Measuring and Increasing HIV Testing among Men Who Have Sex with Men

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Abstract

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Introduction: HIV testing serves as the entry point into care for HIV-infected individuals and an effective prevention intervention because behavior change and antiretroviral treatment can reduce transmission. Increasing testing among men who have sex with men (MSM) may reduce the burden of HIV infection in this high-risk population.

Methods: Data from MSM attending publicly-funded HIV/STI testing programs in King County, Washington, from 2003-2011 were used to evaluate temporal trends in and correlates of HIV intertest intervals (ITI) and reasons for testing. A deterministic, continuous-time model of HIV transmission dynamics was used to estimate the impact of replacing clinic-based tests with home-use tests on population-level prevalence.

Results: The median ITIs among MSM seeking HIV testing at the Public Health – Seattle & King County STD Clinic and Gay City Health Project (GCHP) were 215 (IQR: 124-409) and 257 (IQR: 148-503) days, respectively. Over time, ITIs declined at both clinics. In multivariable analyses, younger age, having only male partners, reporting≥10 male partners in the last year, inhaled nitrite use, history of STI, having a regular healthcare provider, and “regular testing” were associated with shorter ITIs ($p<0.05$).

When asked reasons for testing, 49% of MSM attending GCHP reported it was time for their regular test, 27% reported unprotected sex, 12% reported sex with an HIV-infected partner, 21% reported sex with someone new, 24% were starting a relationship, 21% sought STI/hepatitis screening, 2% suspected primary HIV infection, and 16% reported other reasons.

Based on observed levels of clinic-based testing, our model predicted an equilibrium HIV prevalence of 18.6% for Seattle MSM. If all men replaced clinic-based tests with home-use tests, prevalence increased to 27.4% assuming no changes in testing frequency. Regardless of how much more often MSM tested at home, any replacement of clinic-based testing with home-use tests increased prevalence.

Conclusions: Efforts are needed to increase frequent, regular HIV testing among MSM to increase opportunities for early identification of HIV infection and linkage to care. Home-use tests may reach HIV-infected persons who would not otherwise test. However, our model suggests that replacing clinic-based testing with home-use tests may increase HIV prevalence among Seattle MSM.

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Chapter 1.

HIV intertest interval among men who have sex with men in King County, Washington

1.1 Background

HIV testing serves as both the entry point into care for HIV-infected individuals and an effective prevention intervention because behavior change and antiretroviral treatment can reduce ongoing transmission[1, 2]. The U.S. Centers for Disease Control and Prevention (CDC) recommend testing at least annually for individuals at high risk of acquiring HIV infection, including men who have sex with men (MSM)[3]. More frequent screening (i.e. every three to six months) is recommended for MSM who have multiple or anonymous partners, have sex in conjunction with illicit drug use, or have partners who participate in these activities[4]. Similarly, Public Health - Seattle & King County (PHSKC) recommends annual testing for all sexually-active MSM and quarterly testing for MSM at greater risk of acquiring HIV infection as identified by locally-derived criteria[5, 6].

Despite such recommendations, testing patterns and correlates of HIV testing frequency among MSM are not well understood. Helms et al. described the use of the HIV intertest interval (ITI), the time between the last reported test and the current test among individuals seeking testing, as an estimate of testing frequency[7]. In their analysis of MSM attending STD Clinics in four U.S. metropolitan areas, younger age, black race, and later year of visit were associated with shorter ITIs. Other studies of testing patterns have primarily measured whether individuals have tested in the last year[8-11], although adherence to testing recommendations has also been examined[12].

As a measure of testing frequency, ITIs could be used to monitor the success of HIV testing programs[13], just as community viral load has been proposed as a method for monitoring linkage to care and treatment of HIV-infected persons[14]. We examined temporal trends and correlates of ITIs among MSM in King County, Washington, in order to assess the rate of HIV testing in this population and identify client characteristics to better target HIV testing services and social marketing messages regarding testing.

1.2 Methods

Data Sources

We examined data from three sources: (1) electronic medical records of MSM testing for HIV at the PHSKC STD Clinic from January 1, 2003 until October 6, 2010; (2) individual level data from MSM testing for HIV at the Gay City Health Project's (GCHP) publicly-funded HIV and sexually transmitted infection (STI) testing program targeting MSM from February 2, 2004 until October 6, 2010; and (3) data from PHSKC core HIV/AIDS surveillance and HIV incidence surveillance from January 1, 2004 until October 6, 2010. The initial dates for each data source vary by when complete data were available. The date the STD Clinic converted from clinician-obtained medical and sexual histories to a computer-assisted self-interview data collection system was chosen as the end date for all sources. All men who reported having sex with men in the last year were included as MSM. All MSM diagnosed with HIV infection in King County are included in PHSKC surveillance data, including those first diagnosed at the STD Clinic and GCHP.

PHSKC defines "high risk" MSM as those MSM who meet at least one of the following criteria during the past year: 10 or more oral or anal male sex partners; unprotected anal intercourse with a partner of unknown or discordant HIV status; diagnosis of chlamydial infection, gonorrhea, or early syphilis; or use of methamphetamine or inhaled nitrites[5]. Quarterly testing is recommended for these MSM, and annual testing is recommended for all other sexually-active MSM[6].

Outcome Ascertainment

For men attending the STD Clinic or GCHP, the ITI was defined as the number of days between the most recent HIV test and current HIV testing visit. Full dates (day, month, and year) were available from clinic records for the current visit. The date of the most recent test was routinely obtained by self-report during the clinical visit or, for some men who had previously attended the STD Clinic, may have been obtained directly from the medical record. Dates for the most recent test were recorded as month and year or year only; when necessary, days and months were imputed as previously described[7].

In surveillance data, the ITI was defined as the number of days between the most recent HIV-negative test and first HIV-positive test. These dates were obtained by self-report during an interview or by standard medical record reviews conducted by PHSKC staff or medical providers. When self-reported and documented dates differed, the later date was used for the most recent negative test and the earlier date was used for the first positive test.

In all cases, visits at which ITIs were less than 30 days were assumed to be follow-up tests (i.e. not new tests) and were not included in this analysis. In surveillance data, this results in the exclusion of men with acute HIV infection who had their last negative antibody test on the same date as their first positive RNA test. We considered ITIs of 30 to 90 days consistent with quarterly testing and ITIs of fewer than 365 days consistent with at least annual testing.

Data Analysis

ITIs were $\log_{10}$-transformed in all analyses in order to identify proportional (instead of absolute) increases or decreases in the average ITI per unit change in potential covariates, as described previously[7]. Among MSM testing HIV-negative, temporal trends in ITIs were examined using generalized estimating equations (GEE) linear regression with exchangeable working correlation and robust standard errors to adjust for multiple visits per person. Temporal trends among MSM newly diagnosed with HIV infection were examined using linear regression. Correlates of ITIs were determined among men attending the STD Clinic and GCHP separately because several variables of interest (education, homelessness, having a regular healthcare provider, having health insurance, and testing as part of a regular schedule) were available only for GCHP. GEE models were also used for univariable and multivariable analyses of sociodemographic and HIV risk characteristics. Multivariable analyses included all sociodemographic and risk factors associated with ITIs in univariable analyses ($p<0.05$) unless responses were not available for the entire study period. Multivariable models were adjusted for visit year. The association between being newly diagnosed with HIV infection and ITIs was assessed in separate GEE models, adjusting for age and year of visit. The exponentiated coefficient in these models is the x-fold increase or decrease in the ITI for each one-unit increase in the correlate. Data were analyzed using Stata statistical software version 11.0 (College Station, Texas, U.S.). The study has ethical approval from the Institutional Review Board of the University of Washington.

1.3 Results

Sociodemographic and HIV risk characteristics of the populations studied are described in Table 1.1. The three populations were similar with respect to age, race, and ethnicity. MSM attending the STD Clinic were more likely to have had sex with both men and women than those attending GCHP (16% vs. 10%) and were generally at greater risk for acquiring HIV infection based on PHSKC risk criteria. At the STD Clinic, 357 (2.5%) of HIV tests were positive versus 154 (1.6%) of tests at GCHP.

PHSKC STD Clinic

Between January 1, 2003 and October 6, 2010, there were 15,326 visits to the STD Clinic by MSM seeking HIV testing who reported a prior negative test or did not know their status. In 14,385 (94%) of these visits, clients provided dates for their most recent test or reported no prior test. In the remaining visits, the most recent test date was missing (n=541), reported to be after the current visit (n=35), or within 30 days of the current visit and considered a follow-up test (n=365).

These 14,385 visits were made by 8029 MSM, who made one to 22 visits during this time period; 2619 (33%) of 8029 clients were repeat visitors. At these 14,385 visits, 868 (6%) MSM reported no prior test. At 13,517 visits by men who reported testing previously, ITIs ranged from 30 to 8410 days with a median of 215 days [interquartile range (IQR): 124-409; Figure 1.1]. Men reported an ITI consistent with quarterly testing or with at least annual testing at 13% and 66% of all visits, respectively; in 18% of visits, MSM reported no test in the last two years.

Gay City Health Project

Between February 2, 2004 and October 6, 2010, there were 10,513 visits to GCHP by MSM seeking HIV testing who reported a prior negative test or did not know their status. In 9851 (94%) of these visits, clients provided dates for their most recent test or reported no prior test. In the remaining visits, the most recent test date was missing (n=551), reported to be after the current visit (n=7), or considered a follow-up test (n=104).

These 9851 visits were made by 6147 MSM, who made one to 14 visits during this time period; 1796 (29%) of 6147 clients were repeat visitors. At these 9851 visits, 856 (9%) MSM reported no prior test. At 8995 visits by men who reported testing previously, ITIs ranged from 30 to 8690 days with a median of 257 days (IQR: 148-503; Figure 1.1). Men reported an ITI consistent with quarterly testing or with at least annual testing at 8% and 58% of all visits, respectively; in 24% of visits, MSM reported no test in the last two years.

Surveillance

Between January 1, 2004 and October 6, 2010, 1525 MSM were identified in core HIV/AIDS and HIV incidence surveillance as newly diagnosed with HIV infection in King County. For 951 (62%) of these men, dates were available for the first positive and last negative tests, and 81 (5%) men had never tested prior to being diagnosed. For the remainder, it was unknown whether they had a prior negative test (n=462), the last negative and first positive tests were recorded as occurring the same day (n=30), or the last negative test was recorded as having occurred after the first positive test (n=2).

Of the 1031 MSM with testing histories, 81 (8%) reported no prior test. Among 950 men who reported testing previously, ITIs ranged from 30 to 8019 days with a median of 365 days (IQR: 183-883; Figure 1.1). Among all men with testing histories, 13% and 49% reported an ITI consistent with quarterly testing or with at least annual testing, respectively; 35% of newly-diagnosed men reported no test in the last two years.

Temporal Trends in ITIs

Figure 1.2 depicts temporal trends in ITIs, stratified by HIV status and population. From 2004 to 2010, the median ITI decreased significantly among MSM testing both newly HIV-positive and -negative at GCHP ($p<0.01$ for both). Similarly, at the STD Clinic, the median ITI decreased from 2003 to 2010 among MSM testing both newly HIV-positive and -negative, although this change was not significant ($p>0.05$ for both). Among HIV-positive MSM in surveillance, no changes were observed in ITIs between 2004 and 2010 ($p=0.59$).

Correlates of ITIs

Table 2.2 presents the results of multivariable analyses. All variables significantly associated with ITIs in univariable analyses were included except that history of a bacterial STI was not included in the GCHP analysis because it was only available from visits starting in 2008. At the STD Clinic, younger age, sex with men only in the last year, 10 or more male sex partners in the last year, and a history of STI were associated with shorter ITIs ($p<0.001$ for all). At GCHP, younger age, sex with men only in the last year, 10 or more male sex partners in the last year, inhaled nitrite use in the last year, having a regular healthcare provider, and testing for HIV regularly were associated with shorter ITIs ($p<0.05$ for all).

Race, Hispanic ethnicity, being born outside the U.S., methamphetamine use in the last year, injection drug use in the last year, and reporting testing due to concern about potential symptoms of primary HIV infection were not associated with ITIs in either population ($p>0.05$ for all). In addition, among GCHP attendees, education, being homeless, having health insurance, and reporting unprotected anal sex with an HIV-infected male partner or male partner of unknown status in the last year were not associated with ITIs ($p>0.05$ for all).

HIV Status and ITIs

At the STD Clinic, the median ITI was 278 days (IQR: 161 to 579) among MSM newly diagnosed with HIV infection and 213 days (IQR: 123-405) among those testing HIV-negative. Adjusting for age and visit year, newly-diagnosed men had 1.13-fold (95% CI: 1.03-1.25) longer ITIs compared with men testing negative ($p=0.009$). At GCHP, the median ITI was 359 days (IQR: 203 to 719) among newly-diagnosed MSM and 255 days (IQR: 147 to 500) among those testing negative. Adjusting for age and visit year, newly-diagnosed men had 1.20-fold (95% CI: 1.03-1.40) longer ITIs compared with men testing negative (p=0.017). At both locations, there were no differences in the proportions of men who reported no prior test between MSM testing negative and those newly diagnosed with HIV infection (data not shown).

1.4 Discussion

From 2003 to 2010, the median ITI among MSM attending the PHSKC STD Clinic and GCHP were both less than nine months. Over 90% of men reported prior testing, more than half reported ITIs consistent with at least annual testing, and about one-tenth reported ITIs consistent with quarterly testing. Over time, ITIs declined among men testing both HIV-positive and negative at both clinics, although this change was only statistically significant at GCHP. Encouragingly, these data indicate that many MSM in King County test relatively frequently and that, at least at large publicly-funded testing sites, testing frequency has increased over time. However, among MSM newly diagnosed with HIV, this increase appears to have been driven by changes in the early 2000s and was not replicated in surveillance data. Increases in testing frequency early in the study period may be explained by increased demand for testing following PHKSC introducing rapid testing and pooled nucleic acid amplification testing in late 2003, GCHP introducing HIV/STI testing and beginning to build its client base in 2004, and PHSKC beginning to recommend quarterly testing among high risk MSM in 2005.

Insofar as ITIs among individuals newly diagnosed with HIV infection have the potential to estimate the timing of HIV diagnosis[13], these data suggest that approximately two-thirds of MSM in King County are being diagnosed no more than two years after infection, and only one-sixth could have been infected for more than five years. If we estimate that infection occurred at the midpoint between the last negative and first positive tests, a conservative estimate since testing often occurs in the context of risk, this would suggest that very few MSM are diagnosed late in infection in King County (e.g.[15, 16]). However, in an analysis of persons newly diagnosed with HIV infection in King County from 2005 to 2009, long ITIs did not correspond completely with other measures of late diagnosis such as AIDS diagnosis within one year of HIV diagnosis or CD4 count at diagnosis[13]. Inaccurate reporting of testing history, testing in response to risk, and rapid disease progression among some persons may contribute to these discrepancies.

Including ITIs in surveillance efforts may still be useful for assessing efforts to increase testing and for providing a more complete picture of late HIV diagnosis.

In our study, being younger, having sex with men only (versus with men and women), being at greater risk for HIV acquisition (according to local criteria), having access to a regular healthcare provider, and seeking testing as part of a regular schedule were associated with increased testing frequency. Similarly, younger MSM were found to have shorter ITIs in a study of STD Clinics in four U.S. cities[7], and younger age[8, 9, 11], sex with men only[10], having discussed HIV testing with a regular healthcare provider[8], and HIV risk behaviors[8, 9] have been associated with testing within the last year in other studies. These studies have also reported associations between testing in the last year and black race[7], Hispanic ethnicity[9], greater income[8, 11], and higher levels of education[11], which we did not observe in our study. ITIs may estimate testing frequency more accurately than the proportion of MSM who tested in the last year among individuals approached for participation in research, a strategy which is likely to overestimate frequency. In addition, the metric of proportion testing within the last year is not sufficiently sensitive in a population where testing every three to six months is recommended.

Higher risk MSM may test more often because they adhere to targeted testing recommendations or, if they test in response to perceived exposures, because they engage in behaviors that result in HIV exposure more often than low risk men. More than half of MSM at GCHP reported testing as part of a regular schedule. If the association we observed between testing regularly and shorter ITIs is causal, promoting regular testing could further increase testing frequency. A recent evaluation of National HIV Behavioral Surveillance data suggested that self-reported risk behaviors may not effectively identify those MSM at greatest risk for acquiring HIV infection and more frequent testing for all sexually active MSM may be warranted[11]. Local data suggest, however, that we can identify those who are at greatest risk[5]. While it is encouraging that men reporting behaviors associated with HIV risk tended to have tested more recently, those newly diagnosed with HIV infection continued to have longer ITIs than those testing negative. This difference may represent actual differences in testing frequency, differences in ascertainment of last test date, or differences in the duration of risk between those testing newly HIV-positive and -negative.

Surveillance data in this study included MSM diagnosed at the STD Clinic, GCHP, and many other locations around King County. Longer ITIs among all MSM in surveillance compared to MSM testing newly positive at the STD Clinic and GCHP suggests that MSM diagnosed outside of these two large, publicly-funded programs may spend more time unaware of their infection. Publicly-funded HIV programs may be more effective at promoting testing according to public health guidelines than other providers, and public health departments may need to increase outreach in order to improve early identification of HIV infection among all MSM in their jurisdictions.

Our study does have limitations. First, single ITIs may not be representative of individuals' typical frequency of testing over time, and ITIs may not accurately reflect time spent HIV-infected but undiagnosed due to variation in reasons for HIV testing. Many ITIs relied on self-reported date of last HIV-negative test and, for surveillance data, date of first positive test or HIV diagnosis and are therefore sensitive to both recall bias and social desirability bias. Finally, STD Clinic and GCHP data include only MSM seeking testing at these sites and may not be representative of all MSM in Seattle.

In order to reduce the time that HIV-infected persons are unaware of their status, many public health organizations recommend annual testing for all sexually active MSM and more frequent testing for those at greater risk of acquiring HIV infection (e.g.[3-6, 17-19]). However, these recommendations can be vague or inconsistent across jurisdictions, and whether stratifying recommendations by self-reported behavioral risk factors or recommending more frequent testing for all MSM is more effective will depend on the ability to identify those at greatest risk[5, 11]. Further efforts are needed to identify, implement, and evaluate testing recommendations for MSM in order to increase opportunities for early identification of HIV infection and linkage to care.

Table 1.1 Characteristics of men who have sex with men seeking HIV testing in publicly-funded programs or newly diagnosed with HIV infection in King County, Washington

Characteristic	Median (IQR) or n (%)		
	STD Clinic	**Gay City Health Project**	**Surveillance[a]**
N	14,385	9851	1031
Time period	Jan. 1, 2003 to Oct. 6, 2010	Feb. 2, 2004 to Oct. 6, 2010	Jan. 1, 2004 to Oct. 6, 2010
Age (years)	32 (25 to 41)	32 (25 to 40)	35 (27 to 42)
Race[b]			
White	10,619 (80%)	7089 (79%)	727 (71%)
Black	979 (7%)	401 (4%)	85 (8%)
Asian	955 (7%)	729 (8%)	47 (5%)
Hawaiian Native / Pacific Islander	180 (1%)	97 (1%)	6 (0.6%)
Native American / Alaskan Native	162 (1%)	56 (0.6%)	5 (0.5%)
Multiracial	389 (3%)	566 (6%)	35 (3%)
Hispanic / Latino[b,c]	1511 (11%)	1225 (13%)	126 (12%)
Sex with men & women, last year (versus men only)	2328 (16%)	1030 (10%)	n/a
≥10 male sex partners, last year	4505 (33%)	2423 (26%)	n/a
UAI with HIV-infected partner or partner of unknown HIV status, last year	4148 (29%)	2022 (21%)	n/a
History of STI[d]	5921 (41%)	1263 (26%)	n/a
Methamphetamine use, last year	1161 (8%)	544 (6%)	n/a
Inhaled nitrite use, last year	2038 (14%)	1908 (19%)	n/a
Injection drug use[e]	388 (3%)	86 (0.9%)	111 (11%)
New HIV diagnosis	357 (2.5%)	154 (1.6%)	1031 (100%)

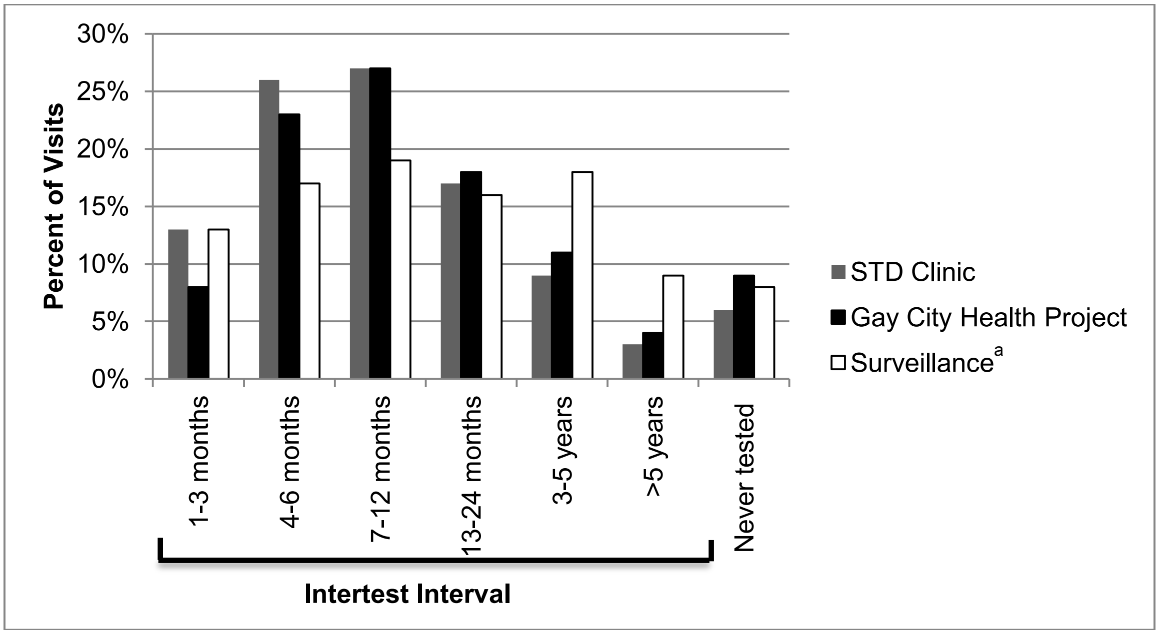
IQR = interquartile range. UAI = unprotected anal intercourse. STI = sexually transmitted infection (syphilis, gonorrhea, or chlamydial infection).
[a]Data from Public Health - Seattle & King County (PHSKC) core HIV/AIDS surveillance and HIV incidence surveillance.
[b]Surveillance data report race and Hispanic/Latino ethnicity as a single characteristic.
[c]Any race.
[d]At the Gay City Health Project (GCHP), history of STI was only collected from 2008 to 2010.
[e]Reported any injection drug use in last year (STD Clinic and GCHP) or MSM/injection drug use reported as mode of transmission (Surveillance).

Table 1.2. Multivariable analyses including sociodemographic and HIV risk characteristics associated with HIV intertest intervals among men who have sex with men, adjusted for year of visit

Correlates	STD Clinic (N = 13,517; Median ITI = 215 days)		Gay City Health Project (N = 8995; Median ITI = 257 days)	
	Fold Increase or Decrease in ITI	95% CI	Fold Increase or Decrease in ITI	95% CI
Age (year)	1.02[a]	1.01 to 1.02	1.02[a]	1.01 to 1.02
Sex with men & women, last year (versus men only)	1.30[a]	1.23 to 1.37	1.09[b]	1.01 to 1.19
≥10 male sex partners, last year	0.77[a]	0.75 to 0.80	0.78[a]	0.74 to 0.81
UAI with HIV-infected partner or partner of unknown HIV status, last year	0.99[c]	0.95 to 1.02	n/a	n/a
History of STI	0.82[a]	0.79 to 0.85	n/a	n/a
Inhaled nitrite use, last year	0.97[c]	0.92 to 1.01	0.92[a]	0.87 to 0.97
Has regular healthcare provider or doctor	n/a	n/a	0.84[a]	0.81 to 0.88
Reported seeking this test as part of a regular schedule	n/a	n/a	0.84[a]	0.81 to 0.88
Visit year	0.99[c]	0.99 to 1.00	0.97[a]	0.96 to 0.98

ITI = intertest interval, in days. CI = confidence interval. UAI = unprotected anal intercourse. STI = sexually transmitted infection; syphilis, gonorrhea, or chlamydial infection.
[a] $p < 0.001$. [b] $p < 0.05$. [c] $p > 0.05$.

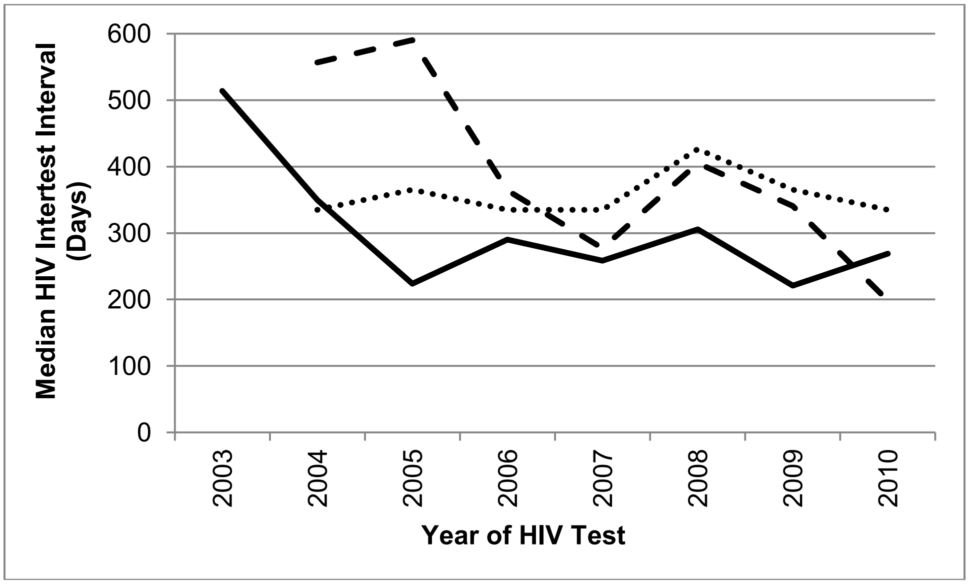
Figure 1.1 HIV intertest intervals among men who have sex with men in King County, Washington



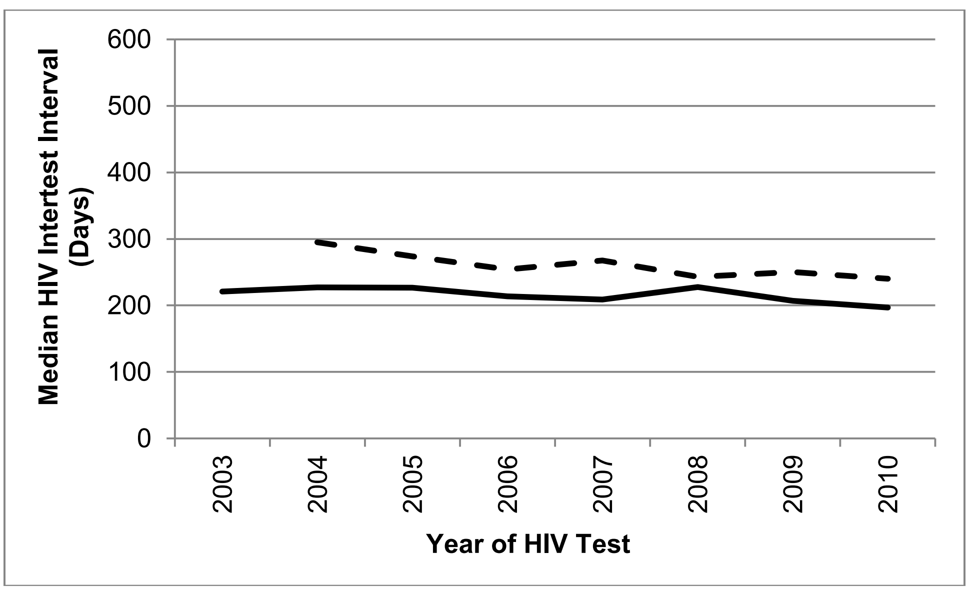
[a]Data from Public Health - Seattle & King County (PHSKC) core HIV/AIDS surveillance and HIV incidence surveillance.

Figure 1.2. Temporal trends in HIV intertest intervals among men who have sex with men (MSM) testing newly HIV-positive (A) and HIV-negative (B) in King County, Washington

1.2A: MSM testing newly HIV-positive



1.2B: MSM testing newly HIV-negative



STD Clinic
Gay City Health Project
Surveillance

Chapter 2.

Why do men who have sex with men test for HIV infection? Results from a community-based testing program

2.1 Background

An estimated 44% percent of HIV-infected men who have sex with men (MSM) in the U.S. are unaware of their infection and therefore unable to enter care and reduce their likelihood of transmitting HIV to others[20]. In an effort to increase awareness of HIV infection, Public Health - Seattle & King County (PHSKC), like many other public health organizations, recommends annual testing for all sexually-active MSM and more frequent testing for MSM at greater risk of acquiring HIV infection[3-6, 17-19]. Gay City Health Project (GCHP), a Seattle community-based organization whose HIV and sexually transmitted infection (STI) testing program is funded primarily by PHSKC, recommends that most MSM test every three months and that only very low risk MSM wait six months between tests.

MSM seek testing for a variety of reasons, including potential exposures, symptoms, learning that a partner or friend was diagnosed with HIV infection, encouragement from healthcare providers or peers, wanting to know one's status, health maintenance, and regular testing[8, 21-27]. Repeat testing on a regular schedule, or "regular testing", has the potential to increase HIV testing by creating habits around testing and normalizing testing. In addition, it does not rely on self-recognition of risk, potential exposures, or symptoms of acute infection to prompt testing. Most previous studies of motivations for testing have relied on data regarding participants' most recent test, which may be sensitive to recall bias, or qualitative data regarding testing in general, which may not represent the reasons men seek specific tests. A recent study of MSM seeking testing at a community-based testing facility in Switzerland found that sexual risk and regular testing were the main motivators for the current test in the majority of men[26]. In that study, age, relationship status, sexual risk behaviors, history of a sexually transmitted infection (STI), and "depressed feelings" were associated with reasons for testing. To our knowledge, no studies have examined correlates of regular testing among U.S. MSM.

Monitoring reasons for seeking HIV testing can be useful for identifying novel methods for increasing testing and for evaluating the effectiveness of interventions to promote regular testing or testing in response to symptoms of acute infection. We examined reasons for seeking HIV testing and correlates of seeking a “regular test” among MSM attending GCHP’s HIV/STI testing program in order to understand their motivations for testing and identify potential targets for increasing regular, frequent testing.

2.2 Methods

Study population

GCHP offers peer-based HIV/STI counseling and testing for MSM in English and Spanish in Seattle’s Capitol Hill neighborhood, the center of the city’s lesbian, gay, bisexual, transgender, and queer (LGBTQ) community. Trained staff deliver client-centered risk-reduction counseling based in motivational interviewing techniques. HIV and syphilis testing was available for the entire study period. Screening for other STIs was available as follows: chlamydial infection and gonorrhea from November 2006 until December 2007 and from March 2011 on; hepatitis A and B from May 2004 until December 2006; and herpes simplex virus from July 2004 until March 2006. Since July 2007, GCHP has also offered testing in outreach settings throughout King County that is targeted towards MSM but open to the community at-large. GCHP recommends quarterly HIV/STI testing for all MSM unless the counselor considers the client to be at very low risk of acquiring HIV.

PHSKC, the primary funding source for GCHP’s testing program, defines “high risk” MSM as MSM who report at least one of the following in the past year: 10 or more oral or anal male sex partners; unprotected anal intercourse (UAI) with a partner of unknown or discordant HIV status; diagnosis of chlamydial infection, gonorrhea, or early syphilis; or use of methamphetamine or inhaled nitrites[5, 6]. PHSKC recommends that these men test quarterly and that all other sexually-active MSM test annually.

Data source

We examined de-identified, electronic records from MSM testing for HIV infection at GCHP’s testing program from its initiation on February 2, 2004 until June 30, 2011. Reasons for seeking testing, sociodemographic characteristics, and risk behaviors were obtained as part of a self-administered written intake survey. All men who reported having sex with men in the prior year were included as MSM.

Reasons for seeking testing

The GCHP intake survey includes the following question: “Why did you decide to be tested today?” Clients could select more than one reason and had the option of writing in other reasons. When calculating the proportion of MSM reporting each reason, clients with multiple visits contributed only one randomly selected visit to avoid oversampling reasons associated with frequent testing.

Correlates of seeking a regular test

We considered regular testing to be the reason for the visit if the client reported “It is time for my regular test”, regardless of the interval since his last test. We examined associations between seeking a regular test and both sociodemographic characteristics and HIV risk behaviors using generalized estimating equations (GEE) Poisson regression with exchangeable working correlation and robust standard errors to adjust for multiple visits per client. A multivariable model was selected using backwards stepwise procedures starting with all sociodemographic and risk behaviors associated with seeking a regular test in univariable analyses ($p<0.05$), adjusting for age and year of visit. Two characteristics associated with seeking a regular test in univariable analyses (reporting a history of a bacterial STI and usually or always disclosing HIV status to male anal sex partners) were not included in the multivariable analysis because they were only available starting in 2008. The association between testing HIV-positive and seeking a regular test was assessed in a separate model, adjusting for age and year of visit. The HIV intertest interval (ITI), the time between the last reported test and the current test, was used as an estimate of testing frequency and calculated as previously described[7, 28]. ITIs were compared between men who tested HIV-positive versus those who tested negative, stratified by whether they were seeking a regular test, using a linear GEE model with exchangeable working correlation and robust standard errors to account for multiple visits per client. ITIs were $\log_{10}$-transformed for this analysis as described previously[7, 28]. The three visits with inconclusive test results (i.e. two with reactive enzyme immunoassays and indeterminate Western blots, one reactive rapid antibody test without confirmatory testing) were not included in analyses describing HIV test results.

Data were analyzed using Stata statistical software version 11.0 (College Station, Texas, U.S.). The study received ethical approval from the University of Washington Human Subjects Division.

2.3 Results

Between February 2, 2004, and June 30, 2011, there were 12,109 visits to GCHP by 7176 unique MSM seeking HIV testing who reported a prior negative test or did not know their status. Sociodemographic and HIV risk characteristics of these men are described in Table 2.1. Men were predominantly white (79%), had at least some post-secondary education (89%), had a regular healthcare provider (62%), and had sex with men only (90%).

Reasons for seeking testing

Figure 2.1 describes the reasons MSM reported for seeking HIV testing at GCHP. At randomly selected visits by 7176 unique MSM, 3481 (49%) reported it was time for their regular test. Of these men, 1455 (42%) reported seeking a regular test as their only reason for testing. When all visits were included in the analysis, reasons reported for seeking testing were similar except that a greater proportion of men (56%) reported that it was time for their regular test.

Reasons for testing & HIV test results

At 12,106 visits with conclusive test results, 190 (1.6%) MSM had positive HIV tests. The likelihood of testing positive at the current visit differed by the reason MSM reported for seeking testing. Including all visits, the proportions of men who tested HIV-positive by reason were as follows: 79 (1.2%) of 6800 men reporting it was time for their regular test, 75 (2.3%) of 3229 men testing because they had unprotected anal or vaginal sex, 50 (3.5%) of 1427 men testing because they had sex with an HIV-infected person, 3 (9.4%) of 32 men testing because they shared needles or works, 27 (0.9%) of 3009 men testing because they had sex with someone new, 37 (1.4%) of 2591 men testing at the start of a new relationship, 28

(1.1%) of 2491 men seeking STI screening, 2 (1.4%) of 145 men seeking hepatitis screening, 20 (10%) of 200 men who suspected primary infection, and 23 (2.4%) of 958 men who had been asked to test by a sex partner.

Regular testing

Men seeking a regular test reported shorter intervals since their last HIV test than men who did not (median of 233 vs. 322 days, respectively; $p<0.001$). Among 6437 visits where MSM reported seeking a regular test and provided information regarding their HIV testing history, 431 (7%) MSM last tested 1 to 3 months prior, 1846 (29%) 4 to 6 months prior, 2177 (34%) 7 to 12 months prior, and 1983 (31%) had not tested in the last year. By contrast, among 4932 visits for non-regular tests with available testing histories, 515 (10%) last tested 1 to 3 months prior, 824 (17%) 4 to 6 months prior, 877 (18%) 7 to 12 months prior, and 2716 (55%) had not tested in the last year.

Table 2.2 presents sociodemographic characteristics and HIV risk behaviors associated with reporting regular testing in univariable and multivariable analyses. In a multivariable analysis adjusting for age, factors associated with reporting regular testing included having a regular healthcare provider and the following behaviors in the previous year: having only male sex partners, having ≥10 male sex partners, inhaled nitrite use, not injecting drugs, and not having UAI with a partner of unknown or discordant HIV status ($p \leq 0.001$ for all). Adjusting for the intertest interval in this analysis did not affect the estimates of association (data not shown).

Regular testing & diagnosis of HIV infection

On average, MSM who reported seeking a regular test were 44% [95% confidence interval (CI): 26-58%] less likely to be newly diagnosed with HIV infection than men who did not report regular testing, adjusting for age and visit year (1.2% vs. 2.1%, respectively; $p<0.001$). Adjusting for the ITI as an estimate of the duration of risk did not affect this estimate (data not shown). Adjusting for risk behaviors, however, did attenuate this association; MSM who reported seeking a regular test were 36% (95% CI: 14-53%) less likely to be newly diagnosed than men who did not when adjusting for number of partners, UAI with a partner of unknown or discordant status, and methamphetamine, nitrite, and injection drug use.

Figure 2.2 depicts HIV ITIs based on whether MSM reported that it was time for their regular test and the result of their HIV test. Among those seeking a regular test, MSM who tested positive for HIV infection had similar ITIs to those testing negative (p=0.16). On the other hand, among those who did not report regular testing, MSM testing positive had longer ITIs than those testing negative (p=0.004).

2.4 Discussion

Regular testing, sexual risk, and new partnerships were important drivers of HIV testing among MSM attending GCHP. From 2004 to 2011, about half of MSM attending GCHP reported seeking a regular test, and this proportion increased over time. Regular testing was associated with shorter ITIs, particularly among men newly diagnosed with HIV infection. However, even among those seeking a regular test, one-third had not tested in the prior year despite GCHP recommendations to test every three to six months.

The likelihood of being diagnosed with HIV infection in our study varied substantially by the reason men reported for seeking testing. MSM who reported testing in response to potential exposures, including unprotected sex, sex with an HIV-infected partner, and sharing needles or works, had a higher than average likelihood of testing positive (2.3%, 3.5%, and 9.4%, respectively). In addition, although only a small number of men reported testing because of concerns about primary HIV infection, one in 10 of these men tested positive. A relatively lower proportion of men seeking a regular test had positive tests (1.2%). However, these men contributed more than 40% of newly identified cases of HIV infection among MSM at GCHP during the study period. Seeking testing after known exposures and in response to symptoms of acute HIV infection has the greatest potential for identifying new cases of HIV soon after infection. However, persons at risk for acquiring HIV may not recognize when they are exposed to HIV[20, 29-31], may engage in risky behavior too frequently to test after each exposure, or may not recognize the symptoms of acute infection[32]. Seeking testing on a regular schedule, on the other hand, has the potential to result in timely identification of new HIV infections simply by ensuring that testing occurs within a set time of any exposure. Because regular testing occurs regardless of risk, however, it depends on frequent testing to reduce the time newly-infected persons are unaware of their infection and can result in repeated negative tests. Our results suggest that motivating MSM to seek testing in response to the symptoms of primary infection may increase case-finding, as has been suggested previously[32], but that regular testing also has its place in identifying new infections. A recent public health education campaign aimed at teaching Seattle MSM to identify the symptoms of primary infection and seek nucleic acid amplification testing was launched in 2009 and is currently being evaluated. A separate campaign aimed at increasing frequent, regular testing among MSM in King, Snohomish, and Pierce counties was launched in June 2012.

In our study, the relationship between regular testing and HIV risk was complicated although PHSKC has promoted regular, quarterly HIV testing among high risk MSM since 2005. Men who inhaled nitrites or had 10 or more male sex partners in the last year were more likely to report seeking a regular test, whereas men who injected drugs or had UAI with a partner of unknown or discordant HIV status were less likely to report seeking a regular test. Similarly, a recent study also found that non-concordant UAI in the last year was associated with a decreased likelihood of "routine" testing among MSM attending a small community-based HIV/STI testing facility in Switzerland[26]. Other studies among MSM have also reported associations between some risk behaviors and recent testing[8, 9, 28]. MSM who have fewer partners or who choose not to discuss HIV status with sex partners may be less aware of their risk of acquiring HIV infection and therefore less open to messages regarding regular or frequent testing. In addition, there may be men for whom HIV risk is one of many competing concerns (e.g. substance use, housing, or employment) that may reduce the salience of HIV risk and make seeking HIV testing regularly challenging. Further research is necessary to understand the complex relationship between risk and HIV testing behavior and to evaluate the impact of quarterly testing recommendations for high risk MSM.

Men who reported sex with both men and women in the last year were less likely to be seeking a regular test at GCHP and have been found to have tested less recently than men who have sex with men only[10, [28, 33]. If messages regarding HIV/STI testing for MSM are geared towards gay-identified men, they may not resonate with or reach other MSM, who may not be as likely to identify with or participate in the gay community[34]. In addition, men who have sex with men and women may be less open about their sexuality[34, 35] and therefore less comfortable accessing services that may identify them as having sex with men. Additional messaging and services targeted specifically for men who have sex with men and women may be necessary to increase testing in this bridge population.

At GCHP, having access to a regular healthcare provider was also associated with seeking a regular test. Similarly, access to a regular healthcare provider was associated with shorter ITIs in this population[28], and having discussed HIV testing with a regular healthcare provider was associated with recent testing in the Young Men's Survey[8]. It is possible that other healthcare providers may have a role in promoting HIV/STI testing among MSM, even if MSM seek these services outside of the primary care setting. Alternatively, this association may reflect the impact of socioeconomic status on access to healthcare and HIV testing more generally; higher education and health insurance were associated with seeking a regular test in our univariable analyses (data not shown) and have been associated with recent testing in other studies[8, 11]. Regardless, the Affordable Care Act, which aims to increase health insurance coverage and ensures coverage of HIV/STI screening and prevention counseling for 'adults at higher risk' such as MSM, has the potential to increase testing in this population. Reducing the barriers that MSM experience in accessing healthcare and educating non-HIV/STI healthcare providers regarding testing recommendations for MSM may also impact testing behaviors.

Our study has several limitations. First, much of our data rely on self-report and may therefore be sensitive to social desirability bias or recall bias. In addition, some clients' understanding of the reason, "It is time for my regular test", are likely to have differed from our interpretation that this test was part of a regular testing schedule. Third, we made multiple comparisons and therefore may have observed associations by chance, although the strength of these associations suggests otherwise. Finally, we used records from GCHP for this analysis because of the richness of data regarding reasons for testing, but these MSM may not be representative of all MSM in Seattle. Screening for STIs other than HIV and syphilis were only available at GCHP for parts of the study period, and clinical evaluation and treatment are not available at GCHP. MSM who experience symptoms of HIV or STIs may therefore be more likely to seek testing at the STD Clinic or a healthcare provider.

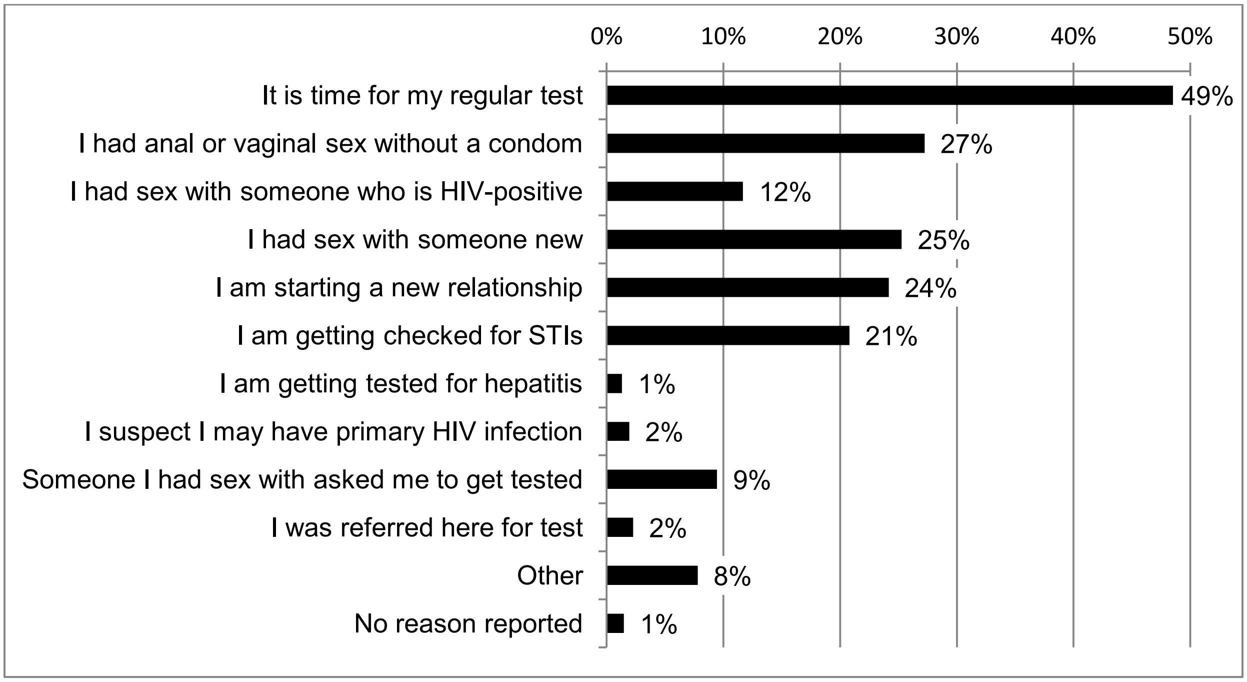
Many public health organizations recommend repeat testing at regular intervals in order to reduce the time that HIV-infected persons are unaware of their status[3-6, 17-19]. Our study suggests that MSM continue to test for a variety of reasons, including regular testing, and that promoting regular testing and testing in response to symptoms of acute HIV infection has the potential to increase awareness of HIV status. Further efforts are needed to identify effective interventions to increase frequent, regular testing among MSM, thereby increasing opportunities for early identification of HIV infection and linkage to care. Particular attention may need to be paid to promoting regular testing among men who have sex with both men and women, inject drugs, or lack access to regular healthcare.

Table 2.1 Characteristics of men who have sex with men seeking HIV testing at Gay City Health Project, 2004 to 2011

Characteristic	n or Median	% or IQR
By Unique MSM (N = 7176)		
Age at first visit (years)	30	24 to 39
Race		
White	4990	79%
Black	295	5%
Asian	550	9%
Native Hawaiian / Pacific Islander	80	1%
Native American / Native Alaskan	49	1%
Multiracial	370	6%
Hispanic / Latino	1027	16%
Education		
Less than high school diploma or equivalent	169	2%
High school diploma or equivalent	853	12%
Some college, Associate's degree, or technical school	2263	32%
College graduate or post-graduate degree	3862	54%
By Visit (N = 12,109)		
Socioeconomic status		
Homeless	132	1%
Has regular healthcare provider or doctor	7497	62%
Has health insurance	8200	68%
HIV risk		
Sex with men and women (versus men only), last year	1261	10%
≥10 male sex partners, last year	2928	25%
UAI with HIV-infected partner or partner of unknown status, last year	2510	21%
Usually or always tells male anal sex partners HIV status (versus never or sometimes)[a]	5320	84%
History of STI[a]	1756	26%
Inhaled nitrite use, last year	2314	19%
Methamphetamine use, last year	639	5%
Injection drug use, last year	109	1%
New HIV diagnosis	190	1.6%

Between February 2, 2004 and June 30, 2011, 7176 unique MSM attended 12,109 HIV testing visits at Gay City Health Project. IQR = interquartile range. STI = sexually transmitted infection (syphilis, gonorrhea, or chlamydial infection). UAI = unprotected anal intercourse. [a] History of STI and frequency of disclosing HIV status to sex partners were only collected from 2008 to 2011.

Figure 2.1. Reasons men who have sex with men reported for seeking HIV testing at Gay City Health Project, 2004 to 2011



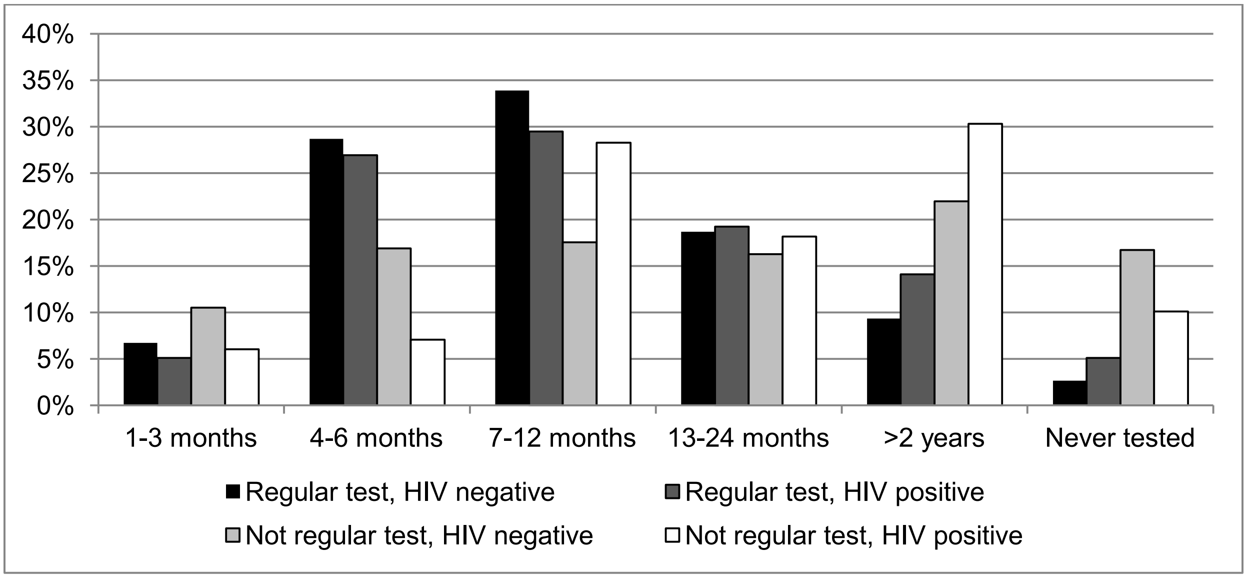
N = 7176 unique MSM. Clients could mark more than one reason. Less than 1% of MSM reported the following reasons for seeking testing: “I shared a needle, cooker, cotton, or rinse water”, “Someone from the health department advised me to test”, “An outreach worker offered me a test”, and “I have to test for a court order”. Starting in 2008, “I suspect I may have primary HIV infection” was added to the list of options, and “I am getting tested for hepatitis” and “Someone from the health department advised me to test” were no longer included.

Table 2.2. Correlates of seeking a regular test among men who have sex with men attending Gay City Health Project: Sociodemographics and HIV risk behaviors

Correlates	Univariable		Multivariable	
	RR	95% CI	RR	95%CI
Age (year)	1.003[b]	1.001 to 1.005		
Education				
Less than high school diploma or equivalent	ref[c]			
High school diploma or equivalent	0.95	0.79 to 1.13		
Some college, Associate's degree, or technical school	1.18	1.00 to 1.39		
College graduate or post-graduate degree	1.29	1.10 to 1.53		
Homeless	0.77[a]	0.62 to 0.96		
Has regular healthcare provider or doctor	1.11[c]	1.07 to 1.16	1.07[b]	1.03 to 1.12
Has health insurance	1.05[a]	1.01 to 1.09		
Sex with men & women (versus men only)	0.67[c]	0.62 to 0.73	0.70[c]	0.64 to 0.76
≥10 male sex partners, last year	1.19[c]	1.15 to 1.24	1.20[c]	1.16 to 1.25
UAI with HIV-infected partner or partner of unknown status, last year	0.83[c]	0.79 to 0.87	0.81[c]	0.77 to 0.85
Usually or always tells male anal sex partners HIV status (versus never or sometimes)	1.30[c]	1.20 to 1.40		
History of STI	1.13[c]	1.07 to 1.19		
Inhaled nitrite use, last year	1.11[c]	1.06 to 1.16	1.08[c]	1.04 to 1.13
Methamphetamine use, last year	0.88[b]	0.81 to 0.97		
Injection drug use, last year	0.49[c]	0.35 to 0.69	0.54[c]	0.39 to 0.74
Year of visit	1.02[c]	1.01 to 1.03	1.02[c]	1.01 to 1.03

The final multivariable model was selected using backwards stepwise procedures starting with all characteristics associated with regular testing in univariable analyses ($p<0.05$) (except “History of STI” and “Usually or always tells male anal sex partners HIV status”, which were only available from 2008-2011), adjusting for age. Race and Hispanic ethnicity were not associated with regular testing in univariable analysis. RR = relative risk, estimated using Poisson regression. CI = confidence interval. UAI = unprotected anal intercourse. STI = sexually transmitted infection (syphilis, gonorrhea, or chlamydial infection). [a] $p < 0.05$. [b] $p < 0.01$. [c] $p < 0.001$.

Figure 2.2. HIV intertest intervals among men who have sex with men seeking HIV testing at Gay City Health Project, by reporting seeking a regular test and HIV test result



Men seeking a regular test at GCHP reported shorter intervals since their last HIV test than men who did not. Among those seeking a regular test, MSM who tested positive for HIV infection had similar ITIs to those testing negative (p=0.16). Among those who did not report regular testing, however, MSM testing positive had longer ITIs than those testing negative (p=0.004).

Chapter 3.

Replacing clinic-based tests with home-use tests may increase HIV transmission among Seattle men who have sex with men: evidence from a mathematical model

3.1 Background

In July 2012, the U.S. Food and Drug Administration (FDA) approved the first over-the-counter home-use HIV test, the OraQuick® In-Home HIV Test (OraSure Technologies, Inc., Bethlehem, PA). Home-use tests, which allow testers to use a rapid HIV test on a self-collected specimen to learn their status at home, have been proposed as a method to increase testing[36-38] and thereby increase opportunities for HIV-infected individuals to enter care and engage in behaviors to reduce ongoing transmission. However, there are concerns about the relatively long window period of available rapid tests, the potential for misinterpretation of test results, reduced access to counseling, and missed opportunities to link HIV-infected persons into care and prevention services[38-41].

In pre-marketing studies for the OraQuick® In-Home HIV Test, 47% of men who have sex with men (MSM) reported that they would definitely or probably buy a home-use HIV test[37]. The test's sensitivity and specificity in the hands of untrained users in uncontrolled settings were 93.0% and 99.98%, respectively, and the test was reported to have a window period of 3 months. In our experience among MSM in Seattle, however, the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test, which uses the same technology as the home-use test, in the hands of trained users identifies fewer than 80% of HIV-infected men diagnosed through the Public Health – Seattle & King County (PHSKC) pooled nucleic acid amplification testing (NAAT) program[42].

The risks and benefits of introducing home-use HIV tests depend not only on the characteristics of the test but also on how it affects testing behavior and linkage to care, particularly among those at highest risk of acquiring HIV infection. However, no studies have been conducted to evaluate the impact of introducing home-use tests in at-risk populations. Using population-based behavioral surveillance data and mathematical modeling, we aimed to estimate the impact of replacing clinic-based HIV tests with home-use tests on population-level HIV prevalence among MSM in Seattle, Washington.

3.2 Methods

We adapted a previously-published, deterministic, continuous-time model that was developed to understand HIV transmission dynamics among MSM in Seattle, Washington[43]. Figure 3.1 depicts how the population has been divided into compartments whose size through time is specified with a system of ordinary differential equations. We used this model because it includes parameters that address two of the most important potential effects of home-use testing: changes in HIV testing behavior (type of test and testing frequency) and linkage to HIV care [antiretroviral therapy (ART) coverage and effects]. The model obtains population-level HIV equilibrium prevalence under each behavioral scenario we consider.

Model framework

Compartments are defined by anal sexual activity level A (none, 1 = low, 2 = high), true HIV serostatus, and HIV testing site C (0 = home-use tests versus 1 = clinic-based tests). HIV-infected men are further subdivided by disease stage and detectability by clinic-based testing or home-use testing. The resulting categories are: primary clinic-/home-, primary clinic+/home-, primary clinic+/home+, chronic infection, and AIDS. The last four categories are divided by diagnosis status, and diagnosed men are further subdivided by ART status. These attributes define 53 compartments, including one for men forgoing all anal sex, used only to calculate prevalence.

Data Sources

Sexual behaviors and clinic-based testing rates were parameterized using a 2003 random digit dial study of Seattle MSM[44].

HIV testing

All compartments that include HIV-infected men are separated into men who test using home-use HIV tests and men who test at clinics. This allows men pursuing different testing strategies to differ with respect to the window period and sensitivity of the test they receive, testing frequency, and initiation of ART. The characteristics of home-use tests are based on the OraQuick® In-Home HIV Test, a rapid HIV-1/2 antibody test performed on oral fluids that has a window period of 3 months and 93% sensitivity after the window period[37]. Clinic-based testing includes either pooled NAAT or antigen-antibody combination assays, which represent the majority of HIV tests received by MSM in King County. We assume these tests have an average window period of 15 days and an approximated 100% sensitivity after the window period[43, 45]. Our base model assumes 100% clinic-based testing and that low-activity men average one test per year and high-activity men average two[44]. Testing rates (θ) are multiplied by the sensitivity of the test.

Other updates to the model

We have also updated several parameters in response to developments since the original model was published in 2009. First, because ART is now recommended for all HIV-infected individuals and may have benefits during acute infection[46], men may now enter treatment during primary infection. We estimated the proportion of days that MSM diagnosed with HIV were on ART during primary infection based on data from MSM enrolled in the University of Washington Primary Infection Clinic cohort from 2009-2012 (Personal communication, Dr. Janine Maenza). Second, based on results from HPTN 052, we estimated that ART results in a 96% reduction in infectiousness[2]. Third, because changing treatment guidelines and public health efforts have increased access to ART since 2003, we have used population-based estimates from PHSKC surveillance to update the proportion of men with diagnosed HIV infection who are on ART during chronic infection or AIDS from 67% to 74% (Personal communication, Dr. Julie Dombrowski). Fourth, the transmission probability per act of receptive unprotected anal intercourse during primary infection has been revised from 2% to 6% to better reflect the estimated increase in the risk of transmission during primary infection versus chronic infection[47, 48].

Initial Conditions

We seeded the model with 10 infected men in primary infection. Half test at home and half in clinics; four are aware of their HIV status; and half are low-activity and half high-activity men. All other men are HIV-negative and distributed according to the activity class distribution described in Table 3.1.

Parameterization

The updated baseline model was recalibrated to represent the HIV epidemic among MSM in Seattle. We then ran the model varying parameter values reflecting hypothetical scenarios of interest. To evaluate the effects of changes in testing behavior, we varied the proportions of men who test at home versus a clinic as well as the testing frequency of home testers relative to clinic testers. We also examined the combined effects of the window period of the home-use test and testing frequency by varying both parameters in a scenario with 100% home-use testing. In order to examine the impact of potential reductions in linkage to care among those diagnosed using home-use tests, we varied the rate of ART initiation among men diagnosed with HIV infection.

The system is coded and solved using Berkeley Madonna 8.3.14 (Berkeley Madonna, Inc., Berkeley, CA). This research received ethical approval from the University of Washington Human Subjects Division.

3.3 Results

Our baseline model considers the epidemic using our observed data, with all HIV testing occurring in a clinic. Equilibrium prevalence is 18.6%, which falls within the range estimated for Seattle MSM (15%, 95% confidence interval (CI): 11-19%)[20].

Figure 3.2 shows equilibrium prevalence when varying the proportion of the population who test at home and the testing frequency among those testing at home. By replacing all clinic-based testing with home-use testing, equilibrium prevalence rises to 27.4%, assuming no changes in testing frequency or ART coverage. If home-use tests increase testing frequency by three-fold, the equilibrium prevalence is 22.3% when all tests occur at home.

Figure 3.3 depicts the equilibrium prevalence at various testing frequencies when all testing occurs at home, while varying the window period of the home-use test. With a window period of three months, equilibrium prevalence is greater than the 18.6% observed in the baseline scenario regardless of how much home-use testing increases testing frequency. If the window period were 2 months, 6 weeks, or 4 weeks, equilibrium prevalence would equal 18.6% if home-use testing increased testing frequency by 2.54, 1.57, or 1.20 times, respectively.

Altering the rate at which men diagnosed with HIV infection initiate ART affects equilibrium HIV prevalence by changing the proportion of men who are receiving treatment, which reduces the likelihood of transmission. Figure 3.4 demonstrates the equilibrium prevalence at varying rates of ART initiation among men diagnosed with HIV infection via home-use tests. If men who receive their initial reactive HIV tests at home initiate ART at the same rate as those who receive their initial reactive tests in a clinic, the proportion of diagnosed men on treatment decreases from 73% when all tests occur in a clinic to 71% when all tests occur at home, and equilibrium prevalence increases from 18.6% to 27.4%. If home-use testing reduces the rate of ART initiation by 50% and the entire population tests at home, the proportion of diagnosed men on treatment falls to 56% and equilibrium prevalence increases to 28.9%. If no one who tests at home initiates ART, the equilibrium prevalence rises to 31.4% when all men test at home.

If we vary the sensitivity of the home-use test to reflect the lower and upper bounds of the 95% confidence interval reported by OraSure (86.6-96.9%), the equilibrium prevalence at 100% home-use testing is 27.8% and 27.2%, respectively, assuming a three-month window period and no changes in testing frequency or ART coverage. If the sensitivity of the home-use test is only 50%, the equilibrium prevalence rises to 30.9% if all men test at home.

3.4 Discussion

Home-use tests have the potential to reach HIV-infected persons who would not otherwise test for HIV infection. However, our model suggests that replacement of clinic-based testing with home-use tests may increase HIV prevalence among Seattle MSM, even if home-use tests allow MSM to test more frequently than clinic-based testing alone. This potential increase in prevalence appears to be driven primarily by the relatively long window period of the approved home-use test when compared with available laboratory-based tests, such as NAAT and antigen-antibody combination assays. To a lesser extent, challenges in linking individuals who receive reactive tests at home into HIV care may also increase HIV prevalence among MSM according to our model.

In practice, home-use tests may impact individual testing behavior in several ways: some MSM who have never tested may test themselves at home, some who previously tested in clinics may test entirely at home instead or may combine clinic and home-use tests, and some may continue to test in clinics only. Our model includes two groups of men, one that tests entirely at home and one that tests entirely in clinics, and therefore does not address men who combine clinic and home-use tests. As demonstrated by our model, any replacement of clinic-based tests with home-use tests with a three-month window period has the potential to increase HIV prevalence. However, if MSM continue to test in clinics as they do now and supplement these tests with home-use tests, the introduction of home-use testing may reduce HIV prevalence in this population. The net effect of home-use tests on the HIV epidemic in MSM will depend on how this population chooses to use home-use tests, which is not yet understood but will likely depend on the cost of the kit[49].

In this model, the length of the window period, or time during which HIV tests are negative in infected persons, contributed substantially to the differences we observed in equilibrium HIV prevalence when men tested at home instead of clinics. The OraQuick® In-Home HIV Test is reported to have a window period of three months[37]. As a result, in our model, the home-use test cannot detect HIV during primary infection, a period when individuals may be 10 or more times more likely to transmit HIV[47, 48], and HIV-infected individuals testing at home are unable to change their seroadaptive behaviors or initiate ART during this highly infectious stage. Regardless of how much more often MSM tested for HIV infection when testing at home, any replacement of clinic-based testing with home-use testing increased equilibrium prevalence. However, if the true window period of the OraQuick device were closer to 6 weeks[50], replacing clinic-based testing with home-use testing would have the potential to reduce HIV prevalence if home-use tests increased testing by 1.6-fold. Developing home-use tests with shorter window periods would improve the likelihood that home-use testing will reduce HIV prevalence among MSM.

Concerns have been raised that individuals who receive their first reactive HIV test at home will be less likely to engage in timely medical care for their infection than individuals who learn their status in a healthcare setting[39-41]. Delaying care can adversely impact the HIV-infected individual's health[51] and contribute to ongoing transmission[2]. In our model, we approximated delays in linkage to care by reducing the rate of ART initiation for men testing at home and saw modest increases in equilibrium HIV prevalence assuming no changes in HIV testing or sexual behavior. It will be important to develop methods for ensuring that individuals with reactive home-use tests link to care immediately to reduce risks to the individual's health and prevent additional transmission.

To our knowledge, this is the first model to describe the potential impact of home-use tests on HIV prevalence in an at-risk population. Using a deterministic model of HIV transmission dynamics parameterized with population-based behavioral surveillance data, we evaluated how changes in test performance, testing frequency, and ART initiation resulting from the use of home-use tests might affect HIV prevalence among MSM in Seattle. Previous models of home-use tests have described the effect of testing with sex partners by MSM to inform condom use on individual-level risk of HIV acquisition[52] and test results in the population expected to test themselves at home who would not otherwise test for HIV infection[37]. The former model suggested that, in most scenarios, individual MSM would be less likely to become infected with HIV during a one-year period if they were to use home-use tests with partners to inform condom use than if they did not use their partners' HIV status to inform condom use and used condoms for fewer than half of anal sex acts[52]. The impact of such "point-of-sex testing" on HIV transmission in the population was not assessed, however. The latter model was developed by the FDA as part of the review process for the OraQuick In-Home HIV Test[37]. This model estimated that one false-negative test would be expected for every 13 true positives and one false positive for every 3,750 true negatives. However, it did not evaluate the effects of these false test results, focused only on those individuals who would otherwise not test, and did not consider the window period of the test.

Our study has several limitations. First, the model does not include men who supplement clinic-based testing with home-use tests and therefore can only estimate the impact of replacing clinic-based testing with home-use tests. Second, because this is a compartmental model, it approximates the effects of home-use tests on HIV testing by altering the average rate of exit from undiagnosed to diagnosed. It therefore does not explicitly account for MSM who would never test at a clinic choosing to test at home. Third, in the absence of up-to-date population-based data from Seattle, we relied on estimates from the 2003 random digit dial study for HIV testing and sexual behavior parameters, which are likely to have changed. In addition, MSM are likely to test with partners prior to sex to inform decisions regarding what sex acts to engage in and whether to use condoms[53-56]. We were unable to model the effects of this "point-of-sex testing", which may affect HIV transmission by changing the rate and accuracy of serosorting. Fourth, the model was very sensitive to the probability of HIV acquisition per act of receptive unprotected anal intercourse during primary infection. As a result, we may have underestimated this parameter[47, 48] and therefore underestimated the impact of the home-use test's inability to detect HIV during this stage on transmission. Finally, these results may not be generalizable to other settings. More than 90% of MSM in Seattle have previously tested for HIV infection and tend to test at least once per year[28, 44]. As a result, tests with long window periods are likely to miss a substantial proportion of undiagnosed HIV infections in Seattle[42]. Home-use tests may have more potential for benefit where incidence is low or the population tests less frequently because infected individuals would be less likely to test during the window period by chance and receive a false-negative result.

This model illustrates potential concerns about how the characteristics of home-use tests and difficulties in linkage to care among individuals who receive reactive tests at home will affect HIV transmission among MSM, particularly if home-use tests replace clinic-based tests. With the introduction of home-use tests, studies will be necessary to understand how home-use tests impact HIV testing, sexual behaviors, and linkage to care and to develop effective methods for mitigating any identified risks. In order to provide a more complete picture of how home-use tests will affect the HIV epidemic, future models should consider the impact on HIV transmission if home-use tests are used to supplement instead of replace clinic-based testing, if they affect sexual risk behavior, and if they are employed in different populations and settings. Despite their potential to reach individuals who would not otherwise test for HIV infection, it is unclear how effective home-use tests will be at reducing the estimated 20% of HIV-infected persons in the U.S. who are unaware of their HIV status[57].

Figure 3.1. Flowchart of a mathematical model of home-use testing among men who have sex with men in Seattle

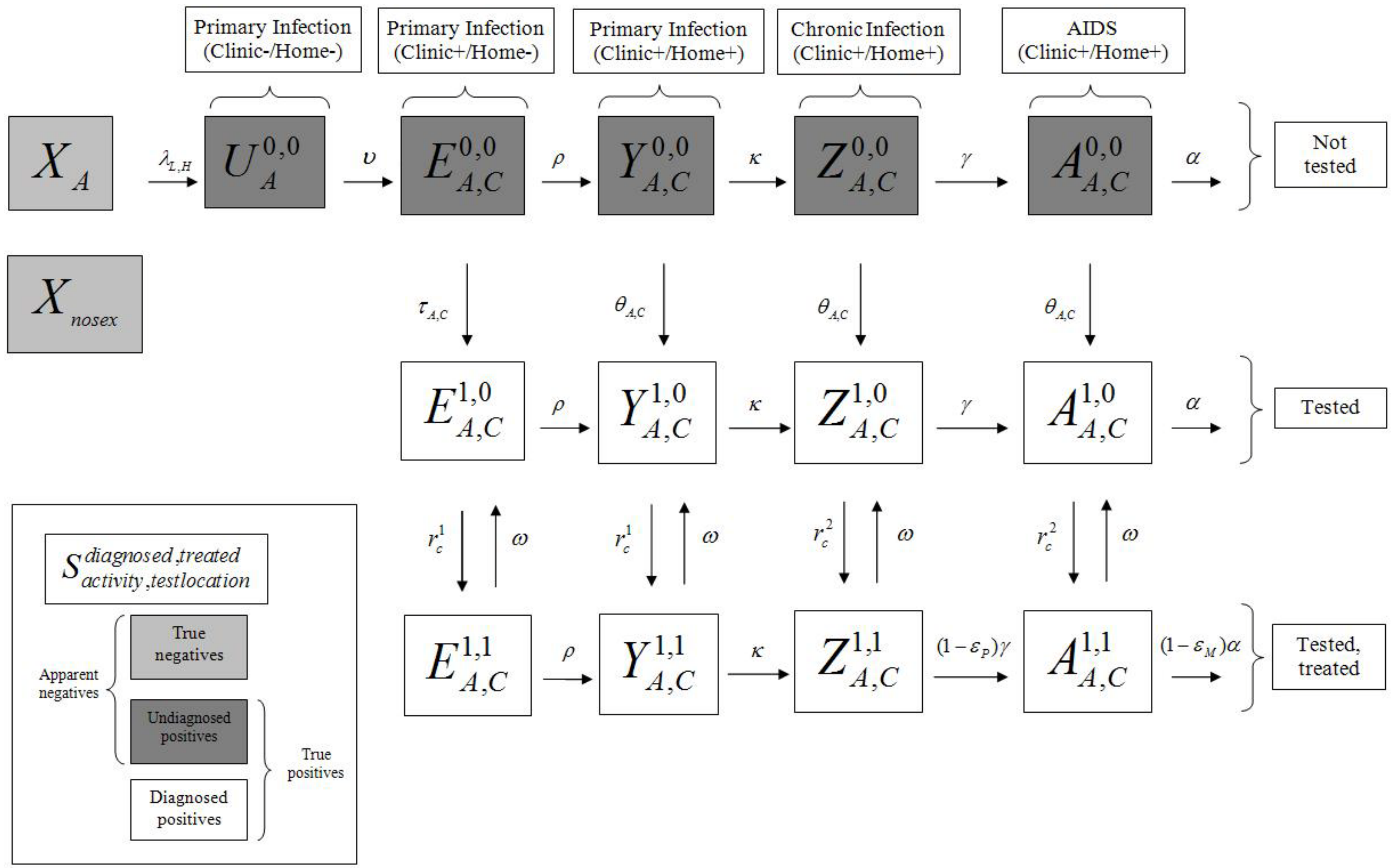
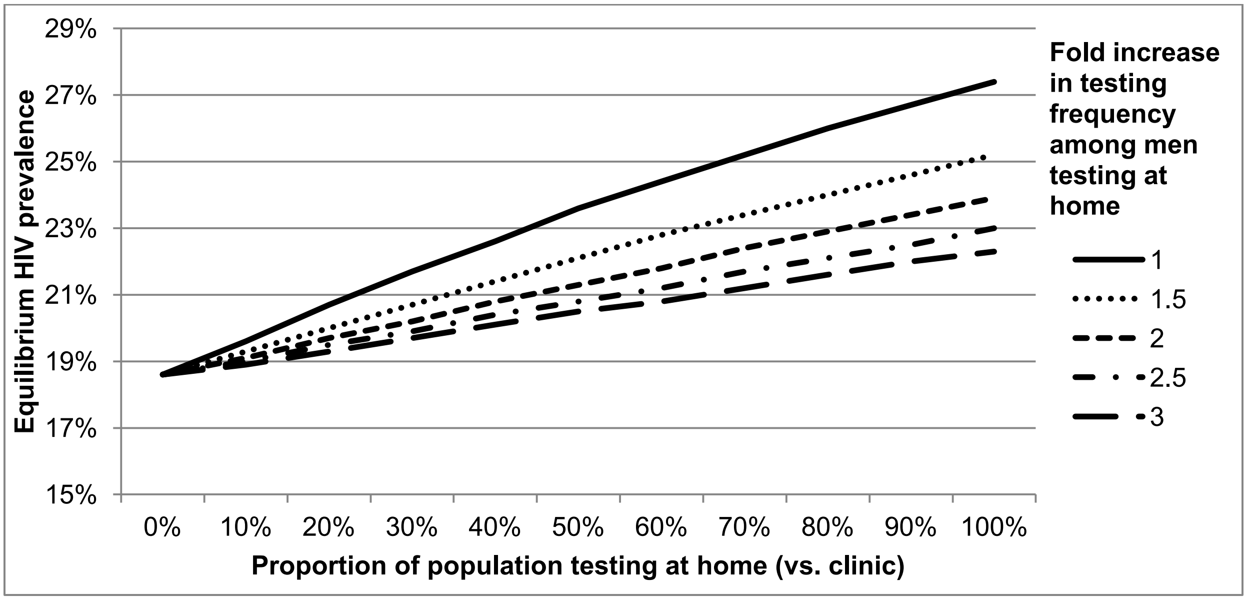


Table 3.1. Inputs for a mathematical model of home-use testing among men who have sex with men in Seattle

Parameter	Value	Source
Population dynamics		
Proportion of men with no anal sex contacts in the prior year	0.39	Derived from [44]
Proportion of low-activity men	0.26	Derived from [44]
Proportion of high-activity men	0.35	Derived from [44]
Duration of sexual activity (1/μ years)	50	
HIV disease dynamics		
Duration of primary clinic-/home- infection (1/ν days)	15	[45]
Duration of primary clinic+/home- infection (1/ρ days)	75	[37]
Duration of primary clinic+/home+ infection (1/κ days)	0[a]	[47, 58, 59]
Duration of chronic infection (1/γ years)	10	[60, 61]
Duration of AIDS (1/α years)	2	[47, 61]
HIV treatment		
Proportion of men with primary infection who are on treatment	0.2	*
Proportion of men with chronic infection or AIDS who are on treatment	0.74	*
Rate of withdrawal from treatment (ω year^{-1})	0.02	[62]
Reduction in rate of disease progression from chronic infection to AIDS as a result of ART (ε_P)	0.6	[61]
Reduction in rate of death after an AIDS diagnosis as a result of ART (ε_M)	0.6	[61]
Reduction in infectiousness as a result of ART (ε_T)	0.96	[2]
HIV testing frequency		
Clinic-based testing (range)		
Low-activity men (θ_L year^{-1})	1 (1-2)	Derived from [44]
High-activity men (θ_H year^{-1})	2 (1-4)	Derived from [44]
Sensitivity of home-use HIV test	0.93	[37]

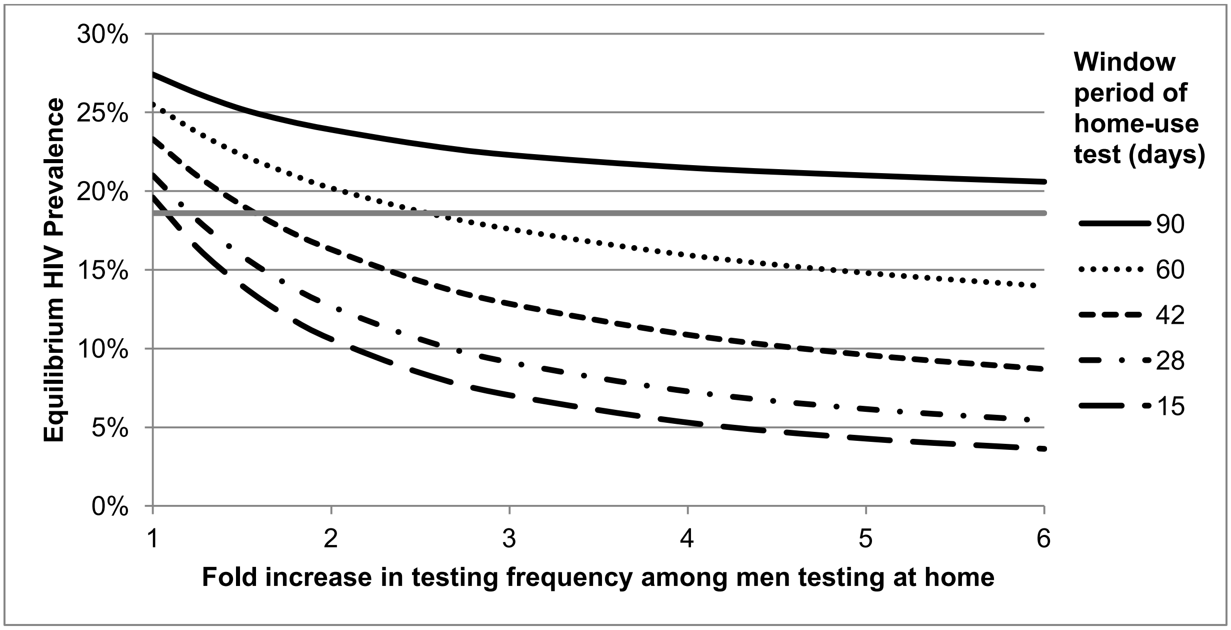
Sexual risk behavior and sexual mixing parameters were described in Cassels *et al*, 2009[43].
* The proportions of Seattle MSM who are on treatment during primary infection and chronic infection or AIDS were derived from data from the University of Washington Primary Infection Clinic cohort (Personal communication, Dr. Janine Maenza) and Public Health – Seattle & King County HIV/STD Program (Personal communication, Dr. Julia Dombrowski), respectively.
[a] In the primary model of home-use tests, the window period of the home-use test equaled the duration of primary infection (90 days); therefore, the duration of primary infection during which HIV was detectable by home tests was 0 days.

Figure 3.2. Equilibrium HIV prevalence for various proportions of home-use testing (vs. clinic-based testing) in the population at varying testing frequencies among those testing at home



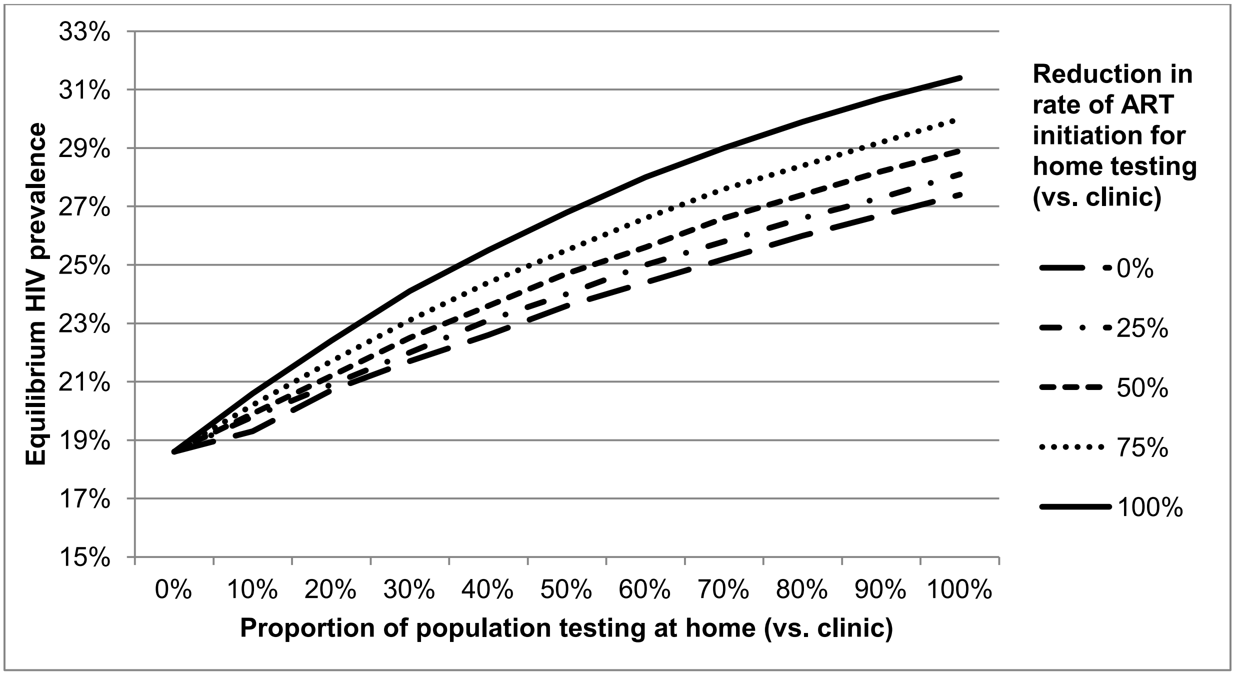
As the proportion of men who have sex with men who test at home instead of in a clinic increases, equilibrium HIV prevalence rises. If home-use tests replace clinic-based testing completely, prevalence increases from 18.6% to 27.4% assuming no changes in testing frequency. Increasing testing frequency among men testing at home reduces this effect on prevalence but does not reverse it completely. Note: A three-fold increase in testing frequency results in an average of three and six tests per year among low- and high-activity men, respectively.

Figure 3.3. Equilibrium HIV prevalence at varying testing frequencies and home-use test window periods when all testing occurs at home



The grey line represents the equilibrium prevalence in the baseline scenario of 100% clinic-based testing: 18.6%. Average testing frequency in the figure ranges from one to six tests per year among low-activity men and two to twelve tests per year among high-activity men. With a 90-day window period, if clinic-based testing is replaced completely by home-use tests, equilibrium prevalence is greater than 18.6% regardless of home much home-use tests increase testing frequency. If the window period of a home-use test were 60, 42, 28, or 15 days, equilibrium prevalence would equal 18.6% if home-use tests increased testing frequency by 2.54, 1.57, 1.20, or 1.07 times, respectively.

Figure 3.4. Equilibrium HIV prevalence for various proportions of home-use testing (vs. clinic-based testing) in the population at varying rates of antiretroviral therapy initiation among men diagnosed with HIV via home-use tests



If home-use tests result in delayed linkage to care and reduce the rate of antiretroviral therapy (ART) initiation, increases in the proportion of men who have sex with men testing at home instead of a clinic result in increases in equilibrium prevalence. Compared with a scenario where all men test at home but there is no change in the rate of ART initiation, a reduction in the rate of ART initiation among men testing at home results in a decrease in the proportion of diagnosed men on treatment from 71% to 56% and an increase in prevalence from 27.4% to 28.9%. If no one who tests at home initiates ART, the equilibrium prevalence rises to 31.4% when all men test at home.

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PROFESSIONAL POSITIONS

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