevated alanine aminotransferase levels were significantly higher in the TDF-FTC group (P=0.04, P<0.001, and P=0.03, respectively). Rates of drug discontinuation because of hepatic or renal abnormalities were higher in the TDF-FTC group (4.7%) than in the placebo group (3.0%, P=0.051). Less than 40% of the HIV-uninfected women in the TDF-FTC group had evidence of recent pill use at visits that were matched to the HIV-infection window for women with seroconversion. The study was stopped early, on April 18, 2011, because of lack of efficacy.

**Conclusions:** Prophylaxis with TDF-FTC did not significantly reduce the rate of HIV infection and was associated with increased rates of side effects, as compared with placebo. Despite substantial counseling efforts, drug adherence appeared to be low.

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### **B. Guidelines:**

**Centers for Disease Control and Prevention. Interim Guidance: Pre-exposure prophylaxis for the prevention of HIV infection in men who have sex with men. [Morbidity and Mortality Weekly Report](#). 2011;60(3):65-68.**

An estimated 56,000 human immunodeficiency virus (HIV) infections occur each year in the United States (1). Men who have sex with men (MSM) account for 53% of the estimated incident infections, and surveillance data suggest that the annual number of new HIV infections among MSM has been rising since the mid-1990s (1). Strategies for reducing acquisition of HIV infection by MSM have included 1) expanded HIV testing so that infected persons can be treated and their risk for transmitting infection minimized; 2) individual, small-group, and community-level behavioral interventions to reduce risk behaviors (2); 3) promotion of condom use; 4) detection and treatment of sexually transmitted infections (3); and 5) mental health and substance abuse counseling when needed. On November 23, 2010, investigators for the Pre-Exposure Prophylaxis Initiative (iPrEX) study announced results from a multinational, randomized, double-blind, placebo-controlled, phase III clinical trial of daily oral antiretrovirals (tenofovir disoproxil fumarate [TDF] and emtricitabine [FTC]) to prevent acquisition of HIV infection among uninfected but exposed MSM (4). This report provides interim guidance to health-care providers based on

the reported results of that trial, which indicated that TDF plus FTC taken orally once a day as pre-exposure prophylaxis (PrEP) is safe and partially effective in reducing HIV acquisition among MSM when provided with regular monitoring of HIV status and ongoing risk-reduction and PrEP medication adherence counseling.

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**Centers for Disease Control and Prevention. [Pre-exposure prophylaxis for the prevention of HIV infection in the United States-2014: A clinical practice guideline.](#)**

*Pre-exposure Prophylaxis for HIV Prevention in the United States - 2013: A Clinical Practice Guideline* provides comprehensive information for the use of daily oral antiretroviral pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV infection in adults. The key messages of the guideline are as follows:

Daily oral PrEP with the fixed-dose combination of tenofovir disoproxil fumarate (TDF) 300 mg and emtricitabine (FTC) 200 mg has been shown to be safe and effective in reducing the risk of sexual HIV acquisition in adults; therefore,

PrEP is recommended as one prevention option for sexually-active adult MSM (men who have sex with men) at substantial risk of HIV acquisition PrEP is recommended as one prevention option for adult heterosexually active men and women who are at substantial risk of HIV acquisition. PrEP is recommended as one prevention option for adult injection drug users (IDU) at substantial risk of HIV acquisition. PrEP should be discussed with heterosexually-active women and men whose partners are known to have HIV infection (i.e., HIV-discordant couples) as one of several options to protect the uninfected partner during conception and pregnancy so that an informed decision can be made in awareness of what is known and unknown about benefits and risks of PrEP for mother and fetus. Currently the data on the efficacy and safety of PrEP for adolescents are insufficient. Therefore, the risks and benefits of PrEP for adolescents should be weighed carefully in the context of local laws and regulations about autonomy in health care decision-making by minors. Acute and chronic HIV infection must be excluded by symptom history and HIV testing immediately before PrEP is prescribed. The only medication regimen approved by the Food and Drug Administration and recommended for PrEP with all the populations specified in this guideline is daily TDF 300 mg co-formulated with FTC 200 mg (Truvada) TDF alone has shown substantial efficacy and safety in trials with IDUs and heterosexually active adults and can be considered as an alternative regimen for these populations, but not for MSM, among whom its efficacy has not been studied. The use of other antiretroviral medications for PrEP, either in place of or in addition to TDF/FTC (or TDF) is not recommended. The prescription of oral PrEP for coitally-timed or other noncontinuous daily use is not recommended. HIV infection should be assessed at least every 3 months while patients are taking PrEP so that those with incident infection do not continue taking it. The 2-drug regimen of TDF/FTC is inadequate therapy for established HIV infection, and its use may engender resistance to either or both drugs. Renal function should be assessed at baseline and monitored at least every 6 months while patients are taking PrEP so that those in whom renal failure is developing do not continue to take it. When PrEP is prescribed, clinicians should provide access, directly or by facilitated referral, to proven effective risk-reduction services. Because high medication

adherence is critical to PrEP efficacy but was not uniformly achieved by trial participants, patients should be encouraged and enabled to use PrEP in combination with other effective prevention methods.

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**Centers for Disease Control and Prevention.** [\*Pre-exposure prophylaxis for the prevention of HIV infection in the United States-2014: Clinical Providers' Supplement.\*](#)

This supplement to the PHS PrEP Clinical Practice Guidelines is intended to provide additional information that may be useful to clinicians providing PrEP. As additional materials become available, this document will be updated.

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**Leibowitz AA, Parker KB, Rotheram-Borus MJ.** A US policy perspective on oral pre-exposure prophylaxis for HIV. [\*American Journal of Public Health.\*](#) 2011;101(6):982-985.

Orally administered pre-exposure prophylaxis is an innovative and controversial HIV prevention strategy involving the regular use of antiretroviral medications by uninfected individuals. Antiretroviral medications protect against potential HIV infection by reducing susceptibility to the virus. Recent clinical trial results indicate that pre-exposure prophylaxis can be safe and efficacious for men who have sexual intercourse with men, yet there remain policy considerations surrounding costs, opportunity costs, and ethical issues that must be addressed before broad implementation in the United States. Resources for HIV prevention are limited, thus cost effectiveness analyses of PrEP implementation in nonexperimental situations are needed to allocate prevention funding most productively. Findings from the randomized clinical trials that PrEP is efficacious should mark the beginning of the policy discussion, not its end.

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**Mayer K, Gazzard B, Zuniga JM, et al.** Controlling the HIV epidemic with antiretrovirals: IAPAC consensus statement on treatment as prevention and pre-exposure prophylaxis. [\*Journal of the International Association of Providers of AIDS Care.\*](#) 2013;12(3):208-213.

In the context of emerging evidence related to pre-exposure prophylaxis and HIV treatment as prevention, an evidence summit was held in mid-2012 to discuss the current state of the science and to provide a platform for consensus building around whether and how these prevention strategies might be implemented globally. Health care providers, researchers, policy makers, people living with HIV/AIDS, and representatives of government authorities, donor agencies, pharmaceutical companies, advocacy organizations, and professional associations attended from 52 countries. An international advisory committee was convened to identify key messages and recommendations based upon the data presented and discussed at the summit. The advisory committee further worked to develop this consensus statement meant to assist relevant

stakeholders in taking stock and mapping out a route forward to enhance the HIV prevention armamentarium.

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### **C. Implementation:**

**Amico KR, Stirratt MJ. Adherence to pre-exposure prophylaxis: Current, emerging, and anticipated bases of evidence. *Clinical Infectious Diseases*. 2014;59(Suppl. 1): S55-S60.**

Despite considerable discussion and debate about adherence to pre-exposure prophylaxis (PrEP) for human immunodeficiency virus (HIV), scant data are available that characterize patterns of adherence to open-label PrEP. The current evidence base is instead dominated by research on adherence to placebo-controlled investigational drug by way of drug detection in active-arm participants of large randomized controlled trials (RCTs). Important differences between the context of blinded RCTs and open-label use suggest caution when generalizing from study product adherence to real-world PrEP use. Evidence specific to open-label PrEP adherence is presently sparse but will expand rapidly over the next few years as roll-out, demonstration projects, and more rigorous research collect and present findings. The current evidence bases established cannot yet predict uptake, adherence, or persistence with open-label effective PrEP. Emerging evidence suggests that some cohorts could execute better adherence in open-label use vs placebo-controlled research. Uptake of PrEP is presently slow in the United States; whether this changes as grassroots and community efforts increase awareness of PrEP as an effective HIV prevention option remains to be determined. As recommended by multiple guidelines for PrEP use, all current demonstration projects offer PrEP education and/or counseling. PrEP support approaches generally fall into community-based, technology, monitoring, and integrated sexual health promotion approaches. Developing and implementing research that moves beyond simple correlates of either study product use or open-label PrEP adherence toward more comprehensive models of sociobehavioral and socioecological adherence determinants would greatly accelerate progress. Intervention research is needed to identify effective models of support for open-label PrEP adherence.

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**Corneli AL, Deese J, Wang M, et al. FEM-PrEP: Adherence patterns and factors associated with adherence to a daily oral study product for pre-exposure prophylaxis. *Journal of Acquired Immune Deficiency Syndromes*. 2014;66(3):324-331.**

**Background:** Several clinical trials have demonstrated the safety and effectiveness of oral tenofovir disoproxil fumarate (TDF), with or without emtricitabine (FTC), as pre-exposure prophylaxis (PrEP) for reducing the risk of HIV acquisition. Adherence to the study product was insufficient to demonstrate the effectiveness of FTC/TDF in 2 PrEP clinical trials conducted among women (FEM-PrEP and the Vaginal and Oral Interventions to Control the Epidemic study), but

further analyses of adherence in these studies may inform PrEP demonstration projects and future HIV prevention clinical trials.

**Methods:** We randomly selected a subcohort of 150 participants randomized to FTC/TDF in 3 FEM-PrEP sites (Bondo, Kenya; Bloemfontein, South Africa; and Pretoria, South Africa) to examine adherence levels over time and to assess factors associated with adherence, based on plasma tenofovir and intracellular tenofovir diphosphate drug concentrations in specimens collected at 4-week visit intervals.

**Results:** We observed drug concentrations consistent with good adherence in 28.5% of all visit intervals when drug was available to use, but only 12% of participants achieved good adherence throughout their study participation. In multivariate analysis, the Bloemfontein site [odds ratio (OR): 2.43; 95% confidence interval (CI): 1.32 to 4.48] and liking the pill color (OR: 2.93; 95% CI: 1.18 to 7.27) were positively associated with good adherence, whereas using oral contraceptive pills at enrollment was negatively associated with good adherence (OR: 0.37; 95% CI: 0.18 to 0.74).

**Conclusions:** Most participants did not regularly adhere to the study product throughout their trial participation, although a small minority did. Few factors associated with good adherence to the study product were identified in FEM-PrEP.

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**Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: A cohort study. *Lancet Infectious Diseases*. 2014 Jul. 22 [Epub. ahead of print].**

In our cohort study, men and transgender women who have sex with men previously enrolled in PrEP trials (ATN 082, iPrEx, and US Safety Study) were enrolled in a 72 week open-label extension. We measured drug concentrations in plasma and dried blood spots in seroconverters and a random sample of seronegative participants. We assessed PrEP uptake, adherence, sexual practices, and HIV incidence. Statistical methods included Poisson models, comparison of proportions, and generalised estimating equations.

We enrolled 1603 HIV-negative people, of whom 1225 (76%) received PrEP. Uptake was higher among those reporting condomless receptive anal intercourse (416/519 [81%] vs 809/1084 [75%],  $p=0.003$ ) and having serological evidence of herpes (612/791 [77%] vs 613/812 [75%]  $p=0.03$ ). Of those receiving PrEP, HIV incidence was 1.8 infections per 100 person-years, compared with 2.6 infections per 100 person-years in those who concurrently did not choose PrEP (HR 0.51, 95% CI 0.26-1.01, adjusted for sexual behaviours), and 3.9 infections per 100 person-years in the placebo group of the previous randomised phase (HR 0.49, 95% CI 0.31-0.77). Among those receiving PrEP, HIV incidence was 4.7 infections per 100 person-years if drug was not detected in dried blood spots, 2.3 infections per 100 person-years if drug concentrations suggested use of fewer than two tablets per week, 0.6 per 100 person-years for use of two to three tablets per week, and 0.0 per 100 person-years for use of four or more tablets per week ( $p<0.0001$ ). PrEP drug concentrations were higher among people of older age, with more schooling, who reported non-condom receptive anal intercourse, who had more sexual partners, and who had a history of syphilis or herpes.



PrEP uptake was high when made available free of charge by experienced providers. The effect of PrEP is increased by greater uptake and adherence during periods of higher risk. Drug concentrations in dried blood spots are strongly correlated with protective benefit.

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**Kessler J, Myers JE, Nucifora KA, et al. Evaluating the impact of prioritization of antiretroviral pre-exposure prophylaxis in New York City. *AIDS*. 2014 Sep. 10 [Epub. ahead of print].**

**Objective:** To compare the value and effectiveness of different prioritization strategies of pre-exposure prophylaxis (PrEP) in New York City (NYC).

**Design:** Mathematical modelling utilized as clinical trial is not feasible.

**Methods:** Using a model accounting for both sexual and parenteral transmission of HIV, we compare different prioritization strategies (PPS) for PrEP with two scenarios - no PrEP and PrEP for all susceptible at-risk individuals. The PPS included PrEP for all MSM, only high-risk MSM, high-risk heterosexuals, and IDUs, and all combinations of these four strategies. Outcomes included HIV infections averted, and incremental cost-effectiveness (per-infection averted) ratios. Initial assumptions regarding PrEP included a 44% reduction in HIV transmission, 50% uptake in the prioritized population and an annual cost per person of \$9762. Sensitivity analyses on key parameters were conducted.

**Results:** Prioritization to all MSM results in a 19% reduction in new HIV infections. Compared with PrEP for all persons at-risk, this PPS retains 79% of the preventive effect at 15% of the total cost. PrEP prioritized to only high-risk MSM results in a reduction in new HIV infections of 15%. This PPS retains 60% of the preventive effect at 6% of the total cost. There are diminishing returns when PrEP utilization is expanded beyond this group.

**Conclusion:** PrEP implementation is relatively cost-inefficient under our initial assumptions. Our results suggest that PrEP should first be promoted among MSM who are at particularly high risk of HIV acquisition. Further expansion beyond this group may be cost-effective, but is unlikely to be cost-saving.

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**Krakower D, Mayer KH. Engaging healthcare providers to implement HIV pre-exposure prophylaxis. *Current Opinion in HIV and AIDS*. 2012;7(6):593-599.**

**Purpose of review:** Recent randomized controlled trials have demonstrated that HIV pre-exposure prophylaxis (PrEP) can decrease HIV incidence among several at-risk populations, including men who have sex with men, serodiscordant couples, and heterosexual men and women. As PrEP is a biomedical intervention that requires clinical monitoring and a high level of medication adherence, maximizing the public health effectiveness of PrEP in real-world settings will require the training of a cadre of healthcare providers to prescribe PrEP. Therefore it is critical to understand provider knowledge, practices, and attitudes towards PrEP prescribing, and to develop strategies for engaging and training providers to provide PrEP.

**Recent Findings:** Limited numbers of studies have focused on PrEP implementation by healthcare providers. These studies suggest that some providers are knowledgeable about PrEP, but many are not, or express misgivings. Although many clinicians report willingness to provide PrEP, few have prescribed PrEP in clinical practice. Provider comfort and skills in HIV risk assessment are suboptimal, which could limit identification of individuals who are most likely to benefit from PrEP use.

**Summary:** Further studies to understand facilitators and barriers to HIV-risk assessment and PrEP prescribing by practicing clinicians are needed. Innovative training strategies and decision-support interventions for providers could optimize PrEP implementation and therefore merit additional research.

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**Li J, Dufrene SL, Okulicz JF. Systemic pre-exposure prophylaxis for HIV: translating clinical data to clinical practice. *Annals of Pharmacotherapy*. 2014;48(4)507-518.**

**Objective:** To assess the real-world implications of oral tenofovir-emtricitabine (TDF-FTC) for HIV pre-exposure prophylaxis (PrEP) in clinical practice and highlight important considerations for its implementation.

**Data sources:** A search of PubMed (January 1996 through June 2013) was conducted using the terms HIV pre-exposure prophylaxis, HIV prevention, tenofovir, and emtricitabine. Abstracts from 2012-2013 HIV/AIDS conferences were also reviewed.

**Study selection and data extraction:** All pertinent original studies and review articles published in English were evaluated for inclusion. Reference citations from identified articles were examined for additional content.

**Data synthesis:** Although antiretroviral therapy has been highly successful in reducing AIDS outcomes and death in HIV-infected patients worldwide, transmission of HIV remains a major global health problem. The recent approval of oral TDF-FTC for HIV PrEP represents the latest biomedical intervention to help control this epidemic. Four published randomized studies evaluated the efficacy and safety of this combination to prevent HIV transmission in several at-risk populations, including men who have sex with men, serodiscordant couples, and heterosexuals residing in endemic regions. Overall, these studies demonstrated significant risk reductions in the incidence of new HIV infections with good short-term tolerability. Despite promising results from clinical studies, several limitations may hinder the utility of PrEP in clinical practice. Most importantly, PrEP was studied in the context of a comprehensive prevention program, including intensive counseling on adherence, high-risk behaviors, and traditional preventative measures. If PrEP is implemented without these adjunct measures, concerns about failure and increased resistance may eventually be realized.

**Conclusion:** The greatest impact of PrEP, both clinically and financially, will likely arise from judicious application in select high-risk populations. If used appropriately, PrEP has the potential to augment reductions in the current incidence of new HIV infections, and pharmacists will have an important role in the careful selection and counseling of these targeted populations.

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**McMahon JM, Myers JE, Kurth AE, et al. Oral pre-exposure prophylaxis (PrEP) for prevention of HIV in serodiscordant heterosexual couples in the United States: Opportunities and challenges. *AIDS Patient Care and STDs*. 2014;28(9):462-474.**

Oral HIV pre-exposure prophylaxis (PrEP) is a promising new biomedical prevention approach in which HIV-negative individuals are provided with daily oral antiretroviral medication for the primary prevention of HIV-1. Several clinical trials have demonstrated efficacy of oral PrEP for HIV prevention among groups at high risk for HIV, with adherence closely associated with level of risk reduction. In the United States (US), three groups have been prioritized for initial implementation of PrEP-injection drug users, men who have sex with men at substantial risk for HIV, and HIV-negative partners within serodiscordant heterosexual couples. Numerous demonstration projects involving PrEP implementation among MSM are underway, but relatively little research has been devoted to study PrEP implementation in HIV-serodiscordant heterosexual couples in the US. Such couples face a unique set of challenges to PrEP implementation at the individual, couple, and provider level with regard to PrEP uptake and maintenance, adherence, safety and toxicity, clinical monitoring, and sexual risk behavior. Oral PrEP also provides new opportunities for serodiscordant couples and healthcare providers for primary prevention and reproductive health. This article provides a review of the critical issues, challenges, and opportunities involved in the implementation of oral PrEP among HIV-serodiscordant heterosexual couples in the US.

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**Schackman BR, Eggman AA. Cost-effectiveness of pre-exposure prophylaxis for HIV: A review. *Current Opinion in HIV and AIDS*. 2012;7(6):587-592.**

**Purpose:** The US Food and Drug Administration (FDA) recently approved the use of tenofovir-emtricitabine for pre-exposure prophylaxis (PrEP) for HIV prevention. PrEP is also being investigated in clinical trials as a component of HIV prevention in resource-limited settings. Cost-effectiveness models are useful in identifying health programs with the greatest societal value and projecting long-term program impacts. This review examines six recent studies of the cost-effectiveness of PrEP for preventing HIV transmission in the USA and South Africa.

**Recent Findings:** Studies used both individual-level and population-level transmission models. PrEP was found to be a cost-effective HIV-prevention intervention in high-risk MSM with HIV incidence at least 2% in the USA (<US\$100 000 per quality-adjusted life year) and in young women in South Africa (cost per life year <GDP per capita). Results were sensitive to the cost and efficacy of PrEP and to assumptions about HIV testing and access to treatment in the absence of PrEP.

**Summary:** Future cost effectiveness studies should consider PrEP implementation issues (uptake in high-risk versus low-risk groups, duration on PrEP, adherence), budget impact, and the role of PrEP as part of combination HIV-prevention strategies including expanded testing and treatment access.

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**Tellalian D, Maznavi K, Bredeek UF, et al. Pre-exposure prophylaxis (PrEP) for HIV infection: results of a survey of HIV healthcare providers evaluating their knowledge, attitudes, and prescribing practices. [AIDS Patient Care and STDS](#). 2013;27(10):553-559.**

Antiretroviral medications can be taken by HIV-negative persons to prevent HIV infection, also known as pre-exposure prophylaxis (PrEP). PrEP was first shown to be effective during the iPrEX study. We conducted a survey involving HIV healthcare providers to document their attitudes and prescribing practices about PrEP in response to this study. An online survey was completed by 189 members and credentialed of the American Academy of HIV Medicine between April 2011 and September 2011. Ninety percent of respondents were familiar with the results of the iPrEX study, and most (78%) were familiar with CDC's interim guidance regarding the use of PrEP in MSM. Only 19% of respondents had prescribed PrEP. The majority of PrEP prescribers were compliant with CDC interim guidance; however, only 61% screened for hepatitis B. Of PrEP prescribers, 78% prescribed to MSM, 31% to MSW, and 28% to WSM. Greatest concerns about prescribing PrEP included development of antiretroviral resistance (32%), potential increase in high-risk behavior, (22%) and poor medication adherence (21%). Fifty-eight percent stated that HIV serodiscordance within a relationship most influenced their decision to prescribe PrEP to the HIV-seronegative partner. This study demonstrates that, despite awareness of the efficacy of PrEP, its use is limited. Survey participants used PrEP most commonly in MSM; however, a significant percentage also prescribed PrEP to women. The best candidate for PrEP is felt to be individuals in an HIV-serodiscordant relationship. Limitations to our study included a low response rate, changes in the evidence base, and the novelty of PrEP.

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### ***E. Opinion***

**Arnold EA, Hazelton P, Lane T, et al. A qualitative study of provider thoughts on implementing pre-exposure prophylaxis (PrEP) in clinical settings to prevent HIV infection. [PLOS One](#). 2012;7(7):e40603.**

A recent clinical trial demonstrated that a daily dose tenofovir disoproxil fumarate and emtricitabine (TDF-FTC) can reduce HIV acquisition among men who have sex with men (MSM) and transgender (TG) women by 44%, and up to 90% if taken daily. We explored how medical and service providers understand research results and plan to develop clinical protocols to prescribe, support and monitor adherence for patients on PrEP in the United States.

Using referrals from our community collaborators and snowball sampling, we recruited 22 healthcare providers in San Francisco, Oakland, and Los Angeles for in-depth interviews from May-December 2011. The providers included primary care physicians seeing high numbers of MSM and TG women, HIV specialists, community health clinic providers, and public health officials. We analyzed interviews thematically to produce recommendations for setting policy around implementing PrEP. Interview topics included: assessing clinician impressions of PrEP and CDC guidance, considerations of cost, office capacity, dosing schedules, and following patients over time.

Little or no demand for PrEP from patients was reported at the time of the interviews. Providers did not agree on the most appropriate patients for PrEP and believed that current models of care, which do not involve routine frequent office visits, were not well suited for prescribing PrEP. Providers detailed the need to build capacity and were concerned about monitoring side effects and adherence. PrEP was seen as potentially having impact on the epidemic but providers also noted that community education campaigns needed to be tailored to effectively reach specific vulnerable populations.

While PrEP may be a novel and clinically compelling prevention intervention for MSM and TG women, it raises a number of important implementation challenges that would need to be addressed. Nonetheless, most providers expressed optimism that they eventually could prescribe and monitor PrEP in their practice.

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**Calabrese SK, Earnshaw VA, Underhill K, et al. The impact of patient race on clinical decisions related to prescribing HIV pre-exposure prophylaxis (PrEP): assumptions about sexual risk compensation and implications for access. *AIDS and Behavior*. 2014;18(2):226-240.**

Antiretroviral pre-exposure prophylaxis (PrEP) has received increasing recognition as a viable prescription-based intervention for people at risk for HIV acquisition. However, little is known about racial biases affecting healthcare providers' willingness to prescribe PrEP. This investigation sought to explore medical students' stereotypes about sexual risk compensation among Black versus White men who have sex with men seeking PrEP, and the impact of such stereotypes on willingness to prescribe PrEP. An online survey presented participants (n = 102) with a clinical vignette of a PrEP-seeking, HIV-negative man with an HIV-positive male partner. Patient race was systematically manipulated. Participants reported predictions about patient sexual risk compensation, willingness to prescribe PrEP, and other clinical judgments. Bootstrapping analyses revealed that the Black patient was rated as more likely than the White patient to engage in increased unprotected sex if prescribed PrEP, which, in turn, was associated with reduced willingness to prescribe PrEP to the patient.

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**Karris MY, Beekmann SE, Mehta SR, et al. Are we prepped for pre-exposure prophylaxis (PrEP)? Provider opinions on the real-world use of PrEP in the United States and Canada. *Clinical Infectious Diseases*. 2014;58(5):704-12.**

Pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate and emtricitabine (Truvada) has demonstrated efficacy in placebo-controlled clinical trials involving men who have sex with men, high-risk heterosexuals, serodiscordant couples, and intravenous drug users. To assist in the real-world provision of PrEP, the Centers for Disease Control and Prevention (CDC) has released guidance documents for PrEP use.

Adult infectious disease physicians were surveyed about their opinions and current practices of PrEP through the Emerging Infections Network (EIN). Geographic information systems analysis was used to map out provider responses across the United States.

Of 1175 EIN members across the country, 573 (48.8%) responded to the survey. A majority of clinicians supported PrEP but only 9% had actually provided it. Despite CDC guidance, PrEP practices were variable and clinicians reported many barriers to its real-world provision.

The majority of adult infectious disease physicians across the United States and Canada support PrEP but have vast differences of opinion and practice, despite the existence of CDC guidance documents. The success of real-world PrEP will likely require multifaceted programs addressing barriers to its provision and will be assisted with the development of comprehensive guidelines for real-world PrEP.

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**Krakower D, Mayer KH. What primary care providers need to know about pre-exposure prophylaxis (PrEP) for HIV prevention: Narrative review. *Annals of Internal Medicine*. 2012;157(7):490-497.**

As HIV prevalence climbs globally, including more than 50 000 new infections per year in the United States, we need more effective HIV prevention strategies. The use of antiretrovirals for preexposure prophylaxis (PrEP) among high-risk persons without HIV is emerging as one such strategy. Randomized, controlled trials have demonstrated that once-daily oral PrEP decreased HIV incidence among at-risk men who have sex with men and African heterosexuals, including serodiscordant couples. An additional randomized, controlled trial of a topical pericoital antiretroviral microbicide gel decreased HIV incidence among at-risk heterosexual South African women. Two other studies in African women did not demonstrate the efficacy of oral or topical PrEP, raising concerns about adherence patterns and efficacy in this population. The U.S. Food and Drug Administration (FDA) Antiviral Drugs Advisory Committee reviewed these studies and additional data in May 2012 and voted to advise the approval of oral tenofovir-emtricitabine for PrEP in high-risk populations. On 16 July 2012, the FDA recommended that this combination medication be approved for use as PrEP in high-risk persons without HIV. Patients may seek PrEP from their primary care providers, and those receiving PrEP require monitoring. Thus, primary care providers should become familiar with PrEP. This review outlines current knowledge about PrEP as it pertains to primary care, including identifying persons likely to benefit from PrEP; counseling to maximize adherence and reduce potential increases in risky behavior; and monitoring for potential drug toxicities, HIV acquisition, and antiretroviral drug resistance. Issues related to cost and insurance coverage are also discussed. Recent data suggest that PrEP, combined with other prevention strategies, holds promise in helping to curtail the HIV epidemic.

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**Krakower D, Ware N, Mitty JA, et al. HIV providers' perceived barriers and facilitators to implementing pre-exposure prophylaxis in care settings: a qualitative study. [AIDS and Behavior](#). 2014;18(9):1712-1721.**

Oral pre-exposure prophylaxis (PrEP) can reduce HIV incidence among at-risk persons. However, for PrEP to have an impact in decreasing HIV incidence, clinicians will need to be willing to prescribe PrEP. HIV specialists are experienced in using antiretroviral medications, and could readily provide PrEP, but may not care for HIV-uninfected patients. Six focus groups with 39 Boston area HIV care providers were conducted (May-June 2012) to assess perceived barriers and facilitators to prescribing PrEP. Participants articulated logistical and theoretical barriers, such as concerns about PrEP effectiveness in real-world settings, potential unintended consequences (e.g., risk disinhibition and medication toxicity), and a belief that PrEP provision would be more feasible in primary care clinics. They identified several facilitators to prescribing PrEP, including patient motivation and normative guidelines. Overall, participants reported limited prescribing intentions. Without interventions to address HIV providers' concerns, implementation of PrEP in HIV clinics may be limited.

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