

among the approximately 150 000 LGB residents of Massachusetts, who as a whole represent 3% of the state's overall adult population.<sup>9,16</sup> ■

### About the Authors

Stewart J. Landers is with John Snow Inc, Boston, MA. Matthew J. Mimiaga is with the Department of Psychiatry, Harvard Medical School/Massachusetts General Hospital, Boston, and the Department of Epidemiology, Harvard School of Public Health, Boston. Kerith J. Conron is with the Institute on Urban Health Research, Northeastern University, Boston.

Correspondence should be sent to Stewart J. Landers, JD, MCP, John Snow Inc, 44 Farnsworth St, Boston, MA 02210 (e-mail: landers@jsi.com). Reprints can be ordered at <http://www.ajph.org> by clicking on the "Reprints/Eprints" link.

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### Contributors

The authors jointly conceptualized the study, interpreted findings, contributed ideas, and participated in the writing of the article. S.J. Landers wrote the final version of the article. M.J. Mimiaga analyzed the data.

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### Human Participant Protection

No protocol approval was needed for this study; however, a data use agreement was reached with the Massachusetts Department of Public Health that allowed us to use data from the Massachusetts Behavioral Risk Factor Surveillance System in our investigation.

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## Off-Label Use of the Female Condom for Anal Intercourse Among Men in New York City

Elizabeth A. Kelvin, PhD, Joanne E. Mantell, PhD, Norman Candelario, MSW, Susie Hoffman, DPH, Theresa M. Exner, PhD, William Stackhouse, PhD, and Zena A. Stein, MA, MBCh

We surveyed 111 male clients of an HIV/AIDS service organization in New York City in 2008 and 2009. Seventeen percent had used the female condom for anal intercourse; of these, 89.3% had used the female condom with male partners, 21.4% with female partners, and 10.7% with both. Users of the female condom for vaginal intercourse were more likely to use it for anal intercourse (odds ratio=12.7; 95% confidence interval=2.5, 64.9;  $P=.002$ ). The safety and efficacy of the female condom for anal intercourse are unknown and should be evaluated. (*Am J Public Health*. 2011;101:2233–2244. doi:10.2105/AJPH.2011.300260)

The female condom was approved for vaginal use by the Food and Drug Administration in 1993,<sup>1</sup> but not for anal use.<sup>2</sup> Despite inconclusive safety data,<sup>3,4</sup> previous studies found that some men who have sex with men used the female condom for anal intercourse.<sup>3,5,6</sup> We conducted a survey among 111 men to describe and examine predictors of anal use of the female condom.

### METHODS

We recruited clients of the health care services at Gay Men's Health Crisis in New York City from December 2008 to June 2009. In stage 1, we recruited 100 men regardless of female condom use to get an estimate of the prevalence of anal use of the device.

**TABLE 1—Descriptive Statistics for Men Who Have Anal Intercourse, Overall and Separately by Female Condom Use: New York City, December 2008–June 2009**

	Total, No. (%) <sup>a</sup>	Men Who Ever Used the Female Condom for Anal Intercourse, No. (%)	Men Who Never Used the Female Condom for Anal Intercourse, No. (%)	P
Total	111 (100)	28 (25.2)	83 (74.8)	
Used female condom for anal intercourse in past 6 mo				
No	88 (79.3)	5 (5.7)	83 (94.3)	
Yes	23 (20.7)	23 (100.0)	0 (0.0)	
Age, y				.268 <sup>b</sup>
< 40	55 (50.0)	11 (20.0)	44 (80.0)	
≥ 40	55 (50.0)	16 (29.1)	39 (70.9)	
Race				.549 <sup>b</sup>
Black	46 (41.4)	14 (30.4)	32 (69.6)	
White	35 (31.5)	8 (22.9)	27 (77.1)	
Other	30 (27.1)	6 (20.0)	24 (80.0)	
Ethnicity				.402 <sup>b</sup>
Hispanic	40 (36.4)	8 (20.0)	32 (80.0)	
Non-Hispanic	70 (63.6)	19 (27.1)	51 (72.9)	
Average annual income, \$				.374 <sup>c</sup>
< 10 000	44 (40.7)	14 (31.8)	30 (68.2)	
10 000–49 000	49 (45.4)	12 (24.5)	37 (75.5)	
≥ 50 000	15 (13.9)	2 (13.3)	13 (86.7)	
Education				.832 <sup>c</sup>
< high school diploma	18 (16.2)	5 (27.8)	13 (72.2)	
High school diploma	60 (54.1)	16 (26.7)	44 (73.3)	
> high school diploma	33 (29.7)	7 (21.2)	26 (78.8)	
Sexual orientation				.298 <sup>c</sup>
Homosexual	80 (74.8)	21 (26.3)	59 (73.8)	
Bisexual	21 (19.6)	4 (19.0)	17 (81.0)	
Heterosexual	6 (5.6)	3 (50.0)	3 (50.0)	
Had male partners in lifetime				.05 <sup>c</sup>
No	4 (3.6)	3 (75.0)	1 (25.0)	
Yes	106 (96.4)	25 (23.6)	81 (76.4)	
Had vaginal intercourse with female partners in lifetime				.211 <sup>b</sup>
No	46 (42.2)	9 (19.6)	37 (80.4)	
Yes	63 (57.8)	19 (30.2)	44 (69.8)	
Had anal intercourse with female partner in lifetime				.185 <sup>b</sup>
No	71 (64.0)	15 (21.1)	56 (78.9)	
Yes	40 (36.0)	13 (32.5)	27 (67.5)	
Had >1 male partner in past 6 mo				.69 <sup>b</sup>
No	31 (27.9)	7 (22.6)	24 (77.4)	
Yes	80 (72.1)	21 (26.3)	59 (73.8)	
Had >1 female partner in past 6 mo				.226 <sup>b</sup>
No	102 (91.9)	24 (23.5)	78 (76.5)	
Yes	9 (8.1)	4 (44.4)	5 (55.6)	
Used female condom for vaginal intercourse				.004 <sup>c</sup>
No	95 (85.6)	19 (20.0)	76 (80.0)	
Yes	16 (14.4)	9 (56.3)	7 (43.8)	

Continued

**TABLE 1—Continued**

Experienced problems with male condoms <sup>d</sup>				.488 <sup>b</sup>
No	31 (29.2)	9 (29.0)	22 (71.0)	
Yes	75 (70.8)	17 (22.7)	58 (77.3)	
Rated male condoms as excellent for disease protection				.232 <sup>b</sup>
No	73 (66.4)	16 (21.9)	57 (78.1)	
Yes	37 (33.6)	12 (32.4)	25 (67.6)	
Rated male condoms as very negatively influencing pleasure of anal intercourse				.036 <sup>c</sup>
No	104 (94.5)	24 (23.1)	80 (76.9)	
Yes	6 (5.5)	4 (66.7)	2 (33.3)	

<sup>a</sup>Due to missing data the total number in some categories is < 111.

<sup>b</sup> $\chi^2$  test.

<sup>c</sup>Fisher's exact test.

<sup>d</sup>Such as slipping, leaking, or breaking.

**TABLE 2—Logistic Regression Models Examining Predictors of Female Condom Use for Anal Intercourse Among Men: New York City, December 2008–June 2009**

	Univariate Model			Multivariate Model	
	No.	OR (95% CI)	P	OR (95% CI)	P
<b>Stage 1 participants (multivariate model n = 87)</b>					
Rated male condoms as excellent for HIV/STI protection	99	2.0 (0.7, 5.9)	.192	8.3 (1.3, 51.2)	.023
Experienced problems with male condoms <sup>a</sup>	97	0.7 (0.2, 2.1)	.521	0.6 (0.1, 2.9)	.556
Rated male condoms as very negatively influencing pleasure of anal intercourse	99	12.3 (2.0, 74.1)	.006	7.7 (0.7, 83.6)	.095
Used female condoms for vaginal intercourse	100	5.9 (1.7, 20.9)	.006	27.5 (2.7, 277.7)	.005
Mean annual income > \$10 000	97	0.4 (0.2, 1.2)	.111	0.7 (0.1, 4.8)	.712
Age > 40 y	99	2.5 (0.8, 7.8)	.119	1.7 (0.4, 7.5)	.488
Black race	100	1.5 (0.9, 2.6)	.129	1.3 (0.6, 3.2)	.529
Hispanic ethnicity	99	0.4 (0.1, 1.4)	.141	0.2 (0.03, 1.4)	.104
Homosexual orientation	96	1.2 (0.4, 3.9)	.727	0.3 (0.04, 2.4)	.262
Education beyond high school diploma	100	0.5 (0.1, 1.5)	.187	0.2 (0.03, 1.7)	.157
<b>Stage 1 and 2 participants (multivariate model n = 96)</b>					
Rated male condoms as excellent for HIV/STI protection	110	1.7 (0.7, 4.1)	.234	3.2 (1.0, 10.4)	.055
Experienced problems with male condoms <sup>a</sup>	106	0.7 (0.3, 1.8)	.489	0.6 (0.2, 2.0)	.423
Rated male condoms as very negatively influencing pleasure of anal intercourse	110	6.7 (1.2, 38.7)	.034	4.2 (0.6, 30.7)	.163
Used female condoms for vaginal intercourse	111	5.1 (1.7, 15.6)	.004	12.7 (2.5, 64.9)	.002
Mean annual income > \$10 000	108	0.6 (0.3, 1.4)	.249	0.7 (0.2, 3.0)	.675
Age > 40 y	110	1.6 (0.7, 4.0)	.27	0.9 (0.3, 2.8)	.88
Black race	111	1.3 (0.8, 1.9)	.29	1.1 (0.6, 2.0)	.827
Hispanic ethnicity	110	0.7 (0.3, 1.7)	.404	0.6 (0.2, 2.0)	.381
Homosexual orientation	107	1.0 (0.4, 2.7)	.974	0.3 (0.1, 1.6)	.161
Education > high school diploma	111	0.9 (0.3, 2.7)	.785	0.7 (0.2, 3.4)	.668

Note. CI = confidence interval; OR = odds ratio; STI = sexually transmitted infection.

<sup>a</sup>Such as slipping, leaking, or breaking.

Participants were eligible if they were male, were at least 18 years old, spoke English, and had had anal intercourse in the past 6 months with a man or woman. In stage 2, we restricted recruitment to anal users of the

female condom to oversample this group, and we added a fifth eligibility criterion: use of the female condom for anal intercourse at least once. The total sample comprised 111 men (100 from stage 1 and 11 from stage 2).

We approached 268 men for screening. Seventy-three men (27.2%) declined to participate, of whom 89.0% refused even to be screened. Eighty-four screened men (41.4%) were ineligible for the study (26 in stage 1;

58 in stage 2); 97% of the ineligible men in stage 2 did not meet the criterion of having used the female condom for anal intercourse.

We computed the lifetime (ever) and active (past 6 months) prevalence of female condom use for anal intercourse for the 100 stage 1 participants. We used logistic regression to examine predictors of anal use of the female condom in the stage 1 sample of 100 and the total sample of 111.

## RESULTS

The lifetime prevalence of female condom use for anal intercourse for the first 100 survey participants (stage 1) was 17.0% (95% confidence interval [CI]=10.8%, 25.7%). The prevalence of active female condom use (past 6 months) was 14.0% (95% CI=8.4%, 22.3%). The demographic characteristics of the study sample overall and separately by anal use of the female condom are presented in Table 1.

Of the 28 men who had used the female condom for anal intercourse, 22 (78.6%) had done so only with male partners, 3 (10.7%) only with female partners, and 3 (10.7%) with both. Eighteen men (64.3%) reported removing the inner ring at last use, and 23 (82.1%) used additional lubricant. Five men (17.9%) reported having experienced problems (slipping, leaking, or breaking) with the female condom during anal intercourse (70.8% reported problems with the male condom). Seven men (25%) reported that the female condom had a very or somewhat negative effect on pleasure during anal intercourse (31.4% experienced this with the male condom).

Of the 18 men who reported removing the inner ring the last time they used the female condom for anal intercourse, 5 (27.8%) experienced problems (slippage or breakage), although not necessarily the last time they used the product; none of the 10 men who left the inner ring in at last use reported problems (Fisher's exact  $P=.128$ ). However, 4 men (40.0%) who had not removed the inner ring at last use said the female condom has a negative impact on pleasure, compared to 3 (16.7%) of the men who had removed the inner ring (Fisher's exact  $P=.207$ ).

In the multivariate model with only stage 1 participants ( $n=87$ , data missing on at least one

variable included in the multivariate model for 13 participants), we found a significant association between female condom use for anal intercourse and female condom use for vaginal intercourse (odds ratio [OR]=27.5; 95% CI=2.7, 277.7;  $P=.005$ ). We also observed an association between female condom use for anal intercourse and rating of the male condom as excellent for prevention of HIV and sexually transmitted infection (OR=8.3; 95% CI=1.3, 51.2;  $P=.023$ ). The association with reporting that the male condom had a very negative impact on pleasure during anal intercourse was of borderline significance (OR=7.7; 95% CI=0.7, 83.6;  $P=.095$ ). After adding the stage 2 participants to the model ( $n=96$ , data missing on at least one variable in the multivariate model for 15 participants), the results were similar except that the association with rating the male condom as excellent for sexually transmitted infection prevention was of only borderline significance (OR=3.2; 95% CI=1.0, 10.4;  $P=.055$ ; Table 2).

## DISCUSSION

We found a 17% lifetime prevalence of female condom use for anal intercourse, which is within the range found in previous studies.<sup>3,5,6</sup> Our study provides the first documentation that the female condom is also used for heterosexual anal intercourse.

Our study was small, so results should be viewed with caution and may not be generalizable to other groups. However, our findings suggest that some couples are using the female condom for anal intercourse in the absence of reliable information regarding safety, efficacy, and optimal method of use for this purpose. These results highlight the urgent need to evaluate the safety and efficacy of the female condom in anal intercourse to fill this knowledge gap and help people make informed choices about the methods they use to protect themselves during anal intercourse. ■

### About the Authors

Elizabeth A. Kelvin, Joanne E. Mantell, Susie Hoffman, Theresa M. Exner, and Zena A. Stein are with the HIV Center for Clinical and Behavioral Studies at the New York State Psychiatric Institute and Columbia University, New York, NY. Norman Candelario is with and at the time of the

study William Stackhouse was with Gay Men's Health Crisis, New York.

Correspondence should be sent to Elizabeth A. Kelvin, HIV Center for Clinical and Behavioral Studies, New York Psychiatric Institute and Columbia University, 1051 Riverside Drive, Unit 15, New York, NY 10032 (e-mail: eak34@columbia.edu). Reprints can be ordered at <http://www.ajph.org> by clicking the "Reprints/Eprints" link.

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### Contributors

E. A. Kelvin originated and designed the study, directed data collection and management procedures, conducted the statistical analysis, and prepared the article. J. E. Mantell, S. Hoffman, T. M. Exner, W. Stackhouse, and Z. A. Stein helped with study design and article preparation. N. Candelario helped with study design, coordinated data collection procedures at Gay Men's Health Crisis, and helped with article preparation.

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### Human Participant Protection

The study procedures were approved by the institutional review boards at the New York State Psychiatric Institute–Columbia University Department of Psychiatry and the Gay Men's Health Crisis research advisory committee.

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