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Capturing HIV incidence among MSM through at-home and self-reported facility-based testing

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Introduction

In the United States, the HIV epidemic is still disproportionately concentrated among men who have sex with men (MSM). In 2014, an estimated 70% of all new HIV infections occurred among MSM¹. The estimated rate of new HIV diagnoses in the U.S. in 2013 was 0.7 per 100 MSM². HIV testing is an essential component of both treatment and prevention efforts. Regular testing can help HIV-positive individuals receive care earlier and link HIV-negative individuals to behavioral and biomedical prevention efforts^{3,4}.

The Centers for Disease Control and Prevention recommends sexually active MSM test for HIV at least once per year and encourage men with elevated risk to test as often as every 3–6 months⁵. While many MSM do not meet this recommended testing frequency⁶, there is indication that MSM are willing to self-test at home instead of accessing traditional facility-based testing services^{7–9}. At-home testing avoids some of the inconvenience and stigma of facility testing, and provides an opportunity to reach populations that are currently not accessing facility services. Furthermore, at-home testing can be used to obtain biologic outcomes in online behavior research, which has become more commonly implemented in HIV prevention research among MSM¹⁰. The first at-home test kit required the user to collect a blood specimen and return the dried blood spot to a specimen collection site before receiving their results by phone or online. Since then, the Food and Drug Administration has approved OraQuick, a commercially available, at-home HIV test that uses an oral fluid technique that allows users to receive their results in 20 minutes¹¹.

The Checking In study was designed to assess methods for retaining a cohort of MSM in a prospective online HIV prevention study¹². All men in this study received at-home HIV specimen collection kits to ascertain study endpoints and to complement their normal facility-based testing behaviors. This analysis reports HIV incidence rates in a cohort of MSM in which new HIV infection outcomes were documented through a combination of at-

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home specimen collection (with testing at a central laboratory), and other HIV testing in community facilities.

Methods

We analyzed follow-up data from a prospective study of Internet research methods among MSM (the “Checking In” study)¹². Participants were recruited through online banner advertisements on social media websites (MySpace, Facebook, Adam4Adam and Black Gay Chat). When possible, advertisements were targeted to men who indicated they were interested in men on their respective profile pages. Participants were recruited between August 2010 and December 2010.

Internet users that clicked on advertisements were directed to an eligibility questionnaire. To be eligible, men had to: be 18 years of age or older; indicate they were white, black or Hispanic; report having sex with at least one male partner in the past year; be willing to take HIV tests through specimen self-collection; and be willing to not move outside of the United States during the 12 months of follow-up. The study was reviewed and approved by the Emory University Institutional Review Board (IRB00031326).

At baseline, participants completed a survey that included questions about demographic characteristics, use of the Internet to meet sex partners, recent sexual behavior and HIV/STD testing history. Participants who did not report being HIV positive were mailed an at-home dried blood spot collection system manufactured by Home Access Health Corporation (Hoffman Estates, IL) for HIV testing. Testing procedures and analysis of the initial specimen collection process were previously described¹³. Participants were requested to call an FDA-approved medical call center to receive their results within 7 days. Participants who returned the at-home specimen collection kit completed bi-monthly surveys and were then mailed a second at-home specimen collection kit after 12 months of follow-up. The bi-monthly surveys contained questions about HIV risk behaviors and HIV testing outside of the study.

This analysis was limited to men who returned the baseline test kit and had a negative HIV antibody test result on the baseline specimen. Participants who lived in a county with <1000 people per square mile (according the 2010 US Census) were categorized as living in a rural area. New HIV infections were men who reported a new HIV diagnosis (outside of study HIV testing) during the bi-monthly follow-up surveys or who had a new HIV positive test at the 12-month follow-up study testing. Individual log-linear Poisson regression models were used to calculate corresponding 95% confidence intervals for crude incidence rates. Incidence rates and confidence intervals were reported by demographic groups and per 100 person-years of follow-up time. For participants who self-reported a new HIV diagnosis, follow-up time was equal to the time elapsed between enrollment and their last complete survey prior to self-reporting a new HIV diagnosis.

Results

We recruited 896 MSM who met all eligibility requirements, provided consent and were sent an at-home test kit. Of the 735 (82.0%, 735/896) baseline test kits returned, 25 (3.4%,

25/735) tested HIV-positive¹³ and the remaining 710 HIV-negative men began the 12 month follow-up and were used in this analysis. Over two-thirds of participants were under 34 years old, of white race, and from an urban area (Table).

During the 12-month follow-up period, 523 (74%, 523/710) participants completed the final (i.e. month 12) survey, 181 were lost to follow-up (26%, 181/710) and 6 (<1%, 6/710) participants self-reported a positive HIV test result. Among the 523 participants who completed the final follow-up survey and received a second at-home test kit, 422 (81%, 422/523) men returned the kit and 101 (19%, 101/523) did not. Of the returned kits, 5 (1.2%, 5/422) were HIV-positive, 353 (84%, 353/422) were HIV-negative and 64 (15%, 64/422) were expired or inadequate specimens.

Overall, there were 11 incident HIV cases and the crude incidence rate of new HIV infection was 1.87 per 100 person-years (95%CI: 1.04–3.38) (Table). Crude rates were highest among black (IR=2.55, 95% CI: 0.64–10.19) and Hispanic (IR=2.79, 95% CI: 0.90–8.64) participants. The crude incidence rate among participants living in urban areas was 2.01 per 100 person-years (95%CI: 1.01–4.03) and the incidence rate among participants living in rural areas was 1.67 per 100 person-years (95%CI: 0.54–5.19). Participants aged 18–24 had the highest crude incidence rate (IR=2.46, 95% CI: 1.02–5.91) compared to other age groups.

Discussion

Throughout the year long follow-up, the combination of continued facility-based testing and at-home tests detected an annual HIV incidence of 1.87%. Given the width of the 95% confidence interval, this is comparable to a 2009 estimate of incidence among MSM in the United States calculated through a weighted analysis of 10 studies (2.39%)¹⁴. Our results also reflect the racial and age disparities seen in HIV incidence rates of longitudinal cohort studies¹⁵.

A limitation of this analysis is that participants did not receive HIV testing at the same intervals. Any testing done between the baseline test and follow-up test at 12 months was initiated, completed and reported by the participant. It is possible that we did not ascertain all HIV tests or all positive HIV test results outside the study tests, which could bias our estimate of HIV incidence. Furthermore, our follow-up resulted in 11 new infections, which does not provide enough data to model the incidence or conduct a time to event analysis. Also, we lost 26% of participants to follow-up; based on our earlier analysis of the primary outcome data, loss to follow-up was higher among black participants, which could result in an inappropriately low estimate of HIV incidence among black participants, and overall¹². Finally, recruitment targeted social media users and this convenience sample may not be representative of the general population of MSM.

However, our study also has strengths. We have laboratory-confirmed baseline HIV negative status in a large cohort of US MSM, and we provide estimates of incidence from rural MSM, which is a population from whom very few HIV incidence data have been reported. Having subgroup-specific rates of HIV incidence is important to support modeling efforts¹⁶. As

previously discussed, this study provides an example in which nearly three quarters of men were retained in the study for 12 months, which is higher than several comparable studies¹². The proportion of test kits returned was similar for the first test kit (82%) and the second kit (81%)¹³.

In summary, our results indicate that a combination approach of annual at-home specimen collection and self-reported results from external tests can feasibly capture HIV incidence in an online prevention study, and that HIV incidence estimates are comparable to offline populations of MSM¹⁵. At-home testing is often a key component in Internet-based HIV prevention studies, which are becoming increasingly valuable and common¹⁰. Benefits of online studies include the ability to protect the identity of participants, collect large amounts of data in a short amount of time, reach otherwise hard to enroll populations (e.g., rural MSM), and potentially provide research access to men who might have an increased risk of HIV infection^{17,18}. Thus, an ability to rigorously document HIV incidence through at-home specimen collection, as demonstrated by our study, is an important tool to increase the rigor of online HIV prevention studies.

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Number of new infections and crude HIV-incidence rates among MSM participating in an online HIV prevention study, United States, 2010

Table

Characteristic	N	%	New infections	Person-years (PY)	Rate per 100 PY	95% CI
Overall	710	100	11	587.3	1.87	1.04 3.38
Race/Ethnicity						
Black	106	15	2	78.5	2.55	0.64 10.19
Hispanic	134	19	3	107.7	2.79	0.90 8.64
White	470	66	6	401.2	1.50	0.67 3.33
Age, in years						
18–24	263	37	5	203.2	2.46	1.02 5.91
25–34	262	37	4	228.7	1.75	0.66 4.66
35–44	107	15	1	93.2	1.07	0.15 7.62
45+	78	11	1	62.3	1.60	0.23 11.39
Highest level of education						
College or graduate school	265	37	5	237.2	2.11	0.88 5.07
Some college or Associates degree	315	44	2	262.0	0.76	0.19 3.05
High school or GED ¹	105	15	3	75.7	3.97	1.28 12.29
Less than high school	25	3.5	1	12.5	8.00	1.13 56.79
Region						
Midwest	128	18	3	105.3	2.85	0.92 8.83
Northeast	106	15	1	89.5	1.12	0.16 7.93
South	283	40	4	230.2	1.74	0.65 4.63
West	190	27	3	160.3	1.87	0.60 5.80
Urbanicity						
Rural ²	223	32	3	179.2	1.67	0.54 5.19
Urban	475	68	8	397.3	2.01	1.01 4.03

¹General Educational Development²Live in a county with less than 1000 people per square mile.