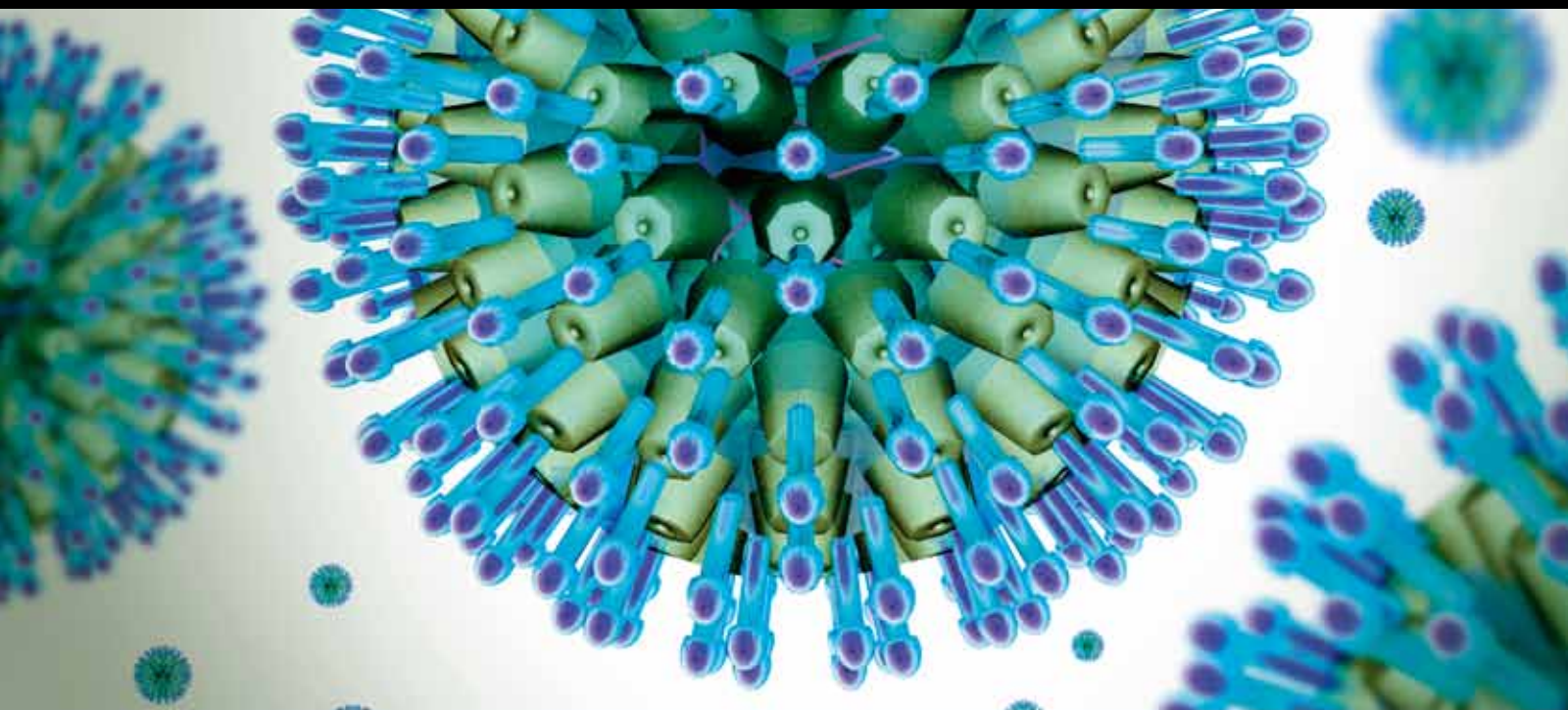


Dual Protection Use to Prevent STIs and Unintended Pregnancy

Guest Editors: Jessica M. Sales, Maura K. Whiteman, Melissa J. Kottke, Tessa Madden, and Ralph J. DiClemente





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Editorial

Dual Protection Use to Prevent STIs and Unintended Pregnancy

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Young women are at greatest risk for unintended pregnancy and contracting a variety of sexually transmitted infections (STIs). For over a decade, medical practitioners, researchers, and professional organizations have recommended comprehensive reproductive health counseling for young women which includes recommending dual protection strategies designed to enhance prevention of both unintended pregnancy and STI/HIV. Although recommended, dual protection is not commonly practiced, especially in the United States. Thus, this special issue presents research articles and review articles to identify and better understand factors influencing dual protection use.

This special issue contains eight papers. Three papers present findings on dual protection use among adolescents and adults in the United States, and two papers report findings on dual protection use among HIV-positive individuals in international settings (Zambia and India). In addition to research articles, three review papers report on biomedical approaches to dual protection, the potential impact of multiple risk messaging on condom use among women, and biological strategies to enhance the measurement of dual protection.

In the article titled “*Correlates of dual-method contraceptive use: an analysis of the national survey of family growth (2006–2008)*”, D. L. Eisenberg et al. report on correlates

of dual contraceptive use among a nationally representative sample of women aged 15–44 living in the United States. Dual contraceptive use was only reported by 7.3% of the 5,178 sexually active women in the sample. Correlates of dual contraceptive use included younger age, nonmarried marital status, and continuous health insurance in the past 12 months.

J. L. Brown et al., in their article titled “*Multiple method contraception use among African American adolescents in four US cities*,” describe the contraceptive practices and type of contraception utilized during the last sexual episode reported by African American adolescents in the United States. They found that 40% used dual (or multiple) contraceptive methods, with a total of 35 different contraceptive combinations identified. Adolescents who believed their partners posed low risk with regard to STI acquisition were more likely to use less effective contraceptive methods (e.g., withdrawal) or to use no contraception.

In the article titled “*Determinants of multimethod contraceptive use in a sample of adolescent women diagnosed with psychological disorders*,” D. L. Lang et al. examined individual-, interpersonal-, and environmental-level factors associated with multimethod use among sexually active adolescent women diagnosed with psychological disorders. Among this subgroup of adolescents, 34.7% of the participants reported

multimethod use in the past three months. In controlled analyses, self-efficacy, multiple partners, pregnancy history, parental communication, parental norms about sex, and neighborhood cohesion were significant predictors of multimethod use.

C. J. Chibwesha et al. present findings pertaining to dual contraceptive use among HIV-infected women in their article, “*Modern contraceptive and dual method use among HIV-infected women in Lusaka, Zambia.*” In this article the authors describe the implementation of a reproductive health counseling intervention conducted in 16 HIV clinics in Lusaka, Zambia. Of the 18,407 women counseled, 59% reported current modern contraceptive use but only 18% reported dual contraceptive use. After counseling, many women not previously using modern contraception desired family planning referrals and successfully accessed services within 90 days.

In the research article titled “*Prevalence of and barriers to dual-contraceptive methods use among married men and women living with HIV in India,*” V. Chakrapani et al. describe the prevalence and correlates of dual-contraceptive methods use and barriers to their use among married persons living with HIV in India. Utilizing a mixed-method approach, they found the prevalence of dual-contraceptive method use increased from 5% before HIV diagnosis to 23% after diagnosis. Condoms were the most commonly used contraceptive method, with prevalence increasing from 13% before diagnosis to 92% after diagnosis. Barriers to using contraceptive methods other than condoms included lack of discussion about other methods by health care providers, lack of acceptability of other methods, and lack of involvement of husbands in family planning counseling.

In the review paper titled “*Multipurpose prevention technologies: biomedical tools to prevent HIV-1, HSV-2, and unintended pregnancies,*” A. R. Thurman et al. provide an overview of existing and novel approaches to multipurpose products that provide simultaneous protection against both unintended pregnancies and STIs. For instance, they discuss how potent antiviral drugs released topically in the female reproductive tract by innovative delivered systems and formulations may provide safe, effective, and acceptable multipurpose prevention tools.

In the article titled “*Are dual-method messages undermining STI/HIV prevention?*” A. O’Leary provides an overview of the literature on multiple risk messages, compliance with dual-use recommendations, predictors of dual use, and interventions developed to encourage dual use. She argues that because simultaneous use of dual methods is not common, and efforts to enhance dual use have not yielded promising results, a randomized controlled trial to explore the impact of multiple risk messaging on condom use among young women should be considered.

In the review titled “*Do women using long-acting reversible contraception reduce condom use? A novel study design incorporating semen biomarkers,*” M. F. Gallo et al. review evidence from previous studies of condom “migration” associated with the use of long-acting reversible contraceptive

methods and propose a novel study design to address the main methodological issues that have limited interpretation of these studies. Specifically, they propose a randomized controlled trial design utilizing the use of a biological marker of semen exposure for measuring changes in condom use to overcome methodological issues.

Disclosure

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Research Article

Correlates of Dual-Method Contraceptive Use: An Analysis of the National Survey of Family Growth (2006–2008)

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Objective. To analyze a nationally representative sample of women for correlates of dual-contraceptive-method use. **Materials and Methods.** We conducted an analysis of the National Survey of Family Growth, 2006–2008, a cross-sectional survey of reproductive-aged women in the United States. **Results.** Dual method use was reported by 7.3% of the 5,178 women in the sample. Correlates of higher rates of dual-contraceptive-method use included age younger than 36 years and nonmarried marital status. Lower rates of dual method use were observed for women with less than a high-school education and women without consistent health insurance in the past year. Compared to women using oral contraceptives, use of the contraceptive injection or long-acting reversible contraception was associated with lower dual-method use. **Conclusions.** The overall rate of dual-method use in the USA is low. Future interventions to promote dual method use should target high-risk groups with modifiable risk factors.

1. Introduction

Sexually transmitted infections (STIs) and unintended pregnancy are important and costly public health issues. The United States has an estimated incidence of 19 million cases of STIs each year which incurs \$15.9 billion in cost to the health care system [1, 2] and unintended pregnancy rates continue to hover at nearly 50% [3]. One proposed strategy to reduce the risks of unintended pregnancy and STI is the promotion of dual-contraceptive-method use. Dual-method protection includes use of a highly effective pregnancy prevention in conjunction with a barrier (e.g., male condom). The male condom is the most commonly used method of sexually transmitted infection (STI) prevention, whereas the oral contraceptive pill and female sterilization are the most common methods of pregnancy prevention in the USA [4].

The burden of unintended pregnancy and STIs is greater among younger and economically disadvantaged men and women [3, 5]. While nearly all women report having used birth control and most have used a condom [4], dual-method use is relatively uncommon. An analysis of the Youth Risk Behavior Surveillance System (YRBS) noted 6.6% of

young women using oral contraceptives also used a condom at last intercourse [6]. According to another study of the YRBS, use of dual-contraceptive methods increased from 3.2% in 1991 to 7.2% in 2001 [7]. A more recent publication reviewing data from the National Longitudinal Study of Adolescent Health noted 14–25% of participants report using dual methods at last intercourse [8].

Most of the previous research focused on adolescents or other populations who carry greater risk of both unintended pregnancy and STI acquisition than the general population. Therefore, we sought to evaluate correlates of dual-method use in a national sample of reproductive-aged women.

2. Materials and Methods

We examined data from the 2006–2008 National Survey of Family Growth (NSFG). The NSFG is a cross-sectional survey conducted by the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention and is a survey of family life, marriage and divorce, pregnancy, infertility, use of contraception, and men's and

TABLE 1: Contraceptive methods used in the last intercourse in past 12 months by nonpregnant females aged 15–44 years, $N = 5178$.

Method	N (%) [†]	Dual	Single
Any method of contraception			
Yes, dual	448 (7.3)		
Yes, single	3341 (68.0)		
No	1389 (24.7)		
Type of contraceptive method			
Nonbarrier methods*	2694 (55.7)	448 (13.1)	2246 (86.9)
Pills	1125 (22.3)	280 (21.7)	845 (78.3)
Sterilization/partner sterilization	1004 (24.1)	78 (4.4)	926 (95.6)
Injectables (Lunelle/Depo-Provera)	211 (2.8)	47 (16.7)	164 (83.3)
LARC	229 (4.6)	16 (3.3)	213 (96.7)
Patch	55 (0.6)	7 (16.0)	48 (84.0)
Ring	100 (2.1)	22 (32.6)	78 (67.4)
Barrier methods	1543 (26.8)	448 (27.1)	1095 (72.9)

* Individual methods do not sum to % of Nonbarrier methods as respondents may have reported >1 Nonbarrier method at last intercourse.

[†] Weighted percent.

women's health [9, 10]. The survey is a national probability sample of individuals living in households and oversamples Blacks, Hispanics, teens, and females. The NSFG was conducted from 2006 to 2010 with 110 areas (primary sampling units) selected. Each year a nationally representative subsample of areas was interviewed. Interviews were conducted by the University of Michigan's Institute for Social Research by trained female professional interviewers in the homes of participants using computer-assisted personal interviewing. Interviews lasted on average 80 minutes.

There were 7,356 women between the ages of 15 and 44 years of age interviewed between July 2006 and December 2008. Our analysis included 5,178 women who represent the experiences of approximately 44.5 million women in the United States. We excluded women who were currently pregnant, have had a hysterectomy, had no sexual partners, or reported only female sex partners and therefore not at risk of unintended pregnancy (see Figure 1). We determined current contraceptive method based on respondents' answers to a single question regarding "contraception method used at last intercourse in the past 12 months [11]". Respondents could provide up to four methods in response to this question allowing for estimation of dual-method use.

We calculated the prevalence of dual-method contraceptive use and evaluated demographic and reproductive characteristics that might be associated with dual-method use. Potential predictors of dual-method use included age group (15–20, 21–25, 26–30, 31–35, 36–40, 41–44 years), gravidity, marital status (married, living with partner, widowed/divorced/separated, never married), race (black, white, other), Hispanic ethnicity, highest level of education (less than high school, high school, some college, or college graduate), continuous insurance coverage for all of the prior 12 months, and number of lifetime and past year sexual partners.

In order to focus on correlates of dual-method use we used all respondents who did not report dual-method use

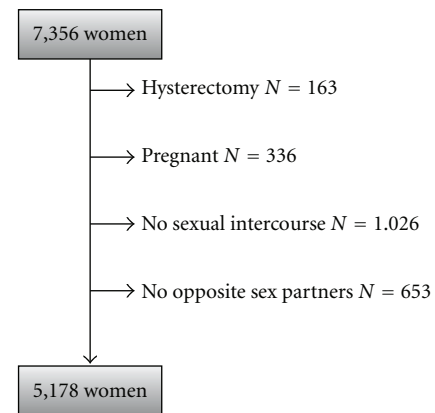


FIGURE 1: National Survey of Family Growth (2006–2008) Analytic Sample.

(including single-method users and respondents using no method) as the referent. After evaluating univariate associations using logistic regression, we used a multivariable logistic regression model to assess independent predictors of dual-method use. Our model included the factors found to be associated with dual-method use in the univariate analysis. Reference groups for the multivariable regression were chosen by lowest rate of dual-method use, by clinical judgment or the category with the largest number of respondents.

For our examination of the association between primary method of contraception and dual-method use, we compared dual-method use to single-method use and excluded those participants not using a primary contraceptive method ($n = 1,389$) or using barrier only method ($n = 1095$), as these women were not eligible for the outcome of interest. "Pill users" included combination and progestin-only oral contraceptives. Users of the transdermal contraceptive patch

TABLE 2: Summary of participants' characteristics by number of methods used.

	All non-pregnant women 15–44 years (<i>N</i> = 5178)	Dual (<i>N</i> = 448)	Single (<i>N</i> = 3341)	None (<i>N</i> = 1389)	<i>P</i> value
Age					<0.0001
15–20	731 (11.7)	134 (22.8)	438 (56.9)	159 (20.3)	
21–25	976 (16.6)	124 (12.0)	595 (63.4)	257 (24.6)	
26–30	1114 (18.4)	79 (5.1)	735 (65.9)	300 (28.9)	
31–35	923 (18.5)	62 (5.2)	598 (67.5)	263 (27.2)	
36–40	853 (19.5)	32 (1.8)	565 (73.1)	256 (25.1)	
41–44	581 (15.2)	17 (2.3)	410 (77.9)	154 (19.8)	
Race					<0.0001
Black	1111 (15.1)	122 (9.4)	662 (61.6)	327 (29.0)	
White	3499 (73.6)	301 (7.4)	2320 (69.8)	878 (22.7)	
Others	568 (11.3)	25 (3.3)	359 (64.5)	184 (32.2)	
Ethnicity					0.0049
Hispanic	1124 (16.5)	63 (4.2)	724 (66.1)	337 (29.7)	
Non Hispanic	4054 (83.5)	385 (7.9)	2617 (68.4)	1052 (23.8)	
Education					0.0003
Less than HS	1088 (17.1)	96 (6.7)	672 (61.1)	320 (32.2)	
High School	1388 (25.8)	116 (7.2)	860 (67.0)	412 (25.9)	
Some College	1123 (20.9)	125 (12)	724 (66.5)	274 (21.5)	
College Graduate	1579 (36.2)	111 (4.9)	1085 (72.9)	383 (22.2)	
Marital Status					<0.0001
Married	2181 (53.3)	47 (1.6)	1461 (72.4)	673 (26.0)	
Living with Partner	693 (13.2)	37 (6.1)	448 (64.4)	208 (29.5)	
Widowed/Divorced/Separated	520 (8.0)	63 (9.8)	319 (63.3)	138 (26.9)	
Never Married	1784 (25.5)	301 (18.9)	1113 (62.2)	370 (18.9)	
Gravidity					<0.0001
0	1539 (28.4)	240 (16.0)	959 (63.8)	340 (20.2)	
1–2	1973 (37)	116 (4.3)	1271 (69.0)	586 (26.7)	
3+	1666 (34.6)	92 (3.3)	1111 (70.4)	463 (26.4)	
Health insurance in the last 12 months					<0.0001
Insured continuously	3630 (71.2)	345 (8)	2385 (70.1)	900 (21.9)	
Uninsured at some time	1535 (28.8)	103 (5.6)	947 (62.4)	485 (32)	
# Lifetime Sexual Partners					0.0008
1	1109 (24.3)	64 (4.9)	764 (72.4)	281 (22.7)	
2–3	1165 (22.9)	110 (9.4)	750 (68.5)	305 (22.1)	
4–9	1851 (34.5)	179 (7.7)	1196 (67.9)	476 (24.5)	
10 or more	1053 (18.3)	95 (7.0)	631 (61.6)	327 (31.3)	
# Sexual Partners in last 12 months					0.0045
1	4316 (86.9)	302 (5.8)	2829 (69.1)	1185 (25.1)	
2	529 (8.2)	94 (18.9)	322 (58.6)	113 (22.5)	
3+	333 (4.9)	52 (13.8)	190 (63.5)	91 (22.7)	
Desires pregnancy in the future					<0.0001
Yes	3153 (55.9)	321 (10.1)	1852 (59.0)	980 (30.9)	
No	1892 (41.3)	118 (3.8)	1396 (79.1)	378 (17.1)	

TABLE 3: Crude and adjusted odds ratios (and 95% confidence intervals) for dual versus non-dual-method use.

	Crude	Adjusted
Age		
15–20	16.3 (9.38–28.5)	7.01 (3.19–15.4)
21–25	7.40 (3.68–14.9)	3.93 (1.90–8.10)
26–30	2.94 (1.69–5.11)	2.36 (1.29–4.31)
31–35	3.04 (1.61–5.74)	3.14 (1.72–5.76)
36–40	Referent	Referent
41–44	1.27 (0.55–2.94)	1.33 (0.57–3.10)
Race		
Black	1.30 (0.87–1.93)	0.97 (0.66–1.44)
White	Referent	Referent
Others	0.43 (0.26–0.72)	0.43 (0.25–0.75)
Ethnicity		
Hispanic	0.52 (0.34–0.79)	0.73 (0.48–1.13)
Non Hispanic	Referent	Referent
Education		
Less than HS	1.41 (0.94–2.11)	0.47 (0.27–0.81)
High school	1.49 (0.94–2.37)	0.94 (0.55–1.58)
Some college	2.61 (1.69–4.02)	1.07 (0.73–1.57)
College graduate	Referent	Referent
Marital status		
Married	Referent	Referent
Living with partner	3.83 (2.08–7.04)	2.87 (1.62–5.07)
Widowed/divorced/ separated	6.45 (3.40–12.3)	7.86 (4.05–15.3)
Never married	13.9 (9.32–20.8)	6.45 (3.62–11.5)
Gravidity		
0	5.58 (3.35–9.28)	1.46 (0.78–2.74)
1–2	1.31 (0.81–2.10)	0.85 (0.50–1.44)
3+	Referent	Referent
Insurance in last 12 month		
Insured continuously	Referent	Referent
Uninsured at some time	0.68 (0.48–0.95)	0.65 (0.47–0.90)
# Lifetime sexual partners		
1	Referent	Referent
2–3	1.96 (1.24–3.10)	1.50 (0.92–2.45)
4–9	1.57 (1.11–2.21)	1.22 (0.82–1.81)
10 or more	1.44 (0.88–2.36)	1.17 (0.72–1.91)
Sexual partner in last 12 months		
1	Referent	Referent
2	3.85 (2.58–5.76)	1.29 (0.87–1.90)
3+	2.57 (1.60–4.14)	0.81 (0.48–1.36)
Desires pregnancy in future		
Yes	2.82 (1.93–4.13)	0.98 (0.60–1.58)
No	Referent	Referent

and those who relied on the contraceptive vaginal ring were grouped together due to small numbers in each contraceptive subgroup. Participants who used either of the injectable contraceptives such as depot medroxyprogesterone acetate (DMPA) or combination injectable contraceptives were grouped together as “injectables.” Women who used either an intrauterine device (IUD) or the contraceptive implant were grouped together as users of long-acting reversible contraceptives (LARCs). And finally, those who relied on either female or male sterilization are grouped together in the “sterilization group.” In cases where respondents reported more than one contraceptive method, we chose the most effective method as defined by Trussell [12] as the primary contraceptive method. We then used this variable as a covariate in an independent multivariable logistic regression to evaluate the impact of primary method on dual-method use. All analyses were conducted in SAS (v. 9.2, SAS Institute, Cary, NC).

3. Results

An estimated 7.3% of US women reported dual-method use at their last intercourse in the last 12 months in the 2006–2008 NSFG. Over two-thirds of women reported a single-method of contraception and one-quarter reported no method used at the last intercourse (see Table 1). Ring users were most likely to report dual-method use with 32.6% dual use at last intercourse, whereas 21.7% of pill users, 16.7% of injectable users, and 16.0% of patch users reported dual-method use at last intercourse. Those relying on sterilization (4.4%) or currently using a LARC method (3.3%) were less likely to report dual-method use than women relying on less effective non-barrier contraceptive methods.

We examined the frequency of dual- and single-method use across demographic and clinical characteristics and found that rates of method use varied by age, race, ethnicity, education, marital status, pregnancy history, insurance status, and number of sexual partners (lifetime and past year; see Table 2). In particular, young women (15–20 years) who are at highest risk of both STI and unintended pregnancy reported the highest rates of dual-method use (22.8%). African American women had higher rates of dual-method use (9.4%) compared with Caucasian or Hispanic women. Education was associated with rates of dual-method use with the highest levels among women with some college education (12.0%). Never married women were most likely to report dual-method use (18.9%), as were nulligravid women (16.0%). Continuously insured women were more likely to report dual-method use (8.0%) than those with some period of no insurance (5.6%). Dual-method use was associated with sexual history (number of lifetime sex partners or in the past year) in the unadjusted analyses. We also examined the impact of future pregnancy intention on dual-method use. We found that women who “want a pregnancy at some time” were more likely to use dual-method protection in our unadjusted analyses.

Results of our logistic regression model are shown in Table 3. Potential confounders identified in the univariate

TABLE 4: Association of primary contraceptive method with dual-method use.

Primary contraceptive method	Crude	Adjusted
Pills	Referent	Referent
Patch/ring	1.40 (0.68–2.89)	1.15 (0.61–2.19)
Injectables (Lunelle/DMPA)	0.73 (0.44–1.23)	0.49 (0.28–0.85)
LARC	0.12 (0.06–0.24)	0.30 (0.14–0.63)
Sterilization	0.16 (0.10–0.25)	0.69 (0.39–1.22)

Note: controlled for age, race, ethnicity, level of education, marital status, gravidity, insurance status in the last 12 months, lifetime number of sexual partners, number of sexual partners in the last 12 months, and pregnancy intention.

analyses included age, race, ethnicity, level of education, marital status, gravidity, insurance status in the last 12 months, lifetime number of sexual partners, number of sexual partners in the last 12 months, and desire for future pregnancy. Women under the age of 36 were significantly more likely to report dual-method use compared to women in the 36–40 years age group. When compared to married women, never married women (OR_{adj} 6.5, 95% CI 3.6–11.5) and those who were widowed/divorced/separated (OR_{adj} 7.9, 95% CI 4.1–15.3) had the highest likelihood of dual-method use. Lack of insurance coverage during the prior year was associated with lower rates of dual-method use (OR_{adj} 0.7, 95% CI 0.5–0.9) compared to women who had continuous coverage. While desire for future childbearing was associated with dual use in our bivariate analysis (OR = 2.8, 95% CI 1.9–4.1), it was no longer significant in our logistic regression model (OR_{adj} = 1.0, 95% CI 0.6–1.6).

Since age and education are closely linked, we examined the results of the logistic regression model with and without age and education. Estimates of effect for age were largely unchanged by excluding education with the exception of the youngest category of women (15–20 year-olds) which was modestly attenuated.

Finally, we used a logistic regression model to examine the relationship of dual-method use by primary method of pregnancy prevention with pill users as the referent group, since pill use was the most common primary method reported (Table 4). After adjusting for all the factors associated with dual-method use from the prior adjusted analysis, women who relied on the contraceptive injection were less likely to report additional barrier use (OR_{adj} 0.5, 95% CI 0.3–0.9). LARC users were significantly less likely to report dual-method use (OR_{adj} 0.3, 95% CI 0.1–0.6). There was no statistically significant difference in the likelihood of dual use in male or female sterilization and patch/ring users compared to pill users.

4. Discussion

Our analysis indicated 7.3% of reproductive-aged women at risk for both pregnancy and STIs in this nationally representative sample reported using dual-method protection at last intercourse. Increased dual-method contraceptive use was associated with younger age and not being married,

but inversely associated with gaps in insurance coverage. A statistically significant lower rate of dual-method use was noted in women relying on the most effective forms of reversible pregnancy prevention: DMPA and LARC methods.

The 7.3% overall rate of dual-method use among the whole sample is consistent with previously published reports [6, 7]. It is encouraging to note the higher rate of dual-method use among teenagers and those under age 25 in this analysis as they have the highest incidence of STIs and unintended pregnancy. Sieving et al. noted a higher rate of two methods of contraception being used at most recent intercourse among older teens versus younger teens [8]. We found 22.8% of 15–20-year olds and 12% of 21–25-year olds reported dual-method protection. In a sample of women using LARC methods, Pazol et al. noted that high-school graduates were more likely than those without a high-school diploma to report condom use at last intercourse [13]. This is also consistent with our finding that higher educational levels are associated with dual-method use.

Few studies have evaluated factors associated with dual-method use. One study of adolescent girls noted that the strongest correlate of dual-method use was a desire to avoid pregnancy [14]. Impulsivity, self-esteem, social support, relationship status, partner communication, fear of condom negotiation, and desire to avoid unintended pregnancy have been associated with dual-method use among adolescents [14, 15].

Our finding of a positive association of dual-method use among respondents who are not currently married compared to married women is not surprising. Married women likely perceive less risk of STI acquisition and unintended pregnancy. This is consistent with other reports of lower rates of condom use among married women [4]. The lower rate of dual-method use reported among women who had a gap in insurance coverage during the past 12 months is likely due to limited access to prescription contraceptive methods or interruptions in continuity of care during these periods [16].

There is concern that women relying on LARC methods may have lower rates of barrier method use. Pazol et al. examined NSFG data from 2002–2003 and found that only 1.9% (95% CI 0.0–4.0) of respondents who reported using LARC methods also used a condom at last intercourse [13]. Our analysis also noted lower rates of dual-method use in women using LARC methods and DMPA. This lower rate may be due to these women feeling reassured that they have a highly effective contraceptive method and not recognizing their continued risk of STI acquisition.

A major strength of our study is that this data represents a national sample of reproductive-aged which reflects the experiences of approximately 44.5 million women in the United States. Our findings are more generalizable than studies that focus on adolescents or clinic-based samples. Our sample size provided sufficiently large numbers to assess differences in dual-method use across many exposure categories. However, there are some limitations of this analysis. Our estimate of 7% dual-method use may be a slight underestimate, as there are some women in the denominator of this analysis that may not be using dual methods or any

contraception due to a desire to conceive. Data regarding current contraceptive method was based on the respondents' reports of contraception at last intercourse which may be affected by both difficulty with recall and social desirability issues. It is difficult to extrapolate dual-method contraceptive use at last intercourse to dual use as a regularly practiced behavior. Additionally, the low number of women reporting using LARC, the patch, or ring for contraception reduces the level of precision of our estimates and makes it difficult to draw conclusions regarding women using these methods. Ideally, we would have liked to have examined other markers of high-risk sexual activity, such as a history of abortion or sexually transmitted infection, but we were limited by questions included in the NSFG survey and underreporting of abortions [17].

5. Conclusions

A small proportion of women who are at risk for unintended pregnancy and STIs use dual-method protection. We believe the findings from this study can be used to inform interventions to improve dual-method use. It is our hope that there will be increased access to prescription contraceptive methods due to the Department of Health and Human Services recommendations for contraceptive coverage [18]. This could alleviate the gaps in insurance coverage which we found to be associated with decreased rates of dual-method use. Our findings of the lowest rates of barrier use among users of the most effective reversible contraceptives (LARC methods and DMPA) suggest that women using these methods are an important group for intervention development to promote dual-method use. A comprehensive approach to educating women about risk factors for unintended pregnancy and STI acquisition along with methods of prevention is essential.

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Review Article

Are Dual-Method Messages Undermining STI/HIV Prevention?

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Adolescent girls and young women who are at risk for unplanned pregnancy and sexually transmitted infection (STI), including HIV, are frequently counseled to use a hormonal contraceptive to protect against the former and condoms to protect against the latter, for example, American College of Obstetricians and Gynecologists, 2011. The present paper reviews the literature on multiple risk messages, compliance with this dual-use recommendation, predictors of dual use, and interventions developed to encourage dual use. Data indicate that simultaneous use of these two methods is not common, and that efforts to encourage dual use have not yielded promising results. An alternative is to recommend condom use alone, since condoms protect very well against STI and HIV, and quite well against pregnancy when used consistently and correctly. The availability of emergency contraception is relevant here. Research utilizing a randomized controlled trial is recommended.

1. Introduction: Why Recommend Dual Protection during Sex?

Unprotected sex can have numerous consequences, including unintended pregnancy and sexually transmitted infections (STI). Among US teens and young women, both are all too common and occur disproportionately within the same population: low-income women of color, especially African American women. In 2009, 410,000 teens aged 15–19 gave birth in the United States [1]. It is estimated that half of all pregnancies are unintended, and the figure is higher—62%—among women with incomes below the poverty level [2]. Poverty is also a risk factor for HIV/AIDS and other STIs [3, 4]. HIV incidence among those aged 13–29 is estimated to be 27% of the total 21,000 cases per year [5]. Data from the National Health and Nutrition Examination Survey (NHANES) indicated that, among sexually experienced girls aged 14–19, 38% had at least one of five STIs [6]. The rate for African American girls was 44%. It is critical that everything possible be done to reduce the prevalence both of unintended pregnancy and STI, the greatest risk for which is largely present among the same young women.

Hormonal contraceptives (HCs), which are highly effective at preventing pregnancy, do not prevent STI, including

Human Immunodeficiency Virus (HIV). On the other hand, male condoms, if used correctly and consistently, greatly reduce transmission of HIV [7] and STI [8, 9]. In an effort to prevent both unintended pregnancy and STI, guidelines for adolescents recommend encouraging the use of both male condoms and another contraceptive: "... sexually active adolescents should be encouraged to use condoms in conjunction with a more effective method of contraception to provide both effective pregnancy prevention and protection against STIs" [10], although it is not known how compliant health care providers are with this recommendation. There are data to suggest that the use of some HCs may potentiate the risk of HIV infection for purely biological reasons, although study findings are inconsistent [11, 12]. On the other hand, condoms, which are highly effective in preventing sexually transmitted infection and transmission, are less effective than HCs in preventing pregnancy, both in typical and perfect use. Because many adolescents and young women are at risk for both unintended pregnancy and STI, it is frequently recommended that such girls and women be counseled to use two forms of protection, one to prevent pregnancy and one to prevent STI [10, 13, 14].

To our knowledge, no published research has tested directly how these two risk messages are processed or

evaluated. A body of literature in social psychology, however, has studied the effects of multiple messages and found them to be complex [15]. Indeed, individual differences in the “need for cognition”—that is, tendency for and enjoyment of thought—can affect whether the second of two messages is even cognitively processed [16].

2. What Do We Know about Multiple Risk Messages?

When measures are used to protect people from harm, some recipients may increase the riskiness of their behavior in other ways. For example, there is evidence that children engage in more hazardous physical activity when wearing safety gear [17]. This phenomenon is known as “risk compensation”, a form of behavioral disinhibition that has been theorized to be a product of “risk homeostasis” [18]. In the area of HIV prevention, concern about risk compensation in the form of reduced condom use (“condom migration”) has been voiced in connection with preventive vaccines, preexposure prophylaxis, and vaginal microbicides [19, 20], all of which are assumed to provide only partial protection against HIV and all of which, at least currently, are recommended for use in conjunction with condoms. While to date evidence for risk compensation in these contexts has been mixed [21–26], concern remains high and the issue is widely believed to be unresolved [27].

Also relevant to this issue is the possibility that reasoning about dual-risk messages opens the door for post hoc justifications for risky behavior. For example, Gold and colleagues studied gay men who had engaged in risky sexual behavior [28, 29]. In these studies, men justified their risk behavior by reasoning such justifications as “AIDS is hard to transmit” and “I’m at less risk than most guys.” It may be that justifications are used to avoid condom use when another form of protection is in place and can be considered to confer safety (e.g., a microbicide; hormonal contraception).

Another form of multiple messages, “hierarchical messages” combines different HIV/STI risk reduction strategies to be used, not concurrently, but rather singly, in descending order of efficacy [30]. For example, if abstinence is not possible, use a male condom; if this is not possible, use a female condom; and so on. While this approach has difficulties, including the use of less effective strategies compared with single-method messages [31, 32], it is less relevant to the present topic and will not be extensively reviewed here.

3. How Often Are Dual-Methods Recommendations Followed?

A review of the literature on dual methods was conducted using the terms “dual method” and “dual protection” in Medline (1996—present) and PsycInfo (1987—present). Only studies conducted in the United States were used. Studies have yielded estimates of 3% to 26% of study samples that report dual method use, for periods of time ranging from last six to the previous six months [33–42]. It should

be noted, however, that the study obtaining the rate of 26% included HIV-positive women and all participants were six months postpartum [23]. This study also distinguished between alternating and simultaneous dual-method use, the former describing use of different methods at different times and the latter indicating use of both methods on every sexual occasion. Of the women reporting dual use in this study, only 64% reported simultaneous use. This finding suggests that a sizeable proportion of women reporting dual use in the studies just cited are in fact engaging in alternating use, meaning that the rates of dual methods *as intended* are overestimated by studies not making this distinction.

Data on contraceptive and condom use are reported from the Youth Risk Behavior Survey, a nationally representative school-based health survey, by the Centers for Disease Control and Prevention [43]. In 2009, use of dual methods (a condom and an HC) at last intercourse was reported by 13.1% of white girls, 53.6% of black girls, and 3.2% of Hispanic girls. Condom use alone, however, was reported by 42.5%, 45.1%, and 44.9% of these groups, respectively. It should be noted that these respondents were aged 15–19, and that condom use decreases with age [44]. In a study of women aged 18–45, the pattern for dual use was reversed: 5% of white women, 15% of African American women, and 16% of Hispanic women were users of condoms in conjunction with an efficient method of birth control [39].

It should be noted that use of dual methods by women appears to be increasing, at least between 1995 and 2002 [45], although this effect is THE strongest for younger women (aged 15–17) and drops off at age 18–19 [45]. This increase, as well as a general increase in condom use and abstinence, are thought to account for declines in teen pregnancy rates [45].

3.1. Predictors of Dual Use. A number of factors have been shown to predict dual methods use. One factor is level of risk, and here the news is unfortunate: those at higher risk are less likely to use dual methods. In one study [33], women with six or more partners were less likely than those with fewer to use methods preventing STI (i.e., condoms). Those with good communication with parents [38, 46], whose sexual debut was later [46], and who had fewer nonsexual risk behaviors [46], have been found to be more likely to use dual methods. On the other hand, another study found that women with more than one sex partner were more likely to use dual methods than any single method [35]. Younger women are more likely to use dual methods than older women [35]. Thus, conflicting results have been obtained regarding this issue.

Aspects of sexual relationships also influence contraception and condom use. Those who report newer and less committed sexual relationships [35, 37, 38, 42] are more likely to be dual methods users than others. Similarly, married or cohabiting women are less likely to use dual methods (or condoms) [39, 42]. Conversely, women whose communication with sex partners was good and who expected good support from partners should they become pregnant [42] were also likely to be dual method users. Also perhaps counterintuitively, women who shared contraceptive

decision-making with their partners were more likely than those who did not to use dual methods [39]. These correlational data are difficult to interpret; however, it may be that women who are relatively empowered in their relationships are able to use the methods that they choose.

Not surprisingly, the most robust predictors of dual method use have to do with women's primary concerns; that is, avoiding pregnancy versus avoiding disease. In fact, in one study, relationship status was significant in bivariate analysis but lost significance when motives for use were entered into the model [46]. Those reporting high levels of motivation to avoid STI and HIV [32, 39] or perceive their partners to possibly have HIV or STI [38] are also more likely to be dual-method than HC-only users. In a study of adolescents, however, desire to avoid pregnancy was associated with dual method use, while concern about STI and HIV did not [34]. It should be noted that this comparison was with the combination of HC alone and condom use alone, and it cannot be determined which of these subgroups may have been responsible for the difference (i.e., HC and condom use may have "cancelled each other out" in the analysis, while condom use may, by itself, have been significantly associated with concern about STI and HIV). Finally, women who express concern about both pregnancy and STI, or have had an STI, or perceived that condoms were effective against STI, were more likely to use dual methods rather than a single method [39].

In the afore-mentioned study that included HIV-infected women, HIV positivity was a strong predictor of dual method usage [41], indicating that women were strongly motivated to prevent transmission of the virus to their partners. Women in this study, who were six months postpartum, were also more likely to report dual method use if they felt that having another pregnancy "would be upsetting" if it occurred within the next six months. Additionally, dual method use was significantly predicted by having abstained from alcohol during the postpartum period.

A study conducted in the Netherlands [36] used hypothetical vignettes to assess behavioral intentions to use condoms. In the vignettes, participants imagined that they had just met someone that they were mutually attracted to and with whom they had decided to have sex. In one vignette, it was stated that there would be no risk of pregnancy, the other contained no such statement. Not surprisingly, intention to have sex without a condom was three times as high for the vignette in which pregnancy was not a concern as for the other. In this study, each participant responded to both vignettes, and the investigators compared condom use intentions for those who changed from condom to noncondom responses when the one with pregnancy concern preceded the other. Those who abandoned condom use intentions differed from the intentions of those who did not in three ways: they had lower perceived seriousness of STI, lower perceptions of friends' perceived seriousness of STI, and they reported lower perceived susceptibility to STI after unprotected sex.

Thus, although studies have yielded some inconsistent results, it appears that most women use a single method of protection, and the method used is based on motivation to

prevent the outcome of greatest concern [47]. This is most often concern about pregnancy, which is associated with HC use; those concerned about STI are more likely to be condom-only or dual-method users.

4. Condoms to Prevent STI and Pregnancy: How Effective Are They?

It is very clear that condoms are effective against HIV [1] and STI [9], when used correctly and consistently. It is also the case that HCs have no appreciable effect on preventing STIs. But what about pregnancy? There is indeed evidence that condoms as typically used are a less effective means of contraception than HC [48]. Condoms, when used perfectly, have a pregnancy rate of 2% and when used typically, it is 17.4%. The pill, when used perfectly, has a pregnancy rate of 0.3% and when used typically, it is 8.7%. However, condoms are in fact superior to other commonly used alternative forms. As typically used, condom failure rates are on a par with those of diaphragms and the cervical cap or sponge for nonparous women and are markedly superior to withdrawal, spermicides, the female condom, and the cervical cap or sponge for parous women [48]. Using data from the National Survey of Family Growth, Pazol and colleagues [49] estimated that if half of all women using HCs only also used condoms, approximately 40% of unplanned pregnancies and abortions could be prevented. In any case, it is clear that many teens do use condoms, although existing data cannot tell us with what consistency. Condom use has been increasing in this age group, presumably in response to HIV/STI prevention programs and is believed to be responsible for decreases in teen pregnancy rates [1, 44]. To gauge the consistency with which condoms are used, it is important to assess use specifically with different partners [50]; however, consistent use appears to be suboptimal. For example, one study found that only 45% of condom-using teenage boys used condoms with every act of sex [44].

The use of male condoms appears to be a viable option for most women. On the other hand, achieving correct and consistent condom use on every occasion of sex is difficult. Interventions that convey knowledge and build skills regarding STI/HIV can be effective enough to prevent new STI infections for as long as a year [51–53]. Given the importance of motivations for women's choice of method described above, interventions that stress the prevalence and seriousness of HIV and other STI may be a useful adjunct to routine contraceptive counseling.

Concerns about unintended pregnancy, regardless of contraceptive method used, are further mitigated by the widespread availability, without prescription, of emergency contraception (EC) [54]. Laws and policies related to accessibility vary somewhat by state [55]. Emergency contraceptives work by preventing ovulation or fertilization, and possibly by preventing implantation of the fertilized egg, although this mechanism has not been supported by clinical data [55]. It has been reported that the contraceptive strategy of condom use with EC backup is increasing in prevalence since EC became available [56].

5. Interventions to Promote Dual Methods Use

A small number of behavioral interventions to increase use of dual methods have been tested. One trial [57], randomized black and Latina adolescent girls on HC either to a video, STI/HIV counseling based on Project RESPECT [52], both the video and counseling, or usual care. The video was designed to promote dual methods and increase perceived vulnerability to HIV. At a three-month follow-up, the women who had received both interventions were significantly more likely to report having used a condom during their most recent sexual encounter, compared with each of the other three groups. Unfortunately, this result was nonsignificant at the 12-month follow-up. This study suffered from severe attrition, with only 55% of participants returning for the three-month follow-up and 49% for the 12-month follow-up. This low-retention rate renders interpretation of the findings difficult.

An analysis of data from the Project RESPECT trial, a condom-focused multisite intervention study conducted in STI clinics, examined uptake of condoms by women in the trial who were using HC [58]. Among these women, condom use increased as a result of the intervention, and most women remained on their HC regimens. Thus, in response to a condom-focused intervention, many women became dual-methods users, although most did not use condoms consistently (i.e., were alternating dual method users).

A more recent study tested a computer-based intervention designed to encourage dual methods use among at-risk women [59]. Participants were at risk for either pregnancy or STI and were enrolled irrespective of type of contraception used. Women were randomized to receive this intervention or general contraceptive information. Based on self-report, the intervention increased the ever-use of dual methods. While the confidence interval of the unadjusted OR (1.38) contained 1.00, when adjusted for baseline differences using a propensity score, this effect became significant (although alternating versus simultaneous use was not assessed). Differences between treatment arms for consistent condom use, STI, unplanned pregnancy, and individual STIs were all nonsignificant. The authors interpreted these findings to suggest that the use of dual methods was not sustained long enough to prevent STI and pregnancy. Use of dual methods was predicted by higher education level, substance use, and use of either hormonal contraceptives or male condoms at baseline.

Finally, a recent study tested a provider-delivered intervention designed to promote dual method use by providing counseling both about STI risk and pregnancy risk, compared with a standard of care in which only pregnancy was addressed [60]. In both conditions, patients chose their preferred method without specific encouragement from the counselor. The primary outcome, rather than use of dual methods per se, was the number of sex acts unprotected by a male or female condom. The intervention group reported 3 fewer unprotected acts than the standard of care group, a difference that approached significance.

In summary, the research on interventions to promote dual-method use is mixed. Condom-focused interventions

that focus attention on the threats of HIV and STI are successful in increasing condom use, even when women are on HC prior to the intervention. Other studies have yielded mixed results—that is, self-reported outcomes at odds with biological ones—and nonsustained or null results. These results suggest that dual methods counseling frequently fails to achieve its desired outcome, consistent and sustained use of HC and condoms at every act of intercourse. Since condoms protect very well against STI, and quite well against pregnancy, and given the availability of EC should condom failure occur, recommending consistent use of condoms may be more effective at preventing STI than recommending the use of dual methods. Moreover, if the method used must protect against the outcome of greatest concern for the woman, and if that outcome is pregnancy, she may be less tempted to abandon condom use if that is her only source of protection. On the other hand, if she is protected from pregnancy by hormonal contraceptives, she may be more tempted to forego condoms, particularly under male resistance. However, I believe that this hypothesis should be tested empirically, by comparing a dual-use recommendation with a condom-only one. I would hypothesize that women in the condom-only arm would acquire fewer STIs, but may need to use EC more often and may even become pregnant more often. In addition, characteristics of successful dual-method users could be identified, in a message-controlled context.

Would such a trial be feasible? Would young women be willing to be randomized to the form of protection that they would use for a prolonged period? Recent evidence suggests that the answer to this question is “yes.” A feasibility study to assess the acceptability of an RCT to examine whether the use of hormonal contraceptives creates biological vulnerability to STIs has been conducted [61]. In this study, potential at-risk participants were asked whether they would be willing to be randomized to hormonal contraceptives or to an IUD. They were also asked to provide urine or endocervical swabs for STI testing. Overall, about 70% of participants said that they would be willing to participate in this trial, indicating that women are willing to be randomized, and suggesting that such a trial is indeed feasible.

Would such a trial be ethical? Of course, informed consent would be obtained, and participants will understand that they can cease participation in the trial (or switch arms?) without consequence. To ensure that participants (and parents/guardians?) were fully informed and willing to be randomized to either intervention, investigators would explain to participants the advantages and disadvantages of condoms and HC as tools for pregnancy and STI prevention.

The ethical sticking point appears to be, for some, randomizing participants to receive a less effective method of contraception. However, the *overall* risks and benefits to study participants must be weighed to determine whether equipoise exists between study arms. On the one hand, the literature indicates that the condoms-only group would receive a less effective pregnancy prevention message than the dual-method (standard of care) arm. Therefore the apparent risk of unintended pregnancy would be increased in the condoms-only arm. But on the other hand, the condoms-only message may be more effective than the dual methods

message for preventing STIs, including HIV. (Could be noted here or elsewhere the negative health consequences of STI acquisition among teenagers.) The potential benefit of STI avoidance could balance or outweigh the increased risk of failed contraception. Moreover, participants would be counseled on emergency contraceptive use and given access to this method in cases of failed contraception. This counseling and access would reduce the risk of unintended pregnancy among all study participants and mitigate the increased risk in the condoms-only arm. Although the recommendation to adolescents and young women at risk for unplanned pregnancy and STI is to use both a hormonal contraceptive to prevent pregnancy and male condoms to prevent STI, there is evidence to suggest that this approach is failing, and if this is so, that a significant, unnecessary burden of STI, including HIV, may be the result. This hypothesis should be tested empirically, using a rigorous design.

6. Looking to the Future: Dual Protection Technologies

It is possible that this issue will be solved by the development of technologies that prevent both pregnancy and STI. The global fight against HIV has led to great efforts to develop topical microbicides that can be applied vaginally to neutralize the virus before it can infect the woman. The premise for the importance of such products was that, since men control condom use and often may not agree to their use, women needed methods to prevent STI/HIV infection that were under their own control and undetectable by partners. The first such candidate was in fact a spermicidal surfactant, nonoxynol-9, which was shown to kill HIV and other sexually transmitted pathogens *in vitro*. Unfortunately, this product caused *in vivo* damage to the epithelium, permitting the entrance of HIV, and actually *increased* the likelihood of infection with the virus [62]. A more recent attempt to create a dual-method product, an acid-buffering gel, showed promise as dual-protection agent [63] but unfortunately was shown to be ineffective against HIV.

Efforts to develop an effective microbicide have continued, and currently focus on antiretroviral products [64]. Recently, the CAPRISA trial of a vaginal gel containing the antiviral tenofovir was shown to reduce HIV incidence by between 38% and 54%, depending on adherence, compared to a placebo [65]. This product does not prevent pregnancy; in fact a pregnancy rate of 4.0 per 100 women-year was observed. Currently, most products in trials are ones that are hoped to enable pregnancy, and are thus not dual-protection agents. However, if an effective microbicide is identified, efforts to create one that also prevents pregnancy will be the next step [66].

7. Conclusion

Until fully effective dual-protection technologies become available, we will continue to face the conundrum of the dual-method message. Should the recommended trial yield the hypothesized results, an argument could be made for

recommending condom-only contraception, and the study results could be informative as to the characteristics of successful dual-method users.

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Research Article

Prevalence of and Barriers to Dual-Contraceptive Methods Use among Married Men and Women Living with HIV in India

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Objective. To describe the prevalence and correlates of dual-contraceptive methods use (condoms and an effective pregnancy prevention method) and barriers to their use among married persons living with HIV (PLHIV) in India. **Methods.** We conducted a quantitative survey (93 men, 97 women), 25 in-depth interviews, seven focus groups, and five key informant interviews. **Results.** Prevalence of dual-contraceptive method use increased from 5% before HIV diagnosis to 23% after diagnosis ($P < 0.001$). Condoms were the most common contraceptive method, with prevalence increasing from 13% before diagnosis to 92% after diagnosis ($P < 0.001$). Barriers to using noncondom contraceptives were lack of discussion about noncondom contraceptives by health care providers, lack of acceptability of noncondom contraceptives among PLHIV, and lack of involvement of husbands in family planning counseling. **Conclusion.** There is a need for interventions, including training of health care providers, to increase dual-contraceptive methods use among married PLHIV.

1. Introduction

The sexual and reproductive health of persons living with HIV (PLHIV) is fundamental to their well-being and that of their partners and children. In 2008, there were an estimated 2.27 million PLHIV in India [1], most of whom were adults in the sexually active and reproductive age range and about two-fifths of whom were women [1].

The major risk for HIV transmission in India is sexual intercourse [1], with most married women living with HIV having acquired it from their husband [2, 3]. Because increased availability of antiretroviral treatment and management of opportunistic infections have greatly improved the prognosis for PLHIV in India, married PLHIV in the reproductive age range face important reproductive health and

family planning decisions. Couples who desire to initiate a pregnancy require careful counselling regarding conception, antenatal care, and childbirth to minimize the risks of transmitting HIV to children and uninfected partners; couples who do not intend to initiate a pregnancy require effective contraception along with protection against both sexually transmitted infections (STIs) and infection or reinfection with HIV [4].

Simultaneous protection against both unwanted pregnancy and STIs/HIV is referred to as dual protection [5]. Theoretically, dual protection can be accomplished by consistent male condom use alone; however, typical use of male condoms (hereafter referred to as condoms) as a contraceptive method results in a one-year cumulative incidence of unintended pregnancy of about 15% [6].

Other contraceptive methods, including male and female sterilization, intrauterine devices (IUDs), and oral hormonal contraceptives, are much more effective than condoms in preventing pregnancy, but do not protect against STIs/HIV [6, 7]. Thus, the most prudent approach to dual protection is the use of dual-contraceptive methods: condom use in combination with a highly *effective* pregnancy prevention method. Although promotion and adoption of dual-contraceptive methods pose more challenges than promotion of a single method (e.g., condoms), in a setting where both unintended pregnancy and STI/HIV transmission are of great concern, adoption of dual-contraceptive methods is necessary for optimal sexual and reproductive health [7].

In 2006, we conducted a mixed-methods study of sexual and reproductive health of PLHIV in India [8]. Here we describe results from this study about prevalence of use of contraceptive methods by married men and women living with HIV, prior to and after their HIV diagnosis, assess factors related to their dual-contraceptive methods use after their HIV diagnosis, and assess barriers to the use of dual-contraceptive methods.

2. Materials and Methods

We used a concurrent triangulation mixed-methods design [9], in which we conducted a quantitative survey, qualitative in-depth interviews, focus group discussions (FGDs), and key informant interviews from August to November 2006. The goal of using mixed methods was to provide a comprehensive understanding of the phenomenon of dual-contraceptive methods use. The quantitative component primarily explored the prevalence and correlates of dual-contraceptive methods use, and the qualitative component focused on the experiences of using one or more contraceptive methods and explored barriers to use of a noncondom contraceptive method.

We recruited heterosexual men and women from district-level PLHIV networks of the Indian Network for People Living with HIV (INP+) in five Indian states (Tamil Nadu, Andhra Pradesh, Maharashtra, West Bengal, and Uttar Pradesh). Eligible participants were known to be HIV positive for at least one year, 18 years of age or older, sexually active in the past 3 months, and able to understand and give consent to the study. The study protocol was reviewed and approved by the Institutional Review Board at the University of Toronto, Canada, and by a community advisory board constituted by INP+. All participants except key informants were paid 250 Indian rupees.

2.1. Quantitative Component. We used systematic sampling to recruit every k th eligible heterosexual man or woman living with HIV, respectively, who attended INP+ support group meetings and drop-in centres of the participating district-level PLHIV networks. This was a simple approach to essentially obtain a random sample. The value of " k " was site specific. Overall, we recruited 100 men and 100 women. In the present study, we restricted the quantitative analyses

to those who reported being currently married (93 men, 97 women).

Using a structured questionnaire, trained interviewers asked participants about their current contraceptive use and their contraceptive use prior to their HIV diagnosis. Participants were asked, "Before you tested positive for HIV, did you or your partner ever use any contraceptive/family planning method?" Participants who answered "yes" were then asked, "Which contraceptive/family planning method did you or your partner use?" and were read the following options: the pill, IUD, condom, spermicide, calendar method, injectables, tubal ligation, and vasectomy. Participants were also asked, "Are you or your partner currently using any contraceptive/family planning method?" Participants who answered "yes" were then asked, "Which contraceptive/family planning methods are you currently using?" and were read the options listed above.

Participants who reported using the pill (oral hormonal contraception), an IUD, injectables, tubal ligation, or vasectomy were scored as using an *effective* contraceptive (pregnancy prevention) method (known to have greater than 90% effectiveness against pregnancy) [6]. Participants who reported using an *effective* pregnancy prevention method *and* condoms were scored as using a dual-contraceptive method.

The survey also assessed demographic, medical, and behavioural covariates, including age, gender, alcohol consumption in the past 3 months, age at first sexual intercourse, whether the participant had a casual sex partner ("your sexual partner whom you have not met before having sex or with whom you have had only casual acquaintance") in the past 3 months, principal reasons for using contraceptives (to prevent unwanted pregnancy, to prevent the risk of transmission of HIV to their partner, to prevent getting STIs, to prevent having an HIV-infected baby, and/or partner's preference for contraceptives), HIV status of spouse, years since HIV diagnosis, whether the participant received post-test HIV counselling, whether the participant was currently on antiretroviral drugs, and last CD4 cell count.

2.2. Qualitative Component. We recruited heterosexual PLHIV to participate in in-depth interviews and FGDs using snowball sampling, with PLHIV associated with the participating district-level networks serving as seeds, and purposive sampling, to ensure inclusion of persons with seroconcordant and serodiscordant spouses. In-depth interviews were conducted with 25 PLHIV (14 men, 11 women) who reported currently being married and living with their spouse. The interview included open-ended questions to explore the contexts of unprotected and safer sex, current and past use of condoms and other contraceptives, reasons for use or nonuse of various contraceptive methods, and experiences in using those methods. A total of 7 FGDs were conducted with married PLHIV. Each FGD was single gender: three with men ($n = 15$) and four with women ($n = 28$). Discussions focused on sexual and reproductive health needs, use of contraceptives, and prevention challenges.

Key informant interviews were conducted with three physicians providing services to PLHIV, one HIV counsellor,

and one PLHIV community leader. A community debriefing meeting was conducted with peer research staff and key PLHIV community leaders where the findings were shared and feedback was obtained as a form of “member checking” to enhance the validity of the findings [10].

2.3. Data Analyses. We conducted parallel mixed data analysis [11] in which the quantitative and qualitative data were first analysed separately and then compared and contrasted.

We described results using frequencies and proportions and used McNemar tests to compare contraception method use prior to and after HIV diagnosis. We used a multivariate logistic regression model with forward selection (using $P < 0.05$ as the entry criterion) to calculate odds ratios (ORs) and corresponding 95% confidence intervals (CIs) for potential demographic, medical, and behavioural correlates of dual-contraceptive methods. The variables considered were age, gender, alcohol consumption in the past 3 months, age at first sexual intercourse, whether the participant had a casual sex partner in the past 3 months, principal reasons for using contraceptives (to prevent unwanted pregnancy, to prevent the risk of transmission of HIV to their partner, to prevent getting STIs, to prevent having an HIV-infected baby, and/or partner's preference for contraceptives), HIV status of spouse, years since HIV diagnosis, whether the participant received posttest HIV counselling, whether the participant was currently on antiretroviral drugs, and last CD4 cell count. To aid in the interpretation of the odds ratio for the CD4 count, the count was divided by 50 so that the odds ratio represented the change in odds for every increase in 50 cells/mL of the CD4 count. Statistical analyses were performed with SPSS 17.

In-depth interviews and FGDs were audiotaped, transcribed verbatim in native languages, and translated into English. Data were explored using narrative thematic analysis and a constant comparative method from grounded theory [12, 13].

3. Results

3.1. Sample Characteristics. Sociodemographic characteristics of study participants are presented in Table 1. The mean age of the survey sample (93 men, 97 women) was 34.1 ± 5.2 years for men and 28.3 ± 4.3 years for women. Sixty-two percent of the men and 71% of the women did not complete high school. Seventy percent of the men and 92% of the women reported being in HIV-seroconcordant relationships. Most PLHIV reported having disclosed their HIV status to their spouse (90% of men, 94% of women). Three men, but no women, reported having a regular sexual partner other than their spouse in the past 3 months. Thirteen men and two women reported having one or more casual partners in the past 3 months.

Twenty-five married PLHIV (14 men, 11 women) participated in in-depth interviews (Table 1). Their mean age was 31.3 ± 4.6 years. Half (52%) did not complete high school. Half (52%) were volunteer peer educators or part-time peer outreach workers for district-level PLHIV networks.

A total of 43 married PLHIV (15 men, 28 women) participated in 7 FGDs (Table 1). The mean age of the FGD participants was 30.3 ± 5.1 years. More than half (58%) did not complete high school. About one-third (37%) were volunteer peer educators or part-time peer outreach workers for district-level PLHIV networks.

3.2. Use of Contraceptives among Married PLHIV: Quantitative Findings. Table 2 describes contraceptive use before and after HIV diagnosis among married PLHIV. Condoms were the most commonly reported contraceptive method used by married PLHIV prior to and after their HIV diagnosis, followed by tubal ligation. Whereas only 28% of PLHIV (30% of men, 27% of women) reported using any contraceptive prior to their HIV diagnosis, 95% of PLHIV reported currently using a contraceptive (96% of men, 95% of women). This increase, which was highly significant ($P < 0.001$), was mainly due to condom use increasing from 13% of married PLHIV (15% of men; 11% of women) before HIV diagnosis to 92% (92% of men, 92% of women) after diagnosis ($P < 0.001$).

Use of *any effective* pregnancy prevention method (the pill, an IUD, injectables, or sterilization) increased from 19% of married PLHIV (18% of men, 21% of women) prior to HIV diagnosis to 25% (18% of men, 31% of women) after HIV diagnosis. However, this increase was not statistically significant ($P = 0.20$). The increase in tubal ligation use was statistically significant ($P < 0.01$), whereas the increase in use of the pill was not statistically significant ($P = 0.33$). The other *effective* pregnancy prevention methods (injectables, IUDs, and vasectomy) were used too infrequently to assess change.

3.3. Use of Dual-Contraceptive Methods among Married PLHIV: Quantitative Findings. Five percent of married PLHIV reported use of dual-contraceptive methods prior to their HIV diagnosis (4% of men, 5% of women), which significantly increased to 23% of married PLHIV after their diagnosis (15% of men, 30% of women) ($P < 0.001$). Thus, over three-fourths of the participants did not use dual-contraceptive methods following their HIV diagnosis; instead, 70% only used condoms (77% of men, 63% of women), 3% only used an *effective* pregnancy prevention method (3% of men, 2% of women), and 5% used neither (4% of men, 6% of women).

When we explored demographic, medical, and behavioral factors associated with dual-contraceptive methods use after HIV diagnosis, the final model after forward selection included five variables (Table 3). Married PLHIV were significantly more likely to report using dual-contraceptive methods if they were female (OR = 2.93, 95% CI = 1.29–6.67), had received posttest HIV counseling (OR = 2.96, 95% CI = 1.22–7.19), used contraception to prevent the risk of transmission of HIV to their partner (OR = 2.30, 95% CI = 1.01–5.20), or used contraception due to partner's preference (OR = 2.76, 95% CI = 1.08–7.06). Furthermore, married PLHIV were significantly less likely to report using dual-contraceptive methods if they had a higher CD4 cell count

TABLE 1: Sociodemographic characteristics of study participants.

Characteristic	Quantitative survey		Qualitative component	
	Men (N = 93)	Women (N = 97)	In-depth Interviews (N = 25)	Focus group discussions (N = 43)
<i>Sex</i>				
Male	93 (100%)	—	14 (56%)	15 (35%)
Female	—	97 (100%)	11 (44%)	28 (65%)
<i>Age (years)</i>				
18–29	21 (23%)	58 (60%)	7 (28%)	16 (37%)
30–39	57 (61%)	38 (39%)	17 (68%)	23 (53%)
40–49	15 (16%)	1 (1%)	1 (4%)	4 (9%)
<i>Education</i>				
<primary	17 (18%)	31 (32%)	1 (4%)	4 (9%)
Primary (5th STD)	19 (20%)	19 (20%)	6 (24%)	9 (21%)
Elementary (8th STD)	22 (24%)	19 (20%)	6 (24%)	12 (28%)
High school (10th STD)	21 (23%)	20 (21%)	7 (28%)	11 (26%)
Higher secondary (12th STD)	9 (10%)	6 (6%)	0 (0%)	5 (12%)
College or higher	5 (5%)	2 (2%)	5 (20%)	2 (5%)
<i>Occupation</i>				
Daily wage laborer	40 (43%)	25 (26%)	2 (8%)	2 (5%)
Private company staff	10 (11%)	7 (7%)	1 (4%)	3 (7%)
Peer educator/outreach worker for PLHIV network	12 (13%)	10 (10%)	13 (52%)	16 (37%)
Self-employed	18 (19%)	3 (3%)	2 (8%)	3 (7%)
Homemaker	0 (0%)	34 (35%)	3 (12%)	12 (28%)
Unemployed	10 (11%)	15 (15%)	2 (8%)	2 (5%)
Other	3 (3%)	3 (3%)	2 (8%)	5 (12%)

TABLE 2: Use of contraceptives before and after HIV diagnosis as reported by married persons living with HIV in India.

Contraceptive use	Before HIV diagnosis		After HIV diagnosis		P value ^a
	Men (n = 93)	Women (n = 97)	Men (n = 93)	Women (n = 97)	
Any contraceptive method	28 (30.1%)	26 (26.8%)	89 (95.7%)	92 (94.8%)	<0.001
Condom use	14 (15.1%)	11 (11.3%)	86 (92.5%)	89 (91.8%)	<0.001
<i>Effective pregnancy prevention methods</i>					
Oral hormonal contraception (“the pill”)	2 (2.2%)	6 (6.2%)	3 (3.2%)	10 (10.3%)	0.33
Intrauterine device	4 (4.3%)	6 (6.2%)	1 (1.1%)	0 (0%)	— ^b
Injectables	1 (1.1%)	1 (1.0%)	0 (0.0%)	1 (1.0%)	—
Tubal ligation	9 (9.7%)	9 (9.3%)	11 (11.8%)	19 (19.6%)	<0.01
Vasectomy	1 (1.1%)	0 (0.0%)	3 (3.2%)	1 (1.0%)	—
Any effective pregnancy prevention method	17 (18.3%)	20 (20.6%)	17 (18.3%)	30 (30.9%)	0.20
Dual-contraceptive methods	4 (4.3%)	5 (5.2%)	14 (15.1%)	29 (29.9%)	<0.001
<i>Ineffective pregnancy prevention methods</i>					
Spermicide	1 (1.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Calendar method	3 (3.2%)	1 (1.0%)	1 (1.1%)	1 (1.0%)	—

^a P value for the change in contraceptive use among men and women combined.^b Numbers too small to assess change.

(OR = 0.73 per increase of 50 cells/mL, 95% CI = 0.62–0.87). To explore possible differences between sexes, we conducted stratified analyses. Results showed that higher CD4 count was associated with less use of dual-contraceptive methods among both men (OR = 0.73 per increase of 50 cells/mL, 95%

CI = 0.55–0.96) and women (OR = 0.75 per increase of 50 cells/mL, 95% CI = 0.62–0.91). In addition, among women, use of contraception to prevent the risk of transmission of HIV to their partner was associated with dual-contraceptive methods use (OR = 4.48, 95%CI = 1.48, 13.54).

TABLE 3: Correlates of dual-contraceptive methods use among married persons living with HIV in India^a

Variable	Odds ratio	95% confidence interval
<i>Sex</i>		
Male	1.00	—
Female	2.93	1.29–6.67
<i>Posttest HIV counselling</i>		
No	1.00	—
Yes	2.96	1.22–7.19
<i>Used contraception to prevent risk of transmission of HIV to partner</i>		
No	1.00	—
Yes	2.30	1.01–5.20
<i>Used contraception due to partner's preference</i>		
No	1.00	—
Yes	2.76	1.08–7.06
Last CD4 cell count (per increase of 50 cells/mL)	0.73	0.62–0.87

^a Odds ratios and 95% confidence intervals were calculated using a multivariate logistic regression model with forward selection (using $P < 0.05$ as the variable entry criterion).

3.4. Barriers to the Use of Effective Contraceptive Methods: Qualitative Findings. We identified three key barriers among married PLHIV to using noncondom contraceptive methods—either alone or along with condoms: lack of discussion by health care providers about contraceptives other than condoms, lack of acceptability of noncondom contraceptives to PLHIV due to misconceptions about and overestimation of their side effects, and lack of involvement of husbands in family planning counseling, placing the burden for contraception on women.

3.4.1. Lack of Discussion by Health Care Providers about Contraceptives other than Condoms. Most of the participants across different states reported that the focus of HIV and family planning counseling for PLHIV was exclusively on condoms, with very little discussion of other contraceptive methods. As a man explained:

First they (HIV counselors) say “Use condoms and have safe sex.” They don’t go to the next level. For general people, what will they say? “If you are not safe, a baby will be born. To avoid that, use Copper-T (IUD) or pills or undergo (sterilization) operation”...but for us there is no choice. Isn’t it? As soon as we go, they will say (mimicking the counselor) “My Lord! Without putting on the cover (condom), don’t even take it out (laughs).”

This explanation was consistent with the data from key informant health care providers. Two key informant physicians explained that doctors and counselors may emphasize the use of condoms to the exclusion of other contraceptives. Another physician key informant thought some doctors may not talk about condoms or any contraceptives because they do not want to convey the notion to PLHIV that they can be sexually active.

Some PLHIV who had been using noncondom contraceptives actually stopped using them in the belief that condoms would be sufficient. An in-depth interview participant (a woman peer counselor) said: “Because we emphasize using condoms even if they already have Copper-T, many then say, “We don’t want Copper-T, we don’t want pills. We will just use *Nirodh* (condoms).” So, in some cases, emphasis on condom use may discourage people from using other contraceptives along with condoms.

Some women reported unintended pregnancies because they did not use condoms consistently and/or did not use a noncondom contraceptive. For instance, a woman said: “Once I had doubt and underwent abortion when my husband was not well. (I thought), now I don’t need a child—later we will...No, I do not use oral pills or Copper-T.” Adequate information and tailored counselling on effective contraceptive methods might have prevented this unintended conception.

Tubal ligation for women after the birth of two or three children is commonly practiced in India [14]. A woman with two children who had previously visited a government hospital for her first delivery before she became HIV positive recounted how the content of counseling changed after her HIV diagnosis to focus mainly on condom use: “Four years back, they (gynecologists) talked about Copper-T, pills, this and that; now they focus only on condoms—then operation (tubal ligation).” Thus, in addition to condoms, some health care providers talked about tubal ligation with HIV-positive couples who were seen as having completed their family.

3.4.2. Lack of Acceptability of Noncondom Contraceptives

Misconceptions about and Overestimation of Side Effects of Oral Contraceptive Pills (OCPs). Several participants, both women and men, had misconceptions about using non-condom contraceptives. For example, a woman said that she would not want to take OCPs because she has a “hot” body:

"I will tell (my husband), "Oh no! My body is usually "hot." I will die. Don't even mention to me about those tablets."

Some women, although they might never have tried OCPs, feared side effects as a result of hearing the accounts of other women who had used OCPs. As a woman said, "I do not have any experience (in taking OCPs), and I shall share what I know. Those who take Mala-D (a brand of OCP) get dizziness, body pain...I do not want to use." This finding suggests that reported experiences of women in informal social networks may influence attitudes toward OCPs.

Concerns That Convalescence from Tubal Ligation Will Result in Loss of Income. Of the 19 women in the quantitative survey who reported having had tubal ligation, ten reported having this procedure after their HIV diagnosis. Of the 11 men who reported that their wives had tubal ligation, two participants indicated that their wives had the procedure following their HIV diagnosis. In focus groups and in-depth interviews, some HIV-positive women did not want to undergo tubal ligation in spite of not wanting to conceive again. For instance, although advised by her doctor to undergo tubal ligation, a woman refused because she thought the procedure would result in loss of wages to her family: "My friends complained of (chronic) stomach ache after the operation...I have to work 24 hours. Only if I work will there be money. I said "I will not do it." My husband also agreed with me." Another woman said, "Once I get operated on, I will become weak...then I need to be at home for a minimum of 6 months. We need to have a good diet. We don't have that sort of a luxury." It appears that fear of inability to work and the perception of the need for prolonged bed rest prevented this woman from undergoing tubal ligation.

Discussions with the HIV-positive peer research staff at the community debriefing meeting revealed that many women were also concerned about the effects of tubal ligation on HIV disease progression. These peer research staff also believed that some health care providers were hesitant to perform tubal ligation for women living with HIV due to fear of contracting HIV themselves.

Concerns That Copper-T (Type of IUD) and OCPs Are Cumbersome and Inconvenient. Negative experiences of friends who used Copper-T led some women to avoid it. For instance, a woman explained: "Two of my neighbors got rid of Copper-T since it did not suit them... One can get pain or fever. There are many problems with it."

A key informant who had been counseling PLHIV on family planning methods explained how difficult it is to "convince" some PLHIV to use contraceptives other than condoms:

We say, "Even if you are on oral pills, you must use condoms when you have sex." We say the same for Copper-T: "Whenever you have sex, always use condoms"...but many would not agree to put on Copper-T in addition to using condoms since it has to be periodically changed. They will make a lot of fuss—even with doctors.

Hence we do not want to talk about it (Copper-T). Even when you talk about pills (in addition to condoms), they would not agree. They will say we are already on "strength pills" (vitamins) and how many more (pills) can we take?

3.4.3. Lack of Involvement of Husbands in Family Planning Counseling. In India, a pregnant wife often resides at her parents' home, so her husband often does not accompany her to antenatal care visits. This was seen as a reason for lack of involvement of husbands in family planning methods. A man with one child explained: "When my wife goes for (antenatal care) visits, they also talk about family control. And they try to convince her to have an operation (tubal ligation). But since I am not going with her, they do not talk about family control with me."

Also, many men living with HIV reported that vasectomy was not discussed with them. Furthermore, they held the misconception that vasectomy might lead to loss of virility as well as to body weakness, which might reduce their capacity to work.

4. Discussion

This mixed-methods investigation suggests that dual-contraceptive methods are not widely used by married men and women living with HIV in India. About one-fourth of participants in the survey reported using dual-contraceptive methods—condom use in combination with an *effective* pregnancy prevention method (OCPs, IUDs, injectables, or sterilization). The main reason for the low prevalence of dual-contraceptive methods use was the low prevalence of the use of *effective* pregnancy prevention methods (25%). This was in contrast to the prevalence of condom use, which increased from 13% before HIV diagnosis to 92% after HIV diagnosis.

We know of no previous studies that examined the prevalence of dual-contraceptive methods use among PLHIV in India. The prevalence of dual-contraceptive methods use among PLHIV in our study (23%) was quite high compared with women in Rwanda (1%) [15] and Malawi (1%) [16] and with men and women in Uganda (4% [17] and 5% [18]), but was lower than that reported among women in Soweto, South Africa (33%) [19], the United States (47%) [20], and Brazil (28%) [21].

We are aware of only two studies that examined change in dual-contraceptive methods use after diagnosis of HIV infection. In Brazil, dual-contraceptive methods use among women increased from 2% before HIV diagnosis to 28% after diagnosis [21]. In Malawi, use among women increased from 0.4% before diagnosis to 1.3% one week after diagnosis [16].

Our quantitative results were consistent with the qualitative findings that health care providers restrict their discussion of contraceptives with PLHIV mainly to condoms and that non-condom contraceptives tend to lack acceptability among PLHIV due to misconceptions about their use and overblown concerns about their side effects. These findings

indicate the need to educate married PLHIV about the benefits of dual-contraceptive methods and to train health care providers to conduct this education effectively, including how to counter misconceptions and unfounded concerns about non-condom contraceptives.

The survey identified posttest HIV counseling as a significant correlate of the use of dual-contraceptive methods, suggesting that discussion of dual-contraceptive methods with married PLHIV during post-test counseling should be emphasized. Using contraceptives to prevent HIV transmission to the spouse was also significantly correlated with dual-contraceptive methods use, suggesting that appeals to personal responsibility in counseling and educational materials might be useful.

The very low prevalence of vasectomy reported in the survey was consistent with the qualitative finding of lack of involvement of many husbands in family planning counseling. Furthermore, the association in the survey between dual-contraceptive methods use and partner's preference for contraception suggests that involvement of both partners in contraceptive counseling and decision making around family planning might help to increase dual-contraceptive methods use.

All contraception, including condoms, is free in India [22]. Furthermore, the Indian government provides monetary incentives for tubal ligation, vasectomy, and IUD insertion [23]. Thus, cost is likely not a barrier to adoption of dual-contraceptive methods use.

The main advantage of the dual-contraceptive methods approach is its efficacy; however, the main drawback is the potential difficulty in motivating people to use two contraceptive methods [7]. A review article on dual protection argued for the importance of promoting dual protection in spite of this difficulty [24]. It is therefore essential that efficient and effective interventions be developed and implemented to promote the use of dual-contraceptive methods among married PLHIV in India, to protect their own and their partner's health, and to prevent unintended pregnancies and consequent possible HIV infection of the infant [25].

The results of this study need to be considered in relation to its limitations. First, all of our participants were associated with PLHIV networks, and more than 40% of the participants in the qualitative component were volunteer peer educators or part-time peer outreach workers for district-level PLHIV networks. Thus, our sample may have been more educated about HIV and contraceptives than the general population of married PLHIV. Furthermore, our finding that counselling focused on condom use to the exclusion of other contraceptive methods may have been skewed by the high proportion in our sample of peer educators/outreach workers, who were trained to focus their education of PLHIV on condom use.

Second, we did not query about consistency or concurrency of use of each of the various contraceptive methods either before or after HIV diagnosis. However, we did query about consistency of condom use in the past 3 months (after HIV diagnosis) and reported previously that the prevalence of consistent condom use with regular partners was 69%

among men and 73% among women [8], compared to the prevalence of current condom use reported here (not taking consistency into account) of 92% among men and 92% among women. Thus, the prevalence of *consistent* dual-contraceptive methods use was undoubtedly even lower than the 23% prevalence of dual-contraceptive methods use measured with the imperfect methodology used in the current study.

Third, we relied on the participant's self-report of spouse's use of contraceptives. Men may have underreported non-condom contraceptive use among their wives because they were not in direct control of their use (e.g., OCPs) or may not have known about their use (e.g., OCPs or IUDs).

Finally, it is possible that responses were influenced by social desirability bias due to the sensitive nature of discussions of sexual behavior and contraception in India. However, because condom distribution and promotion of safer sex are commonplace in PLHIV networks, study participants, who attended these networks, were accustomed to such discussions.

Despite these limitations, our study has offered useful information for designing interventions to promote use of dual-contraceptive methods among married men and women living with HIV in India.

5. Conclusion

There is a need for interventions to promote use of dual-contraceptive methods among married men and women living with HIV in India who do not want a child or who want to postpone childbirth. These interventions should promote the husband's involvement in family planning counselling (including discussion of vasectomy) and should provide tailored couples counselling around the benefits of dual-contraceptive methods use (prevention of infection and pregnancy) and the recommended dual-contraceptive methods (condoms *and* a highly *effective* pregnancy prevention method). PLHIV should be presented with the entire range of contraceptive options, and common misconceptions about various contraceptives should be clarified. HIV health care providers and educators and obstetricians/gynaecologists need to be trained about the sexual and reproductive health needs and rights of PLHIV and to be competent in offering family planning counselling in a nonjudgmental, unbiased, PLHIV-centered manner. There is a need for national guidelines to integrate HIV care and reproductive health services [19].

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Research Article

Modern Contraceptive and Dual Method Use among HIV-Infected Women in Lusaka, Zambia

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HIV-infected women in sub-Saharan Africa are at substantial risk of unintended pregnancy and sexually transmitted infections (STIs). Linkages between HIV and reproductive health services are advocated. We describe implementation of a reproductive health counseling intervention in 16 HIV clinics in Lusaka, Zambia. Between November 2009 and November 2010, 18,407 women on antiretroviral treatment (ART) were counseled. The median age was 34.6 years (interquartile range (IQR): 29.9–39.7), and 60.1% of women were married. The median CD4⁺ cell count was 394 cells/uL (IQR: 256–558). Of the women counseled, 10,904 (59.2%) reported current modern contraceptive use. Among contraceptive users, only 17.7% reported dual method use. After counseling, 737 of 7,503 women not previously using modern contraception desired family planning referrals, and 61.6% of these women successfully accessed services within 90 days. Unmet contraceptive need remains high among HIV-infected women. Additional efforts are needed to promote reproductive health, particularly dual method use.

1. Introduction

The Millennium Development Goals, adopted in New York in 2000, promote universal education and gender equality, maternal and child health, and prevention and treatment for HIV/AIDS [1]. Provision of comprehensive reproductive health care is central to attaining these goals [2]. Worldwide, as many as one-third of the 357,000 annual maternal deaths are attributable to unintended pregnancies; the majority of these mortalities occur in low- and middle-income countries [3–6]. Enhanced access to family planning services in sub-Saharan Africa would result in marked reductions in unintended pregnancies and unsafe abortions and a projected 69% decrease in maternal deaths and a 57% decrease in newborn deaths [4]. In addition to substantial risks of dying from pregnancy complications [7], women in a sub-Saharan Africa are also at increased risk of HIV and other sexually transmitted infections [8, 9]. Providing safe, effective contraception to HIV-infected women who desire it

has also been identified by the World Health Organization as a primary strategy for prevention of pediatric infections [10].

In Zambia, as in many other sub-Saharan African countries, HIV-infected women of childbearing age represent a vulnerable population. The burden of STIs is high among HIV-infected pregnant women in this setting [11]. Additionally, only 20–40% of HIV-infected Zambian couples, whether serodiscordant or concordant, report use of a modern contraceptive method other than condoms [12, 13]. Public health programs that emphasize dual family planning methods—highly effective modern contraception coupled with condom use—will ensure protection from both unintended pregnancy, and STIs, and should form the cornerstone of reproductive health care. In HIV care and treatment programs, medication adherence counseling provides a unique window of opportunity to address preventive health recommendations, including family planning and STI prevention. In this paper, we describe implementation of

an integrated, reproductive health peer counselor program in 16 public-sector HIV clinics in Lusaka, Zambia. We also report (1) baseline modern contraceptive and dual method use among HIV-infected women receiving antiretroviral treatment, (2) uptake of modern contraceptive and dual methods following peer counseling, and (3) predictors of modern contraceptive and dual method use among HIV-infected women.

2. Materials and Methods

Lusaka is home to almost 2 million people [14]. The HIV prevalence rate among pregnant women is 21% [15], and the majority of women infected with HIV are of reproductive age. The Ministry of Health's ART program was established in 2004 and covers the entire city. Over 100,000 HIV-infected individuals in Lusaka are now receiving care in this system. Due to the large volumes of patients and human resource shortages [16], peer educators conduct most ART counseling sessions. Prior to our intervention, neither routine family planning nor dual method counseling was provided during peer counseling sessions. To expand the scope and effectiveness of these counseling visits, we designed and implemented a reproductive health peer counselor program integrated within 16 primary care HIV clinics in Lusaka.

We trained 109 peer counselors to deliver a standardized counseling message, emphasizing dual methods. The counseling intervention was implemented within the context of routine clinical care. With the aid of a printed counseling tool, peer educators delivered a comprehensive reproductive health message, including information on the range of barrier methods, hormonal and intrauterine contraception, and permanent sterilization. Women who desired access to reproductive health services were referred to a separate, on-site family planning department. In order to support public-sector reproductive health service provision, we also trained 42 family planning nurses. Training was based on the national family planning curriculum and nurses who successfully completed both a classroom-based course and a mentored, clinical practicum-received certification. Public-sector family planning clinics provided condoms, oral contraceptive pills (OCPs), depot medroxyprogesterone acetate (DMPA), Jadelle levonorgestrel implants, and copper intrauterine devices (IUDs). Women who wished to undergo permanent sterilization were referred to a center with surgical facilities, such as the University Teaching Hospital.

Our analysis cohort included HIV-infected women aged 16–50 years and on ART at one of the 16 intervention clinics. To be eligible, a woman had to have at least one reproductive health counseling visit documented in her medical record between November 2009 and November 2010. We report baseline sociodemographic data, CD4⁺ cell count (cells/uL), hemoglobin level (g/dL), and history of tuberculosis. These data were ascertained through review of women's electronic medical and laboratory records. Laboratory results were assessed within 90 days of the woman's counseling visit. We also report use of modern contraception, including dual method use. Peer counselors collected data relating

to reproductive health counseling and contraceptive use on a clinical form developed for the project. We considered condoms, OCPs, DMPA, Jadelle, IUDs, and sterilization as modern contraception. Dual method use was defined as use of condoms to prevent STIs coupled with use of a short- or long-term reversible contraceptive or sterilization. Contraceptive use data were self-reported.

Univariate and multivariate regression analyses were used to identify sociodemographic and other predictors independently associated with modern contraceptive and dual method use, as well as with access to family planning services within 90 days of a counseling visit. Crude odds ratios (ORs) and 95% confidence intervals (CIs) were computed using logistic regression models. Adjusted odds ratios (AORs) and their corresponding 95% CIs were generated using generalized estimating equations to account for clustering at the site level. All statistical analyses were performed using SAS version 9.1.3 (SAS Institute Inc, Cary, North Carolina). Ethical approval for this study was obtained from the University of Zambia Biomedical Research Ethics Committee (Lusaka, Zambia) and the University of Alabama at Birmingham Institutional Review Board (Birmingham, AL, USA).

3. Results

Between November 2009 and November 2010, 32,998 women had a least one clinic visit at a site where the counseling program had been implemented. Project staffing levels had been calculated on an estimated 20,000 clinical visits during the one-year implementation period. Therefore, for logistic reasons, not all women accessing HIV treatment services at participating clinics received reproductive health counseling. Over the study period, documented reproductive health counseling visits were available for 18,407 (55.8%) HIV-infected women. Baseline characteristics of women who completed at least one counseling visit compared with those who did not receive reproductive health counseling are detailed in Table 1. With the exception of median CD4⁺ cell count and median treatment duration, differences between women who received the counseling intervention and those who did not were not clinically significant.

3.1. Cohort Description. Our analysis cohort included 18,407 HIV-infected women. At enrolment, the median age was 34.6 years (IQR: 29.9–39.7 years), 60.1% of women were married, 87.4% had one or more living children, and 39.2% had completed some secondary education. 63.0% of women reported their monthly income as $\geq 200,000$ Zambian kwacha (approximately \$45). The median CD4⁺ cell count was 394 cells/uL (IQR: 256–558 cells/uL), and the median hemoglobin level was 12.4 g/dL (IQR: 11.3–13.4 g/dL). The median time on ART was 709 days (IQR: 262–1,302 days). 3,441 (18.7%) women reported a history of or current active tuberculosis infection. Less than half (42.5%) of the women in our cohort had disclosed their serostatus to a partner. Furthermore, most women (77.1%) did not know or did not provide information about their partner's HIV status at the time of enrollment into care.

TABLE 1: Baseline characteristics of HIV-infected women aged 16–50 years receiving antiretroviral treatment at 16 public-sector clinics in Lusaka, Zambia (November 2009–November 2010).

	Women with documented RH counseling		Women with no documented RH counseling visit		P-value
	N	Value	N	Value	
Age at 1st visit (years), median (IQR)	18,407	34.6 (29.9–39.7)	14,591	34.7 (29.5–40.9)	<0.001 ⁺⁺
16–24	1,246	6.8%	1,263	8.7%	<0.001 ^{**}
25–34	8,362	45.4%	6,232	42.7%	
≥35	8,799	47.8%	7,096	48.6%	
Marital status	14,180		11,135		0.076 ^{**}
Married	8,523	60.1%	6,570	59.0%	
Single/divorced/widowed	5,657	39.9%	4,565	41.0%	
Education	16,910		13,441		0.016 ^{**}
None	4,677	27.7%	3,785	28.2%	
Primary	5,603	33.1%	4,246	31.6%	
Secondary or more	6,630	39.2%	5,410	40.2%	
Number of living children, median (IQR)	14,385	2 (1–3)	11,373	2 (1–3)	0.061 ⁺⁺
0	1,806	12.6%	1,505	13.2%	0.106 ^{**}
≥1	12,579	87.4%	9,868	86.8%	
Monthly income	12,243		9,400		<0.001 ^{**}
<ZMK 200,000	4,532	37.0%	3,864	41.1%	
≥ZMK 200,000	7,711	63.0%	5,536	58.9%	
CD4 ⁺ cell count (cells/uL), median (IQR)	18,231	394 (256–558)	14,419	357 (228–522)	<0.001 ⁺⁺
<250	4,361	23.9%	4,187	29.0%	<0.001 ^{**}
250–350	3,338	18.3%	2,819	19.6%	
≥351	10,532	57.8%	7,413	51.4%	
Hemoglobin (g/dL), median (IQR)	18,175	12.4 (11.3–13.4)	14,248	12.2 (11.0–13.1)	<0.001 ⁺⁺
≤8.0	363	2.0%	482	3.4%	<0.001 ^{**}
8.1–9.9	1,365	7.5%	1,276	9.0%	
≥10.0	16,447	90.5%	12,490	87.7%	
History or current tuberculosis	18,407		14,591		0.493 ^{**}
Yes	3,441	18.7%	2,771	19.0%	
No	14,966	81.3%	11,820	81.0%	
Time on ART (days), median (IQR)	18,407	709 (262–1,302)	14,591	659 (245–1,180)	<0.001 ⁺⁺
HIV status disclosure to partner	18,407		14,591		0.028 ^{**}
Yes	7,823	42.5%	6,026	41.3%	
Unknown	10,584	57.5%	8,565	58.7%	
Partner's HIV status	18,407		14,591		<0.001 ^{**}
Negative	621	3.4%	456	3.1%	
Positive	3,598	19.5%	2,599	17.8%	
Unknown	5,332	29.0%	4,362	29.9%	
Missing	8,856	48.1%	7,174	49.2%	

RH: reproductive health; IQR: interquartile range; ZMK: Zambian Kwacha; ART: antiretroviral therapy.

^{**}Person's chi-square test; ⁺⁺Wilcoxon rank sum test.

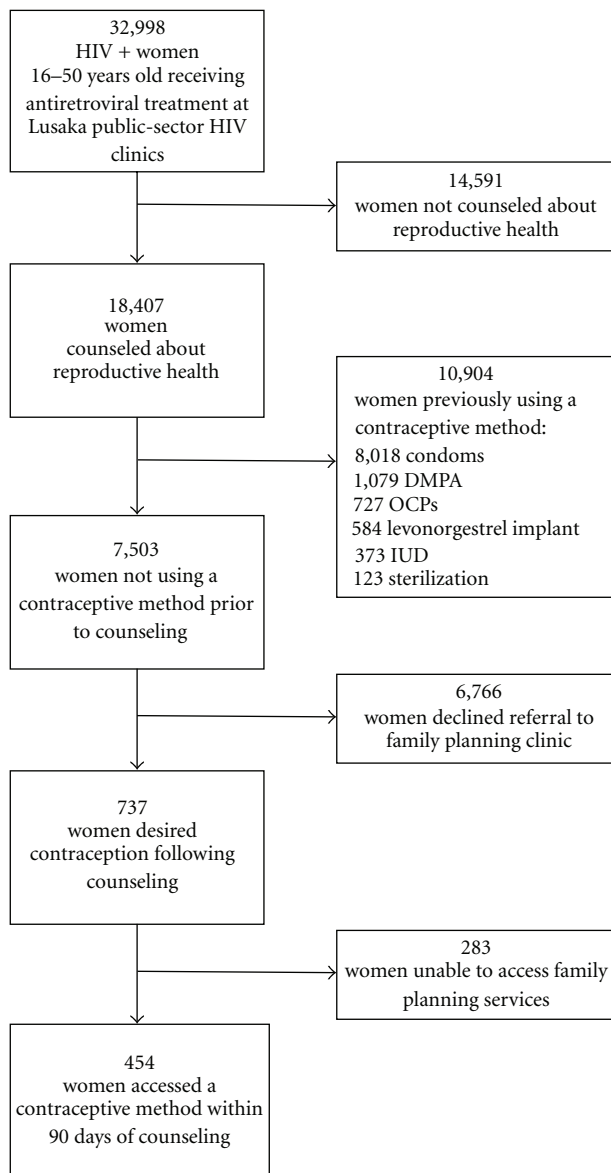


FIGURE 1: Description of the study cohort.

3.2. Baseline Modern Contraceptive and Dual Method Use. Of the 18,407 women included in the analysis, 10,904 (59.2%) reported current use of a modern contraceptive method: 73.5% of women reported condom use, 9.9% DMPA use, 6.7% OCP use, 5.4% levonorgestrel implant use, 3.4% IUD use, and 1.1% had undergone permanent sterilization (Figure 1). Among the 10,904 women who reported use of a modern contraceptive method at their counseling visit, 1,927 (17.7%) stated that they used dual methods for both pregnancy and STI prevention.

3.3. Impact of the Counseling Intervention and Unmet Contraceptive Need. Of the 7,503 (40.8%) women in our cohort not using modern contraception, 737 (9.8%) women desired contraception after counseling and 71 stated an intention to use dual methods. 454 of 737 (61.6%) women who desired

contraception successfully accessed family planning services within 90 days of their counseling visit. Our data, therefore, indicate that nearly 40% of women who desired reproductive health services were unable to access public-sector services (i.e., free from point-of-service user fees). This represents substantial unmet contraceptive need within Lusaka's public health system.

In univariate analysis, age was the only factor associated with successful access to contraceptive services within 90 days of a counseling visit. In multivariate analysis, women 25–34 years (AOR: 0.53; 95% CI: 0.30–0.92) or ≥35 years (AOR: 0.49; 95% CI: 0.25–1.00) had lower odds of accessing contraceptive services than women 16–24 years. Women who reported a higher monthly income also had lower odds of accessing contraceptive services than women who were less wealthy (AOR: 0.68; 95% CI: 0.47–0.98). By contrast, multiparae were more likely to access reproductive health services within 90 days than women with no living children (AOR: 1.83; 95% CI: 1.17–2.88).

3.4. Predictors of Modern Contraceptive Use. In univariate analysis, women were less likely to report modern contraceptive use if ≥35 years, single, divorced, or widowed, with undisclosed HIV status, and if their partner's HIV status was unknown (Table 2). Conversely, women 25–34 years with one or more living children, those reporting higher monthly incomes, those with CD4⁺ cell counts ≥250 cells/uL or hemoglobin levels ≥8.1 g/dL, and those without a history of tuberculosis infection had increased odds of contraceptive use. In multivariate analysis, age, marital status, HIV status disclosure, parity, CD4⁺ cell count, and hemoglobin level remained associated with modern contraceptive use. Women ≥35 years old (AOR: 0.63; 95% CI: 0.52–0.77), single, divorced, or widowed women (AOR: 0.30; 95% CI: 0.27–0.34), and those for whom HIV status disclosure was unknown (AOR: 0.75; 95% CI: 0.64–0.87) had lower odds of using modern contraception. The odds of using modern contraception were higher among women with one or more living children (AOR: 1.47; 95% CI: 1.21–1.78), and among healthier women with CD4⁺ cell counts of 250–350 cells/uL (AOR: 1.18; 95% CI: 1.05–1.33) or ≥351 cells/uL (AOR: 1.23; 95% CI: 1.10–1.38) than among nullipara and those with low CD4⁺ cell counts. A similar association was observed for hemoglobin levels 8.1–9.9 g/dL (AOR: 1.56; 95% CI: 1.24–1.97) and ≥10.0 g/dL (AOR: 2.16; 95% CI: 1.72–2.71).

3.5. Predictors of Dual Method Use. In univariate analysis, women who were ≥35 years, single, divorced, or widowed and those who did not provide information regarding HIV status disclosure had a lower odds of dual method use (Table 3). Higher odds of dual method use were observed among women with one or more living children, those with CD4⁺ cell counts ≥351 cells/uL, and those who did not report a history of tuberculosis. In multivariate analysis, women ≥35 years (AOR: 0.51; 95% CI: 0.41–0.63) were less likely to report dual method use than those 16–24 years. Women who were single, divorced, or widowed were also less likely to use dual methods than married women (AOR:

TABLE 2: Predictors of modern contraceptive use among HIV-infected women aged 16–50 years receiving antiretroviral treatment at 16 public-sector clinics in Lusaka, Zambia (November 2009–November 2010).

	Women using modern contraception <i>N</i> = 11,358	Women not using modern contraception <i>N</i> = 7,049	Crude OR (95% CI)	Adjusted OR (95% CI)
Age at 1st visit (years)				
16–24	736 (6.5%)	510 (7.2%)	1.00	1.00
25–34	5,747 (50.6%)	2,615 (37.1%)	1.52 (1.35–1.72)	1.05 (0.87–1.25)
≥35	4,875 (42.9%)	3,924 (55.7%)	0.86 (0.76–0.97)	0.63 (0.52–0.77)
Marital status				
Married	6,503 (72.9%)	2,020 (38.4%)	1.00	1.00
Single/divorced/widowed	2,414 (27.1%)	3,243 (61.6%)	0.23 (0.22–0.25)	0.30 (0.27–0.34)
Education				
None	2,862 (27.4%)	1,815 (28.2%)	1.00	1.00
Primary	3,493 (33.4%)	2,110 (32.7%)	1.05 (0.97–1.14)	1.13 (0.99–1.28)
Secondary or more	4,108 (39.3%)	2,522 (39.1%)	1.03 (0.96–1.12)	1.13 (1.00–1.27)
Number of living children				
0	1,041 (11.6%)	765 (14.2%)	1.00	1.00
≥1	7,947 (88.4%)	4,632 (85.8%)	1.26 (1.14–1.39)	1.47 (1.21–1.78)
Monthly income				
<ZMK 200,000	2,709 (35.9%)	1,823 (38.8%)	1.00	1.00
≥ZMK 200,000	4,835 (64.1%)	2,874 (61.2%)	1.13 (1.05–1.22)	1.03 (0.92–1.15)
CD4 ⁺ cell count (cells/uL)				
<250	2,473 (22.0%)	1,887 (27.1%)	1.00	1.00
250–350	2,042 (18.1%)	1,295 (18.6%)	1.20 (1.10–1.32)	1.18 (1.05–1.33)
≥351	6,746 (59.9%)	3,784 (54.3%)	1.36 (1.27–1.46)	1.23 (1.10–1.38)
Hemoglobin (g/dL)				
≤8.0	168 (1.5%)	195 (2.8%)	1.00	1.00
8.1–9.9	710 (6.3%)	655 (9.4%)	1.26 (1.00–1.59)	1.56 (1.24–1.97)
≥10.0	10,355 (92.2%)	6,090 (87.8%)	1.97 (1.60–2.43)	2.16 (1.72–2.71)
History or current tuberculosis				
Yes	1,999 (17.6%)	1,442 (20.5%)	1.00	1.00
No	9,359 (82.4%)	5,607 (79.5%)	1.20 (1.12–1.30)	1.06 (0.96–1.18)
HIV status disclosure to partner				
Yes	5,985 (52.7%)	1,838 (26.1%)	1.00	1.00
Unknown	5,373 (47.3%)	5,211 (73.9%)	0.32 (0.30–0.34)	0.75 (0.64–0.87)
Partner's HIV status				
Negative	476 (4.2%)	145 (2.1%)	1.00	1.00
Positive	2,700 (23.8%)	898 (12.7%)	0.92 (0.75–1.12)	0.76 (0.54–1.06)
Unknown	3,357 (29.6%)	1,975 (28.0%)	0.52 (0.43–0.63)	0.75 (0.56–0.99)
Missing	4,825 (42.5%)	4,031 (57.2%)	0.36 (0.30–0.44)	0.66 (0.48–0.89)

OR: odds ratio; 95% CI: 95% confidence interval.

0.75; 95% CI: 0.66–0.86). Conversely, women with one or more living children (AOR: 2.07; 95% CI: 1.59–2.70), those with CD4⁺ cell counts ≥351 cells/uL (AOR: 1.25; 95% CI: 1.09–1.45), and those with no prior history of tuberculosis infection (AOR: 1.17; 95% CI: 1.01–1.35) had higher odds of dual method use.

4. Discussion

We successfully implemented a peer-led counseling intervention in ART clinics, focusing on dual family planning method use to prevent unintended pregnancies and STIs. Our initial projections were that 20,000 HIV-infected women

TABLE 3: Predictors of dual method use among HIV-infected women aged 16–50 years receiving antiretroviral treatment at 16 public-sector clinics in Lusaka, Zambia (November 2009–November 2010).

	Women using dual methods N = 2,247	Women not using dual methods N = 9,111	Crude OR (95% CI)	Adjusted OR (95% CI)
Age at 1st visit (years)				
16–24	170 (7.6%)	566 (6.2%)	1.00	1.00
25–34	1,269 (56.5%)	4,478 (49.1%)	0.94 (0.79–1.13)	0.80 (0.62–1.04)
≥35	808 (36.0%)	4,067 (44.6%)	0.66 (0.55–0.80)	0.51 (0.41–0.63)
Marital status				
Married	1,407 (77.9%)	5,096 (71.7%)	1.00	1.00
Single/divorced/widowed	400 (22.1%)	2,014 (28.3%)	0.72 (0.64–0.81)	0.75 (0.66–0.86)
Education				
None	562 (27.0%)	2,300 (27.4%)	1.00	1.00
Primary	692 (33.2%)	2,801 (33.4%)	1.01 (0.89–1.14)	1.02 (0.86–1.21)
Secondary or more	830 (39.8%)	3,278 (39.1%)	1.04 (0.92–1.17)	1.06 (0.90–1.24)
Number of living children				
0	154 (8.4%)	887 (12.4%)	1.00	1.00
≥1	1,685 (91.6%)	6,262 (87.6%)	1.55 (1.30–1.85)	2.07 (1.59–2.70)
Monthly income				
<ZMK 200,000	538 (35.0%)	2,171 (36.1%)	1.00	1.00
≥ZMK 200,000	999 (65.0%)	3,836 (63.9%)	1.05 (0.93–1.18)	0.93 (0.82–1.07)
CD4 ⁺ cell count (cells/uL)				
<250	438 (19.7%)	2,035 (22.5%)	1.00	1.00
250–350	394 (17.7%)	1,648 (18.2%)	1.11 (0.96–1.29)	1.05 (0.87–1.26)
≥351	1,397 (62.7%)	5,349 (59.2%)	1.21 (1.08–1.37)	1.25 (1.09–1.45)
Hemoglobin (g/dL)				
≤8.0	28 (1.3%)	140 (1.6%)	1.00	1.00
8.1–9.9	120 (5.4%)	590 (6.5%)	1.02 (0.65–1.60)	1.01 (0.51–2.02)
≥10.0	2,076 (93.3%)	8,279 (91.9%)	1.25 (0.83–1.89)	1.31 (0.80–2.16)
History or current tuberculosis				
Yes	333 (14.8%)	1,666 (18.3%)	1.00	1.00
No	1,914 (85.2%)	7,445 (81.7%)	1.29 (1.13–1.46)	1.17 (1.01–1.35)
HIV status disclosure to partner				
Yes	1,291 (57.5%)	4,694 (51.5%)	1.00	1.00
Unknown	956 (42.5%)	4,417 (48.5%)	0.79 (0.72–0.86)	1.03 (0.85–1.25)
Partner's HIV status				
Negative	102 (4.5%)	374 (4.1%)	1.00	1.00
Positive	564 (25.1%)	2,136 (23.4%)	0.97 (0.76–1.23)	0.92 (0.69–1.22)
Unknown	721 (32.1%)	2,636 (28.9%)	1.00 (0.79–1.27)	1.03 (0.70–1.51)
Missing	860 (38.3%)	3,965 (43.5%)	0.80 (0.63–1.00)	0.89 (0.65–1.22)

OR: odds ratio; 95% CI: 95% confidence interval.

would access care across the participating clinics during the 12-month implementation period. Our team of peer educators counseled 18,407 HIV-infected women enrolled in care during this period, demonstrating the feasibility of this approach in a low-resource, African setting. At their baseline counseling visit, nearly 60% of women reported use of a modern contraceptive method; the majority used solely condoms. Among contraceptive users, only 26.5% reported

use of a highly effective modern contraceptive method. Dual method use was also low at 17.7%.

Older, single women with lower CD4⁺ cell counts were less likely to be using modern contraception. These findings highlight a vulnerable population of HIV-infected women. As the health of women with lower CD4⁺ cell counts improves on ART and as unmarried women enter new sexual partnerships, both groups remain at risk for

unintended pregnancy and STIs. Future reproductive health policy and programming should be expanded beyond a focus on married, healthy women [17].

We were disappointed at the low numbers of women who desired access to family planning services and were unable to obtain it in a timely fashion. We can only speculate as to the reasons for this. In Lusaka, family planning services are not integrated within HIV clinics, and most family planning clinics are only open to patients in the afternoons. A woman who has already spent much of her morning in an ART clinic is less likely to return to spend another half-day in a family planning clinic. Periodic stock-outs of reproductive health commodities may also limit women's access to family planning services. Additionally, we speculate that most messages in the community promote condom use over use of more effective modern contraception or dual method use. Providers' attitudes towards sexual and reproductive healthcare for HIV-infected patients [18, 19] and misconceptions regarding the safety of hormonal contraceptive methods among women on ART may also play a role in limiting HIV-infected women's access to family planning [20].

The strengths of our study include the successful implementation of a standardized and comprehensive reproductive health counseling intervention. This intervention was acceptable to both providers and patients. Using a peer educator model, we demonstrate that it is possible to reach a sizeable number of HIV-infected women attending public ART clinics. It also became evident through our intervention that strengthening reproductive health care requires stronger linkages between family planning clinics, STI services, and HIV screening and treatment [21], as well as improved community understanding. Our study had several limitations. Contraceptive method and condom use were self-reported and thus subject to bias. Additionally, we did not assess the impact of our counseling intervention on pregnancy rates.

This study confirms the findings of smaller Zambian clinical trials [12, 22, 23] and demonstrates that 40% of HIV-infected women on ART are not using any form of modern contraception. Among contraceptive users, less than 30% use highly effective modern methods and even fewer use dual methods. Our counseling intervention improved uptake of modern contraceptives and dual method use modestly. Demographic and Health Surveys have demonstrated that knowledge of modern contraception is high among Zambians [24]. Additional quantitative and qualitative research should address fertility desires and barriers to dual method use in this population, guiding future public health interventions. Male partner involvement through couples counseling should be investigated further [25].

Our findings also underscore important challenges faced by HIV-infected women attempting to access family planning services within the public health system. Unmet contraceptive need is as high as 40% among these women. Strengthening public-sector service provision, with the goal of ensuring that no woman is turned away from a family planning clinic empty handed, should be an urgent priority. Finally, integrating family planning service provision into

HIV care and treatment clinics will likely improve access to reproductive health services [26].

5. Conclusions

We successfully demonstrate the feasibility of integrating comprehensive reproductive health counseling into HIV care and treatment. We confirm that nearly 60% of HIV-infected women receiving care within the Zambian public-sector report use of a modern contraceptive method. However, only 27% of these women use highly effective hormonal or long-term reversible methods, and even fewer women report dual method use. Additional efforts are needed to promote dual method use, particularly among older, unmarried women and those with more advanced HIV disease. These interventions should be coupled with health system changes that address critical bottlenecks in reproductive health service provision.

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Research Article

Determinants of Multimethod Contraceptive Use in a Sample of Adolescent Women Diagnosed with Psychological Disorders

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Objective. Despite recommendations for concurrent use of contraceptives and condoms to prevent unintended pregnancy and STIs, multimethod contraceptive use among women is poor. This study examined individual-, interpersonal-, and environmental-level factors that predict multimethod use among sexually active adolescent women diagnosed with psychological disorders. **Methods.** This multisite study analyzed data from 288 sexually active adolescent women who provided sociodemographic, psychosocial, and behavioral data related to birth control and condom use. **Results.** 34.7% of the participants reported multimethod use in the past three months. Controlling for empirically and theoretically relevant covariates, a multivariable logistic regression identified self-efficacy, multiple partners, pregnancy history, parental communication, parental norms about sex, and neighborhood cohesion as significant predictors of multimethod use. **Conclusions.** While continued targeted messages about multi-method contraceptive use are imperative at the individual level, an uptake in messages targeting interpersonal- and environmental-level factors such as adolescents' parents and the broader community is urgently needed.

1. Introduction

Sexually transmitted infections (STIs) and unintended pregnancy are two significant public health issues that continue to affect adolescent women in the US today. Current estimates by the Centers of Disease Control and Prevention (CDC) suggest that 25% of adolescent women in the US have an STI [1], a prevalence twice as high as that among adolescent men of the same age [2]. Similarly, an estimated 82% of adolescent pregnancies are unintended despite widespread accessibility of safe, effective, and affordable contraceptive technology [3]. While a national decline in unintended pregnancies among adolescent women between 1991 and 2009 has been documented, the US continues to have higher rates of unintended teen pregnancies compared to other developed nations, particularly among adolescents residing in southern states [4].

Data on the prevalence of STIs and unintended pregnancy among adolescent women diagnosed with psychological disorders are largely lacking, although extant research among adolescents demonstrates an association between mental illness and high-risk sexual behavior including early initiation of sexual activity, sex with multiple partners, and unprotected sex [5–11]. Results from these studies suggest that this vulnerable population is at great risk for acquiring STIs including HIV as well as experiencing unintended pregnancy.

Adolescents living with psychological disorders are characterized by a unique profile of antecedent factors covering the spectrum of individual-, interpersonal- and environmental-level factors that contribute to their engaging in high-risk sexual behaviors and risk for STI/HIV infection. These factors include personal attributes (e.g., impulsivity, self-destructive behaviors, cognitive impairment, substance

use, and poor judgment), family context (e.g., parental attitudes and behavior, parent-adolescent communication, parental monitoring, and discipline), peer and partner relationships (e.g., relationship concerns, peer influence, and partner communication), and environmental context (e.g., poverty) [12–17]. While the aforementioned studies have associated this risk profile with elevated exposure to STI/HIV infection, a similar risk profile may also result in unintended pregnancy among adolescent women seeking mental health services, although no studies to date have established this association.

Due to the prevalence of STIs and unintended pregnancies among youth, professional organizations such as the CDC, American Medical Association, American Academy of Pediatrics, and the American College of Obstetrics and Gynecology have recommended dual protection strategies toward the prevention of both STIs/HIV and unintended pregnancy [18–20]. Despite these recommendations, studies have demonstrated that dual-protection is not a commonly used strategy. For example, data from the Youth Risk Behavior Survey suggest that only 6.6% of young women surveyed used both a condom and oral contraception at their last sexual intercourse [21]. Similarly, data from the National Survey of Family Growth suggest that 8.5% of adolescent women reported the same dual-protection method of condom use and oral contraception in the previous 30 days [22]. However, among a sample of African-American adolescent women, 13.5% reported using dual protection [23].

Correlates of dual-protection use have been investigated by few studies showing that, among adolescent men and women between the ages of 14 and 22, younger African-American adolescents who communicated with their parents about HIV-related issues were more likely to report dual-protection use [21, 22]. Among low-income, minority, urban adolescent African-American women, those with a history of STIs who reported concerns about both pregnancy and HIV infection were also more likely to report dual-protection use [23]. Finally, in a recent study investigating correlates of dual-protection use in an array of contextual influences including individual-, interpersonal-, and community-level factors, results suggest that lower impulsivity, fearful relationship style, and fear of condom negotiation as well as higher self-esteem, social support, and partner communication self-efficacy were positively associated with dual-protection use [24]. No studies to date have investigated factors associated with dual-protection or multimethod contraceptive use among adolescent women seeking psychological services. The distinction between dual-protection and multimethod use suggests that the former category includes those who use dual methods concurrently, while the latter category includes those who use multiple contraceptive methods, but not necessarily concurrently.

The current study examines the prevalence of multimethod use as well as individual, interpersonal, and environmental factors associated with multimethod use among a sample of urban adolescent females seeking psychological services at the time of the study.

2. Methods

2.1. Participants. This is a substudy of a larger multisite family-based randomized clinical trial designed to evaluate the efficacy of an intervention to reduce HIV risk behaviors and STIs while enhancing HIV-preventive psychosocial and structural factors among adolescents diagnosed with psychological disorders. Adolescents were eligible if they were between the ages of 13 and 18, received a clinician-based psychological diagnosis along the externalizing-internalizing spectrum of disorders, received in- or out-patient mental health treatment at one of the study recruitment sites, lived with a parent or guardian who was also willing to participate in the study, and provided informed consent. Externalizing disorders include those that manifest in one's outward behavior (e.g., conduct disorder, oppositional defiant disorder), while internalizing disorders include those that manifest in terms of one's thoughts and feelings (e.g., depression, anxiety). Adolescents diagnosed with schizophrenia and other psychotic disorders were excluded. Additionally, adolescents were excluded if they had a history of sexually aggressive behavior (i.e., perpetrators of sexual assault or molestation), were currently pregnant, were known to have tested positive for HIV, or had cognitive deficits precluding them from completing the assessment independently or participating in group activities. Participants were enrolled in the study at three recruitment sites: Brown University, Providence, Rhode Island, University of Illinois, Chicago, and Emory University, Atlanta, Georgia. Clinics and hospitals providing mental health services to adolescents served as recruitment sites. Of 1102 adolescents who met eligibility criteria, 891 (81%) agreed to participate and subsequently completed baseline assessments. Of the 891 participants, 288 (32.3%) were sexually active females who completed baseline assessment prior to randomization in the HIV trial and comprised the sample analyzed in the current study. The remaining 603 participants were either male or sexually inexperienced females and were excluded from the current analyses. The Institutional Review Boards at Brown University, University of Illinois, Chicago, and Emory University approved the study protocol.

2.2. Procedures. Adolescents and parents completed an audio-assisted computerized interview at baseline. The adolescent interview assessed sociodemographic characteristics, sexual behavior patterns, and psychosocial characteristics as well as psychological symptomology. The parent interview assessed sociodemographic characteristics, parent norms about sexual behavior, and variables addressing the frequency of parent-adolescent interactions such as communication about sex. On average, interviews were 90 minutes in duration for teens and parents independently.

2.3. Measures

Multimethod Use. Participants were asked to identify on a list of commonly used birth control methods the one(s) they utilized in the previous 3 months: male condom, pill, diaphragm, cervical cap, gels/creams/suppositories or foams,

Depo-Provera, and other (not further identified). Those who reported condom use and at least one other birth control method were categorized as multimethod users; those who reported using no birth control and/or only one birth control method were categorized as non-multimethod users.

Participants' age, race, ethnicity, current relationship status, and history of pregnancy were collected from adolescent participants. Family income and parent marital status were collected from parent participants.

Individual-Level Measures

Sex Partner Variables. Adolescent participants were asked how many sexual partners they had in the past 3 months. Those reporting two or more partners in the past 3 months were categorized as having multiple partners. Additionally, participants were asked whether or not they were in a current relationship with a sex partner.

Condom Use Self-Efficacy. Adolescents' self-efficacy for condom use was assessed using a 13-item scale that included items such as "How confident do you feel that you could use a condom when your partner doesn't want to?" or "How confident do you feel that you could use a condom with a new partner?" [25]. Answer options ranged from 1 (very sure I could) to 4 (very sure I could not); these responses were reverse coded such that higher scores on the condom use self-efficacy scale suggest higher perceived self-efficacy for condom use. Responses may range from 13 to 52. Cronbach's alpha reliability for this scale was .93, indicating a high level of internal consistency.

Interpersonal-Level Measures

Sexual Communication with Parent. The Miller Sexual Communication scale was used to assess the frequency of communication between parents and adolescents with regard to 6 areas including initiation of sex, contraception, condom use, transmission of HIV/AIDS, peer pressure regarding sexual behavior, and selection of sexual partner [26, 27]. Parents were asked to indicate how frequently these topics were discussed with their adolescent daughter in the past 3 months with answer options including 1 (never), 2 (once), 3 (a few times), and 4 (more than 3 times). Parent responses to the six areas of communication were summed for a total communication frequency score with higher scores suggesting more frequent communication. Responses may range from 6 to 24. Cronbach's alpha reliability for this scale was .85, indicating a high level of internal consistency.

Parental Norms about Sex. Adolescents' perceptions of parents' degree of approval of the adolescent's sexual activity was assessed with this 7-item scale [28]. Sample items include "My parents think it is ok to have sex after one or two dates" and "My parents think it is ok to have sex with the person I love." Answer options ranged from 1 (very true) to 5 (very false) with a possible range of score from 7 to 35. Cronbach's

alpha reliability for this scale was .75, indicating an adequate level of internal consistency.

Environmental-Level Measures

Neighborhood Cohesion. Neighborhood cohesion was assessed using a 6-item scale assessing whether adolescent respondents (1) visited neighbors, (2) could go to their neighbors for advice, (3) regularly talked to people in their neighborhood, (4) knew people's names, (5) felt comfortable asking to borrow things, and (6) felt comfortable asking neighbors to watch their home [29, 30]. Answer options ranged from 1 (strongly disagree) to 5 (strongly agree). Cronbach's alpha reliability for this scale was .88, indicating a high level of internal consistency.

2.4. Statistical Analysis. First, descriptive analyses were conducted to obtain means, standard deviations, and proportions for relevant sociodemographic variables. Additionally, bivariate analyses consisting of chi-square and independent samples *t*-tests were performed to examine the associations between multimethod and non-multimethod use and sociodemographic variables as well as to identify potential covariates. Finally, a multivariable logistic regression model was conducted to explore whether individual-, interpersonal-, and environmental-level factors predicted multimethod use after controlling for confounders. Data were analyzed using PASW 18.

3. Results

A total of 288 adolescent women participated in this study with a mean age of 15.29 (SD = 1.26; range 13–18). One-third of parents ($n = 96$) reported being married, and approximately 59% ($n = 159$) of families reported an annual income of less than \$30,000. Nearly 31.0% ($n = 89$) of families self-identified as Caucasian, 54.5% ($n = 157$) as African American, 12.5% ($n = 36$) as Hispanic, and 2% ($n = 6$) as other. Among parents, 18.1% ($n = 52$) had not completed high school. Mental disorders represented in this sample are as follows: oppositional defiant disorder (75.8%), ADHD (56.3%), conduct disorder (49.6%), generalized anxiety disorder (42.4%), major depression (41.3%), mania (29.7%), posttraumatic stress disorder (27.1%), and hypomania (26.9%). These rates represent dual diagnoses, therefore will not add up to 100%. Among adolescent participants, 57.6% ($n = 166$) reported having a current sex partner, and 16.2% ($n = 46$) reported a pregnancy in the past. Finally, 34.7% ($n = 100$) of adolescent participants reported multimethod use, while 50% ($n = 144$) used only one form of protection, and 15.3% (44) used no protection at all.

Descriptive statistics as well as differences between multimethod and non-multimethod users are presented in Table 1. Of these, adolescent age, ethnicity, household income, parent marital status, and adolescent current relationship status were statistically related to multimethod use at $P \leq .20$ level and were therefore included as

covariates in the multivariable logistic regression model [31]. Although race was not associated with multimethod use at the bivariate level ($P = .68$), we controlled for this variable in our multivariable model predicting multimethod use outcome based on the prior literature suggesting that African-American adolescent women had higher rates of dual-protection use compared to other groups [23]. Bivariate associations between individual-, interpersonal-, and environmental level factors and multimethod use are presented in Table 2.

Results of the multivariable logistic regression model are presented in Table 3. After controlling for covariates, significant predictors of multimethod use emerged among all three contextual levels of analysis. Among individual-level predictors, with each unit increase in condom use self-efficacy, adolescent women were 7% more likely to report multimethod use ($P = .004$). Additionally, participants who reported multiple sex partners were nearly three times more likely to report multimethod use compared to participants reporting a single sex partner ($P = .011$). Finally, pregnancy was a marginally significant predictor suggesting that those with a history of pregnancy were 59% less likely to report multimethod use ($P = .052$). Neither race nor ethnicity was significantly related to multimethod use. Among interpersonal-level predictors, with each unit increase in communication about sex (as reported by the parent), adolescent women were 3% less likely to report multimethod use ($P = .028$). Moreover, for each unit increase in positive parental norms about sex, adolescent women were nearly 8% more likely to report multimethod use ($P = .014$). Finally, the single environmental predictor examined in this study was significant, suggesting that adolescent women residing in cohesive neighborhood environments were nearly twice as likely to report multimethod use compared to those residing in less cohesive neighborhood environments ($P = .041$).

4. Discussion

The prevalence of multimethod use among this sample of adolescent women was nearly 35%, which is higher compared to rates reported elsewhere in the literature [21–23]. This may be a function of the way in which multimethod use was measured in this study, that is, by assessing contraceptive behaviors within the past 3 months rather than assessing concurrent use at last intercourse. Alternatively, the higher rate of multimethod use observed in this sample of adolescent women receiving mental health treatment may also be a function of greater exposure and access to hormonal contraception through ongoing and regular contact with prescribing mental health and primary care professionals.

Another departure from the extant literature is that in this sample age was not significantly related to multimethod use ($P = .818$). This is not altogether surprising given that previous research may have not included a host of contextual influences in models examining multimethod use. Our results suggest that other factors are more important in determining whether female adolescents use multiple contraceptives rather than “being older,” and it is possible that, in previous studies, age may have been a proxy

for some of these factors (e.g., having multiple partners). Specifically, our study identified factors associated with multimethod use at three contextual levels: individual, interpersonal, and environmental. First, at the individual level, adolescent women receiving psychological services who had a history of pregnancy were marginally less likely to report multimethod use than those without a history of pregnancy. The prior literature has consistently shown that four risk factor domains are associated with repeat teen pregnancy: disadvantaged socioeconomic background, single family household, psychological and emotional instability manifested in aggressive behavior, and exposure to chaotic environments and risky peer networks (e.g., violence and substance use) [32–38]. The current sample of adolescent women is characterized by a similar pattern of risk factors. Specifically, adolescent women in this study are particularly disadvantaged by virtue of their psychological and emotional disorders, with oppositional defiant disorder, ADHD, and conduct disorder being the most prevalent. These disorders are largely characterized by aggression, antisocial behaviors, and attention problems, all of which are documented risk factors for repeat teen pregnancy.

Having multiple partners significantly predicted multimethod use, suggesting that although adolescent women may understand the risk associated with having multiple partners, those with single partners may feel unduly protected in their relationship with one sex partner, thus deciding against multimethod use. This is consistent with prior findings suggesting that condom use declines as relationships become more serious and exclusive [39–42]. In fact, the literature suggests that among adolescents, it takes less than one month for condom use to decline to levels observed among well-established, long-term relationships [43]. As such, education and prevention messages regarding multimethod use should particularly focus on adolescent women reporting monogamous relationships in addition to continuing to address the risk of having multiple partners.

Finally, at the individual level, condom use self-efficacy was a significant predictor of multimethod use. Previous research suggests that among adolescents who feel confident in their condom use skills, consistent condom use increases [44–46]; however, fewer studies have assessed whether self-efficacy predicts contraceptive use beyond condoms. Findings from one such study suggest that contraceptive self-efficacy, while not predicting condom use specifically, was a significant predictor of contraceptive use in general among adolescent females [47]. Even though the current study measured condom use self-efficacy rather than contraceptive self-efficacy, our results corroborate this previous finding. It may be that self-efficacy in one sexually related domain such as using condoms may generalize to other forms of contraception.

Among interpersonal-level factors, an unexpected result suggests that, based on parent report, more frequent communication about sex with their adolescent daughters (including sex, condoms, contraception, HIV/AIDS, peer pressure, and sexual partner selection) was related to less multimethod use. Previous research has shown that parental communication about sex positively impacts sexual risk behaviors and often

TABLE 1: Characteristics of multimethod and non-multimethod users.

	Multimethod users (<i>n</i> = 100)		Non-multimethodusers (<i>n</i> = 188)		<i>P</i>
	Mean (SD)	<i>N</i> (%)	Mean (SD)	<i>N</i> (%)	
<i>Sociodemographic factors</i>					
Age of adolescent	15.08 (1.22)		15.40 (1.27)		.038
Race					.680
Caucasian		30 (30.0)		59 (31.4)	
African American		58 (58.0)		99 (52.7)	
Other		3 (3.0)		3 (1.6)	
Ethnicity					.190
Hispanic		9 (9.0)		27 (14.4)	
Family income					.190
≤30 K/year		60 (64.5)		99 (56.3)	
>30 K/year		33 (35.5)		77 (43.8)	
Parent marital status					.161
Married/remarried		28 (28.0)		68 (36.2)	
Single parent		72 (72.0)		120 (63.8)	
Adolescent current sex partner					.001
Yes		72 (72.0)		94 (50.0)	
No		28 (28.0)		94 (50.0)	

TABLE 2: Bivariate associations between study variables and multimethod use and non-use.

	Multimethod users (<i>n</i> = 100)		Non-multimethod users (<i>n</i> = 188)		<i>p</i>
	Mean (SD)	<i>N</i> (%)	Mean (SD)	<i>N</i> (%)	
<i>Individual level factors</i>					
Condom use self-efficacy	47.34 (5.38)		43.47 (10.19)		.001
Multiple sex partners					.002
Yes		30 (30.0)		27 (14.7)	
No		70 (70.0)		157 (85.3)	.189
Pregnancy history					
Yes		12 (12.2)		34 (18.3)	
No		86 (87.8)		152 (81.7)	
<i>Interpersonal level factors</i>					
Sexual communication	8.45 (10.11)		10.11 (10.12)		.187
Parental norms about sex	26.56 (5.64)		24.28 (6.25)		.003
<i>Environmental level factors</i>					
Neighborhood cohesion					.007
Low cohesion		47 (48.0)		120 (64.5)	
High cohesion		51 (52.0)		66 (35.5)	

mitigates the effect of peer norms on adolescents' sexual risk behaviors [48–50]. Adolescents whose parents talk to them frequently and openly about sex also tend to use condoms more often and have fewer sexual partners thereby reducing their risk for STIs/HIV [48, 49, 51]. Yet, some research suggests that these protective effects may be mitigated for adolescents who are already sexually active [49]. Although this study measured the frequency and general content area of communication with adolescents, we did not measure the quality of the interactions nor the specific messages that were related to the adolescents within each content

area. It may be possible that for our sample of adolescent women, who already experienced their sexual debut, some aspect of the communication process, either the style or the parental attitudes toward sex and contraception, could have contributed to the reversal of a protective effect. In fact, the current study also found a significant effect for parental norms about sex, suggesting that adolescents whose parents reported more positive attitudes toward sex were more likely to report multimethod use. Thus, it is feasible that more negative parental attitudes toward sex may interject a negative tone or more negative messages in

TABLE 3: Multivariable associations between individual-, interpersonal- and environmental level factors and multimethod use.

	Prevalence ratio	AOR ^a	95% conf. interval
Individual level factors			
Condom use self-efficacy	n/a	1.07	1.02–1.12
Multiple partners	0.49	2.87	1.27–6.48
Pregnancy history	1.49	0.41	0.17–1.00
Interpersonal level factors			
Sexual communication	n/a	0.97	0.94–0.99
Parental norms about sex	n/a	1.08	1.02–1.14
Environmental level factors			
Neighborhood cohesion	1.35	1.91	1.03–3.55

^a Adjusted odds ratio using non-multimethod users as the referent category; models are controlling for adolescent age, race, ethnicity, household income, parent marital status, and adolescent current relationship status.

Model fit: $\chi^2 = 54.30$; $P = .001$.

parental communication to adolescents. As these negative messages then become reinforced with increased frequency in communication, a reduction in multimethod use may result.

Finally, neighborhood cohesion was a significant environmental-level factor associated with multimethod use suggesting that adolescent women living in a more cohesive environment, characterized by positive social contact and familiarity with neighbors, are nearly twice as likely to report multimethod use compared to adolescents residing in less cohesive environments. The mechanism by which neighborhood cohesion acts to increase condom use and other forms of contraception is unknown. Prior studies have suggested that a cohesive neighborhood environment may offer support to its adolescent residents in the form of caring, tolerance, and respect. In turn these characteristics may impact an adolescent's sense of self [51]. Research assessing the associations between social dynamics, sense of self, and health outcomes supports the assertion that social disorder can shape an individual's self-concept and subsequently can influence that individual's drug use and sexual risk taking [52, 53]. Among adolescent women coping with psychological disorders, the positive impact of neighborhood support and cohesion may be particularly salient. Further research is necessary to uncover the underlying mechanisms by which neighborhood cohesion is associated with various protective sexual health outcomes including condom use and multimethod use, particularly among adolescent women with psychological disorders.

4.1. Limitations. Several limitations to this study need to be acknowledged. First, the generalizability of the findings is limited to (a) adolescents meeting the specific criteria for inclusion in the randomized clinical trial and (b) the three geographic regions of the county from which the data are obtained. Second, data included in the current analyses were obtained through self-report and may reflect social desir-

ability bias. Third, the multimethod use measure assessed condom use and one other birth control method. This could include a hormonal method such as the birth control pill or some other type of barrier method such as the diaphragm. The various possible combinations of multiple methods were not explored in this study as this would have significantly restricted the sample size available for analysis. Fourth, the multiple methods of contraceptive use were assessed over the previous 3 months with no assessment of concurrent use. Finally, length of relationship may play a role in adolescents' willingness to utilize contraception and should be assessed in future studies.

5. Conclusion

Understanding multilevel factors that predict multimethod contraceptive use among adolescent women with psychological disorders is crucial both in terms of clinical practice as well as in the design of STI/HIV and pregnancy prevention programs. Research should further investigate the specific factors that contribute to this protective behavior. Mental health as well as primary care providers should continue to focus on addressing issues of multimethod as well as dual-protection use with their female adolescent population. Furthermore, while public health professionals have historically focused on designing and implementing STI/HIV prevention programs separately from pregnancy prevention programs, given the high rates of STIs and unintended pregnancy among adolescent women, especially among those with compromised psychological states, it is advisable to design programs that target both epidemics concurrently through programs that incorporate modifiable factors at the individual, interpersonal, and environmental levels.

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Review Article

Multipurpose Prevention Technologies: Biomedical Tools to Prevent HIV-1, HSV-2, and Unintended Pregnancies

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Statistics clearly show an unmet need for highly effective contraception, especially in less developed countries. Many of these countries are at the core of the HIV/AIDS epidemic and show very high prevalence rates for other sexually transmitted infections (STIs) such as that caused by HSV-2. A woman at risk of unintended pregnancy due to unprotected intercourse is also at risk for HIV/STI. Owing to their causative interrelationship, combining protection against these conditions will result in enhanced prevention and health benefits. Existing multipurpose prevention modalities such as condoms and physical barriers, albeit efficacious, face cultural hurdles that have so far hindered their widespread use. Success has recently been demonstrated in large clinical trials, demonstrating proof of concept of microbicides in reducing the incidence of HIV-1 and HSV-2 among at-risk populations. The challenge heretofore is to refine these products to make them more potent, convenient, accessible, and acceptable. Potent antiviral drugs released topically in the female reproductive tract by innovative delivered systems and formulations will provide safe, effective, and acceptable multipurpose prevention tools. This paper provides an overview of existing and novel approaches to multipurpose prevention strategies.

1. Significant Need for Innovative, Effective, and Acceptable Multipurpose Prevention Technologies

Effective multipurpose prevention technologies (MPTs) for women's reproductive health is an area searching for innovative strategies and approaches to increase access and adherence [1]. Here, we will discuss technologies designed to prevent pregnancy and sexually transmitted infections (STIs) and combinations of antiviral drugs to provide synergistic prophylaxis against multiple STIs. Unintended or mistimed pregnancies and STIs are prevalent and morbid problems worldwide. Although distinct issues with varying causes, the same behavior, unprotected intercourse, puts a woman at risk for both problems. Therefore, prevention of two or more of these conditions could potentially be targeted by one multipurpose product.

2. Unintended or Mistimed Pregnancies: A Significant Problem Worldwide

Almost half of all pregnancies worldwide, estimated to be over 100 million annually, are unintended or mistimed [2, 3]. In 2008, this resulted in 43 million abortions, half of which were performed under unsafe conditions, leading to almost 100,000 maternal deaths and 5 million women left with temporary or permanent disabilities [3]. Despite the existence of a variety of effective contraceptives available worldwide, discontinuation or nonuse remains high, primarily due to cost, side effects, inconvenient dosing schedules, poor access to prescription products, and/or poor acceptance of the method. This results in an unacceptably high rate of unintended or mistimed pregnancies. Statistics clearly show an unmet need for highly effective contraception, especially in less developed countries, where 99% of maternal deaths occur [2, 3].

3. The Human Immunodeficiency Virus Type 1 (HIV-1) Pandemic

Less developed countries, especially those of sub-Saharan Africa and south Asia, are also at the core of the acquired immunodeficiency syndrome (AIDS) epidemic. Over 33 million people worldwide are infected with human immunodeficiency virus type 1 (HIV-1) and 22.4 million, the majority of whom are women, live in sub-Saharan Africa [4]. Although progress has been made in preventing new HIV-1 infections, AIDS-related illnesses remain a leading cause of death globally [5]. In 2008, some communities in the USA, including pockets of the District of Columbia, had HIV-1 incidence rates similar to that of sub-Saharan Africa [6].

4. Impact of Lower Genital Tract Infections on HIV-1 Acquisition

Despite a global pandemic, it is estimated that approximately 99% of unprotected vaginal exposures to HIV-1 do not result in a productive infection [7]. This is in part due to the formidable protection afforded by an intact, healthy cervico-vaginal epithelium. Three lower genital tract infections have been highly associated with an increased susceptibility to HIV-1 infection, even after controlling for other high-risk sexual behaviors [8–10]. Specifically, they are *Trichomonas vaginalis* (TV) [11, 12], bacterial vaginosis (BV) [13–17], and herpes simplex virus type 2 (HSV-2) [18–20]. These infections are all highly prevalent, not reportable, frequently recurrent, and often asymptomatic. These attributes represent a perfect storm for perpetuating the spread of HIV-1. Sexual transmission of HIV-1, in the absence of cofactors, is poorly efficient. Lower genital tract infections enhance HIV-1 acquisition through the cervicovaginal mucosa by inducing a proinflammatory state, weakening the integrity of the epithelial barrier, and/or decreasing local innate immunity and normal epithelial defenses, in addition to disrupting the protective effects of the normal, lactobacilli-dominated vaginal microbiome [21]. This is why MPT products which protect against HIV-1 and lower genital tract infections which function as HIV-1 susceptibility cofactors are likely to have a synergistic effect in stemming the epidemic.

5. Rationale for Multipurpose Prevention Technologies (MPTs)

MPTs offer solutions to more than one reproductive need. This translates into several benefits for the users such as improved convenience, adherence, effectiveness, cost-reduction, and environmental impact. For the most part, existing MPTs, for example, male condoms, have been proven to be effective against unintended pregnancies and STIs [22, 23]. However, prevalence of use is generally low due to acceptance and compliance issues [24]. New MPTs should be more effective and less user dependent, not interfere with sexual pleasure, and provide additional health benefits.

6. Existing MPTs and Improved Derivatives

6.1. Male and Female Condoms. MPT barrier methods include the male and female condom, diaphragms, and cervical caps. The cornerstone MPT is the male condom. This established product provides highly effective protection from pregnancy [22] and HIV-1 [23], when used correctly. Low cost and worldwide over-the-counter availability are additional desirable features of the male condom. The main obstacle to using the male condom as an effective MPT, however, is reflected in the disparity between the theoretical failure rates (2–3%) versus typical failure rates at one year of use (approximately 15%), indicating that this method suffers from inconsistent and improper use, mainly due to acceptability issues [24]. Many women cannot negotiate condom use with their male partner, as this could imply distrust in the relationship, so many experts advocate considering other options for MPT [25]. Health and community education has been a main format of increasing acceptance of condoms, particularly by men [25]. Access to free male condoms has reduced the incidence of STIs in targeted populations, such as military members [26]. Other strategies such as advocating for reduced pricing of condoms or distributing free condom packs at nightclubs frequented by at-risk groups, such as men who have sex with men, have also been undertaken to reduce the spread of STIs [27].

The female condom (FC) has been advocated as a means for a female controlled physical barrier method to prevent pregnancy and STIs. Female condoms, like male condoms, prevent semen from reaching the cervix and vagina. The contraceptive efficacy of female condoms has been shown to be comparable to or even slightly higher than male condoms [28, 29]. The female condom performed as well as the male condom in reducing the recurrence of bacterial STIs [30]. Although there are no formal HIV-1 prevention trials with the female condom, mathematical models predict an effectiveness of 63–82% [31, 32]. The first female condom or FC1 was approved by the United States (US) Food and Drug Administration (FDA) in 1993. It is made of polyurethane and marketed under many trade names including the Reality female condom or the FC1 female condom [33, 34]. However, the polyurethane made a distracting crinkling noise with intercourse and was more expensive than the FC2, a newer female condom, manufactured by the Female Health Company, which is made of a synthetic latex (nitrile) [34]. The cost of the FC2 remains higher than that of a male condom. In an effort to further reduce costs and improve acceptability, organizations such as the World Health Organization (WHO) have investigated the performance of the FC2 using an *in vitro* design, after subjecting the condoms to multiple rounds of washing, disinfecting, drying, and relubrication, and found that the integrity of the condoms remained high [35]. Although the FC2 is currently recommended for single use, epidemiologic studies show the FC2 to have comparable cost-effectiveness to the male condom, especially when widely distributed to at-risk populations as a method to decrease HIV-1 transmission [32]. The FC1 and FC2 condoms are shown in Figure 1.



FIGURE 1: Design of the FC1 and the FC2.



FIGURE 2: PATH Woman's Condom.

In an effort to increase acceptance and use of the female condom, the Program for Appropriate Technology in Health (PATH) has produced a novel FC product, the contraceptive efficacy of which is currently being tested in an NICHD-funded multicenter trial. A subset study, conducted by CONRAD, will look at biomarkers of semen exposure in the female vagina, before and after product use. The PATH Woman's Condom (WC) performed well in a short-term acceptability study and in a comparative crossover study with the FC1 [36, 37]. The WC has a pliable polyurethane pouch, a soft outer ring, and 4 elliptical foam pieces on the outside of the pouch that cling to the vagina to stabilize the device. The distal end of the pouch and foam pieces are packaged in a capsule that serves as an insertion aid and dissolves quickly after insertion (Figure 2). This design change was put in place to increase acceptability of the WC.

6.2. Female Diaphragms. The cervix has a higher density of CD4 cells and CCR5 chemokine receptors than the vagina [38]. It has also been identified as an initial site of SIV infection in macaque experiments [39]. These and other lines of evidence suggest that the endocervix is a primary infection site for HIV-1 and other STIs [40]. Several groups have tried to employ diaphragms as MPTs. Diaphragms have traditionally been used for contraception and offer similar failure rates as male condoms [41]. Cross-sectional studies and case control studies showed that acquisition of *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT) is lower among women who choose diaphragms than women who choose other nonbarrier methods of contraception [42, 43] reviewed in [44]. Based on these observational data, the Methods for Improving Reproductive Health in Africa or MIRA trial was launched to compare the efficacy of the Ortho All-Flex diaphragm, lubricant gel (Replens) and condoms to condoms alone in preventing HIV-1, GC, and CT in at-risk women [45, 46]. In these large trials, there was no statistically significant difference in the incidence of HIV-1 [45] or GC and CT [46] among the two cohorts. However, the proportion of women using condoms in the diaphragm plus condom group was significantly lower than the condom alone group (54% versus 85%, $P < 0.001$), suggesting that the diaphragm plus lubricant provided at least as effective protection against HIV-1, GC, and CT as condoms alone, although these studies were not designed to test a noninferiority hypothesis [45, 46].

A disadvantage of traditional female diaphragms is that they require fitting by a health care professional and are therefore available by prescription only in many countries. PATH, in collaboration with CONRAD, developed and tested the SILCS diaphragm, a new, single size (one size fits most) contraceptive diaphragm designed to offer easier insertion and removal, increased comfort, elimination of latex-related odors and allergic reactions, and greater durability than latex diaphragms. The SILCS diaphragm is made of silicone, which is sturdy and more tolerant of extreme storage temperatures. It has a polymer material spring, which is less expensive and easier to assemble than metal springs, which are used in several latex diaphragms. The SILCS diaphragm performed well in phase I postcoital barrier effectiveness testing, performed in the USA [47]. Data also showed that couples in low resource settings preferred the SILCS diaphragm over the Ortho All-Flex diaphragm in a comparative cross-over study [48]. CONRAD studied the clinical efficacy of the SILCS diaphragm with BufferGel, from 2008 to 2009 in a USAID-funded study. The data from this study are in analysis, and FDA approval of this device could be as early as this year. The SILCS diaphragm (shown in Figure 3) is currently also being considered as a delivery system for tenofovir 1% gel and other candidate microbicides.

6.3. Chemical Barriers (Contraceptive Microbicides). Spermicides are the mainstay of contraceptive chemical barrier methods. In the USA, the only FDA-approved spermicide available, which is widely used as a condom lubricant or in vaginally inserted foams, gels, and films, is nonoxynol-9 (N9). N9 is a surfactant that immobilizes or kills sperm



FIGURE 3: The SILCS diaphragm.

by disrupting the lipid membrane. Early in the development of dual technology products, N9 and C31G (also known as SAVVY, developed by BioSyn, Inc.), both surfactants, were found to inhibit HIV-1 cell entry *in vitro* [49–53]. However, the *in vitro* and early preclinical and clinical data did not translate into effective, large-scale *in vivo* prevention methods, with some data indicating that frequent use of surfactants increased the susceptibility of the female genital tract to HIV-1, likely due to subclinical inflammation caused by these detergents [54–56].

The second generation of chemical barriers as MPTs was large, polyanionic sulfated, or sulfonated polymers that targeted the positively charged regions of the viral envelope of HIV-1 and/or blocked attachment, fusion or entry of the virus into host cells. These compounds included cellulose sulfate (CS or Ushercell, developed by TOPCAD/CONRAD), Carrageenan (also known as Carraguard and PC-515, developed by the Population Council), and PRO 2000 (also known as PRO 2000/5, developed by Indevus Pharmaceuticals). Ushercell also showed contraceptive properties equivalent to that of N9, in a noncomparative clinical trial where a 6% CS gel was used by 200 couples as their sole contraceptive method [57]. Although *in vitro* and early clinical data were promising for all these different HIV-1 entry inhibitors, large-scale prevention trials showed no increased protection over placebo [58–61].

Finally, products which worked to maintain the normal acidic pH of the vagina were introduced as potential MPTs. It was hypothesized that these products would maintain the healthy vaginal pH in the presence of semen and would work to partially inactivate pathogens that are acid sensitive, including HIV-1. Unfortunately, BufferGel (developed by ReProtect LLC) was found to have no significant protective effect for HIV-1 [62]. However, it was shown to be safe and spermicidal [63]. Table 1 summarizes recent MPT clinical trials.

Although research and development of dual contraceptive microbicides has yet to produce a safe and effective product, researchers continue to discover new approaches to achieve this goal. Examples of these efforts include dermaseptins, magainins and other antimicrobial peptides [68–71], AZT derivatives [72], cellulose conjugates [73], and other new dual action compounds [68].

7. Innovative MPTs on the Horizon

Results from the randomized, double-blind, placebo-controlled Centre for the AIDS Program of Research in South Africa (CAPRISA) 004 trial, demonstrating that 1% tenofovir vaginal gel reduced the incidence of HIV-1 by 39% overall and also reduced the incidence of primary HSV-2 infection by 51%, provided proof that potent antiretroviral agents could prevent HIV-1 and other prevalent HIV-1 susceptibility cofactors like HSV-2 [74]. Although a resounding proof-of-concept, the observed 39% protection certainly leaves room for improvement. Reduced user-dependence, more convenient dosing, and increased potency are some of the goals for improving future MPTs.

7.1. Innovative Dosage Forms for Intravaginal Delivery of Tenofovir for the Prevention of HIV-1 and HSV1/2 Sexual Transmission. Adherence is a prime concern in large prevention trials. Although all users of tenofovir gel experienced a significant protection against HIV-1 acquisition in the CAPRISA 004 trial, protection was related to adherence. Specifically, high (>80% of sexual acts protected by microbicide use), intermediate (50–80% of sexual acts used microbicide), and low adherence (<50% of sexual acts associated with microbicide use) users had a 54%, 38%, and 28% reduction in HIV-1 incidence, respectively, compared to placebo users [74]. To increase adherence, CONRAD is currently developing an intravaginal ring capable of releasing tenofovir in amounts that generate tissue concentrations similar to those attained by the 1% gel in a rabbit pharmacokinetic (PK) study. Designed in collaboration with Dr. Kiser (University of Utah), the tenofovir ring is made of hydrophilic polyurethane loaded with more than 1 gram of tenofovir, with a daily release rate of at least 10 mg/d for a target 90-day duration. The ring has approximate dimensions of 55 mm outer diameter and 5.5 mm cross-sectional diameter, only slightly larger than the commercially available contraceptive NuvaRing. Phase 1 clinical evaluation of the tenofovir ring is expected to initiate in early 2012.

Other intravaginal dosage forms for TFV are a fast-dissolve film and a fast-dissolve tablet. The TFV fast dissolve film, under development at the University of Pittsburgh and Magee-Womens Research Institute, is also small and is expected to provide similar tissue concentrations of TFV as compared to the TFV gel given its concentrated TFV dose. The tablet is under development by CONRAD with an estimated phase I trial in 2012. Unlike the gel dosage form, use of a vaginal applicator is not required for the film or the tablet and multiple doses may be packaged together in compact containers, thereby making them attractive dosage forms based on increased portability and potentially lowering manufacturing costs and environmental impact.

7.2. Enhanced Protection against HSV/HIV Genital Infection. Multiple lines of evidence indicate that HSV-2 infection is a significant HIV-1 susceptibility cofactor and that HSV-2 and HIV-1 have potential negative impacts on both infections [18, 19, 75–78]. However, despite the strong epidemiologic

TABLE 1: Contraceptive and microbicide data on multipurpose prevention technologies.

Product/developer (common brands)	<i>In vivo</i> human contraceptive data	<i>In vivo</i> human microbicide data	
	Supportive	Supportive	Non-supportive/Inconclusive
Physical barriers			
Male condom/several	✓ [22]	✓ [23]	
Female condom/several (FC1, FC2, PATH Women's Condom)	✓ [28, 29]	✓ [30–32]	
Female diaphragm/several (Ortho All Flex)	✓ [41]		✓ [45, 46]
SILCS diaphragm/CONRAD	Data in Analysis		Not studied
chemical Barriers: surfactants			
Nonoxynol-9/several	✓		✓ [55]
C31G/BioSyn (SAVVY)	✓ [64]		✓ [54, 56]
Chemical barriers: attachment, entry and fusion inhibitors: (polyanionic sulfated or sulfonated polymers)			
Cellulose Sulfate (Ushercell, CS)/Polydex Pharmaceuticals, Program for the Topical Prevention of Conception and Disease (Rush University), CONRAD	✓ [57]		✓ [58, 61]
Carrageenan/Population Council (Carraguard, PC-515)			✓ [59]
PRO2000/Indevus Pharmaceutical (PRO2000/5)	<i>In vitro</i> , no large human studies		✓ [60, 62]
Acid buffers and vaginal defense enhancers			
BufferGel/ReProtect LLC	✓ [65]		✓ [62]
Acidform Gel (Amphora) Instead Sciences	✓ [66, 67]	No large human efficacy trials	

and observational data linking these two infections, randomized controlled trials using prophylactic oral acyclovir (ACV) in HSV-2-positive individuals to reduce the incidence of HIV-1 have not shown a significant preventative effect [79, 80]. In addition, ACV prophylaxis in HSV-2 and HIV-1 seropositive individuals did not reduce transmission of HIV-1 to seronegative sexual partners [81]. The potential reasons for failure of the interventional trials are several but include persistence of inflammatory infiltrates, compliance with prophylactic therapy, and adequate delivery of antiviral medications to genital tissues.

Frank disruption of the genital epithelium by HSV-2 lesions is likely not the only mechanism by which the genital mucosa becomes more susceptible to HIV-1 infection [21]. The surrounding epithelium has subclinical changes in inflammatory and innate immune response, including an influx of CD4+ and CD8+ cells, which persist for months even after an epithelial lesion has healed, leaving apparently normal genital epithelium still vulnerable to HIV-1 infection [82, 83]. Oral ACV therapy does not alter the persistence of these HIV-1 target cells [82, 83].

Compliance with prophylactic therapy was assessed by participant report and pill counting [80] and with serum and urine ACV levels [79]. PK data indicated that compliance

with daily oral therapy was poor in one trial [79]. It is likely that compliance with preventative treatment would increase with a more convenient and long acting dosing regimen such as an intravaginal ring. It is known that plasma and vaginal levels of ACV are poorly correlated ($r = 0.28$, $P > 0.05$), with vaginal secretions containing 15–170% (mean 79%) of plasma ACV levels [84, 85]. PK studies demonstrate that peak vaginal concentrations of ACV are reached 30–60 minutes after oral dosing [85]. Peak vaginal concentrations of ACV (0.8–3.6 nmols/g or 0.18–0.81 $\mu\text{g/mL}$) after daily oral dosing have also been shown to be below the 50% inhibitory dose of ACV for HSV-2 (approximately 0.91 $\mu\text{g/mL}$) [86]. These data suggest that higher oral doses of ACV would be required to prevent primary infection by HSV-2 or to reduce recurrent genital epithelial replication and shedding. In addition, missed doses of oral ACV may significantly affect adequate genital concentrations of the drug.

This is why we have begun to develop a tenofovir and ACV combination vaginal product. We believe that the efficacy of tenofovir in preventing primary HSV-2 infections, shown in the CAPRISA 004 study [74], may be improved significantly by adding topical delivery of ACV. We also hypothesize that increasing the concentration of tenofovir in the genital tissues will increase its effectiveness. These

hypotheses are supported by data from the CAPRISA-004 trial, which directly correlated the concentrations of tenofovir and its active metabolite tenofovir diphosphate, in genital tract secretions and tissues with the likelihood of preventing HIV-1 or HSV-2 [87]. Tenofovir and ACV will be synergistic in an MPT product to prevent HIV-1 and HSV-2. We hypothesize that ACV, delivered topically and vaginally, will result in higher local tissue concentrations, which would reduce or control HSV-2 epithelial replication and the subclinical changes in the genital mucosa associated with recurrent HSV-2 outbreaks.

CONRAD is currently developing an intravaginal ring for the sustained dual delivery of tenofovir and ACV. Tenofovir and ACV have similar hydrophilicity and therefore may be suitably coformulated in hydrophilic polyurethanes. In collaboration with Controlled Therapeutics (East Kilbride, Scotland), a 10% tenofovir/10% ACV hydrophilic polyurethane ring with dimensions similar to NuvaRing was developed that is capable of releasing milligram quantities of each drug daily for up to one month. Ongoing product development efforts continue to increase these release rates as well as extend the duration of drug release.

Another intravaginal ring design well suited for use as a sustained MPT dosage form, and particularly for codelivery of tenofovir and ACV, is the drug pod-based Versaring technology currently being developed by Auritec and Oak Crest Research Institute (Pasadena, Calif). This technology uses a silicone elastomer ring as primarily a physical holder for ten individually formulated—and subsequently independently rate-controlled—drug cores or pods (~3–20 mg drug per pod) that provides remarkably controlled release profiles. With CONRAD's collaboration, a tenofovir/ACV combination intravaginal ring using this technology is also currently under development.

Although randomized controlled trials of Carraguard failed to demonstrate efficacy in preventing HIV-1 infection [59], it was found to be safe, well tolerated, and physically stable. These properties make carrageenan a good delivery vehicle for other microbicide candidates. Furthermore, it has demonstrated high anti-HPV activity *in vitro* [88]. The Population Council commenced early preclinical and animal testing of a combination MIV-150, a nonnucleoside reverse transcriptase inhibitor developed by Medivir and zinc acetate, prepared in a delivery vehicle of carrageenan gel [89], named PC 1005. This MPT showed complete protection against RT-SHIV infection for up to 8 hours after daily dosing for 14 days [89]. *In vitro* data suggest that zinc salts have activity against HIV-1 [90] and HSV-2 [91, 92].

7.3. Innovative MPT for the Prevention of HIV-1 Acquisition and Unintended Pregnancies. Although the recent news of tenofovir as an anti-HIV-1 microbicide is compelling, tenofovir is not a contraceptive. To solve this problem, we are also currently developing an MPT with extended dosing of levonorgestrel (LNG) and tenofovir in an intravaginal ring which would be effective for at least 90 days (Figure 4). We chose LNG because of its long track record of safety and efficacy [93, 94]. The WHO previously developed a

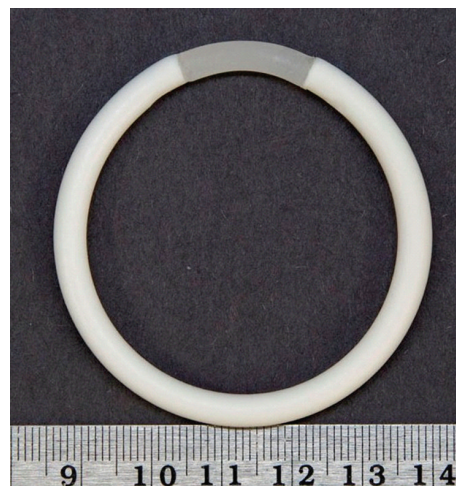


FIGURE 4: Segmented intravaginal ring for codelivery of tenofovir (long white segment) and levonorgestrel (short segment). Photo courtesy of Dr. Patrick Kiser (University of Utah).

microdose LNG eluting silicone vaginal ring as a one-year contraceptive product, which went through extensive safety, efficacy, and acceptability testing. The product was not pursued at the time, however, due to funding considerations [95–97].

The tenofovir/LNG intravaginal ring under development in collaboration with the University of Utah builds on both the millidose tenofovir vaginal ring described above and WHO's work on the microdose LNG ring. One of the major challenges to developing a combination ring for these two particular drugs is the large (three orders of magnitude) difference in target release rates between tenofovir and LNG. Moreover, LNG's hydrophobicity lends itself to formulation in, and delivery from, hydrophobic polymers. The design of our ring overcomes both of these challenges by formulating the drugs separately in two independent drug-loaded segments, with the tenofovir segment comprising more than 80% of the ring's total volume (maintaining the ring's capacity to deliver 10 mg/d tenofovir) and the short LNG segment formulated with hydrophobic polyurethanes for delivery of 20 μ g/d LNG. Dr. Kiser's group has previously reported on two-segment polyurethane intravaginal rings for the codelivery of tenofovir and dapivirine [98]. Phase 2b dose and safety testing of this product is expected to begin in the next year.

In collaboration with PATH (Program for Appropriate Technology in Health), CONRAD is also testing the delivery of TFV gel by SILCS, a one-size-fits-all diaphragm with contraceptive barrier properties. This combination should provide coitally associated contraception and prevention of HIV-1 and HSV-2 acquisition.

The International Partnership for Microbicides (IPM) has developed an intravaginal ring which elutes dapivirine (TMC120), a nonnucleoside reverse transcriptase inhibitor (NNRTI), for one month [99–101]. Dapivirine has been shown to be effective in preventing HIV-1 infection *in vitro*, using cell line and tissue explant models [102]. Dapivirine

has been studied in phase 1 and 2 dosing and safety studies [103, 104]. IPM has partnered with the Population Council in developing an MPT intravaginal ring which elutes dapivirine and levonorgestrel, showing promise in early laboratory and preclinical studies [105].

8. Conclusions

Multipurpose prevention technologies, MPTs, encompass simultaneous prevention of STIs and unintended pregnancies as well as prevention of more than one STI or reproductive tract infection. Established methods include barrier devices such as male and female condoms and female diaphragms. Innovations to these traditional MPT products are underway to improve accessibility, acceptability, and efficacy. Although clinical trials failed to demonstrate efficacy against HIV-1 transmission for the first generations of chemical MPT products including spermicides (nonoxynol-9 and C31G), polyanionic sulfated or sulfonated polymers (cellulose sulfate, carrageenan, and PRO 2000), and vaginal pH buffers (BufferGel), research and development continues to optimize the contraceptive properties of some of these compounds or to use these compounds as delivery vehicles for more potent antivirals or spermicides. Some of them, for instance carrageenan, are being further considered for new applications. Proof of concept for a chemical MPT, tenofovir vaginal gel, has just been demonstrated for the prevention of HIV-1 and primary HSV-2 infections. Research is underway to simplify the dosing of tenofovir vaginal gel and develop other delivery systems for tenofovir alone or in combination with contraceptive hormones (e.g., levonorgestrel) or other potent antivirals.

Women at risk for unintended pregnancies are by definition also at risk of STIs, and women who are at risk of one STI are also likely at risk of several different STIs. Data support that women find MPT products desirable and acceptable [106]. Simplifying and extending the dosing regimen, decoupling prophylaxis from coital acts, and developing female controlled protection products are all innovative strategies and approaches to increase the use of these much needed technologies. MPTs are likely to have a synergistic impact on the epidemics of sexually transmitted infections and unintended pregnancies and facilitate implementation and uptake of these biomedical preventative interventions.

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Review Article

Do Women Using Long-Acting Reversible Contraception Reduce Condom Use? A Novel Study Design Incorporating Semen Biomarkers

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Long-acting reversible contraceptive (LARC) methods are highly effective against pregnancy. A barrier to their widespread promotion can include the concern they will lead reduced condom use and, thus, will put couples at higher risk for sexually transmitted infections (STIs). We review evidence from previous studies of condom “migration” associated with the use of LARC and propose a novel study design to address the two main methodological issues that have limited these earlier studies. Namely, we propose to use a randomized controlled trial design and to use a biological marker of semen exposure for measuring changes in condom use.

1. Introduction

Because long-acting reversible contraception (LARC) methods have very high efficacy and low burden to users after their initiation, the American College of Obstetricians and Gynecologists recommends that women be offered LARC as first-line contraceptive methods [1]. These methods, which include intrauterine devices (IUD) or systems (IUS) and contraceptive implants, avoid the need for frequent visits for resupply, are highly cost effective, and allow a rapid return to fertility after their removal. However, while LARC methods are extremely effective against pregnancy, they offer no protection against the transmission of HIV and other sexually transmitted infections (STIs). Thus, policy makers, funders, and providers might hesitate to support and promote the use of LARC, in part, because of concerns that women who initiate their use (or their male partners) could be less motivated to use condoms [2, 3]. Because women using LARC essentially are no longer at risk of pregnancy, they may choose not to use condoms or may no longer be able to convince their partner to use condoms solely for disease prevention. Because condoms, used consistently and

correctly, remain the most effective method of protection against HIV/STIs for sexually active individuals [4, 5], changes in condom use patterns from the introduction of LARC could put women and their partners at increased risk of infection. Similar concerns about condom “migration” related to the introduction of other interventions, such as microbicides, circumcision, and preexposure prophylaxis for HIV prevention, also have been raised [6, 7].

1.1. Literature on Condom “Migration”. The available evidence—albeit limited—supports the possibility that LARC use could lead to reduced condom use. A multivariable analysis of a nationally representative survey of women in the US found that condom use was lower for women using injectables, intrauterine devices or implants compared to women using oral contraception [8], and a survey of reproductive-aged women in Baltimore revealed a significantly lower prevalence of condom use among implant users than nonusers [9]. Similarly, a study among Hispanic and African-American female adolescents in Manhattan found condom use in the prior month was lower among women relying on the injectable or implant compared to those using

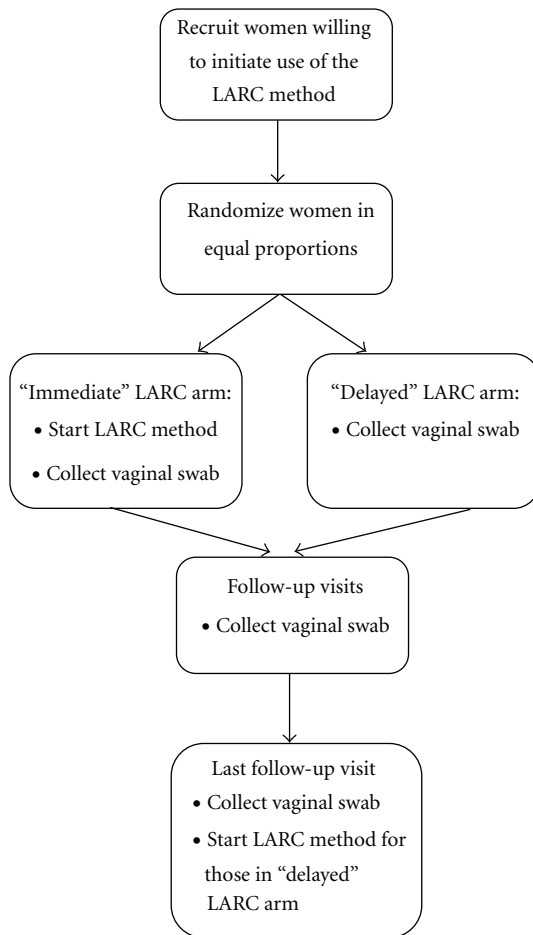


FIGURE 1: Proposed study schema.

condoms only [10]. A case-control study of adolescents in Texas found that condom use among implant users was lower than among oral contraceptive users [11].

Three prospective cohort studies also have evaluated the association between LARC and condom use. A study of adolescents in San Francisco found that women who chose to use implants reported less condom use after two years of followup than at baseline [12]. Condom use among implant users was also lower than among those who chose to use oral contraception or condoms alone. In a study conducted in three large urban hospitals of 1,073 women initiating use of implant or injectable contraception, consistent condom use within the past three months declined after one year of followup [13]. Only one study, conducted among 98 postpartum adolescents in Pennsylvania who chose to use either implants or oral contraception, failed to find differences between groups in the levels of condom use reported [14].

Prior studies on condom migration suffer from two main methodological weaknesses: reliance on self-reports of condom use and lack of randomization. Participant reports of condom use could be inaccurate for many reasons, including recall bias or—especially in intervention studies

in which condoms are heavily promoted or distributed—social desirability bias [15–18]. Studies that have detected biological markers of semen (e.g., prostate-specific antigen [PSA] or y-chromosome DNA) in vaginal fluid specimens collected from women who reported no recent exposure suggest substantial underreporting of unprotected sex [19–24]. Furthermore, misreporting of unprotected sex might not be distributed randomly across a study population, as suggested by a recent study that assessed predictors of discordance between spermatozoa detection and self-reported lack of unprotected sex [25]. For example, if the misreporting of condom use were to differ with respect to the use of other contraceptive methods, the conclusions reached by previous studies on condom migration could be misleading.

The second—and perhaps more serious—limitation of past studies involves the lack of randomization for assigning women to method use. Women who choose different contraceptive methods often vary by their characteristics [26]. Confounding by indication could occur if the women who choose to use LARC methods (or the women whose providers promote LARC methods to) are predominantly those at low risk of HIV/STIs and, thus, infrequent users of condoms. Those who opt to initiate a LARC method may have inherently different patterns of condom use than those who choose not to use the method; thus, earlier studies could be biased as a result of systematic differences between groups. Few studies on the relationship between use of LARC and condoms have attempted to control for these differences and thus are subject to confounding; moreover, controlling for these factors would likely be difficult as not all factors influencing condom use (e.g., perceived HIV/STI risk, ability to negotiate condom use with partner) are known or easily measured.

2. Randomized Controlled Trial Using a Semen Biomarker

We propose a randomized design for studying the effect of introducing a specific type of LARC method (i.e., IUD, IUS, or contraceptive implant) on condom use that addresses both major methodological weaknesses inherent in the previous studies. Under this design, women at risk of pregnancy without contraindications to the method [27, 28] would be randomized to one of two groups: (1) “immediate” start of the LARC method or (2) “delayed” start of the LARC method (i.e., at completion of their last study follow-up visit) (Figure 1). Participants would be asked to complete an enrollment visit and follow-up visits scheduled at regular intervals during the period (e.g., 6–12 months) following enrollment. Vaginal specimens would be collected—either by swabbing by the participant herself or by a study provider—at all study visits for testing for PSA, and participants would be counseled on correct and consistent use of condoms. The study would assess whether use of the LARC method affects the number of unprotected sex acts (i.e., without a condom) as measured by the detection of an objective biomarker of unprotected intercourse, such as PSA, in the vaginal swab.

PSA, a glycoprotein produced by the prostate gland and secreted into the seminal plasma, was first identified by forensic scientists who were trying to find a substance in seminal fluid to facilitate the investigation of rape cases [29]. More recently, PSA has been used in contraception and HIV/STI research to assess recent (i.e., within the previous 48 hours) exposure to semen [30–33]. While several laboratory assays can be employed to quantify PSA levels or other biomarkers of semen exposure (e.g., Y-chromosome DNA), they require specialized laboratory equipment and training. More recently, a low-cost, rapid test that can be used by laboratory technicians without specialized training has been showed to provide reliable and valid semiquantitative measures of PSA and, thus, makes the use of PSA as a semen biomarker feasible in a wide range of research settings [34].

3. Challenges to Study Design

Ideally, such a study would be conducted in a site in which the women normally do not have access or are naïve to use of the specific LARC method. Participants would be randomized to receive the LARC method at enrollment or after the end of followup. Precedent for this type of design in which the introduction of the intervention is delayed in the control arm until the end of study participation can be found, for example, in the recent trials on the effect of circumcision on HIV acquisition in which men were randomized to immediate or delayed circumcision [35]. Ethically, investigators cannot withhold a LARC method (even for a limited interval) from women in settings where the normal standard of care allowed for its provision. Consequently, depending on the availability of the LARC method, this study design might not be feasible in all settings.

Another limitation is the potential for the request for swab collection to influence participant behavior. Women could either be asked for their consent to test their collected vaginal specimens for PSA at time of enrollment or, retroactively, at their last study visit. Although a randomized controlled trial did not find evidence that the advance knowledge of testing for PSA caused women to report more unprotected sex [36], such knowledge still could cause women to modify their behavior (e.g., abstain from unprotected sex before study visits). Asking for consent for PSA testing retroactively circumvents the possibility of behavioral change from swab collection; however this approach requires another reason to justify swab collection during the study (e.g., as an opportunity for STI testing) and would risk losing data from women who do not return for their last visit or who decline to consent to the testing. Regardless of the timing of the consenting process for PSA testing, women simply might tend to change behavior in general before attending study visits; for example, women may abstain from sex before a scheduled pelvic examination due to hygienic concerns.

Any study of risk compensation will have problems with generalizability. Even if the proposed study does not demonstrate evidence of condom migration from the initiation of the contraceptive implant, this would not preclude its

occurrence in other settings or with other populations. The effect of adopting a LARC method on participant levels of condom use could vary by numerous factors, including participant characteristics, participant perceived risk of STIs, quality of provider counseling and patient-provider rapport, and social norms surrounding condom use. Study findings from one setting cannot be assumed to be generalizable to other populations.

4. Conclusions

The proposed study design addresses two methodical weaknesses (i.e., reliance on self-reported data and lack of randomized design) that have limited the interpretation of findings from previous studies on this topic. More broadly, the detection of semen biomarkers could be applied to research on condom migration associated with other contraceptive methods and with HIV-prevention interventions, including male circumcision and oral or topical microbicides. Given that the occurrence of condom migration from the introduction of LARC methods or HIV-prevention interventions could vary by study populations, the utility of testing for PSA might be even more useful for on-going, population-level surveillance of changes in condom use patterns. This surveillance could provide accurate information with which to identify subgroups in a setting that might benefit from more intensive condom counseling. Also, by monitoring the frequency of PSA detection in a population, providers could evaluate and compare the effectiveness of different methods of counseling on condom use. Researchers should consider incorporating testing for semen biomarkers routinely into studies as well as surveillance requiring measures of unprotected sex.

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Research Article

Multiple Method Contraception Use among African American Adolescents in Four US Cities

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We report on African American adolescents' ($N = 850$; M age = 15.4) contraceptive practices and type of contraception utilized during their last sexual encounter. Respondents completed measures of demographics, contraceptive use, sexual partner type, and ability to select "safe" sexual partners. 40% endorsed use of dual or multiple contraceptive methods; a total of 35 different contraceptive combinations were reported. Perceived ability to select "safe" partners was associated with not using contraception ($OR = 1.25$), using less effective contraceptive methods ($OR = 1.23$), or hormonal birth control ($OR = 1.50$). Female gender predicted hormonal birth control use ($OR = 2.33$), use of less effective contraceptive methods (e.g., withdrawal; $OR = 2.47$), and using no contraception ($OR = 2.37$). Respondents' age and partner type did not predict contraception use. Adolescents used contraceptive methods with limited ability to prevent both unintended pregnancies and STD/HIV. Adolescents who believed their partners posed low risk were more likely to use contraceptive practices other than condoms or no contraception. Reproductive health practitioners are encouraged to help youth negotiate contraceptive use with partners, regardless of the partner's perceived riskiness.

1. Introduction

A sizeable minority of adolescents experience unintended pregnancies and sexually transmitted diseases (STDs) [1, 2]. Unintended pregnancy rates are the highest among individuals less than 20 years of age, despite availability of effective contraceptive methods [2]. STD rates are particularly concerning for young African American adolescents [3] because national estimates show that African American youth between the ages of 15 and 24 experience the highest rates of chlamydia and gonorrhea [3, 4], and these STD increase susceptibility to HIV [5–7].

Clinical adolescent medicine guidelines recommend comprehensive reproductive health counseling to encourage

use of a "dual method" strategy to prevent pregnancy through hormonal birth control use and STD/HIV through consistent use of male latex condoms [8, 9]. However, research suggests that use of hormonal birth control use is associated with decreased condom use [10, 11], and, despite being the recommended practice, rates of reported dual method use among adolescents are low with usage rates ranging from 5.5% to 14.6% [8, 12–14]. The prevalence of dual method use among African American adolescents is uncertain. A nationally representative sample of adolescents indicated that dual method use was significantly lower among African American youth [8]. However, other studies have suggested that dual method use may be more prevalent among African American adolescents [13, 14].

Few studies have examined factors associated with African American adolescents' selection and use of dual method protection strategies [13–16]. Further, most studies have focused on African American female adolescents' use of dual methods with only one study including males [15]. Selection of contraceptive methods and use of dual methods may vary based on the type of partner and characteristics of the relationship. For example, a qualitative study found that the type of sexual partner influenced dual method use; dual use of condoms and hormonal birth control was less likely in relationships with steady sexual partners [17]. Another study identified that consistent use of hormonal birth control as the only contraception method was more likely with steady sexual partners [18]. Thus, evidence suggests that adolescents may vary their contraception method use by partner type. In addition, adolescents' perceived ability to identify "risky" sexual partners may impact contraception selection and use. Indeed, lower condom use has been linked to perceiving a partner as "safe" or presenting low risk for STD/HIV transmission [19, 20].

To address gaps in the existing research, this study examines the contraception methods used by African-American adolescents in four US cities. This study examines the influence of partner type and perceived ability to select safe sexual partners in relationship to contraception use. In addition, a large sample of African American adolescent females and males was recruited, allowing us to examine whether contraception practices differ by gender or age. We describe the types and combinations of contraception methods used during respondents' last sexual encounter and predict adolescents' use of contraception method types based on their gender, age, pregnancy history, perceived ability to select safer sexual partners, and the type of sexual partner.

2. Methods

2.1. Study Design. Project iMPPACS was a longitudinal intervention project for African American adolescents living in low-income urban areas designed to evaluate the effect of community-wide media campaigns to supplement and reinforce (i.e., act as "booster sessions") small group interventions to increase condom use and reduce sexual risk-taking. The media boosters were implemented to prevent decay of the small group intervention's impact to lower HIV and STI risk over time [21–23]. The design of Project iMPPACS was a 2 (sexual risk reduction or a general health promotion intervention) by 2 (media present or media absent) by 6 (time: baseline, 3, 6, 12, 18, and 36 months after-recruitment) randomized controlled trial implemented in two northern cities (Providence, RI, and Syracuse, NY) and two southern cities (Columbia, SC, and Macon, Ga). Once recruited, consented, and assented, adolescents completed a baseline audio computer-assisted self-interview to assess their sexual attitudes, beliefs, and sexual behaviors. Analyses reported in this paper are limited to baseline data collected prior to participation in the small group intervention sessions. Additional information on implementation of Project iMPPACS can be found elsewhere [24]. All study procedures

were approved by the Institutional Review Boards at the affiliated study institutions.

2.2. Measures

2.2.1. Demographics. Demographic characteristics assessed were age (14–15 versus 16–17 at baseline) and gender.

2.2.2. Contraceptive Use during Last Sexual Encounter. The contraceptive behavior item was only asked of respondents reporting at least one lifetime event of vaginal sex ($N = 850$). The item stem was "The last time you had vaginal sex, what method did you or your partner use to prevent pregnancy? (check all that apply)." The responses were (1) no method was used to prevent pregnancy, (2) birth control pills, (3) condoms (rubber), (4) Depo-Provera (injectable birth control), (5) had sex during a safe time of the month (rhythm method), (6) pulled out before ejaculating (cumming)/withdrawal, and (7) some other methods.

2.2.3. Sexual Partner Type during the Last Sexual Encounter. Research shows differences in regularity and type of contraceptive use by partner type among adolescents and adults [25–28]. Thus, respondents characterized their sexual partner during the most recent sexual encounter as one of three possible partner types: (1) someone you just met or a casual friend, (2) someone you knew well, but not a regular or "steady" partner, and (3) a steady boyfriend or girlfriend.

2.2.4. Thematic Mediator of Condom Use. Behavioral change is produced through modification of the causal mediating variables [29, 30]. For the analyses reported in this paper, we used a measure of one of the three mass media themes directly related to condom use: that a person can select a "safe sexual partner." We label this as the *Select* variable [31] and constructed it from three items in the Condom Attitude Scale [32]: "A condom is not necessary if you are pretty sure the other person does not have a sexually transmitted disease," "A condom is not necessary if you know your partners," and "A condom is not necessary when you and your partner agree not to have sex with anyone else." All responses to these items were coded from 1: Strongly Disagree to 6: Strongly Agree, such that high index values represent a belief that sex partners can be identified as safe (polychoric $\alpha = .83$, $M = 2.12$, $SD = 1.25$, $N = 850$).

2.2.5. Pregnancy History. Previous pregnancies or attempts to get pregnant may affect the type of contraception utilized. A single item asked participants to indicate whether they or a partner had a previous pregnancy or tried to get pregnant during the past 12 months. Response options were (1) no or (2) yes.

2.3. Statistical Methods. Summary statistics and bar charts describe participants' reported use of contraception methods during their last sexual encounter. Tetrachoric correlations were then calculated between contraceptive methods. Respondents' contraceptive methods were then classified

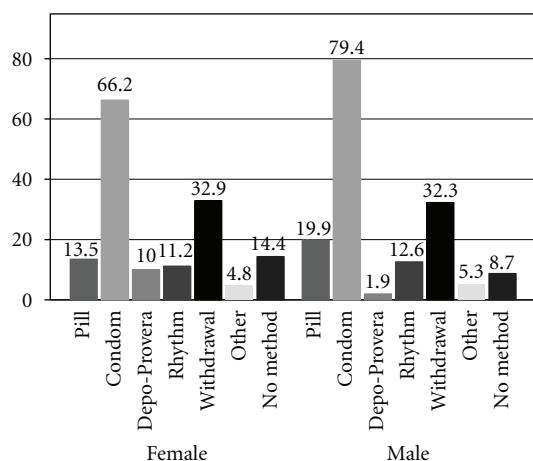


FIGURE 1: Prevalence of contraceptive method at last sex by gender ($N = 850$). Notes: percents sum to greater than 100% because of use of dual or multiple contraceptive methods.

into one of six mutually exclusive categories: (1) condoms only, (2) condoms plus some other nonhormonal method, (3) Birth control pills or hormonal method (Depo-Provera) plus some method other than condoms, (4) condoms and hormonal method only, (5) All combinations not including condoms or hormonal methods, and (6) no method. To predict the contraceptive use classification, we use multinomial logistic regression [33] looking at the ability of respondents' gender, older age, type of partner at last sex event, the Select mediator, and pregnancy history to predict a respondent's membership in a multiple contraceptive typology. In the multinomial logistic regression model, the comparison condition was use of only condoms given our focus on dual and multiple contraception use.

3. Results

3.1. Respondent Characteristics. For this paper, we selected iMPPACS baseline survey respondents who reported on contraceptive use the last time they had vaginal sex ($N = 850$). African American adolescent females ($n = 437$) and males ($n = 413$) were recruited in four mid-sized cities: Syracuse, NY ($n = 212$, 25%), Providence, RI ($n = 198$, 23%), Macon, Ga ($n = 226$, 27%), and Columbia, SC ($n = 214$, 25%). Participants were 14 to 17 years old (M age = 15.4, $SD = 1.1$). The majority (93%) were living in their family's home, most often with their mother in the household (84%) and less frequently with their father in the home (20%). Most participants (73%) qualified for a free or reduced price lunch at school. Eighty-five percent were in high school (i.e., grades 9 through 12), 13% were in junior high (i.e., grades 7, 8), and 2% were not in school at the time of study enrollment. Fourteen percent of adolescent females ($n = 61$) reported one or more previous pregnancies and nine percent of adolescent males ($n = 36$) reported previously impregnating a partner.

3.2. Descriptive Statistics: Reported Contraceptive Use. Figure 1 shows the distribution of types of contraceptives used at

the last vaginal sex event. For both males and females, the most common method was the male condom and the second most common method was withdrawal. The percentages sum to over 100% because of multiple contraceptive usage, so that the marginal distributions of each method give a distorted representation of contraceptive use.

Figure 2 shows the (tetrachoric) correlations between use of each method. The statistically significant dual methods were condoms/birth control pills, condoms/rhythm, condoms/withdrawal, withdrawal/rhythm, and other method/rhythm. However, even these significant correlations understate the variety of contraceptive use: 35 different contraceptive method combinations were reported by this adolescent sample (not counting the 12%, $n = 99$, who reported "no method used" at the last vaginal sex event). The most frequent combination was condoms/withdrawal (11%, $n = 92$), followed by condom/birth control pills (7%, $n = 58$), condom/birth control pills/withdrawal (4%, $n = 31$), condom/withdrawal/rhythm (3.5%, $n = 30$), and condom/rhythm (3.4%, $n = 29$). The most frequent method used alone was condoms (35%, $n = 294$), but single use of *any* of the other methods was rare: the next most recent single use was withdrawal (9%, $n = 76$) followed by birth control pill (<2%, $n = 16$). In other words, except for exclusive use of the male condom, virtually all contraceptive methods were dual or multiple in this sample.

3.3. Predicting Contraceptive Dual Use. To capture the heterogeneity in contraceptive use, the self-reported combinations of contraceptive uses were classified into six mutually exclusive types: (1) condoms only ("Condoms Only," 36%), (2) Condoms plus some other non-hormonal method ("Condoms Plus," 20%), (3) birth control pills or hormonal method (Depo-Provera) plus some method other than condoms ("Hormonal Plus," 4%), (4) condoms and hormonal method only ("Both," 18%), (5) all combinations not including condoms or hormonal methods ("Some Less Effective Method," 12%), and (6) no method ("No Method," 12%). Next, we predicted the typology using type of sex partner at last sex, the Select mediator, pregnancy history, age, and gender of the respondent in a multinomial logistic regression model. Because the focus is on dual/multiple use, the comparison classification was Condoms Only. These results are shown in Table 1.

Results show that gender (Female) and the Select mediator are the primary predictors of the typology. Select is significantly positively associated with all methods relative to Condoms Only except for the Condoms Plus and Condom and Hormonal Only groups. In particular, it is a strong predictor of No Method used. Female gender is also predictive of Hormonal Plus and the two most risky categories, the Less Effective Method and No Method groups. For the most recent sex event, the type of sex partner and respondent age has little ability to predict the type of dual/multiple contraceptive use adjusting for the other variables in the equation. Previous pregnancies or pregnancy attempts were associated with decreased likelihood of all methods relative to the Condom Only group except Condoms Plus.

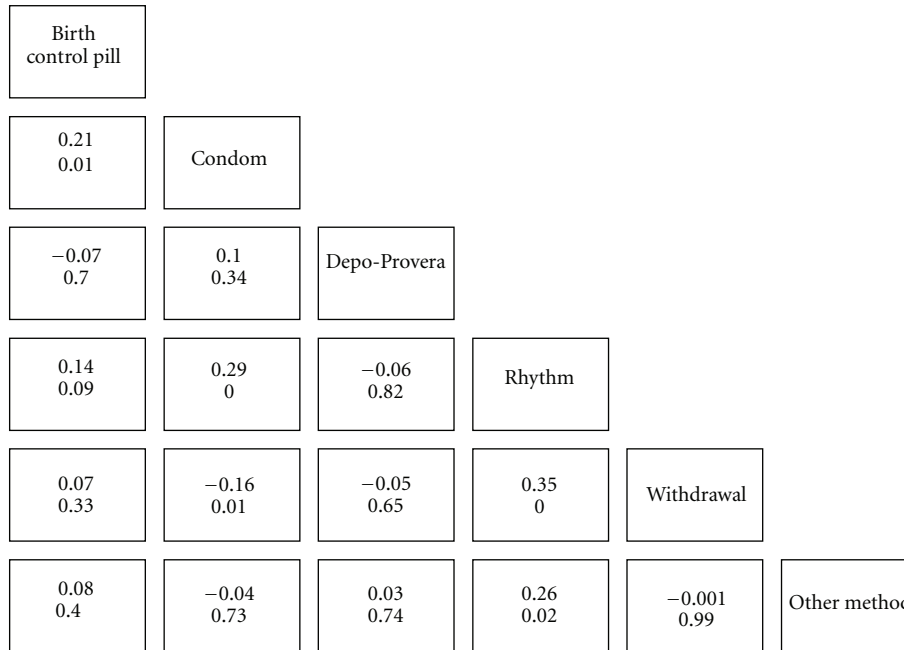


FIGURE 2: Tetrachoric correlations between contraceptive methods ($N = 850$). Note: significance level of correlation below coefficient.

TABLE 1: Results of predicting dual/multiple contraceptive use typology ($N = 850$).

Predictor variable	Contraceptive use category				
	Condoms Plus	Hormonal Plus	Condom and Hormonal Only	Some Less Effective Method	No Method
Select safe partners	1.01 (.85 – 1.20)	1.50 (1.15– 1.96)	1.16 (.98–1.37)	1.23 (1.01–1.49)	1.25 (1.03–1.51)
Someone you just met or casual partner	.64 (.31–1.33)	1.46 (.47–4.51)	.72 (.35–1.49)	1.13 (.49–2.60)	1.77 (.83–3.87)
Someone you knew well but not a steady partner	.76 (.48–1.19)	.55 (.20 –1.55)	.46 (.27–.78)	.98 (.57–1.72)	.97 (.55–1.74)
Female	1.01 (.67 –1.50)	2.23 (1.02–4.89)	1.18 (.77–1.80)	2.47 (1.49–4.10)	2.37 (1.41–3.97)
16-17 years old at baseline	.69 (.47 –1.01)	3.76 (1.64–8.65)	1.39 (.93–2.07)	1.15 (.72–1.82)	.94 (.58–1.51)
Pregnancy attempt or pregnancy in past 12 months	.45 (.18–1.13)	.18 (.06 –.55)	.40 (.16 –.96)	.35 (.13–.90)	.11 (.05–.24)

Notes: entries are odds ratios relative to the omitted group (Condoms Only). Bold, italic coefficients are significant at .05 level or less. Confidence intervals of odds ratio in parentheses.

4. Discussion

Current guidelines recommend the use of dual contraception methods to prevent unintended pregnancy and STD/HIV. Although the most common single contraception method used was the male latex condom (a strategy that affords both pregnancy and STD prevention), most adolescents did report the use of dual or multiple contraceptive methods. However, the types and combinations of contraceptive methods used provide varying degrees of reliable birth control and STD prevention. Similar to previous studies with African American adolescents [13, 14] only a minority of youth reported the use of hormonal birth control in

combination with condoms, the dual method that provides the best protection against both pregnancy and STD/HIV. Instead, adolescents more frequently endorsed combining contraceptive practices that provide less effective protection against STD/HIV and unintended pregnancies (e.g., use of withdrawal and rhythm methods) and in some cases suggest improper use of a single method when used in conjunction with other contraceptive practices (e.g., use of condoms in combination with withdrawal) [34].

The perceived ability to select safe partners corroborates past research that has used survey, experimental, and qualitative methods [35–38] to show that adolescents (and adults) use informal rules (e.g., “heuristics”) to choose safe partners

and to decide when to have sex [39], although such strategies are flawed and may result in negative health outcomes [40]. In this case, the use of this informal rule predicted the most risky contraceptive decisions. Individuals who believed they could identify safe partners were more likely to report using no contraception or using methods other than condoms. Consequently, adolescents who perceive that their partners present low STD risk may also forgo use of other effective contraceptive methods to prevent pregnancy. In contrast, the type of partner during the last sexual encounter was not predictive of the contraceptive method used. Thus, it appears that adolescents are using their partner *risk* heuristic rather than partner *type* heuristic when deciding about contraceptive methods. It may be that adolescents who believe they can select safe sexual partners make such estimations based upon a partner's individual characteristics (e.g., prior sexual experience) or other relationship factors (e.g., mutual monogamy) rather than focusing upon the partner type.

Female gender also predicted the two most ineffective and risky categories as well: not using any contraceptive method and use of less effective contraceptive methods (e.g., withdrawal). Females were also more likely to report use of hormonal birth control as a primary contraceptive method (i.e., Hormonal Plus method type). Previous research highlights that young women tend to have less power in sexual relationships with their male partners which in turn may limit their ability to negotiate preventative sexual practices including condom use [41]. Thus, one may hypothesize that adolescent girls select contraceptive methods that maximize control (e.g., birth control pills), whereas their male partner has greater control of other contraceptive practices (e.g., condom use). Furthermore, one partner's use of a particular contraceptive method may moderate the perceived need for the other partner to use additional methods. For example, in a dyad where a young woman is using hormonal birth control, there may be less perceived need to also use condoms. In contrast to previous studies where age differences in contraceptive practices have been observed [8], age was not predictive of contraceptive methods in our study, perhaps because the age range in our sample was restricted.

4.1. Limitations. Several limitations should be acknowledged. We do not have data regarding the extent to which the contraceptive method reported was consistently or properly used. For example, we did not assess condom use errors or the consistency by which birth control pills were taken. We also assessed only the most popular methods and did not assess methods that are less commonly used by adolescents (e.g., vaginal ring). Thus, actual rates of hormonal birth control usage may be slightly higher than reported by participants. Further, the contraception method measure focused on the methods used to prevent pregnancy during the last sexual event, so reported methods may not fully reflect participants' typical contraceptive practices across sexual encounters. Additionally, the participants were recruited from four medium-sized cities; results may not generalize to youth from larger cities or rural areas.

4.2. Conclusions. Our findings highlight the need to further understand how adolescents select contraceptive methods. Because contraception is used within the context of a dyad, studies should examine how adolescents communicate and negotiate the use of individual, dual, and multiple contraceptive practices with their partners. Knowledge of contraceptive practices could then facilitate the development of appropriate intervention messages to prevent both unintended pregnancies and STD/HIV among African American adolescents. Interventions may benefit from inclusion of material to improve adolescents' ability to communicate with partners about contraceptive methods and explain the health risks posed by incorrect appraisal of a partner's risk. Such prevention programs could also target the power differential within sexual partnerships and provide adolescent females with strategies to negotiate safer sexual practices. Ultimately, comprehensive sexual health services and interventions will facilitate adolescents' ability to have healthy sexual relationships and prevent negative health outcomes.

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