

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

More than Just Oral PrEP: Exploring Interest in Rectal Douche, Dissolvable Implant, Removable Implant, and Injection HIV Prevention Approaches among Racially Diverse Men Who Have Sex With Men

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-063474
Article Type:	Original research
Date Submitted by the Author:	01-Apr-2022
Complete List of Authors:	<p>Martinez, Omar; Temple University, Levine, Ethan; Temple Univeristy, College of Liberal Arts; Temple University Munoz-Laboy, Miguel; Stony Brook University, School of Social Welfare Carballo-Diéguez, Alex; Columbia University Medical Center, HIV Center Bauermeister, José; University of Pennsylvania School of Nursing, Family and Community Health Chacon, Alexi; Temple University, School of Social Work Jacobson, Jeffrey; Temple University School of Medicine Bettiker, Robert; Temple University School of Medicine Sutton, Madeline; Morehouse School of Medicine Rudolph, Abby; Temple University College of Public Health, Wu, Elwin; Columbia University School of Social Work Rhodes, S; Wake Forest School of Medicine Tanner, Amanda; University of North Carolina at Greensboro School of Health and Human Sciences, Mann, Lilli; Wake Forest University, Valentin, Omar; University of Miami Ilarraza, Ariel; Temple University Pardes, Mariana; Temple University Davison, Robin; Temple University Fernandez, Maria; Nova Southeastern University</p>
Keywords:	HIV & AIDS < INFECTIOUS DISEASES, PUBLIC HEALTH, SEXUAL MEDICINE

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3 **More than Just Oral PrEP: Exploring Interest in Rectal Douche, Dissolvable Implant,**
4 **Removable Implant, and Injection HIV Prevention Approaches among Racially Diverse**
5 **Men Who Have Sex With Men**
6
7

8 **Keywords:** biomedical HIV prevention approaches, Men who have sex with men, rectal douche,
9 dissolvable implant, removable implant, injection
10
11

12 **Word Count:** 3890
13

14
15 Omar Martinez, JD, MPH, MS
16 Temple University, School of Social Work
17 Philadelphia, United States
18

19
20 Ethan Levine, PhD
21 Temple University
22 Philadelphia, United States
23

24
25 Miguel Muñoz-Laboy DrPH
26 Associate Professor, Stony Brook University
27 Stony Brook, United States
28

29
30 Alex Carballo-Diéguez, PhD
31 Columbia University Medical Center, HIV Center
32 New York, United States
33

34
35 Jose Bauermeister PhD
36 University of Pennsylvania School of Nursing, Family and Community Health
37 Philadelphia, Pennsylvania
38

39
40 Alexi Chacon, MSc
41 Temple University
42 Philadelphia, United States
43

44
45 Jeffrey Jacobson, MD
46 Temple University, Lewis Katz School of Medicine
47 Philadelphia, United States
48

49
50 Robert Bettiker, MD
51 Temple University, Lewis Katz School of Medicine
52 Philadelphia, United States
53

54
55 Madeline Sutton, MD
56 Morehouse School of Medicine
57 Atlanta, United States
58
59
60

1
2
3 Abby Rudolph, PhD
4 Temple University, College of Public Health
5 Philadelphia, United States
6

7
8 Elwin Wu, PhD
9 Columbia University, School of Social Work
10 New York, United States
11

12 Scott Rhodes, PhD
13 Wake Forest University School of Medicine, Department of Social Sciences and Health Policy
14 Winston-Salem, United States
15

16
17 Amanda Tanner, PhD
18 University of North Carolina-Greensboro, Department of Public Health Education
19 Greensboro, United States
20

21
22 Lilli Mann, MPH
23 Wake Forest University
24 Wake Forest, United States
25

26 Omar Valentin, MPH
27 University of Miami
28 Miami, United States
29

30
31 Ariel Ilarraza
32 Temple University
33 Philadelphia, United States
34

35 Mariana Pardes
36 Temple University
37 Philadelphia, United States
38

39
40 Robin Davison, JD
41 Temple University
42 Philadelphia, United States
43

44
45 Maria Fernandez, PhD
46 Nova Southeastern University
47 Fort Lauderdale, United States
48

49 Corresponding Author:
50 Alexi Chacon, MSc
51 Address: 910 Fitzwater Street, Apt. B
52 Philadelphia, PA 19147
53 Email: alexix213@gmail.com
54 Cell: 818-456-2066 Fax: N/A
55
56
57
58
59
60

Abstract:

Objectives HIV scholars and practitioners have worked to expand strategies for prevention among marginalized populations who are disproportionately impacted by the epidemic, such as racial minority men who have sex with men (MSM). Given this urgency, the objective of this study was to assess interest in biomedical prevention strategies.

Methods This exploratory & cross sectional study investigated interest in four biomedical prevention tools – rectal douche, dissolvable implant, removable implant, and injection – among a racially diverse sample of MSM from the Northeast Corridor region between Philadelphia and Trenton. Data was collected as part of screening for *Connecting Latinos en Pareja*, a couples-based HIV prevention intervention for Latino MSM and their partners.

Results A total of 381 individuals participated in the screener and provided information about their interest in bio tools. Approximately 26% of participants identified as Black, 28% as White, and 42% as “other” or multiracial; 49% identified as Latino. A majority (54%) reported some form of child sexual abuse. Of those participants who reported being in a primary relationship (n=217), two thirds reported unprotected anal sex within that relationship over the past 90 days (n=138, 64%) and approximately half (n=117, 54%) reported unprotected anal sex outside of the relationship in this period. A majority of participants reported interest in all bio tools assessed, including dissolvable implants (60%), removable implants (64%), rectal douching (79%), and an injection (79%). Although interest in bio tools was broadly unassociated with demographics and sexual risk behaviors, analyses revealed significant associations between reports of child sexual abuse and interest in implant and injection methods.

Conclusions The authors recommend investing in these prevention methods, particularly rectal douching and injection, as a means of preventing HIV among racial minority MSM. Given the interest in biomedical prevention tools, future studies should explore and identify potential strategies for adherence and retention.

Key words: biomedical HIV prevention approaches, rectal douche, dissolvable implant, removable implant, injection, men who have sex with men

Strengths & Limitations:

- Data for this study came from a preliminary screening for a larger study on HIV prevention and thus analysis is limited to the variables and demographics that were collected in the screening.
- The sample is limited to individuals in the northeast corridor, which may impact generalizability of findings.

- This study collected data on different forms of childhood sexual abuse and determined its link to HIV prevention bio tool preferences.

INTRODUCTION

In recent years, considerable advances have been made in decreasing overall HIV infection and transmission rates in the United States. However, the HIV epidemic continues to disproportionately impact racial and ethnic minorities and sexual and gender minority communities. Data has revealed an urgent national emergency as “The Invisible US Hispanic/Latino HIV Crisis.”(1) While the number of new cases decreased in 2019 for gay and bisexual Black and white men, HIV infection rates in gay and bisexual Latinx men increased from 6,800 new cases/year in 2010 to 7,900/year in 2019.(2) Seven in ten new HIV diagnoses occur among gay and bisexual men, even though they comprise about 2% of the US population (3). Among gay and bisexual men, racial and ethnic minorities continue to be disproportionately impacted by the epidemic.

If current trends continue, 1 in 4 Latino gay and bisexual men and 1 in 2 Black gay and bisexual men will be diagnosed with HIV during their lifetimes (4). Moreover, HIV surveillance data provides minimal information detailing which social determinants of health may impact risk behaviors, healthcare use and access (5-8). Social determinants of health that should be examined include socioeconomic status, social support, and exposure to violence (5-8). It is thus difficult, if not impossible, to determine the extent to which populations whose HIV risk is exacerbated by these and other interacting syndemic factors benefit from overall declines in diagnoses.

Biomedical prevention approaches, including pre-exposure prophylaxis (PrEP) for HIV negative individuals [8-10], treatment as prevention (TasP) for people living with HIV [11-14], and condoms for both HIV negative and people living with HIV, have emerged as effective biomedical prevention tools to address the global HIV epidemic among men who have sex with men (MSM). PrEP, for example, is an effective HIV prevention tool [15], recommended by the World Health Organization [16] and the Centers for Disease Control [17] for persons at substantial risk for HIV infection. Some of the recent progress in curbing HIV infection and transmission has been attributed to increases in PrEP use within and beyond the U.S. However, challenges remain among those who would benefit from PrEP, and use remains somewhat low, particularly among Black and Latino MSM [18, 19].

1
2
3 A number of explanations have been proposed for low PrEP uptake amongst racial minority
4 MSM, including (mis)perception of HIV infection risk, concerns about medication side effects,
5 low health literacy, concerns about stigma, access to affordable healthcare, and access to care
6 providers who are both knowledgeable and culturally sensitive [18, 19].
7
8

9
10 Immigration-related barriers are particularly pronounced among Latino MSM. Temporary
11 immigrants and undocumented individuals lack access to healthcare coverage under the
12 Affordable Care Act, as well as a range of social service programs that might otherwise facilitate
13 access or mitigate barriers to PrEP use [19]. Biomedical interventions that require less
14 interactions with a healthcare system could be essential in improving adherence. Given recent
15 increases in anti-immigrant rhetoric, even U.S.-born individuals and documented immigrants
16 may avoid pursuing care for fear of discrimination. Concerns about stigma could be addressed by
17 culturally relevant sex education programs that are tailored to the experiences of Black and
18 Latino MSM [20].
19
20
21
22

23 Several challenges exist with prescription-based prevention products like PrEP and TasP,
24 including adherence and access to medication [21, 22]. Prevention tools such as condoms pose
25 their own challenges. Not only must condoms be present at each sexual encounter, but some at-
26 risk individuals also consider condom use disruptive or detrimental to sexual pleasure [23, 24].
27 This concern has been documented in research on racial minority MSM, including one study of
28 Latino gay couples in which a participant described community members as “tired of using
29 condoms” and in urgent need of alternative prevention methods [25: pg.11].
30
31
32
33

34 However, the following four biomedical intervention tools have the potential to address the
35 previously outlined concerns: rectal douches, dissolvable implants, removable implants, and
36 injections [25]. Not all of these biomedical tools are on the market and each intervention has
37 varying levels of effectiveness in preventing HIV transmission. If and when these methods
38 become available in the market, they could shift HIV prevention from the realm of interpersonal
39 sexual encounters to the realm of individual healthcare. Such a shift may help individuals feel
40 more in control of their bodies and decision-making.
41
42
43

44 For example, rectal douches present a feasible opportunity to also apply a topical rectal
45 microbicide. Research has shown that MSM who douche also have an increased likelihood of
46 applying a rectal microbicide gel [26]. Many individuals who engage in anal intercourse use
47 cleansing douches regularly before and even afterwards [27-29]. Preventive rectal douching
48 might thus align relatively easily with those individuals’ existing sexual practices, rather than
49 place additional demands in the form of daily medication or changes to sexual communication
50 and behavior (as may be required for condom use, which must be negotiated with each anal sex
51 partner before or during each sexual encounter). There is a desire for “invisible” biomedical
52 interventions that do not interfere with intercourse and help protect against stigma because of
53
54
55
56
57
58
59
60

1
2
3 their invisibility from family members, partners, household members and community members
4 [30].
5
6

7 Removable implants are still in the early stages of clinical development but are a promising
8 method towards ensuring that individuals receive both consistent and on-time drug release [31-
9 32]. Subcutaneous implants could potentially deliver the appropriate dosage of antiretroviral
10 drugs for 12 months or longer with a single implant [31]. There are implants in the pre-clinical
11 stage that are looking at combining medications that prevent against other STIs, including the
12 Hepatitis B virus [31].
13
14

15
16 The benefits of implants include fewer interactions with the healthcare system, easy removal and
17 lower dose/day with no oral medication required [31]. Similar medical technologies are being
18 researched in biodegradable implants that can breakdown over time and be expelled from the
19 body without a healthcare interaction [33-34]. Both removable and dissolvable implants require
20 either single or periodic medical appointments, which may be more manageable for some
21 individuals than daily medications and can help add to the medication's "invisibility."
22
23

24
25
26 Injectable antiretroviral medication requires less uptake than rectal douching but more healthcare
27 interactions than dissolvable and removable implants. There is high acceptability among users
28 despite the required 8-week interval injections [35]. Long-acting PrEP in an injectable form has
29 been tested in Phase 1 and Phase 2 clinical trials. Both phases found comparable efficacy to
30 standard PrEP [36-37].
31
32

33
34 The aims of this paper are to 1) explore demographic characteristics and sexual risk behaviors
35 among a racially diverse sample of MSM; 2) investigate interest and correlates of interest in four
36 different biomedical HIV prevention methods among racially diverse MSM, and 3) consider
37 promising approaches for HIV prevention among MSM who face an elevated risk of HIV
38 infection and transmission.
39
40

41 **METHODS**

42 **Setting and recruitment**

43
44
45 This exploratory cross-sectional study investigated interest in four biomedical prevention tools –
46 rectal douches, dissolvable implants, removable implants, and injections - among a racially
47 diverse sample of MSM from the Northeast Corridor region between Philadelphia and Trenton.
48 Data were collected as part of screening for *Connecting Latinos en Pareja*, a couples-based HIV
49 prevention intervention for Latino MSM and their partners. Research staff invited participants to
50 complete a preliminary screening through online social networking apps and social media
51 platforms including Grindr, Facebook, Instagram and the online profiles of AIDS service
52
53
54
55
56
57
58
59
60

1
2
3 organizations in the region. Research assistants posted study flyers on our social media profiles
4 as another recruitment strategy. These flyers included broad and general information about the
5 study including self-identifying as MSM and details about participant incentives. Research
6 methods have been published elsewhere (38). This study was approved by the Institutional
7 Review Board of Temple University in Philadelphia, PA, USA.
8
9

10 11 **Procedures**

12
13
14 Participants took an average of 20 min to complete the anonymous online screening survey. The
15 screening survey was programmed in REDCap, a secure questionnaire development, data entry
16 and analysis platform. Participants were recruited through community-based organizations and
17 online social venues, including Facebook, Grindr, Twitter and Instagram. The first screen of the
18 online survey briefly described the screening process and asked potential participants to provide
19 consent for screening.
20
21

22
23 For this analysis, inclusion in the sample required that participants complete questions gaging
24 interest in biomedical prevention tools. These questions appeared at the end of the survey, and
25 some prospective participants in *Connecting Latinos en Pareja* declined to submit responses to
26 those specific questions and thus, were not included in the sample. Although this resulted in
27 notable loss (out of 533 participants, 381 completed bio tool questions), subsequent analyses did
28 not find substantial demographic differences between the overall sample and those participants
29 retained for this analysis.
30
31

32 33 **Measures**

34
35
36 Sociodemographic data that was collected in the study included age, race/ethnicity, health
37 insurance status, country of birth, education, and employment status. We also inquired about
38 history of child sexual abuse prior to age 14, using six individual questions (e.g., “someone tried
39 to touch me in a sexual way, or make me touch them;” “I believe that I was sexually abused”).
40
41

42
43 Sexual behavior over the past 90 days was assessed in terms of overall reports of anal sex with
44 men (yes/no), total anal sex partners, any anal sex within primary relationships (yes/no),
45 unprotected anal sex within primary relationships (yes/no), any anal sex outside primary sexual
46 relationships (yes/no), and any unprotected anal sex outside primary relationships (yes/no).
47
48

49
50 Participants were asked about PrEP use in the past 90 days. Finally, participants were asked how
51 interested they would be in the use of rectal douche, dissolvable implant, removable implant and
52 injection for HIV prevention (definitely not interested, probably not interested, probably
53 interested, definitely interested) if they become available.
54
55

Statistical Analysis

Sample demographic characteristics, sexual behavior in the past 90 days, PrEP use in the past 90 days, reports of child sexual abuse, and interest in bio tools were calculated using percentages or means as appropriate. Chi-squared tests were conducted to explore associations between interest in various bio tools and other variables. For bivariate analyses, we used dichotomous versions of interest in each prevention method (probably or definitely not interested vs. probably or definitely interested). When reporting univariate and bivariate statistics, we only report on raw data rather than imputing or making other substitutions to compensate for missing cases. Once skip patterns are taken into account (e.g., only participants in primary relationships were asked about sexual behavior within and outside those relationships), missing cases only resulted in minor data loss (between 0.3% and 7%). All analyses were done in Stata, version 13.0.

Patient Involvement

No patients were involved.

RESULTS

Participant Characteristics

Among 381 MSM who provided data for this exploratory analysis, approximately 26% (n=98) of participants identified as Black, 28% as White (n=106), and 41% as “other” or multiracial (n=156) using mutually exclusive categories for race. In a separate question on ethnicity, nearly half (n=186, 49%) identified as Latino. A third of the sample (n=124, 33%) reported having attained at least a bachelor’s degree. A majority (n=206, 54%) reported at least some form of child sexual abuse before age 14. Of those participants who reported being in a primary relationship (n=217), two thirds reported unprotected anal sex within that relationship over the past 90 days (n=138, 64%) and just over half (n=117, 54%) reported unprotected anal sex outside of the relationship in the past 90 days.

Interest in Biomedical Prevention Tools

A majority of participants reported probable or definite interest in all biomedical prevention tools assessed, including dissolvable implants (n=229, 60%), removable implants (n=242, 64%), rectal douching (n=300, 79%), and an injection (n=300, 79%). Approximately one fifth of participants reported at least some PrEP use in the past 90 days (n=85, 22%). Sample characteristics appear in Table 1, with more detailed information regarding interest in biomedical prevention tools in Table 2.

Table 1 Sample Characteristics (n=381)	
	M (SD) or N (%)
<i>Age (n=376)</i>	30.84 (10.89)
<i>Identify as Latino/Hispanic/Afro-Latino (n=379)</i>	186 (49%)
<i>Race (mutually exclusive, n=375)</i>	
Black Only	98 (26%)
Asian, Asian American, Pacific Islander Only	9 (2%)
Native American, American Indian, Alaska Native Only	6 (2%)
White Only	106 (28%)
Other and/or Multiracial	156 (42%)
<i>Biomedical Prevention Tools</i>	
PrEP Use in Past 90 Days	85 (22%)
Interested in Rectal Douche for HIV Prevention ¹	300 (79%)
Interested in Dissolvable Implant for HIV Prevention ¹	229 (60%)
Interested in Removable Implant for HIV Prevention ¹	242 (64%)
Interested in Injection for HIV Prevention ¹	300 (79%)
<i>Sexual Behavior, General</i>	
Anal Sex with Man, Past 90 Days (n=380)	309 (81%)
Total Anal Sex Partners, Past 90 Days (n=304)	4.86 (8.10)
<i>Sexual Risk Behavior, Primary Relationship</i>	
Any Anal Sex, Past 90 Days (n=217)	196 (90%)
Unprotected Anal Sex, Past 90 Days (n=195)	138 (71%)
<i>Sexual Risk Behavior, Outside Primary Relationship</i>	
Any Anal Sex, Past 90 Days (n=217)	126 (58%)
Unprotected Anal Sex, Past 90 Days (n=201)	117 (58%)
<i>Child Sexual Abuse, Before age 14</i>	
Someone tried to touch me in a sexual way, or make me touch them (n=379)	166 (44%)
Someone threatened to hurt me or tell lies about me unless I did something sexual with them (n=379)	69 (18%)
Someone tried to make me do sexual things or watch sexual things (n=377)	132 (35%)
Someone molested me (n=376)	114 (30%)

Someone on the internet tried to get me to talk about sex when I did not want to (n=377)	69 (18%)
Someone on the internet tried to get me to do sexual things when I did not want to (n=379)	69 (18%)
I believe that I was sexually abused (n=375)	109 (29%)
Answered yes to at least one CSA question (n=380)	206 (54%)
<i>Protective Factors</i>	
Health Insurance (n=380)	325 (86%)
Born in US (n=380)	314 (82%)
Bachelor's Degree or Higher (n=377)	124 (33%)
Employed Fulltime	187 (49%)
*Operationalized as indicating "definite" or "probable" interest in using this prevention method.	

	<i>Definitely Not Interested</i>	<i>Probably Not Interested</i>	<i>Probably Interested</i>	<i>Definitely Interested</i>
Rectal Douche	33 (9%)	48 (13%)	117 (31%)	183 (48%)
Dissolvable Implant	69 (18%)	83 (22%)	111 (29%)	118 (31%)
Removable Implant	55 (14%)	84 (22%)	111 (29%)	131 (34%)
Injection	30 (8%)	51 (13%)	110 (29%)	190 (50%)

Bivariate analyses revealed few connections between demographics and interest in various biomedical HIV prevention methods. Participants with bachelor's degrees were less likely to report interest in rectal douching (n=377, $\chi^2 = 10.48$, df=1, p<.01, n=377) and more likely to report interest in removable implants ($\chi^2 = 4.57$, df=1, p<.05, n=377) than peers who did not possess a college degree. Age, race, Latino ethnicity, health insurance, being born in the U.S., and fulltime employment were unassociated with interest in various prevention tools.

We documented a positive association between overall reports of anal sex within primary relationships in the past 90 days and interest in injections ($\chi^2 = 3.97$, df=1, p<.05, n=217). Otherwise, there were no associations between interest in biomedical interventions and the sexual behaviors addressed here. PrEP use in the past 90 days was not associated with interest in other methods.

There were associations between reports of child sexual abuse before age 14 and for all prevention methods except for rectal douching. Interest in dissolvable implants was positively associated with the following statements: someone tried to touch me in a sexual way, or make me touch them ($\chi^2 = 5.13$, df=1, p<.05, n=379); someone threatened to hurt or tell lies about me unless I did something sexual ($\chi^2 = 4.15$, df=1, p<.05, n=379); someone tried to make me do sexual things or watch sexual things ($\chi^2 = 6.46$, df=1, p<.05, n=377); someone molested me ($\chi^2 =$

4.43, $df=1$, $p<.05$, $n=376$); someone on the internet tried to get me to talk about sex when I didn't want to ($\chi^2 = 4.31$, $df=1$, $p<.05$, $n=377$); and I believe I was sexually abused ($\chi^2 = 7.60$, $df=1$, $p<.01$, $n=375$). Interest in dissolvable implants was also positively associated with overall reports of child sexual abuse ($\chi^2 = 5.22$, $df=1$, $p<.05$, $n=380$).

Interest in removable implants was positively associated with the following statements: someone tried to touch me in a sexual way, or make me touch them ($\chi^2 = 5.05$, $df=1$, $p<.05$, $n=379$); someone threatened to hurt or tell lies about me unless I did something sexual ($\chi^2 = 4.07$, $df=1$, $p<.05$, $n=379$); someone tried to make me do sexual things or watch sexual things ($\chi^2 = 8.91$, $df=1$, $p<.01$, $n=377$); and I believe I was sexually abused ($\chi^2 = 4.90$, $df=1$, $p<.05$, $n=375$).

Interest in removable implants was also positively associated with overall reports of child sexual abuse ($\chi^2 = 8.15$, $df=1$, $p<.01$, $n=380$). Interest in injections was positively associated with the following statements: someone tried to touch me in a sexual way, or make me touch them ($\chi^2 = 7.00$, $df=1$, $p<.01$, $n=379$); someone tried to make me do sexual things or watch sexual things ($\chi^2 = 10.77$, $df=1$, $p<.01$, $n=377$); someone molested me ($\chi^2 = 3.96$, $df=1$, $p<.05$, $n=376$); and I believe I was sexually abused ($\chi^2 = 4.93$, $df=1$, $p<.05$, $n=375$). Interest in dissolvable implants was also positively associated with overall reports of child sexual abuse ($\chi^2 = 5.02$, $df=1$, $p<.05$, $n=380$). Table 3 below lays out our bivariate analyses.

Table 3: Bivariate Analyses (n=381)	Rectal Douche		Dissolvable Implant		Removable Implant		Injection	
	Not Interes ted	Interes ted	Not Interes ted	Interes ted	Not Interes ted	Interes ted	Not Interes ted	Interes ted
	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)
Age (n=376)	30.69 (9.37)	30.88 (11.28)	31.00 (11.21)	30.73 (10.69)	30.96 (10.92)	30.77 (10.89)	30.30 (10.90)	30.99 (10.90)
Identify as Latino/Hispani c/Afro-Latino (n=379)	34 (42%)	152 (51%)	68 (45%)	118 (52%)	59 (43%)	127 (53%)	34 (43%)	152 (51%)

<i>Race (mutually exclusive, n=375)</i>									
Black Only	23 (29%)	75 (25%)	42 (28%)	56 (25%)	37 (27%)	61 (26%)	17 (22%)	81 (27%)	
Asian, Asian American, Pacific Islander Only	3 (4%)	6 (2%)	4 (3%)	5 (2%)	6 (4%)	3 (1%)	4 (5%)	5 (2%)	
Native American, American Indian, Alaska Native Only	0 (0%)	6 (2%)	1 (1%)	5 (2%)	1 (%)	5 (2%)	0 (0%)	6 (2%)	
White Only	24 (30%)	82 (29%)	46 (31%)	60 (27%)	42 (31%)	64 (27%)	24 (30%)	82 (28%)	
Other and/or Multiracial	30 (38%)	126 (43%)	57 (38%)	99 (44%)	51 (37%)	105 (44%)	34 (43%)	122 (41%)	
<i>PrEP Use in Past 90 Days</i>	24 (30%)	61 (20%)	33 (22%)	52 (23%)	29 (21%)	56 (23%)	12 (15%)	73 (24%)	
<i>Sexual Behavior, General</i>									
Anal Sex with Man, Past 90 Days (n=380)	68 (84%)	241 (81%)	121 (80%)	188 (83%)	113 (82%)	196 (81%)	60 (75%)	249 (83%)	
Total Anal Sex Partners, Past 90 Days (n=304)	4.79 (6.23)	4.88 (8.56)	4.25 (4.99)	5.24 (9.55)	4.17 (4.82)	5.24 (9.44)	4.05 (5.24)	5.05 (8.63)	
<i>Sexual Risk Behavior, Primary Relationship</i>									
Any Anal Sex, Past 90 Days (n=217)	36 (92%)	160 (90%)	78 (89%)	118 (92%)	73 (94%)	123 (89%)	38 (83%)	158 (92%)*	

Unprotected Anal Sex, Past 90 Days (n=195)	26 (72%)	112 (70%)	54 (69%)	84 (72%)	55 (73%)	83 (68%)	28 (74%)	110 (70%)
<i>Sexual Risk Behavior, Outside Primary Relationship</i>								
Any Anal Sex, Past 90 Days (n=217)	20 (51%)	106 (59%)	54 (61%)	72 (56%)	47 (60%)	79 (57%)	28 (61%)	98 (57%)
Unprotected Anal Sex, Past 90 Days (n=201)	23 (58%)	94 (58%)	53 (65%)	64 (54%)	42 (58%)	75 (58%)	23 (61%)	94 (58%)
<i>Child Sexual Abuse, Before age 14</i>								
Someone tried to touch me in a sexual way, or make me touch them (n=379)	36 (45%)	130 (44%)	55 (37%)	111 (49%)*	50 (36%)	116 (48%)*	25 (31%)	141 (47%)* *
Someone threatened to hurt me or tell lies about me unless I did something sexual with them (n=379)	16 (20%)	53 (18%)	20 (13%)	49 (22%)*	18 (13%)	51 (21%)	12 (15%)	57 (19%)
Someone tried to make me do sexual things or watch sexual things (n=377)	25 (31%)	107 (36%)	41 (27%)	91 (40%)*	35 (25%)	97 (41%)* *	15 (19%)	117 (39%)* *

Someone molested me (n=376)	22 (28%)	92 (31%)	36 (24%)	78 (34%)*	35 (26%)	79 (33%)	17 (21%)	97 (33%)*
Someone on the internet tried to get me to talk about sex when I did not want to (n=377)	14 (18%)	55 (19%)	20 (13%)	49 (22%)*	20 (14%)	49 (21%)	12 (15%)	57 (19%)
Someone on the internet tried to get me to do sexual things when I did not want to (n=379)	13 (16%)	56 (19%)	22 (15%)	47 (21%)	21 (15%)	48 (20%)	11 (14%)	58 (19%)
I believe that I was sexually abused (n=375)	22 (28%)	87 (29%)	32 (21%)	77 (34%)* *	31 (22%)	78 (33%)*	15 (19%)	94 (32%)
Answered yes to at least one CSA question (n=380)	44 (54%)	162 (54%)	71 (47%)	135 (59%)	62 (44%)	144 (60%)* *	35 (43%)	171 (57%)
<i>Protective Factors</i>								
Health Insurance (n=380)	74 (91%)	251 (84%)	134 (89%)	191 (83%)	120 (87%)	205 (85%)	70 (86%)	255 (86%)
Born in US (n=380)	70 (86%)	244 (82%)	128 (84%)	186 (82%)	118 (86%)	196 (81%)	67 (84%)	247 (82%)
Bachelor's Degree or Higher (n=377)	38 (48%)	86 (29%)* *	44 (29%)	80 (35%)	36 (26%)	88 (36%)*	24 (30%)	100 (34%)
Employed Fulltime	47 (58%)	140 (47%)	76 (50%)	111 (49%)	71 (51%)	116 (48%)	37 (46%)	150 (50%)
*p<.05, **p<.01, ***p<.001 in								

chi squared analysis										
----------------------	--	--	--	--	--	--	--	--	--	--

DISCUSSION

In order to reduce demographic imbalances in HIV transmission, it is essential to develop and promote innovative biobehavioral approaches to HIV prevention among those who are highly impacted and vulnerable. The study findings have important implications for HIV prevention programming, including investment in and potential uptake of various biomedical tools.

Within this exploratory analysis, sexual minority MSM reported high prevalence estimates of sexual risk behaviors. More than half of the sample reported unprotected anal sex with primary partners, and more than half of those with primary partners reported unprotected anal sex outside of those relationships within the past 90 days. This data reinforces the need to continue prioritizing HIV prevention among racially diverse MSM. Investment in the different biomedical tools that were investigated in this study will serve that goal.

Our findings show a high desirability amongst MSM to use the four biomedical prevention approaches assessed here. Rectal douching and injection emerged as the most desirable among study participants. If these biomedical prevention approaches are proven efficacious and approved by the FDA, it is important that promotional efforts for these biomedical approaches be implemented in racially diverse MSM communities. Strategies for promotional efforts can include peer-navigation, social media campaigns and community collaborative approaches. All promotion efforts should make sure to address the unique barriers to HIV prevention and care that Latinx MSM experience, including discrimination, stigma, and anti-immigration rhetoric.

The most important findings in this study were the associations between reports of child sexual abuse in and interest in different prevention methods. A majority of participants (54%) reported at least some form of child sexual abuse before age 14. Other studies have documented the high prevalence estimates of sexual risk behaviors and childhood sexual abuse [39, 40]. Prevalence estimates of child sexual abuse in this sample rank among the highest up to date in the literature. We found that participants who reported any child sexual abuse, as well as some who reported particular forms of in-person and online abusive experiences, were more likely to express interest in dissolvable implants, removable implants, and injections. There was no association between child sexual abuse and interest in rectal douching as an HIV prevention strategy.

Our research adds to a body of work investigating the acceptability of HIV prevention biomedical tools in different countries and populations. Previous studies have found that different populations in countries outside of the U.S. have a high acceptability for long-acting injectable PrEP as well as for rectal douching. LAI PrEP was found to be more highly acceptable

1
2
3 amongst men than females in both the U.S. and countries outside of the U.S. but only compared
4 against standard PrEP, leaving out other biomedical prevention tools [41]. Our findings delve
5 deeper and show that amongst MSM, LAI PrEP as a biomedical tool for HIV prevention tool is
6 preferred over both removable and dissolvable implants. A study investigating the acceptability
7 of rectal douching amongst a sample of Peruvian men found that rectal douching was likely to be
8 used when condoms were not used [42]. This study's findings compare the acceptability of
9 rectal douching to three other biomedical prevention tools and find that within our sample,
10 acceptability of rectal douching (79%) is equal to acceptability of LAI injection (79%). Overall,
11 our research corroborates prior studies which indicate that there is an increased acceptability for
12 biomedical interventions that prevent HIV transmission apart from standard oral PrEP [43-44].
13
14
15
16
17

18 Although it is impossible to infer causal mechanisms from the cross-sectional exploratory data, it
19 is worth noting that implants and injections occur separate from individual sexual encounters.
20 Whereas individuals may face pressure around safer sex practices when engaging directly with
21 prospective partners, including pressure to engage in or forego rectal douching or condom use,
22 these pressures are far less likely to come into play during medical appointments. Providing
23 resources that separate HIV prevention strategies from sexual encounters may empower MSM,
24 including those who have experienced child sexual abuse, to make independent decisions about
25 their bodies and boundaries.
26
27
28
29

30 The increased interest in biomedical interventions that require medical appointments points to a
31 larger need for providers to undergo antibias training to ensure the equitable distribution of PrEP
32 in healthcare settings. Provider bias may allow stigma to prevent the prescription of PrEP to
33 individuals who need it most [45]. Qualitative studies have shown that providers' bias against the
34 LGBTQ+ community and their views on sex have prevented prescription to patients [45].
35 Providers have been shown to know little about PrEP and the criteria that should be used to
36 identify patients that would benefit from the medication [45].
37
38
39

40 POC MSM have expressed wanting stigma free PrEP access and that should extend to the
41 interventions covered in this study [46]. It is possible that these biases will act as barriers to
42 uptake for the biomedical prevention tools investigated in this study. Given the interest in all four
43 biomedical interventions that has been displayed in our findings, plans to scale up access should
44 also be paired with antibias training to ensure that POC MSM are not discriminated against when
45 seeking out these interventions. Antibias and informational training has been found to increase
46 knowledge of PrEP amongst providers along with an increased prescription rate [47].
47
48
49
50

51 This study found no associations between interest in various biomedical prevention tools and
52 age, race, or Hispanic/Latino ancestry. Socioeconomic indicators, for the most part, were also not
53 associated with interest in those tools. Although null findings are rarely regarded as noteworthy
54 in scientific literature, we believe that these particular findings are valuable for HIV prevention.
55
56
57
58
59
60

1
2
3 The data indicates that a general strategy of promoting various prevention methods, rather than a
4 range of approaches tailored to different demographic groups, may be appropriate when working
5 with racially diverse MSM.
6
7

8 **Limitations**

9

10
11 This study has several limitations. An important limitation to this study is that it was limited to a
12 subsection of the Northeast Corridor of the U.S and utilized convenience sampling. However,
13 given the large sample size of MSM who responded to our survey and the similarity in the
14 proportion of ethnic/racial minorities among our respondents to that of the latest US Census,
15 there is an increased likelihood that our findings may be generalizable. Asking about potential
16 interest in various prevention strategies is also not equivalent to documenting uptake and
17 adherence to those strategies, were they to become available.
18
19

20
21 Data for this analysis came from a preliminary screening for a larger study on HIV prevention,
22 Connecting Latinos en Pareja, causing limitations in the variables that could be included during
23 data collection. Questions regarding childhood sexual abuse were included in order to further
24 expand the research team's previous research with the intention of exploring intimate partner
25 violence in the formal study itself. Additionally, relevant variables to the immigrant community,
26 including history of incarceration and visa status are anticipated to be incorporated in future
27 surveys within the research team's future formal studies. Consequently, the full range of
28 variables/predictors that would be included for a comprehensive analysis were not part of the
29 preliminary screening. However, future papers from this research team will be able to fill in the
30 analysis gaps that are present in the study. Additionally we hope to conduct future surveys that
31 are able to investigate how interest in different biomedical tools relate to an individual's interest
32 in and adherence to standard oral PrEP.
33
34
35
36
37
38

39 More research is needed to understand intended and actual usage of biomedical prevention tools
40 globally among individuals whose sexual behaviors may expose them to HIV. Additionally,
41 although this study documented several significant associations between child sexual abuse and
42 interest in implant and injection prevention methods, these data do not reveal the causes or logics
43 behind such associations. Qualitative and mixed methods investigations are warranted to further
44 investigate connections among exposure to violence in youth and adulthood, approaches to
45 navigating sexual consent and boundaries, and HIV/STI prevention strategies among MSM.
46
47
48

49 **CONCLUSIONS**

50

51
52 Biomedical prevention tools – both existing and new potential products that could become
53 available in the market – have the potential to profoundly impact the global HIV epidemic.
54 Although challenges will certainly arise, including securing adherence and access, this is true for
55
56
57
58
59
60

1
2
3 all prevention methods including those which have had a demonstrable impact on HIV infection
4 rates such as PrEP and condoms. Our study shows a high desirability of four biomedical
5 prevention tools not currently available in the market – rectal douche, dissolvable implant,
6 removable implant, and injection – among a sample of men who have sex with men who could
7 potentially benefit from these given their sexual risk profiles. This desirability transcends
8 demographic categories including race, age, and socioeconomic status. Methods that move HIV
9 prevention from interpersonal sexual encounters to individual medical appointments may be
10 particularly valuable for those who have experienced sexual abuse. Transitioning HIV prevention
11 to individual medical appointments means increasing access to biomedical interventions that go
12 beyond oral PrEP and can include those investigated in our study, such as implants and
13 injections.
14
15
16
17
18

19 **Acknowledgments** We would like to thank all the study participants for their time and effort.
20 We thank our research assistants for their exceptional work interviewing research participants.
21 We gratefully acknowledge the contribution of all community collaborative members, AIDS
22 service organizations, clinics, and health centers in the Northeast Corridor that supported the
23 recruitment of study participants.
24
25
26

27 **Contributors:**

28 Design and data collection: OM, OV, AI, and MP.

29 Analysis and interpretation: OM and EL.

30 Drafting the manuscript: ACD, JAB, JJ, RB, MS, AR, EW, SR, AT, LM, OV, AI, MP, RD, AC,
31 and MIF.
32
33
34

35 **Competing interests:** None declared.
36
37

38 **Funding:** This work was supported by the Centers for Disease Control and Prevention under a
39 grant from the Minority HIV and AIDS Research Initiative (MARI 1U01PS005124; PI:
40 Martinez).
41
42

43 **Data Sharing:** Due to confidentiality and sensitivity issues, the data will be shared upon request
44 and through a controlled access repository.
45
46

47 **Disclaimer:** The views expressed in this presentation are those of the authors and not necessarily
48 those of the Centers for Disease Control and Prevention.
49
50

51 **Ethics approval:** The Temple University Institutional Review Board approved the current study
52 (IRB #24120).
53
54
55
56
57
58
59
60

References

1. Centers for Disease Control and Prevention, *HIV Surveillance Report, 2017*. Available at: <http://www.cdc.gov/hiv/library/reports/surveillance/>, 2018. **vol. 29**.
2. Satcher Johnson, A., R. Song, and H.I. Hall, *Estimated HIV Incidence, Prevalence, and Undiagnosed Infections in US States and Washington, DC, 2010-2014*. Journal Of Acquired Immune Deficiency Syndromes (1999), 2017. **76(2)**: p. 116-122.
3. Hess, K.L., et al., *Lifetime risk of a diagnosis of HIV infection in the United States*. Annals Of Epidemiology, 2017. **27(4)**: p. 238-243.
4. Stephenson, R. and C. Finneran, *Receipt and Perpetration of Intimate Partner Violence and Condomless Anal Intercourse Among Gay and Bisexual Men in Atlanta*. AIDS & Behavior, 2017. **21(8)**: p. 2253-2260.
5. Muñoz-Laboy, M., et al., *Syndemic Conditions Reinforcing Disparities in HIV and Other STIs in an Urban Sample of Behaviorally Bisexual Latino Men*. Journal Of Immigrant And Minority Health, 2018. **20(2)**: p. 497-501.
6. Martinez, O., et al., *Syndemic factors associated with adult sexual HIV risk behaviors in a sample of Latino men who have sex with men in New York City*. Drug And Alcohol Dependence, 2016. **166**: p. 258-262.
7. Bauermeister, J., et al., *Where You Live Matters: Structural Correlates of HIV Risk Behavior Among Young Men Who Have Sex with Men in Metro Detroit*. AIDS & Behavior, 2015. **19(12)**: p. 2358-2369.
8. Hosek, S.G., et al., *The acceptability and feasibility of an HIV preexposure prophylaxis (PrEP) trial with young men who have sex with men*. Journal Of Acquired Immune Deficiency Syndromes (1999), 2013. **62(4)**: p. 447-456.
9. Grant, R.M., et al., *Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men*. New England Journal of Medicine, 2010. **363(27)**: p. 2587-2599.
10. Baeten, J.M., et al., *Antiretroviral prophylaxis for HIV prevention in heterosexual men and women*. The New England Journal of Medicine, 2012. **367(5)**: p. 399-410.
11. Jiwatram-Negrón, T. and N. El-Bassel, *Systematic Review of Couple-Based HIV Intervention and Prevention Studies: Advantages, Gaps, and Future Directions*. AIDS & Behavior, 2014. **18(10)**: p. 1864-1887.
12. Cohen, M.S., et al., *Prevention of HIV-1 Infection with Early Antiretroviral Therapy*. New England Journal of Medicine, 2011. **365(6)**: p. 493-505.
13. Rodger, A.J., et al., *Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy*. JAMA, 2016. **316(2)**: p. 171-181.
14. *Risk of HIV transmission through condomless sex in MSM couples with suppressive ART: The PARTNER2 Study extended results in gay men*. AIDS & Hepatitis Digest, 2018. **5(4)**: p. 3-5.
15. Bauermeister, J.A., et al., *PrEP awareness and perceived barriers among single young men who have sex with men*. Curr HIV Res, 2013. **11(7)**: p. 520-7.

16. World Health Organization, *Guideline on When to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV*. 2015, World Health Organization: Geneva, Switzerland.
17. Centers for Disease Control and Prevention, *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014: A Clinical Practice Guideline*. 2014, US Public Health Service.
18. Serota, D.P., et al., *Beyond the Biomedical: Preexposure Prophylaxis Failures in a Cohort of Young Black Men Who Have Sex With Men in Atlanta, Georgia*. *Clinical Infectious Diseases*, 2018. **67**(6): p. 965-970.
19. Page, K.R., et al., *Promoting pre-exposure prophylaxis to prevent HIV infections among sexual and gender minority Hispanics/Latinxs*. *AIDS Education and Prevention*, 2017. **29**(5): p. 389-400.
20. Taggart T, Liang Y, Pina P, Albritton T. Awareness of and willingness to use PrEP among Black and Latinx adolescents residing in higher prevalence areas in the United States. *PloS one*. 2020 Jul 6;15(7):e0234821.
21. Arnold, E.A., G.M. Rebhook, and S.M. Kegeles, *'Triply cursed': racism, homophobia and HIV-related stigma are barriers to regular HIV testing, treatment adherence and disclosure among young Black gay men*. *Culture, Health & Sexuality*, 2014. **16**(6): p. 710-722.
22. Pérez-Figueroa, R.E., et al., *Acceptability of PrEP Uptake Among Racially/Ethnically Diverse Young Men Who Have Sex With Men: The P18 Study*. *AIDS Education & Prevention*, 2015. **27**(2): p. 112-125.
23. St. Lawrence, J.S., et al., *Measuring perceived barriers to condom use: Psychometric evaluation of the Condom Barriers Scale*. *Assessment*, 1999. **6**(4): p. 391-404.
24. Crosby, R., et al., *Negative perceptions about condom use in a clinic population: comparisons by gender, race and age*. *International Journal Of STD & AIDS*, 2013. **24**(2): p. 100-105.
25. Biello, K.B., et al., *MSM at Highest Risk for HIV Acquisition Express Greatest Interest and Preference for Injectable Antiretroviral PrEP Compared to Daily, Oral Medication*. *AIDS And Behavior*, 2018. **22**(4): p. 1158-1164.
26. Hambrick HR, Park SH, Goedel WC, Morganstein JG, Kreski NT, Mgbako O, Duncan DT. Rectal douching among men who have sex with men in Paris: implications for HIV/STI risk behaviors and rectal microbicide development. *AIDS and Behavior*. 2018 Feb;22(2):379-87.
27. Carballo-Diéguez, A., et al., *The Use of Rectal Douches among HIV-uninfected and Infected Men who Have Unprotected Receptive Anal Intercourse: Implications for Rectal Microbicides*. *AIDS & Behavior*, 2008. **12**(6): p. 860-866.
28. Carballo-Diéguez, A., et al., *Why rectal douches may be acceptable rectal-microbicide delivery vehicles for men who have sex with men*. *Sexually Transmitted Diseases*, 2010. **37**(4): p. 228-233.
29. Carballo-Diéguez, A., et al., *Rectal Douching Associated with Receptive Anal Intercourse: A Literature Review*. *AIDS And Behavior*, 2018. **22**(4): p. 1288-1294.
30. Montgomery ET, Atujuna M, Krogstad E, Hartmann M, Ndwayana S, O'Rourke S, Bekker LG, van der Straten A, Minnis AM. The invisible product: preferences for sustained-release, long-acting pre-exposure prophylaxis to hiv among south african youth. *Journal of acquired immune deficiency syndromes (1999)*. 2019 Apr 15;80(5):542.

31. Weld ED, Flexner C. Long-acting implants to treat and prevent HIV infection. *Current Opinion in HIV and AIDS*. 2020 Jan;15(1):33.
32. Cobb DA, Smith NA, Edagwa BJ, McMillan JM. Long-acting approaches for delivery of antiretroviral drugs for prevention and treatment of HIV: a review of recent research. *Expert opinion on drug delivery*. 2020 Sep 1;17(9):1227-38.
33. Li L, Johnson LM, Krovi SA, Demkovich ZR, van der Straten A. Performance and stability of tenofovir Alafenamide formulations within subcutaneous biodegradable implants for HIV pre-exposure prophylaxis (PreP). *Pharmaceutics*. 2020 Nov;12(11):1057.
34. Schlesinger, E., Johengen, D., Luecke, E., Rothrock, G., McGowan, I., van der Straten, A., & Desai, T. (2016). A tunable, biodegradable, thin-film polymer device as a long-acting implant delivering tenofovir alafenamide fumarate for HIV pre-exposure prophylaxis. *Pharmaceutical research*, 33(7), 1649-1656.
35. Beymer MR, Holloway IW, Pulsipher C, Landovitz RJ. Current and future PrEP medications and modalities: on-demand, injectables, and topicals. *Current hiv/aids Reports*. 2019 Aug;16(4):349-58.
36. McGowan I, Dezzutti CS, Siegel A, Engstrom J, Nikiforov A, Duffill K, Shetler C, Richardson-Harman N, Abebe K, Back D, Else L. Long-acting rilpivirine as potential pre-exposure prophylaxis for HIV-1 prevention (the MWRI-01 study): an open-label, phase 1, compartmental, pharmacokinetic and pharmacodynamic assessment. *The Lancet HIV*. 2016 Dec 1;3(12):e569-78.
37. Walensky RP, Jacobsen MM, Bekker LG, Parker RA, Wood R, Resch SC, Horstman NK, Freedberg KA, Paltiel AD. Potential clinical and economic value of long-acting preexposure prophylaxis for South African women at high-risk for HIV infection. *The Journal of infectious diseases*. 2016 May 15;213(10):1523-31.
38. Martinez, O., et al., *A couple-based HIV prevention intervention for Latino men who have sex with men: study protocol for a randomized controlled trial*. *Trials*, 2018. **19**(1): p. 1-1.
39. Brennan-Ing, M., et al., *Substance Use and Sexual Risk Differences among Older Bisexual and Gay Men with HIV*. *Behavioral Medicine*, 2014. **40**(3): p. 108-115.
40. Muñoz-Laboy, M., et al., *Syndemic Conditions Reinforcing Disparities in HIV and Other STIs in an Urban Sample of Behaviorally Bisexual Latino Men*. *Journal of Immigrant & Minority Health*, 2018. **20**(2): p. 497-501.
41. Tolley EE, Zangeneh SZ, Chau G, Eron J, Grinsztejn B, Humphries H, Liu A, Siegel M, Bertha M, Panchia R, Li S. Acceptability of long-acting injectable cabotegravir (CAB LA) in HIV-uninfected individuals: HPTN 077. *AIDS and Behavior*. 2020 Sep;24(9):2520-31.
42. Kinsler JJ, Galea JT, Lama JR, Segura P, Peinado J, Casapia M, Ortiz A, Nadjat-Haiem C, Montano SM, Sanchez J. Rectal douching among Peruvian men who have sex with men, and acceptability of a douche-formulated rectal microbicide to prevent HIV infection. *Sexually transmitted infections*. 2013 Feb 1;89(1):62-.
43. Ogunbajo A, Tsai AC, Kanki PJ, Mayer KH. Acceptability of and Preferences for Long-Acting Injectable HIV PrEP and Other PrEP Modalities among Sexual Minority Men in Nigeria, Africa. *AIDS and Behavior*. 2022 Jan 21:1-3.2

- 1
2
3 44. Galea JT, Kinsler JJ, Imrie J, Nureña CR, Sánchez J, Cunningham WE. Rectal douching
4 and implications for rectal microbicides among populations vulnerable to HIV in South
5 America: a qualitative study. *Sexually transmitted infections*. 2014 Feb 1;90(1):33-5.
6
7 45. Pleuhs B, Quinn KG, Walsh JL, Petroll AE, John SA. Health care provider barriers to
8 HIV pre-exposure prophylaxis in the United States: a systematic review. *AIDS Patient
9 Care and STDs*. 2020 Mar 1;34(3):111-23.
10
11 46. Lau JY, Wong NS, Lee KC, Kwan TH, Lui GC, Chan DP, Lee SS. What makes an
12 optimal delivery for PrEP against HIV: A qualitative study in MSM. *International journal
13 of STD & AIDS*. 2022 Jan 2:09564624211060824.
14
15 47. Sales JM, Cwiak C, Haddad LB, Phillips A, Powell L, Tamler I, Sheth AN. Impact of
16 PrEP training for family planning providers on HIV prevention counseling and patient
17 interest in PrEP in Atlanta, Georgia. *Journal of acquired immune deficiency syndromes
18 (1999)*. 2019 Aug 1;81(4):414.
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Sample Characteristics (n=381)

	M (SD) or N (%)
<i>Age (n=376)</i>	30.84 (10.89)
<i>Identify as Latino/Hispanic/Afro-Latino (n=379)</i>	186 (49%)
<i>Race (mutually exclusive, n=375)</i>	
Black Only	98 (26%)
Asian, Asian American, Pacific Islander Only	9 (2%)
Native American, American Indian, Alaska Native Only	6 (2%)
White Only	106 (28%)
Other and/or Multiracial	156 (42%)
<i>Biomedical Prevention Tools</i>	
PrEP Use in Past 90 Days	85 (22%)
Interested in Rectal Douche for HIV Prevention ¹	300 (79%)
Interested in Dissolvable Implant for HIV Prevention ¹	229 (60%)
Interested in Removable Implant for HIV Prevention ¹	242 (64%)
Interested in Injection for HIV Prevention ¹	300 (79%)
<i>Sexual Behavior, General</i>	
Anal Sex with Man, Past 90 Days (n=380)	309 (81%)
Total Anal Sex Partners, Past 90 Days (n=304)	4.86 (8.10)
<i>Sexual Risk Behavior, Primary Relationship</i>	
Any Anal Sex, Past 90 Days (n=217)	196 (90%)
Unprotected Anal Sex, Past 90 Days (n=195)	138 (71%)
<i>Sexual Risk Behavior, Outside Primary Relationship</i>	
Any Anal Sex, Past 90 Days (n=217)	126 (58%)
Unprotected Anal Sex, Past 90 Days (n=201)	117 (58%)
<i>Child Sexual Abuse, Before age 14</i>	
Someone tried to touch me in a sexual way, or make me touch them (n=379)	166 (44%)
Somone threatened to hurt me or tell lies about me unless I did something sexual with them (n=379)	69 (18%)
Someone tried to make me do sexual things or watch sexual things (n=377)	132 (35%)
Someone molested me (n=376)	114 (30%)
Someone on the internet tried to get me to talk about sex when I did not want to (n=377)	69 (18%)
Someone on the internet tried to get me to do sexual things when I did not want to (n=379)	69 (18%)
I believe that I was sexually abused (n=375)	109 (29%)
<i>Answered yes to at least one CSA question (n=380)</i>	206 (54%)
<i>Protective Factors</i>	
Health Insurance (n=380)	325 (86%)
Born in US (n=380)	314 (82%)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Bachelor's Degree or Higher (n=377)	124 (33%)
Employed Fulltime	187 (49%)

¹Operationalized as indicating "definite" or "probable" interest in using this prevention method.

For peer review only

Interest in Using Biomedical Prevention Tools (n=381)

	<i>Definitely Not Interested</i>	<i>Probably Not Interested</i>
Rectal Douche	33 (9%)	48 (13%)
Dissolvable Implant	69 (18%)	83 (22%)
Removable Implant	55 (14%)	84 (22%)
Injection	30 (8%)	51 (13%)

For peer review only

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

	<i>Probably Interested</i>	<i>Definitely Interested</i>
	117 (31%)	183 (48%)
	111 (29%)	118 (31%)
	111 (29%)	131 (34%)
	110 (29%)	190 (50%)

For peer review only

Bivariate Analyses (n=381)

	<i>Rectal Douche</i>	
	Not Interested M (SD) or N (%)	Interested M (SD) or N (%)
<i>Age (n=376)</i>	30.69 (9.37)	30.88 (11.28)
<i>Identify as Latino/Hispanic/Afro-Latino (n=379)</i>	34 (42%)	152 (51%)
<i>Race (mutually exclusive, n=375)</i>		
Black Only	23 (29%)	75 (25%)
Asian, Asian American, Pacific Islander Only	3 (4%)	6 (2%)
Native American, American Indian, Alaska Native Only	0 (0%)	6 (2%)
White Only	24 (30%)	82 (29%)
Other and/or Multiracial	30 (38%)	126 (43%)
<i>PrEP Use in Past 90 Days</i>	24 (30%)	61 (20%)
<i>Sexual Behavior, General</i>		
Anal Sex with Man, Past 90 Days (n=380)	68 (84%)	241 (81%)
Total Anal Sex Partners, Past 90 Days (n=304)	4.79 (6.23)	4.88 (8.56)
<i>Sexual Risk Behavior, Primary Relationship</i>		
Any Anal Sex, Past 90 Days (n=217)	36 (92%)	160 (90%)
Unprotected Anal Sex, Past 90 Days (n=195)	26 (72%)	112 (70%)
<i>Sexual Risk Behavior, Outside Primary Relationship</i>		
Any Anal Sex, Past 90 Days (n=217)	20 (51%)	106 (59%)
Unprotected Anal Sex, Past 90 Days (n=201)	23 (58%)	94 (58%)
<i>Child Sexual Abuse, Before age 14</i>		
Someone tried to touch me in a sexual way, or make me touch them (n=379)	36 (45%)	130 (44%)
Someone threatened to hurt me or tell lies about me unless I did something sexual with them (n=379)	16 (20%)	53 (18%)
Someone tried to make me do sexual things or watch sexual things (n=377)	25 (31%)	107 (36%)
Someone molested me (n=376)	22 (28%)	92 (31%)
Someone on the internet tried to get me to talk about sex when I did not want to (n=377)	14 (18%)	55 (19%)
Someone on the internet tried to get me to do sexual things when I did not want to (n=379)	13 (16%)	56 (19%)
I believe that I was sexually abused (n=375)	22 (28%)	87 (29%)
<i>Answered yes to at least one CSA question (n=380)</i>	44 (54%)	162 (54%)
<i>Protective Factors</i>		
Health Insurance (n=380)	74 (91%)	251 (84%)
Born in US (n=380)	70 (86%)	244 (82%)
Bachelor's Degree or Higher (n=377)	38 (48%)	86 (29%)**
Employed Fulltime	47 (58%)	140 (47%)

*p<.05, **p<.01, ***p<.001 in chi squared analysis

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

<i>Dissolvable Implant</i>		<i>Removable Implant</i>	
Not Interested	Interested	Not Interested	Interested
M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)
31.00 (11.21)	30.73 (10.69)	30.96 (10.92)	30.77 (10.89)
68 (45%)	118 (52%)	59 (43%)	127 (53%)
42 (28%)	56 (25%)	37 (27%)	61 (26%)
4 (3%)	5 (2%)	6 (4%)	3 (1%)
1 (1%)	5 (2%)	1 (%)	5 (2%)
46 (31%)	60 (27%)	42 (31%)	64 (27%)
57 (38%)	99 (44%)	51 (37%)	105 (44%)
33 (22%)	52 (23%)	29 (21%)	56 (23%)
121 (80%)	188 (83%)	113 (82%)	196 (81%)
4.25 (4.99)	5.24 (9.55)	4.17 (4.82)	5.24 (9.44)
78 (89%)	118 (92%)	73 (94%)	123 (89%)
54 (69%)	84 (72%)	55 (73%)	83 (68%)
54 (61%)	72 (56%)	47 (60%)	79 (57%)
53 (65%)	64 (54%)	42 (58%)	75 (58%)
55 (37%)	111 (49%)*	50 (36%)	116 (48%)*
20 (13%)	49 (22%)*	18 (13%)	51 (21%)
41 (27%)	91 (40%)*	35 (25%)	97 (41%)**
36 (24%)	78 (34%)*	35 (26%)	79 (33%)
20 (13%)	49 (22%)*	20 (14%)	49 (21%)
22 (15%)	47 (21%)	21 (15%)	48 (20%)
32 (21%)	77 (34%)**	31 (22%)	78 (33%)*
71 (47%)	135 (59%)	62 (44%)	144 (60%)**
134 (89%)	191 (83%)	120 (87%)	205 (85%)
128 (84%)	186 (82%)	118 (86%)	196 (81%)
44 (29%)	80 (35%)	36 (26%)	88 (36%)*
76 (50%)	111 (49%)	71 (51%)	116 (48%)

<i>Injection</i>	
Not Interested	Interested
M (SD) or N (%)	M (SD) or N (%)
30.30 (10.90)	30.99 (10.90)
34 (43%)	152 (51%)
17 (22%)	81 (27%)
4 (5%)	5 (2%)
0 (0%)	6 (2%)
24 (30%)	82 (28%)
34 (43%)	122 (41%)
12 (15%)	73 (24%)
60 (75%)	249 (83%)
4.05 (5.24)	5.05 (8.63)
38 (83%)	158 (92%)*
28 (74%)	110 (70%)
28 (61%)	98 (57%)
23 (61%)	94 (58%)
25 (31%)	141 (47%)**
12 (15%)	57 (19%)
15 (19%)	117 (39%)**
17 (21%)	97 (33%)*
12 (15%)	57 (19%)
11 (14%)	58 (19%)
15 (19%)	94 (32%)
35 (43%)	171 (57%)
70 (86%)	255 (86%)
67 (84%)	247 (82%)
24 (30%)	100 (34%)
37 (46%)	150 (50%)

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	4-5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	6
		(d) If applicable, describe analytical methods taking account of sampling strategy	6
		(e) Describe any sensitivity analyses	6
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	6
Outcome data	15*	Report numbers of outcome events or summary measures	6-7
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-7

		(b) Report category boundaries when continuous variables were categorized	6-7
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6-7
Discussion			
Key results	18	Summarise key results with reference to study objectives	7-8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8-9
Generalisability	21	Discuss the generalisability (external validity) of the study results	9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	11

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

More than Just Oral PrEP: Exploring Interest in Rectal Douche, Dissolvable Implant, Removable Implant, and Injection HIV Prevention Approaches among Racially Diverse Men Who Have Sex With Men in the Northeast Corridor

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-063474.R1
Article Type:	Original research
Date Submitted by the Author:	02-Jun-2022
Complete List of Authors:	Martinez, Omar; Temple University, Levine, Ethan; Temple University, College of Liberal Arts; Temple University Munoz-Laboy, Miguel; Stony Brook University, School of Social Welfare Carballo-Diéguez, Alex; Columbia University Medical Center, HIV Center Bauermeister, José; University of Pennsylvania School of Nursing, Family and Community Health Chacon, Alexi; Temple University, School of Social Work Jacobson, Jeffrey; Temple University School of Medicine Bettiker, Robert; Temple University School of Medicine Sutton, Madeline; Morehouse School of Medicine Rudolph, Abby; Temple University College of Public Health, Wu, Elwin; Columbia University School of Social Work Rhodes, S; Wake Forest School of Medicine Tanner, Amanda; University of North Carolina at Greensboro School of Health and Human Sciences, Mann, Lilli; Wake Forest University, Valentin, Omar; University of Miami Ilarraza, Ariel; Temple University Pardes, Mariana; Temple University Davison, Robin; Temple University Fernandez, Maria; Nova Southeastern University
Primary Subject Heading:	HIV/AIDS
Secondary Subject Heading:	Evidence based practice
Keywords:	HIV & AIDS < INFECTIOUS DISEASES, PUBLIC HEALTH, SEXUAL MEDICINE



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

BMJ Open : first published as 10.1136/bmjopen-2022-063474 on 18 August 2022. Downloaded from <http://bmjopen.bmj.com/> on July 12, 2024 by guest. Protected by copyright.



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3 **More than Just Oral PrEP: Exploring Interest in Rectal Douche, Dissolvable Implant,**
4 **Removable Implant, and Injection HIV Prevention Approaches among Racially Diverse**
5 **Men Who Have Sex With Men in the Northeast Corridor**
6
7

8 **Keywords:** biomedical HIV prevention approaches, Men who have sex with men, rectal douche,
9 dissolvable implant, removable implant, injection
10
11

12 **Word Count:** 3890
13

14
15 Omar Martinez, JD, MPH, MS
16 Temple University, School of Social Work
17 Philadelphia, United States
18

19
20 Ethan Levine, PhD
21 Temple University
22 Philadelphia, United States
23

24
25 Miguel Muñoz-Laboy DrPH
26 Associate Professor, Stony Brook University
27 Stony Brook, United States
28

29
30 Alex Carballo-Diéguez, PhD
31 Columbia University Medical Center, HIV Center
32 New York, United States
33

34
35 Jose Bauermeister PhD
36 University of Pennsylvania School of Nursing, Family and Community Health
37 Philadelphia, Pennsylvania
38

39
40 Alexi Chacon, MSc
41 Temple University
42 Philadelphia, United States
43

44
45 Jeffrey Jacobson, MD
46 Temple University, Lewis Katz School of Medicine
47 Philadelphia, United States
48

49
50 Robert Bettiker, MD
51 Temple University, Lewis Katz School of Medicine
52 Philadelphia, United States
53

54
55 Madeline Sutton, MD
56 Morehouse School of Medicine
57 Atlanta, United States
58
59
60

1
2
3 Abby Rudolph, PhD
4 Temple University, College of Public Health
5 Philadelphia, United States
6

7
8 Elwin Wu, PhD
9 Columbia University, School of Social Work
10 New York, United States
11

12 Scott Rhodes, PhD
13 Wake Forest University School of Medicine, Department of Social Sciences and Health Policy
14 Winston-Salem, United States
15

16
17 Amanda Tanner, PhD
18 University of North Carolina-Greensboro, Department of Public Health Education
19 Greensboro, United States
20

21
22 Lilli Mann, MPH
23 Wake Forest University
24 Wake Forest, United States
25

26 Omar Valentin, MPH
27 University of Miami
28 Miami, United States
29

30
31 Ariel Ilarraza
32 Temple University
33 Philadelphia, United States
34

35 Mariana Pardes
36 Temple University
37 Philadelphia, United States
38

39
40 Robin Davison, JD
41 Temple University
42 Philadelphia, United States
43

44
45 Maria Fernandez, PhD
46 Nova Southeastern University
47 Fort Lauderdale, United States
48

49 Corresponding Author:
50 Alexi Chacon, MSc
51 Address: 910 Fitzwater Street, Apt. B
52 Philadelphia, PA 19147
53 Email: alexix213@gmail.com
54 Cell: 818-456-2066 Fax: N/A
55
56
57
58
59
60

Abstract:

Objectives HIV scholars and practitioners have worked to expand strategies for prevention among marginalized populations who are disproportionately impacted by the epidemic, such as racial minority men who have sex with men (MSM). Given this urgency, the objective of this study was to assess interest in biomedical prevention strategies.

Methods This exploratory & cross sectional study investigated interest in four biomedical prevention tools – rectal douche, dissolvable implant, removable implant, and injection – among a racially diverse sample of MSM from the Northeast Corridor region between Philadelphia and Trenton. Data was collected as part of screening for *Connecting Latinos en Pareja*, a couples-based HIV prevention intervention for Latino MSM and their partners.

Results A total of 381 individuals participated in the screener and provided information about their interest in bio tools. Approximately 26% of participants identified as Black, 28% as White, and 42% as “other” or multiracial; 49% identified as Latino. A majority (54%) reported some form of child sexual abuse. Of those participants who reported being in a primary relationship (n=217), two thirds reported unprotected anal sex within that relationship over the past 90 days (n=138, 64%) and approximately half (n=117, 54%) reported unprotected anal sex outside of the relationship in this period. A majority of participants reported interest in all bio tools assessed, including dissolvable implants (60%), removable implants (64%), rectal douching (79%), and an injection (79%). Although interest in bio tools was broadly unassociated with demographics and sexual risk behaviors, analyses revealed significant associations between reports of child sexual abuse and interest in implant and injection methods.

Conclusions The authors recommend investing in these prevention methods, particularly rectal douching and injection, as a means of preventing HIV among racial minority MSM. Given the interest in biomedical prevention tools, future studies should explore potential strategies for adherence.

Key words: biomedical HIV prevention approaches, rectal douche, dissolvable implant, removable implant, injection, men who have sex with men

Strengths & Limitations:

- Data for this study came from a preliminary screening for a larger study on HIV prevention and thus analysis is limited to the variables and demographics that were collected in the screening.
- The sample is limited to individuals in the northeast corridor, which may impact generalizability of findings.

- This study collected data on different forms of childhood sexual abuse and determined its link to HIV prevention bio tool preferences.

INTRODUCTION

In recent years, considerable advances have been made in decreasing overall HIV infection and transmission rates in the United States. However, the HIV epidemic continues to disproportionately impact racial and ethnic minorities and sexual and gender minority communities. Data has revealed an urgent national emergency as “The Invisible US Hispanic/Latino HIV Crisis.” [1] While the number of new cases decreased in 2019 for gay and bisexual Black and white men, HIV infection rates in gay and bisexual Latinx men increased from 6,800 new cases/year in 2010 to 7,900/year in 2019.[2] Seven in ten new HIV diagnoses occur among gay and bisexual men, even though they comprise about 2% of the US population[3]. Among gay and bisexual men, racial and ethnic minorities continue to be disproportionately impacted by the epidemic.

If current trends continue, 1 in 4 Latino gay and bisexual men and 1 in 2 Black gay and bisexual men will be diagnosed with HIV during their lifetimes [4]. Moreover, HIV surveillance data provides minimal information detailing which social determinants of health may impact risk behaviors, healthcare use and access [5-8]. Social determinants of health that should be examined include socioeconomic status, social support, and exposure to violence (5-8). It is thus difficult, if not impossible, to determine the extent to which populations whose HIV risk is exacerbated by these and other interacting syndemic factors benefit from overall declines in diagnoses.

Biomedical prevention approaches, including pre-exposure prophylaxis (PrEP) for HIV negative individuals [8-10], treatment as prevention (TasP) for people living with HIV [11-14], and condoms for both HIV negative and people living with HIV, have emerged as effective biomedical prevention tools to address the global HIV epidemic among men who have sex with men (MSM). PrEP, for example, is an effective HIV prevention tool [15], recommended by the World Health Organization [16] and the Centers for Disease Control [17] for persons at substantial risk for HIV infection. Some of the recent progress in curbing HIV infection and transmission has been attributed to increases in PrEP use within and beyond the U.S. However, challenges remain among those who would benefit from PrEP, and use remains somewhat low, particularly among Black and Latino MSM [18, 19].

1
2
3 A number of explanations have been proposed for low PrEP uptake amongst racial minority
4 MSM, including (mis)perception of HIV infection risk, concerns about medication side effects,
5 low health literacy, concerns about stigma, access to affordable healthcare, and access to care
6 providers who are both knowledgeable and culturally sensitive [18, 19].
7
8

9
10 Immigration-related barriers are particularly pronounced among Latino MSM. Temporary
11 immigrants and undocumented individuals lack access to healthcare coverage under the
12 Affordable Care Act, as well as a range of social service programs that might otherwise facilitate
13 access or mitigate barriers to PrEP use [19]. Biomedical interventions that require less
14 interactions with a healthcare system could be essential in improving adherence. Given recent
15 increases in anti-immigrant rhetoric, even U.S.-born individuals and documented immigrants
16 may avoid pursuing care for fear of discrimination. Concerns about stigma could be addressed by
17 culturally relevant sex education programs that are tailored to the experiences of Black and
18 Latino MSM [20].
19
20
21
22

23 Several challenges exist with prescription-based prevention products like PrEP and TasP,
24 including adherence and access to medication [21, 22]. Prevention tools such as condoms pose
25 their own challenges. Not only must condoms be present at each sexual encounter, but some at-
26 risk individuals also consider condom use disruptive or detrimental to sexual pleasure [23, 24].
27 This concern has been documented in research on racial minority MSM, including one study of
28 Latino gay couples in which a participant described community members as “tired of using
29 condoms” and in urgent need of alternative prevention methods [25: pg.11].
30
31
32
33

34 However, the following four biomedical intervention tools have the potential to address the
35 previously outlined concerns: rectal douches, dissolvable implants, removable implants, and
36 injections [25]. Not all of these biomedical tools are on the market and each intervention has
37 varying levels of effectiveness in preventing HIV transmission. If and when these methods
38 become available in the market, they could shift HIV prevention from the realm of interpersonal
39 sexual encounters to the realm of individual healthcare. Such a shift may help individuals feel
40 more in control of their bodies and decision-making.
41
42
43

44 For example, rectal douches present a feasible opportunity to also apply a topical rectal
45 microbicide. Research has shown that MSM who douche also have an increased likelihood of
46 applying a rectal microbicide gel [26]. Many individuals who engage in anal intercourse use
47 cleansing douches regularly before and even afterwards [27-29]. Preventive rectal douching
48 might thus align relatively easily with those individuals’ existing sexual practices, rather than
49 place additional demands in the form of daily medication or changes to sexual communication
50 and behavior (as may be required for condom use, which must be negotiated with each anal sex
51 partner before or during each sexual encounter). There is a desire for “invisible” biomedical
52 interventions that do not interfere with intercourse and help protect against stigma because of
53
54
55
56
57
58
59
60

1
2
3 their invisibility from family members, partners, household members and community members
4 [30].
5
6

7 Removable implants are still in the early stages of clinical development but are a promising
8 method towards ensuring that individuals receive both consistent and on-time drug release [31-
9 32]. Subcutaneous implants could potentially deliver the appropriate dosage of antiretroviral
10 drugs for 12 months or longer with a single implant [31]. There are implants in the pre-clinical
11 stage that are looking at combining medications that prevent against other STIs, including the
12 Hepatitis B virus [31].
13
14

15
16 The benefits of implants include fewer interactions with the healthcare system, easy removal and
17 lower dose/day with no oral medication required [31]. Similar medical technologies are being
18 researched in biodegradable implants that can breakdown over time and be expelled from the
19 body without a healthcare interaction [33-34]. Both removable and dissolvable implants require
20 either single or periodic medical appointments, which may be more manageable for some
21 individuals than daily medications and can help add to the medication's "invisibility."
22
23

24
25 Injectable antiretroviral medication requires less uptake than rectal douching but more healthcare
26 interactions than dissolvable and removable implants. There is high acceptability among users
27 despite the required 8-week interval injections [35]. Long-acting PrEP in an injectable form has
28 been tested in Phase 1 and Phase 2 clinical trials. Both phases found comparable efficacy to
29 standard PrEP [36-37]. Phase IIb/III investigated the efficacy and safety of long-acting injectable
30 PrEP (cabotegravir) in the following populations: HIV-negative MSM, transgender women and
31 cisgender women at risk of sexually acquiring HIV. The most recent two phases of this clinical
32 trial found that injectable PrEP is more effective at preventing the transmission of HIV in the
33 aforementioned populations compared to a daily oral emtricitabine/tenofovir disoproxil fumarate
34 (TDF/FTC) tablet [38-39].
35
36
37
38
39

40 This paper aims to address the following question: amongst racially diverse MSM, what factors
41 are correlated with interest in four biomedical HIV prevention methods including dissolvable
42 implants, removable implants, rectal douching and injection. We used these findings to explore
43 promising approaches for HIV prevention among MSM who face an elevated risk of HIV
44 infection and transmission. Additionally, this paper looks at demographic characteristics and
45 sexual risk behaviors among a racially diverse sample of MSM.
46
47
48

49 **METHODS**

50 **Setting and recruitment**

51
52
53
54
55
56
57
58
59
60

1
2
3 This exploratory cross-sectional study investigated interest in four biomedical prevention tools –
4 rectal douches, dissolvable implants, removable implants, and injections - among a racially
5 diverse sample of MSM from the Northeast Corridor region between Philadelphia and Trenton.
6 Data were collected as part of screening for *Connecting Latinos en Pareja*, a couples-based HIV
7 prevention intervention for Latino MSM and their partners. Research staff invited participants to
8 complete a preliminary screening through online social networking apps and social media
9 platforms including Grindr, Facebook, Instagram and the online profiles of AIDS service
10 organizations in the region. Research assistants posted study flyers on our social media profiles
11 as another recruitment strategy. These flyers included broad and general information about the
12 study including self-identifying as MSM and details about participant incentives. Research
13 methods have been published elsewhere [40]. This study was approved by the Institutional
14 Review Board of Temple University in Philadelphia, PA, USA.
15
16
17
18
19

20 **Procedures**

21
22
23 Participants took an average of 20 min to complete the anonymous online screening survey. The
24 screening survey was programmed in REDCap, a secure questionnaire development, data entry
25 and analysis platform. Participants were recruited through community-based organizations and
26 online social venues, including Facebook, Grindr, Twitter and Instagram. The first screen of the
27 online survey briefly described the screening process and asked potential participants to provide
28 consent for screening.
29
30

31
32 For this analysis, inclusion in the sample required that participants complete questions gaging
33 interest in biomedical prevention tools. These questions appeared at the end of the survey, and
34 some prospective participants in *Connecting Latinos en Pareja* declined to submit responses to
35 those specific questions and thus, were not included in the sample. Although this resulted in
36 notable loss (out of 533 participants, 381 completed bio tool questions), subsequent analyses did
37 not find substantial demographic differences between the overall sample and those participants
38 retained for this analysis.
39
40
41
42

43 **Measures**

44
45 Sociodemographic data that was collected in the study included age, race/ethnicity, health
46 insurance status, country of birth, education, and employment status. We also inquired about
47 history of child sexual abuse prior to age 14, using six individual questions (e.g., “someone tried
48 to touch me in a sexual way, or make me touch them;” “I believe that I was sexually abused”).
49
50

51
52 Sexual behavior over the past 90 days was assessed in terms of overall reports of anal sex with
53 men (yes/no), total anal sex partners, any anal sex within primary relationships (yes/no),
54
55
56
57
58
59
60

1
2
3 unprotected anal sex within primary relationships (yes/no), any anal sex outside primary sexual
4 relationships (yes/no), and any unprotected anal sex outside primary relationships (yes/no).
5
6

7 Participants were asked about PrEP use in the past 90 days. Finally, participants were asked how
8 interested they would be in the use of rectal douche, dissolvable implant, removable implant and
9 injection for HIV prevention (definitely not interested, probably not interested, probably
10 interested, definitely interested) if they become available.
11
12

13 **Statistical Analysis**

14
15
16 Sample demographic characteristics, sexual behavior in the past 90 days, PrEP use in the past 90
17 days, reports of child sexual abuse, and interest in bio tools were calculated using percentages or
18 means as appropriate. Chi-squared tests were conducted to explore associations between interest
19 in various bio tools and other variables. For bivariate analyses, we use used dichotomous
20 versions of interest in each prevention method (probably or definitely not interested vs. probably
21 or definitely interested). When reporting univariate and bivariate statistics, we only report on raw
22 data rather than imputing or making other substitutions to compensate for missing cases. Once
23 skip patterns are taken into account (e.g., only participants in primary relationships were asked
24 about sexual behavior within and outside those relationships), missing cases only resulted in
25 minor data loss (between 0.3% and 7%). All analyses were done in Stata, version 13.0.
26
27
28
29
30

31 **Patient and Public Involvement**

32
33 No patients were involved. We established a local Community Advisory Board (CAB) who met
34 quarterly throughout the study to promote community engagement and utilization of research
35 findings.
36
37

38 **RESULTS**

39 **Participant Characteristics**

40
41
42 Among 381 MSM who provided data for this exploratory analysis, approximately 26% (n=98) of
43 participants identified as Black, 28% as White (n=106), and 41% as “other” or multiracial
44 (n=156) using mutually exclusive categories for race. In a separate question on ethnicity, nearly
45 half (n=186, 49%) identified as Latino. A third of the sample (n=124, 33%) reported having
46 attained at least a bachelor’s degree. A majority (n=206, 54%) reported at least some form of
47 child sexual abuse before age 14. Of those participants who reported being in a primary
48 relationship (n=217), two thirds reported unprotected anal sex within that relationship over the
49 past 90 days (n=138, 64%) and just over half (n=117, 54%) reported unprotected anal sex outside
50 of the relationship in the past 90 days.
51
52
53
54
55
56
57
58
59
60

Interest in Biomedical Prevention Tools

A majority of participants reported probable or definite interest in all biomedical prevention tools assessed, including dissolvable implants (n=229, 60%), removable implants (n=242, 64%), rectal douching (n=300, 79%), and an injection (n=300, 79%). Approximately one fifth of participants reported at least some PrEP use in the past 90 days (n=85, 22%). Sample characteristics appear in Table 1, with more detailed information regarding interest in biomedical prevention tools in Table 2.

Table 1 Sample Characteristics (n=381)	
	M (SD) or N (%)
<i>Age (n=376)</i>	30.84 (10.89)
<i>Identify as Latino/Hispanic/Afro-Latino (n=379)</i>	186 (49%)
<i>Race (mutually exclusive, n=375)</i>	
Black Only	98 (26%)
Asian, Asian American, Pacific Islander Only	9 (2%)
Native American, American Indian, Alaska Native Only	6 (2%)
White Only	106 (28%)
Other and/or Multiracial	156 (42%)
<i>Biomedical Prevention Tools</i>	
PrEP Use in Past 90 Days	85 (22%)
Interested in Rectal Douche for HIV Prevention ¹	300 (79%)
Interested in Dissolvable Implant for HIV Prevention ¹	229 (60%)
Interested in Removable Implant for HIV Prevention ¹	242 (64%)
Interested in Injection for HIV Prevention ¹	300 (79%)
<i>Sexual Behavior, General</i>	
Anal Sex with Man, Past 90 Days (n=380)	309 (81%)
Total Anal Sex Partners, Past 90 Days (n=304)	4.86 (8.10)
<i>Sexual Risk Behavior, Primary Relationship</i>	
Any Anal Sex, Past 90 Days (n=217)	196 (90%)
Unprotected Anal Sex, Past 90 Days (n=195)	138 (71%)
<i>Sexual Risk Behavior, Outside Primary Relationship</i>	
Any Anal Sex, Past 90 Days (n=217)	126 (58%)
Unprotected Anal Sex, Past 90 Days (n=201)	117 (58%)

<i>Child Sexual Abuse, Before age 14</i>	
Someone tried to touch me in a sexual way, or make me touch them (n=379)	166 (44%)
Someone threatened to hurt me or tell lies about me unless I did something sexual with them (n=379)	69 (18%)
Someone tried to make me do sexual things or watch sexual things (n=377)	132 (35%)
Someone molested me (n=376)	114 (30%)
Someone on the internet tried to get me to talk about sex when I did not want to (n=377)	69 (18%)
Someone on the internet tried to get me to do sexual things when I did not want to (n=379)	69 (18%)
I believe that I was sexually abused (n=375)	109 (29%)
<i>Answered yes to at least one CSA question (n=380)</i>	206 (54%)
<i>Protective Factors</i>	
Health Insurance (n=380)	325 (86%)
Born in US (n=380)	314 (82%)
Bachelor's Degree or Higher (n=377)	124 (33%)
Employed Fulltime	187 (49%)
¹ Operationalized as indicating "definite" or "probable" interest in using this prevention method.	

	<i>Definitely Not Interested</i>	<i>Probably Not Interested</i>	<i>Probably Interested</i>	<i>Definitely Interested</i>
Rectal Douche	33 (9%)	48 (13%)	117 (31%)	183 (48%)
Dissolvable Implant	69 (18%)	83 (22%)	111 (29%)	118 (31%)
Removable Implant	55 (14%)	84 (22%)	111 (29%)	131 (34%)
Injection	30 (8%)	51 (13%)	110 (29%)	190 (50%)

Bivariate analyses revealed few connections between demographics and interest in various biomedical HIV prevention methods. Participants with bachelor's degrees were less likely to report interest in rectal douching (n=377, $\chi^2 = 10.48$, df=1, p<.01, n=377) and more likely to report interest in removable implants ($\chi^2 = 4.57$, df=1, p<.05, n=377) than peers who did not possess a college degree. Age, race, Latino ethnicity, health insurance, being born in the U.S., and fulltime employment were unassociated with interest in various prevention tools.

We documented a positive association between overall reports of anal sex within primary relationships in the past 90 days and interest in injections ($\chi^2 = 3.97$, df=1, p<.05, n=217). Otherwise, there were no associations between interest in biomedical interventions and the

sexual behaviors addressed here. PrEP use in the past 90 days was not associated with interest in other methods.

There were associations between reports of child sexual abuse before age 14 and for all prevention methods except for rectal douching. Interest in dissolvable implants was positively associated with the following statements: someone tried to touch me in a sexual way, or make me touch them ($\chi^2 = 5.13$, $df=1$, $p<.05$, $n=379$); someone threatened to hurt or tell lies about me unless I did something sexual ($\chi^2 = 4.15$, $df=1$, $p<.05$, $n=379$); someone tried to make me do sexual things or watch sexual things ($\chi^2 = 6.46$, $df=1$, $p<.05$, $n=377$); someone molested me ($\chi^2 = 4.43$, $df=1$, $p<.05$, $n=376$); someone on the internet tried to get me to talk about sex when I didn't want to ($\chi^2 = 4.31$, $df=1$, $p<.05$, $n=377$); and I believe I was sexually abused ($\chi^2 = 7.60$, $df=1$, $p<.01$, $n=375$). Interest in dissolvable implants was also positively associated with overall reports of child sexual abuse ($\chi^2 = 5.22$, $df=1$, $p<.05$, $n=380$).

Interest in removable implants was positively associated with the following statements: someone tried to touch me in a sexual way, or make me touch them ($\chi^2 = 5.05$, $df=1$, $p<.05$, $n=379$); someone threatened to hurt or tell lies about me unless I did something sexual ($\chi^2 = 4.07$, $df=1$, $p<.05$, $n=379$); someone tried to make me do sexual things or watch sexual things ($\chi^2 = 8.91$, $df=1$, $p<.01$, $n=377$); and I believe I was sexually abused ($\chi^2 = 4.90$, $df=1$, $p<.05$, $n=375$).

Interest in removable implants was also positively associated with overall reports of child sexual abuse ($\chi^2 = 8.15$, $df=1$, $p<.01$, $n=380$). Interest in injections was positively associated with the following statements: someone tried to touch me in a sexual way, or make me touch them ($\chi^2 = 7.00$, $df=1$, $p<.01$, $n=379$); someone tried to make me do sexual things or watch sexual things ($\chi^2 = 10.77$, $df=1$, $p<.01$, $n=377$); someone molested me ($\chi^2 = 3.96$, $df=1$, $p<.05$, $n=376$); and I believe I was sexually abused ($\chi^2 = 4.93$, $df=1$, $p<.05$, $n=375$). Interest in dissolvable implants was also positively associated with overall reports of child sexual abuse ($\chi^2 = 5.02$, $df=1$, $p<.05$, $n=380$). Table 3 below lays out our bivariate analyses.

Table 3: Bivariate Analyses (n=381)	Rectal Douche		Dissolvable Implant		Removable Implant		Injection	
	Not Interes ted	Interes ted	Not Interes ted	Interes ted	Not Interes ted	Interes ted	Not Interes ted	Interes ted
	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)	M (SD) or N (%)

<i>Age (n=376)</i>	30.69 (9.37)	30.88 (11.28)	31.00 (11.21)	30.73 (10.69)	30.96 (10.92)	30.77 (10.89)	30.30 (10.90)	30.99 (10.90)
<i>Identify as Latino/Hispanic/Afro-Latino (n=379)</i>	34 (18%)	152 (82%)	68 (36%)	118 (64%)	59 (31%)	127 (69%)	34 (18%)	152 (82%)
<i>Race (mutually exclusive, n=375)</i>								
Black Only	23 (23%)	75 (77%)	42 (42%)	56 (58%)	37 (37%)	61 (63%)	17 (17%)	81 (83%)
Asian, Asian American, Pacific Islander Only	3 (33%)	6 (67%)	4 (44%)	5 (56%)	6 (66%)	3 (34%)	4 (44%)	5 (56%)
Native American, American Indian, Alaska Native Only	0 (0%)	6 (100%)	1 (16%)	5 (84%)	1 (16%)	5 (84%)	0 (0%)	6 (100%)
White Only	24 (22%)	82 (78%)	46 (43%)	60 (57%)	42 (39%)	64 (61%)	24 (22%)	82 (78%)
Other and/or Multiracial	30 (19%)	126 (81%)	57 (36%)	99 (64%)	51 (32%)	105 (68%)	34 (21%)	122 (79%)
<i>PrEP Use in Past 90 Days</i>	24 (28%)	61 (72%)	33 (38%)	52 (62%)	29 (34%)	56 (66%)	12 (14%)	73 (86%)
<i>Sexual Behavior, General</i>								
Anal Sex with Man, Past 90 Days (n=380)	68 (22%)	241 (78%)	121 (39%)	188 (61%)	113 (36%)	196 (64%)	60 (19%)	249 (81%)
Total Anal Sex Partners, Past 90 Days (n=304)	4.79 (6.23)	4.88 (8.56)	4.25 (4.99)	5.24 (9.55)	4.17 (4.82)	5.24 (9.44)	4.05 (5.24)	5.05 (8.63)

<i>Sexual Risk Behavior, Primary Relationship</i>									
Any Anal Sex, Past 90 Days (n=217)	36 (18%)	160 (82%)	78 (39%)	118 (61%)	73 (37%)	123 (63%)	38 (19%)	158 (81%)*	
Unprotected Anal Sex, Past 90 Days (n=195)	26 (18%)	112 (82%)	54 (39%)	84 (61%)	55 (39%)	83 (61%)	28 (20%)	110 (80%)	
<i>Sexual Risk Behavior, Outside Primary Relationship</i>									
Any Anal Sex, Past 90 Days (n=217)	20 (15%)	106 (85%)	54 (42%)	72 (58%)	47 (37%)	79 (63%)	28 (22%)	98 (78%)	
Unprotected Anal Sex, Past 90 Days (n=201)	23 (19%)	94 (81%)	53 (45%)	64 (55%)	42 (35%)	75 (65%)	23 (19%)	94 (81%)	
<i>Child Sexual Abuse, Before age 14</i>									
Someone tried to touch me in a sexual way, or make me touch them (n=379)	36 (21%)	130 (79%)	55 (33%)	111 (67%)*	50 (30%)	116 (70%)*	25 (15%)	141 (85%)* *	
Someone threatened to hurt me or tell lies about me unless I did something sexual with them (n=379)	16 (23%)	53 (77%)	20 (28%)	49 (71%)*	18 (26%)	51 (74%)	12 (17%)	57 (83%)	

Someone tried to make me do sexual things or watch sexual things (n=377)	25 (18%)	107 (82%)	41 (31%)	91 (69%)*	35 (26%)	97 (74%)* *	15 (11%)	117 (89%)* *
Someone molested me (n=376)	22 (19%)	92 (81%)	36 (31%)	78 (69%)*	35 (30%)	79 (70%)	17 (14%)	97 (86%)*
Someone on the internet tried to get me to talk about sex when I did not want to (n=377)	14 (20%)	55 (80%)	20 (28%)	49 (72%)*	20 (28%)	49 (72%)	12 (17%)	57 (83%)
Someone on the internet tried to get me to do sexual things when I did not want to (n=379)	13 (18%)	56 (82%)	22 (31%)	47 (69%)	21 (30%)	48 (70%)	11 (15%)	58 (85%)
I believe that I was sexually abused (n=375)	22 (20%)	87 (80%)	32 (29%)	77 (71%)* *	31 (28%)	78 (72%)*	15 (13%)	94 (87%)
Answered yes to at least one CSA question (n=380)	44 (21%)	162 (79%)	71 (34%)	135 (66%)	62 (30%)	144 (70%)* *	35 (16%)	171 (84%)
<i>Protective Factors</i>								
Health Insurance (n=380)	74 (22%)	251 (78%)	134 (41%)	191 (59%)	120 (36%)	205 (64%)	70 (21%)	255 (79%)
Born in US (n=380)	70 (22%)	244 (77%)	128 (40%)	186 (60%)	118 (37%)	196 (63%)	67 (21%)	247 (79%)

Bachelor's Degree or Higher (n=377)	38 (30%)	86 (70%)* *	44 (35%)	80 (65%)	36 (29%)	88 (71%)*	24 (19%)	100 (81%)
Employed Fulltime	47 (25%)	140 (75%)	76 (40%)	111 (60%)	71 (37%)	116 (63%)	37 (19%)	150 (81%)
*p<.05, **p<.01, ***p<.001 in chi squared analysis								

DISCUSSION

In order to reduce demographic imbalances in HIV transmission, it is essential to develop and promote innovative biobehavioral approaches to HIV prevention among those who are highly impacted and vulnerable. The study findings have important implications for HIV prevention programming, including investment in and potential uptake of various biomedical tools.

Within this exploratory analysis, sexual minority MSM reported high prevalence estimates of sexual risk behaviors. More than half of the sample reported unprotected anal sex with primary partners, and more than half of those with primary partners reported unprotected anal sex outside of those relationships within the past 90 days. This data reinforces the need to continue prioritizing HIV prevention among racially diverse MSM. Investment in the different biomedical tools that were investigated in this study will serve that goal.

Our findings show a high desirability amongst MSM to use the four biomedical prevention approaches assessed here. Rectal douching and injection emerged as the most desirable among study participants. If these biomedical prevention approaches are proven efficacious and approved by the FDA, it is important that promotional efforts for these biomedical approaches be implemented in racially diverse MSM communities. Strategies for promotional efforts can include peer-navigation, social media campaigns and community collaborative approaches. All promotion efforts should make sure to address the unique barriers to HIV prevention and care that Latinx MSM experience, including discrimination, stigma, and anti-immigration rhetoric.

The most important findings in this study were the associations between reports of child sexual abuse in and interest in different prevention methods. A majority of participants (54%) reported at least some form of child sexual abuse before age 14. Other studies have documented the high prevalence estimates of sexual risk behaviors and childhood sexual abuse [41, 42]. Prevalence estimates of child sexual abuse in this sample rank among the highest up to date in the literature. We found that participants who reported any child sexual abuse, as well as some who reported particular forms of in-person and online abusive experiences, were more likely to express interest

1
2
3 in dissolvable implants, removable implants, and injections. There was no association between
4 child sexual abuse and interest in rectal douching as an HIV prevention strategy.
5
6

7 Our research adds to a body of work investigating the acceptability of HIV prevention
8 biomedical tools in different countries and populations. Previous studies have found that
9 different populations in countries outside of the U.S. have a high acceptability for long-acting
10 injectable PrEP as well as for rectal douching. LAI PrEP was found to be more highly acceptable
11 amongst men than females in both the U.S. and countries outside of the U.S. but only compared
12 against standard PrEP, leaving out other biomedical prevention tools [43]. Our findings delve
13 deeper and show that amongst MSM, LAI PrEP as a biomedical tool for HIV prevention tool is
14 preferred over both removable and dissolvable implants. A study investigating the acceptability
15 of rectal douching amongst a sample of Peruvian men found that rectal douching was likely to be
16 used when condoms were not used [44]. This study's findings compare the acceptability of
17 rectal douching to three other biomedical prevention tools and find that within our sample,
18 acceptability of rectal douching (79%) is equal to acceptability of LAI injection (79%). Overall,
19 our research corroborates prior studies which indicate that there is an increased acceptability for
20 biomedical interventions that prevent HIV transmission apart from standard oral PrEP [45-46].
21
22
23
24
25
26

27 Although it is impossible to infer causal mechanisms from the cross-sectional exploratory data, it
28 is worth noting that implants and injections occur separate from individual sexual encounters.
29 Whereas individuals may face pressure around safer sex practices when engaging directly with
30 prospective partners, including pressure to engage in or forego rectal douching or condom use,
31 these pressures are far less likely to come into play during medical appointments. Providing
32 resources that separate HIV prevention strategies from sexual encounters may empower MSM,
33 including those who have experienced child sexual abuse, to make independent decisions about
34 their bodies and boundaries.
35
36
37
38

39 The increased interest in biomedical interventions that require medical appointments points to a
40 larger need for providers to undergo antibias training to ensure the equitable distribution of PrEP
41 in healthcare settings. Provider bias may allow stigma to prevent the prescription of PrEP to
42 individuals who need it most [47]. Qualitative studies have shown that providers' bias against the
43 LGBTQ+ community and their views on sex have prevented prescription to patients [47].
44 Providers have been shown to know little about PrEP and the criteria that should be used to
45 identify patients that would benefit from the medication [47].
46
47
48

49 POC MSM have expressed wanting stigma free PrEP access and that should extend to the
50 interventions covered in this study [48]. It is possible that these biases will act as barriers to
51 uptake for the biomedical prevention tools investigated in this study. Given the interest in all four
52 biomedical interventions that has been displayed in our findings, plans to scale up access should
53 also be paired with antibias training to ensure that POC MSM are not discriminated against when
54
55
56
57
58
59
60

1
2
3 seeking out these interventions. Antibias and informational training has been found to increase
4 knowledge of PrEP amongst providers along with an increased prescription rate [49].
5
6

7 This study found no associations between interest in various biomedical prevention tools and
8 age, race, or Hispanic/Latino ancestry. Socioeconomic indicators, for the most part, were also not
9 associated with interest in those tools. Although null findings are rarely regarded as noteworthy
10 in scientific literature, we believe that these particular findings are valuable for HIV prevention.
11 The data indicates that a general strategy of promoting various prevention methods, rather than a
12 range of approaches tailored to different demographic groups, may be appropriate when working
13 with racially diverse MSM.
14
15

16 17 18 **Limitations**

19
20 This study has several limitations. An important limitation to this study is that it was limited to a
21 subsection of the Northeast Corridor of the U.S and utilized convenience sampling. However,
22 given the large sample size of MSM who responded to our survey and the similarity in the
23 proportion of ethnic/racial minorities among our respondents to that of the latest US Census,
24 there is an increased likelihood that our findings may be generalizable. Asking about potential
25 interest in various prevention strategies is also not equivalent to documenting uptake and
26 adherence to those strategies, were they to become available.
27
28
29
30

31 Data for this analysis came from a preliminary screening for a larger study on HIV prevention,
32 Connecting Latinos en Pareja, causing limitations in the variables that could be included during
33 data collection. Questions regarding childhood sexual abuse were included in order to further
34 expand the research team's previous research with the intention of exploring intimate partner
35 violence in the formal study itself. Additionally, relevant variables to the immigrant community,
36 including history of incarceration and visa status are anticipated to be incorporated in future
37 surveys within the research team's future formal studies. Consequently, the full range of
38 variables/predictors that would be included for a comprehensive analysis were not part of the
39 preliminary screening. However, future papers from this research team will be able to fill in the
40 analysis gaps that are present in the study. Additionally we hope to conduct future surveys that
41 are able to investigate how interest in different biomedical tools relate to an individual's interest
42 in and adherence to standard oral PrEP.
43
44
45
46
47

48 More research is needed to understand intended and actual usage of biomedical prevention tools
49 globally among individuals whose sexual behaviors may expose them to HIV. Additionally,
50 although this study documented several significant associations between child sexual abuse and
51 interest in implant and injection prevention methods, these data do not reveal the causes or logics
52 behind such associations. Qualitative and mixed methods investigations are warranted to further
53
54
55
56
57
58
59
60

investigate connections among exposure to violence in youth and adulthood, approaches to navigating sexual consent and boundaries, and HIV/STI prevention strategies among MSM.

CONCLUSIONS

Biomedical prevention tools – both existing and new potential products that could become available in the market – have the potential to profoundly impact the global HIV epidemic. Although challenges will certainly arise, including securing adherence and access, this is true for all prevention methods including those which have had a demonstrable impact on HIV infection rates such as PrEP and condoms. Our study shows a high desirability of four biomedical prevention tools not currently available in the market – rectal douche, dissolvable implant, removable implant, and injection – among a sample of men who have sex with men who could potentially benefit from these given their sexual risk profiles. This desirability transcends demographic categories including race, age, and socioeconomic status. Methods that move HIV prevention from interpersonal sexual encounters to individual medical appointments may be particularly valuable for those who have experienced sexual abuse. Transitioning HIV prevention to individual medical appointments means increasing access to biomedical interventions that go beyond oral PrEP and can include those investigated in our study, such as implants and injections.

Acknowledgments We would like to thank all the study participants for their time and effort. We thank our research assistants for their exceptional work interviewing research participants. We gratefully acknowledge the contribution of all community collaborative members, AIDS service organizations, clinics, and health centers in the Northeast Corridor that supported the recruitment of study participants.

Contributors:

Design and data collection: OM, OV, AI, and MP.

Analysis and interpretation: OM and EL.

Drafting the manuscript: ACD, JAB, JJ, RB, MS, AR, EW, SR, AT, LM, OV, AI, MP, RD, AC, and MIF.

Competing interests: None declared.

Funding: This work was supported by the Centers for Disease Control and Prevention under a grant from the Minority HIV and AIDS Research Initiative (MARI 1U01PS005124; PI: Martinez).

Data Sharing: Due to confidentiality and sensitivity issues, the data will be shared upon request and through a controlled access repository.

Disclaimer: The views expressed in this presentation are those of the authors and not necessarily those of the Centers for Disease Control and Prevention.

Ethics approval: The Temple University Institutional Review Board approved the current study (IRB #24120).

References

1. Centers for Disease Control and Prevention, *HIV Surveillance Report, 2017*. Available at: <http://www.cdc.gov/hiv/library/reports/surveillance/>, 2018. **vol. 29**.
2. Satcher Johnson, A., R. Song, and H.I. Hall, *Estimated HIV Incidence, Prevalence, and Undiagnosed Infections in US States and Washington, DC, 2010-2014*. *Journal Of Acquired Immune Deficiency Syndromes* (1999), 2017. **76(2)**: p. 116-122.
3. Hess, K.L., et al., *Lifetime risk of a diagnosis of HIV infection in the United States*. *Annals Of Epidemiology*, 2017. **27(4)**: p. 238-243.
4. Stephenson, R. and C. Finneran, *Receipt and Perpetration of Intimate Partner Violence and Condomless Anal Intercourse Among Gay and Bisexual Men in Atlanta*. *AIDS & Behavior*, 2017. **21(8)**: p. 2253-2260.
5. Muñoz-Laboy, M., et al., *Syndemic Conditions Reinforcing Disparities in HIV and Other STIs in an Urban Sample of Behaviorally Bisexual Latino Men*. *Journal Of Immigrant And Minority Health*, 2018. **20(2)**: p. 497-501.
6. Martinez, O., et al., *Syndemic factors associated with adult sexual HIV risk behaviors in a sample of Latino men who have sex with men in New York City*. *Drug And Alcohol Dependence*, 2016. **166**: p. 258-262.
7. Bauermeister, J., et al., *Where You Live Matters: Structural Correlates of HIV Risk Behavior Among Young Men Who Have Sex with Men in Metro Detroit*. *AIDS & Behavior*, 2015. **19(12)**: p. 2358-2369.
8. Hosek, S.G., et al., *The acceptability and feasibility of an HIV preexposure prophylaxis (PrEP) trial with young men who have sex with men*. *Journal Of Acquired Immune Deficiency Syndromes* (1999), 2013. **62(4)**: p. 447-456.
9. Grant, R.M., et al., *Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men*. *New England Journal of Medicine*, 2010. **363(27)**: p. 2587-2599.
10. Baeten, J.M., et al., *Antiretroviral prophylaxis for HIV prevention in heterosexual men and women*. *The New England Journal of Medicine*, 2012. **367(5)**: p. 399-410.
11. Jiwatram-Negrón, T. and N. El-Bassel, *Systematic Review of Couple-Based HIV Intervention and Prevention Studies: Advantages, Gaps, and Future Directions*. *AIDS & Behavior*, 2014. **18(10)**: p. 1864-1887.

12. Cohen, M.S., et al., *Prevention of HIV-1 Infection with Early Antiretroviral Therapy*. New England Journal of Medicine, 2011. **365**(6): p. 493-505.
13. Rodger, A.J., et al., *Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy*. JAMA, 2016. **316**(2): p. 171-181.
14. *Risk of HIV transmission through condomless sex in MSM couples with suppressive ART: The PARTNER2 Study extended results in gay men*. AIDS & Hepatitis Digest, 2018. **5**(4): p. 3-5.
15. Bauermeister, J.A., et al., *PrEP awareness and perceived barriers among single young men who have sex with men*. Curr HIV Res, 2013. **11**(7): p. 520-7.
16. World Health Organization, *Guideline on When to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV*. 2015, World Health Organization: Geneva, Switzerland.
17. Centers for Disease Control and Prevention, *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014: A Clinical Practice Guideline*. 2014, US Public Health Service.
18. Serota, D.P., et al., *Beyond the Biomedical: Preexposure Prophylaxis Failures in a Cohort of Young Black Men Who Have Sex With Men in Atlanta, Georgia*. Clinical Infectious Diseases, 2018. **67**(6): p. 965-970.
19. Page, K.R., et al., *Promoting pre-exposure prophylaxis to prevent HIV infections among sexual and gender minority Hispanics/Latinxs*. AIDS Education and Prevention, 2017. **29**(5): p. 389-400.
20. Taggart T, Liang Y, Pina P, Albritton T. Awareness of and willingness to use PrEP among Black and Latinx adolescents residing in higher prevalence areas in the United States. PloS one. 2020 Jul 6;15(7):e0234821.
21. Arnold, E.A., G.M. Rebchook, and S.M. Kegeles, *'Triply cursed': racism, homophobia and HIV-related stigma are barriers to regular HIV testing, treatment adherence and disclosure among young Black gay men*. Culture, Health & Sexuality, 2014. **16**(6): p. 710-722.
22. Pérez-Figueroa, R.E., et al., *Acceptability of PrEP Uptake Among Racially/Ethnically Diverse Young Men Who Have Sex With Men: The P18 Study*. AIDS Education & Prevention, 2015. **27**(2): p. 112-125.
23. St. Lawrence, J.S., et al., *Measuring perceived barriers to condom use: Psychometric evaluation of the Condom Barriers Scale*. Assessment, 1999. **6**(4): p. 391-404.
24. Crosby, R., et al., *Negative perceptions about condom use in a clinic population: comparisons by gender, race and age*. International Journal Of STD & AIDS, 2013. **24**(2): p. 100-105.
25. Biello, K.B., et al., *MSM at Highest Risk for HIV Acquisition Express Greatest Interest and Preference for Injectable Antiretroviral PrEP Compared to Daily, Oral Medication*. AIDS And Behavior, 2018. **22**(4): p. 1158-1164.
26. Hambrick HR, Park SH, Goedel WC, Morganstein JG, Kreski NT, Mgbako O, Duncan DT. Rectal douching among men who have sex with men in Paris: implications for HIV/STI risk behaviors and rectal microbicide development. AIDS and Behavior. 2018 Feb;22(2):379-87.

- 1
- 2
- 3
- 4 27. Carballo-Diéguez, A., et al., *The Use of Rectal Douches among HIV-uninfected and*
- 5 *Infected Men who Have Unprotected Receptive Anal Intercourse: Implications for Rectal*
- 6 *Microbicides*. *AIDS & Behavior*, 2008. **12**(6): p. 860-866.
- 7 28. Carballo-Diéguez, A., et al., *Why rectal douches may be acceptable rectal-microbicide*
- 8 *delivery vehicles for men who have sex with men*. *Sexually Transmitted Diseases*, 2010.
- 9 **37**(4): p. 228-233.
- 10 29. Carballo-Diéguez, A., et al., *Rectal Douching Associated with Receptive Anal*
- 11 *Intercourse: A Literature Review*. *AIDS And Behavior*, 2018. **22**(4): p. 1288-1294.
- 12 30. Montgomery ET, Atujuna M, Krogstad E, Hartmann M, Ndwayana S, O'Rourke S,
- 13 Bekker LG, van der Straten A, Minnis AM. The invisible product: preferences for
- 14 sustained-release, long-acting pre-exposure prophylaxis to hiv among south african
- 15 youth. *Journal of acquired immune deficiency syndromes (1999)*. 2019 Apr 15;80(5):542.
- 16 31. Weld ED, Flexner C. Long-acting implants to treat and prevent HIV infection. *Current*
- 17 *Opinion in HIV and AIDS*. 2020 Jan;15(1):33.
- 18 32. Cobb DA, Smith NA, Edagwa BJ, McMillan JM. Long-acting approaches for delivery of
- 19 antiretroviral drugs for prevention and treatment of HIV: a review of recent research.
- 20 *Expert opinion on drug delivery*. 2020 Sep 1;17(9):1227-38.
- 21 33. Li L, Johnson LM, Krovi SA, Demkovich ZR, van der Straten A. Performance and
- 22 stability of tenofovir Alafenamide formulations within subcutaneous biodegradable
- 23 implants for HIV pre-exposure prophylaxis (PreP). *Pharmaceutics*. 2020
- 24 Nov;12(11):1057.
- 25 34. Schlesinger, E., Johengen, D., Luecke, E., Rothrock, G., McGowan, I., van der Straten,
- 26 A., & Desai, T. (2016). A tunable, biodegradable, thin-film polymer device as a long-
- 27 acting implant delivering tenofovir alafenamide fumarate for HIV pre-exposure
- 28 prophylaxis. *Pharmaceutical research*, 33(7), 1649-1656.
- 29 35. Beymer MR, Holloway IW, Pulsipher C, Landovitz RJ. Current and future PrEP
- 30 medications and modalities: on-demand, injectables, and topicals. *Current hiv/aids*
- 31 *Reports*. 2019 Aug;16(4):349-58.
- 32 36. McGowan I, Dezzutti CS, Siegel A, Engstrom J, Nikiforov A, Duffill K, Shetler C,
- 33 Richardson-Harman N, Abebe K, Back D, Else L. Long-acting rilpivirine as potential
- 34 pre-exposure prophylaxis for HIV-1 prevention (the MWRI-01 study): an open-label,
- 35 phase 1, compartmental, pharmacokinetic and pharmacodynamic assessment. *The Lancet*
- 36 *HIV*. 2016 Dec 1;3(12):e569-78.
- 37 37. Walensky RP, Jacobsen MM, Bekker LG, Parker RA, Wood R, Resch SC, Horstman NK,
- 38 Freedberg KA, Paltiel AD. Potential clinical and economic value of long-acting
- 39 preexposure prophylaxis for South African women at high-risk for HIV infection. *The*
- 40 *Journal of infectious diseases*. 2016 May 15;213(10):1523-31.
- 41 38. Eshleman, S. H., Fogel, J. M., Piwowar-Manning, E., Chau, G., Cummings, V., Agyei,
- 42 Y., ... & Marzinke, M. A. (2022). Characterization of human immunodeficiency virus
- 43 (HIV) infections in women who received injectable cabotegravir or tenofovir disoproxil
- 44 fumarate/emtricitabine for HIV prevention: HPTN 084. *The Journal of Infectious*
- 45 *Diseases*, 225(10), 1741-1749.
- 46 39. Landovitz, R. J., Donnell, D., Clement, M. E., Hanscom, B., Cottle, L., Coelho, L., ... &
- 47 Grinsztejn, B. (2021). Cabotegravir for HIV prevention in cisgender men and transgender
- 48 women. *New England Journal of Medicine*, 385(7), 595-608.
- 49
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59

- 1
2
3 40. Martinez, O., et al., *A couple-based HIV prevention intervention for Latino men who have*
4 *sex with men: study protocol for a randomized controlled trial*. *Trials*, 2018. **19**(1): p. 1-
5 1.
- 6
7 41. Brennan-Ing, M., et al., *Substance Use and Sexual Risk Differences among Older*
8 *Bisexual and Gay Men with HIV*. *Behavioral Medicine*, 2014. **40**(3): p. 108-115.
- 9
10 42. Muñoz-Laboy, M., et al., *Syndemic Conditions Reinforcing Disparities in HIV and Other*
11 *STIs in an Urban Sample of Behaviorally Bisexual Latino Men*. *Journal of Immigrant &*
12 *Minority Health*, 2018. **20**(2): p. 497-501.
- 13
14 43. Tolley EE, Zangeneh SZ, Chau G, Eron J, Grinsztejn B, Humphries H, Liu A, Siegel M,
15 Bertha M, Panchia R, Li S. Acceptability of long-acting injectable cabotegravir (CAB
16 LA) in HIV-uninfected individuals: HPTN 077. *AIDS and Behavior*. 2020
17 Sep;24(9):2520-31.
- 18
19 44. Kinsler JJ, Galea JT, Lama JR, Segura P, Peinado J, Casapia M, Ortiz A, Nadjat-Haiem
20 C, Montano SM, Sanchez J. Rectal douching among Peruvian men who have sex with
21 men, and acceptability of a douche-formulated rectal microbicide to prevent HIV
22 infection. *Sexually transmitted infections*. 2013 Feb 1;89(1):62-.
- 23
24 45. Ogunbajo A, Tsai AC, Kanki PJ, Mayer KH. Acceptability of and Preferences for Long-
25 Acting Injectable HIV PrEP and Other PrEP Modalities among Sexual Minority Men in
26 Nigeria, Africa. *AIDS and Behavior*. 2022 Jan 21:1-3.2
- 27
28 46. Galea JT, Kinsler JJ, Imrie J, Nureña CR, Sánchez J, Cunningham WE. Rectal douching
29 and implications for rectal microbicides among populations vulnerable to HIV in South
30 America: a qualitative study. *Sexually transmitted infections*. 2014 Feb 1;90(1):33-5.
- 31
32 47. Pleuhs B, Quinn KG, Walsh JL, Petroll AE, John SA. Health care provider barriers to
33 HIV pre-exposure prophylaxis in the United States: a systematic review. *AIDS Patient*
34 *Care and STDs*. 2020 Mar 1;34(3):111-23.
- 35
36 48. Lau JY, Wong NS, Lee KC, Kwan TH, Lui GC, Chan DP, Lee SS. What makes an
37 optimal delivery for PrEP against HIV: A qualitative study in MSM. *International journal*
38 *of STD & AIDS*. 2022 Jan 2:09564624211060824.
- 39
40 49. Sales JM, Cwiak C, Haddad LB, Phillips A, Powell L, Tamler I, Sheth AN. Impact of
41 PrEP training for family planning providers on HIV prevention counseling and patient
42 interest in PrEP in Atlanta, Georgia. *Journal of acquired immune deficiency syndromes*
43 *(1999)*. 2019 Aug 1;81(4):414.
- 44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	3
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-8
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	6-8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-15
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-15
Bias	9	Describe any efforts to address potential sources of bias	6-7
Study size	10	Explain how the study size was arrived at	6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	8
		(c) Explain how missing data were addressed	8
		(d) If applicable, describe analytical methods taking account of sampling strategy	8
		(e) Describe any sensitivity analyses	8
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7 & 8
		(b) Give reasons for non-participation at each stage	7 & 8
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	8
Outcome data	15*	Report numbers of outcome events or summary measures	

1			
2	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
3			8-15
4			
5			
6			
7			
8			
9			
10			
11	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
12			8-15
13			
14	Discussion		
15	Key results	18	Summarise key results with reference to study objectives
16	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
17			17
18			
19			
20	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
21			15-17
22			
23			
24	Generalisability	21	Discuss the generalisability (external validity) of the study results
25			15-17
26			
27	Other information		
28	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based
29			18
30			
31			
32			

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.