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Updated Estimates of the Number of Men Who Have Sex With Men (MSM) With Indications for HIV Pre-exposure Prophylaxis

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In 2018, the U.S. Public Health Service (USPHS) published updated clinical guidelines for the use of preexposure prophylaxis (PrEP) to reduce the risk of HIV infection among men who have sex with men (MSM), heterosexual women and men, and persons who inject drugs.¹ PrEP is one of the main tools being used to achieve the Ending the HIV Epidemic in the U.S. incidence-reduction goals.² Thus, policy makers need accurate estimates of the number of U.S. adults having indications for PrEP.

In this letter, we provide updated estimates of the percentage and number of MSM who have indications for PrEP. CDC reported in 2015 that 24.7% of MSM had indications for PrEP, based on an analysis of 2007–2012 data from the National Health and Nutrition Examination Survey (NHANES).³ In a May 2020 article in this journal, "Estimated Number of Men Who Have Sex With Men With Indications for HIV Pre-exposure Prophylaxis in a National Sexual Network Study," Weiss et al⁴ estimated that 34.0% of sexually active HIV-uninfected MSM met USPHS indications for PrEP, based on sexual risk behaviors reported among a convenience sample of 4,904 MSM aged 15–65 years in the United States recruited online between July 2017 and January 2019.

To obtain updated nationally representative estimates of the percentage and number of MSM with indications for PrEP, we analyzed NHANES data from 2009 through 2016 using an approach similar to Smith et al³. We estimated the percentage of sexually active HIV-uninfected MSM with indications for PrEP and the percentage of all sexually active MSM (i.e., both HIV-infected and HIV-uninfected) who had risk factors consistent with indications for PrEP.

Methods

According to the updated USPHS guidelines, PrEP use is indicated for adult, HIVuninfected MSM who had at least one male sex partner in the past 6 months, are not in a monogamous partnership with a recently tested, HIV-uninfected man, and who, in the past 6 months, either had any anal sex without a condom or had a bacterial STI (i.e., syphilis, gonorrhea, or chlamydia) diagnosed or reported. For this analysis, we pooled sexual behavior data from NHANES cycles 2009–2010 through 2015–2016, which include data for Bates et al.

We estimated two measures among sexually active, 18- to 59-year-old MSM: the *percentage* of HIV-uninfected MSM with PrEP indications and the *percentage* of all MSM with risk behaviors consistent with recommended PrEP use, including MSM with HIV. To identify risk behaviors indicating recommended PrEP use, we first limited the NHANES sample to sexually active MSM, defined as men who had any male sex partners in the past 12 months, including those with male sex partners who were not anal sex contacts. We then removed HIV-infected MSM (for the percentage of HIV-uninfected MSM with PrEP indications measure only) and identified those with indications for PrEP as MSM who had 2 or more anal sex partners in the past 12 months and who either had any condomless sexual contact or a diagnosed bacterial STI (i.e., gonorrhea or chlamydia, as NHANES does not collect data on syphilis diagnoses) in the past 12 months. We applied NHANES weights as recommended to yield nationally representative estimates and calculated 95% confidence intervals using a logit transformation. All analyses used STATA 15.⁵

To obtain an estimate of the number of MSM in 2016 with indications for PrEP, we used the HIV Optimization and Prevention Economics (HOPE) model. HOPE is a mathematical model that simulates HIV incidence and prevalence for the U.S. population aged 13 years and older using inputs obtained from HIV surveillance systems, the published literature, and other publicly available data sources.^{6,7} The HOPE model starts with an initial population in 2010, then simulates HIV incidence, deaths, and other outcomes moving forward in time. The model was calibrated to match 2018 incidence, prevalence, and other surveillance measures by transmission group⁸ and to match population growth rates by age group⁹. We derived the relevant MSM population inputs for the initial population in the HOPE model in several steps. First, we determined the size of the U.S. sexually active MSM population in 2010, which was approximately 4.67 million based on 2013 published estimates.¹⁰ Second, we distributed the 2010 population between high- and low-risk categories of sexual behavior by applying the estimated percentage of all sexually active MSM who had behaviors consistent with recommended PrEP use from our NHANES analysis. Third, we used surveillance data to calculate that approximately 581,000 MSM aged 13 years and older had HIV in 2010.¹¹ Fourth, we distributed the HIV-infected MSM population between high- and low-risk categories to obtain HIV prevalence among high-risk MSM of approximately 23.4%, matching national surveillance data.¹² Of the 4.09 million sexually active HIV-uninfected MSM in 2010 (4.67 million less 581,000), those in the high-risk category were considered to have indications for PrEP use. Finally, we ran the HOPE model from 2010 through 2016 to simulate the number of MSM with indications for PrEP use in 2016.

Results

We found that 33.7% (95% confidence interval (CI): 22.1%, 47.7%) of sexually active HIV-uninfected MSM (18–59 years) had indications for recommended PrEP use. We also found that 37.3% (95% CI: 26.8%, 49.3%) of all sexually active MSM had risk behaviors consistent with recommended PrEP use.

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HOPE model simulations showed that in 2016 approximately 1.82 million MSM (13 and older) had high-risk behaviors consistent with recommended PrEP use, of which almost 440,000 were HIV-infected. Thus, 1.36 million HIV-uninfected MSM had indications for PrEP use in 2016 (Table 1).

Discussion

Our analysis used an approach similar to Smith et al,³ but found a higher percentage and number of MSM with indications for PrEP. Smith et al analyzed 2007–2012 NHANES data to estimate that 24.7% of 18- to 59-year-old HIV-uninfected men who reported having had sex with a man in the past 12 months had indications for PrEP. Smith et al¹³ then applied the 24.7% estimate to derive the number of MSM in each state and the District of Columbia. They estimated that 813,970 MSM in the United States had indications for PrEP in 2015 (Table 1).

Weiss et al³ used a network study sample to estimate the percentage of sexually active MSM who had indications for PrEP. Their findings were almost identical to results from our 2009–2016 NHANES analysis (Table 1), suggesting a robust finding that the percentage of MSM with indications for PrEP has increased since the Smith et al analysis: one-third of sexually active HIV-uninfected MSM have indications for PrEP use.

Our results are consistent with other recent study findings of increases in the prevalence of risk behaviors for HIV infection among MSM. Data collected in Seattle for 2013–2018¹⁴, San Francisco for 2014–2017¹⁵, and at the U.S. national level for 2005–2017^{16–18} showed increases in condomless sex and the number of casual sexual partners among MSM¹⁸. The rise in risk behaviors among MSM may be driven, in part, by increased availability and use of PrEP^{14,15}.

A limitation of the current and previously published analyses is the inability to identify risk factors that exactly match the indications for PrEP using data available in surveys. The NHANES sexual behavior data are only collected from individuals 18 to 59 years of age. Moreover, NHANES uses a 12-month look-back period instead of the 6-month period indicated in USPHS guidelines for PrEP use. Although the guidelines recommend PrEP use for any MSM not in a monogamous partnership who report PrEP-indicated behaviors in the past 6 months, our analysis, like the Smith et al³ study, required two or more sex partners in the past 12 months. This added restriction may bias downward the percentage of MSM with PrEP indications. Conversely, a 12-month recall period may also result in respondents overstating their number of sex partners, resulting in upward bias in the percentage of MSM eligible for PrEP. Additionally, because NHANES did not collect information about sex partners, we were unable to apply the USPHS criteria related to partners' HIV status; thus, we assumed that MSM in a single monogamous relationship were not susceptible to HIV infection.

Our findings, along with the recent Weiss et al³ results, suggest that as of 2016 approximately one-third of sexually active HIV-uninfected MSM in the United States, or almost 1.4 million MSM, have indications for PrEP. These updated estimates of the

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percentage and number of MSM with PrEP indications provide important inputs for health care and public health resource planning.

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Conflicts of Interest and Source of Funding

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Estimated Percentages and Numbers of MSM with Indications for PrEP Use, 3 studies

	NHANES 2009–2016 A	NHANES 2009–2016 $^{ m A}$ – WEISS ET AL., 2020 $^{ m A}$ – SMITH ET AL., 2018 $^{ m A}$	SMITH ET AL., 2018^{A}
Percentage (95% CI)	33.7% (22.1%–47.7%)	34.0% (32.4%–35.6%)	24.7% ^c
Number (year)	$1,355,633$ b (2016)	ł	813,970 (2015)

a. Values shown are the percentage and number of sexually active HIV-uninfected MSM.

^b Determined by applying the estimated percentage from the NHANES 2009–2016 analysis (37.3%) of *all* sexually active MSM aged 13 and older with risk behaviors consistent with recommended PrEP use (i.e., not limited to HIV-uninfected MSM) to the HOPE model 2010 initial population of all sexually active MSM to identify high-risk MSM. Surveillance-based estimates of HIV infections among MSM were then distributed between high-risk and low-risk MSM to match a 2010 calibration target of 23.4% HIV prevalence among high-risk MSM. Uninfected, high-risk MSM, by definition are indicated for PrEP use. Using the 2010 population inputs, we ran the HOPE model from 2010 through 2016 to simulate the number of HIV-uninfected MSM with indications for PrEP use in 2016.

^c. Determined using 2007–2012 NHANES data on risk behavior among sexually active HIV-uninfected MSM aged 18–59 years.

Abbreviations: MSM= men who have sex with men; PrEP = preexposure prophylaxis; NHANES = National Health and Nutrition Examination Survey; HOPE = HIV Optimization and Prevention Economics