

## Contraception among HIV Concordant and Discordant Couples in Zambia: A Randomized Controlled Trial

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### ABSTRACT

**Objectives:** This study examines the impact of an intervention to promote dual-method contraceptive use among HIV concordant and discordant couples already using condoms for HIV prevention.

**Methods:** A three-armed randomized, controlled trial was conducted at a voluntary HIV testing and counseling clinic in Lusaka, Zambia; 251 couples were randomized. Control couples received family planning education and referral to an outside clinic for nonbarrier contraceptives, intervention 1 couples received education and offer of contraceptives at the research clinic, and intervention 2 couples received intervention 1 plus a presentation designed to reduce outside pressures to conceive.

**Results:** There was a 3-fold higher contraceptive initiation rate in both intervention arms compared with the control arm. The interventions had no impact on incident pregnancy, largely due to high levels of contraceptive discontinuation and user failure. HIV-positive women who initially selected injectable contraception were less likely to abandon the method and significantly less likely to conceive than other study participants.

**Conclusions:** Improving access to nonbarrier contraceptives among couples already using condoms for HIV prevention increased dual-method use. Selection of longer-acting injectable contraception was associated with lower pregnancy rates among HIV-positive women. Further research is needed to identify ways to help couples in this population continue to correctly use nonbarrier contraceptives.

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This research was conducted with funding from NICHD R01-40125, NIAID R01-23980 and R01-40951 and R21-33863, NIMH R01-46571 and R01-66767, Fogarty AIDS International Training in Research Program (AITRP) FIC D43 TW001042, NIH Centers for AIDS Research, the Social & Behavioral Science Core of the Emory Center for AIDS Research (CFAR) P30 AI050409, and International AIDS Vaccine Initiative.

None of the authors have any conflicts of interest.

## INTRODUCTION

ZAMBIA, A CENTRAL AFRICAN COUNTRY of 9 million people, has a human immunodeficiency virus (HIV) seroprevalence of approximately 16.5% among sexually active adults in urban areas.<sup>1</sup> HIV has penetrated into the general population, and most infected people are in steady unions.<sup>2</sup> Of the 820,000 people currently living with HIV in Zambia, 57% are women of reproductive age (15–45 years).<sup>1</sup> In Lusaka, the capital city, 20% of cohabiting couples have discordant HIV test results (one partner HIV negative and the other HIV positive), and 23% are concordant positive couples.<sup>3</sup> This high prevalence of HIV occurs in a context of high fertility; Zambia's total fertility rate of 5.9 births per woman<sup>4</sup> is among the highest in the world. The country's contraceptive prevalence rate is relatively low, with only 23% of women of reproductive age reporting using a modern contraceptive method, and 27% reporting an unmet need for family planning.<sup>4</sup>

The coupling of HIV prevention and family planning services under an integrated reproductive health framework is taking hold in Africa and around the world.<sup>5,6</sup> For women who do not currently desire pregnancy, the dual-method approach—combining condoms for HIV/sexually transmitted disease (STD) prevention with longer-acting, more effective contraceptives for added protection against pregnancy—simultaneously prevents both heterosexual and perinatal HIV transmission. Prevention of unplanned pregnancies remains a cost-effective and economically feasible way to prevent pediatric HIV disease in most of Africa. This approach also reduces the number of AIDS orphans, a growing problem that has overwhelmed extended family and community networks in sub-Saharan Africa.<sup>7,8</sup> Despite the growth of integrated HIV and family planning services, however, little evidence exists of the health impact of integrating these services. We conducted a three-armed, randomized, controlled trial (RCT) to assess the impact of family planning education and improved contraceptive access on nonbarrier contraceptive use and pregnancy incidence in a population of predominantly HIV discordant couples participating in an HIV research project in Lusaka, Zambia. A greater understanding of the impact of the promotion of family planning on dual-method use has the potential to inform the integration of

HIV/AIDS and family services, providing a mechanism for reducing the spread of HIV through both heterosexual and mother-to-child transmission.

## MATERIALS AND METHODS

*The Zambia-Emory HIV Research Project (ZEHRP)*

The Zambia-Emory HIV Research Project (ZEHRP) has established a voluntary HIV counseling and testing (VCT) center for cohabiting couples in Lusaka. Many couples who get tested at this center enroll in ongoing HIV research projects and receive free outpatient care at the research clinic. Ethical approval for this study was obtained from IRBs at the University of Alabama Birmingham, Emory University, and the Ministry of Health, Zambia. Participants in the family planning RCT were couples already enrolled in other studies at the ZEHRP research center. Recruitment of cohabiting couples and procedures of the ZEHRP same-day HIV VCT center in Lusaka, Zambia have been described elsewhere.<sup>3</sup> All couples attend a presentation on family planning methods on the day they receive VCT, separate from the family planning education received as part of this RCT. Eligibility criteria for inclusion in ZEHRP follow-up studies and data collection at 3-monthly intervals have been described.<sup>9</sup> At the time of recruitment for the family planning RCT, couples enrolled in ongoing studies included HIV discordant couples, a small comparison group of concordant HIV-negative couples, and previously discordant couples in whom seroconversion of the negative partner had occurred (now concordant positive couples). Couples enrolled in any research project at the center are given a free, unlimited supply of condoms. Counseling on condom use is serostatus specific: HIV discordant and concordant positive couples are advised to use condoms with every act of intercourse. This information is given during initial posttest counseling when the couple receives the results together and, for those who enroll in follow-up studies, is repeated at each subsequent study visit if condom use questionnaires indicate that condoms are being used inconsistently. A trained nurse or social worker also helps these couples overcome any barriers to condom use. Mutual monogamy is emphasized for

concordant negative couples during posttest counseling. Condom use with any partner besides the cohabiting partner is also stressed.

### *Family planning RCT*

From September 9, 1996, through August 31, 1997, all couples attending an ongoing study follow-up visit were eligibility screened for the family planning RCT ( $n = 608$ ). Eligibility screening involved a urine pregnancy test (Betatex, Omega Diagnostics, Alva, Scotland) and the administration of a brief questionnaire during which the husband and wife were interviewed separately. Couples were ineligible ( $n = 329$ ) if the woman was  $>38$  years old or the man was  $>60$  years old (28%), if the woman was pregnant (15%),  $<1$  month postpartum (3%), or currently using an intrauterine contraceptive device (IUD) or hormonal method of birth control (17%), or if the couple was considered infertile (63%). Infertility was defined as prior surgical sterilization, self-report of infertility on a prior medical questionnaire, or a 24-month period in the last 5 years without using an IUD, hormonal method of birth control, or breastfeeding without a resultant pregnancy. Couples ineligible for a nonpermanent reason (i.e., pregnancy or  $<1$  month postpartum) could be rescreened for eligibility at subsequent study visits.

Twenty-eight couples were screened and found eligible but declined to participate. These couples did not differ significantly on background characteristics from those couples who enrolled. The remaining 251 couples were randomized. Because the interventions involved group presentations, randomization was by day rather than by couple. Days were randomized in advance with the use of a random number table; therefore, each individual day of the 300+ enrollment period days had an equal chance of being randomized to any given intervention/control. Block randomization was not used. Assignment was concealed from staff involved in data collection and patient care until enrolling couples had signed the informed consent document.

Enrolled men and women separately completed identical questionnaires about fertility decision making in the couple and knowledge of, attitudes about, and prior use of contraceptives. All groups then received a 20–30-minute educational talk on family planning methods given by

a trained nurse or clinical officer, similar to the talk they had heard 3–21 months previously on the day they were initially tested for HIV. The talk covered contraceptive methods and the concept of family planning, risks of unprotected sex, and vertical transmission of HIV. The dual-method approach, a more effective contraceptive method for pregnancy prevention combined with condoms for protection against HIV and other STDs, was emphasized. Discussion was encouraged. The control group then received a 20–30-minute talk on STDs to control for greater time spent in the clinic by the other two groups and was referred to the Lusaka Planned Parenthood Association of Zambia (PPAZ) clinic for family planning methods. Registration and revisit fees (approximately U.S. \$1.54 and \$0.76, respectively) were paid for by the research project.

After the family planning presentation, the intervention 1 group was offered contraceptives free of charge at the ZEHRP research center clinic. These services were also provided to ineligible couples in a compassionate care arm. The intervention 2 group received the same talks and services as the intervention 1 group, with the addition of participation in a group presentation about Zambian inheritance law and will preparation. Our hypothesis was that couples planning for the death of one or both partners might make an informed choice to limit the size of their families. In addition, we hypothesized that instructing women on statutory inheritance laws might free them from spousal and familial pressure to conceive.

Nonbarrier family planning methods provided free of charge at the research clinic included oral contraceptives (OCs) (combined estrogen-progestogen pills and progestogen-only pills), injectables (Noristerat or Depo-Provera, Upjohn, Kalamazoo, MI), and IUDs. Condoms and spermicides were provided to all couples but were not included in our nonbarrier contraception outcome measure based on prior data in discordant couples showing no association between condom use and pregnancy.<sup>10</sup>

Women in either intervention group who desired Norplant (Wyeth-Ayerst, Philadelphia, PA) or surgical sterilization were referred to the University Teaching Hospital, and transport and service fees were paid. The PPAZ clinic (control group) provided the same methods as the research center clinic, with the addition of Norplant insertions on site. Research center staff were

trained and certified at the PPAZ clinic so family planning service provision was standardized between the two sites.

Follow-up data collected every 3 months through November 30, 1998, included urine pregnancy testing and information on current contraceptive use. Self-reported contraceptive data for user-independent methods (injectables, Norplant, IUDs, and surgical sterilization) were verified with PPAZ and research center charts, but compliance with OCs was not assessed. Women who missed a follow-up visit received a hand-delivered reminder letter and subsequently a nurse home visit to encourage follow-up or ascertain the reason for lack of follow-up. These procedures were discontinued after two consecutive missed follow-up visits. Follow-up ranged from 1 to 24 months and was similar in the three arms (median 12.2–14.3 months). Data were entered on site using the statistical program Epi Info (Centers for Disease Control and Prevention [CDC], Atlanta, GA).

### *Analysis*

The primary outcome was initiation of a non-barrier contraceptive within 3 months of randomization. Couples were considered initial method acceptors if they received a nonbarrier contraceptive method (OC, injectable, Norplant, or IUD) or had a surgical sterilization done (tubal ligation or vasectomy) within 3 months of randomization. We examined the frequency of non-barrier contraceptive use across intervention arms and background sociodemographic characteristics. In order to examine whether dual-method use was occurring, we also examined the prevalence of self-reported condom use among couples in the three RCT arms. Couples with incomplete data were removed from the analysis samples; couples with incomplete data did not differ from couples with complete data in terms of demographic or socioeconomic characteristics. To identify differences in contraceptive use and condom use across intervention arms and by background characteristics, tests for bivariate association (chi-square tests) were performed. We also examined the impact of the intervention on incident pregnancy using Kaplan-Meier survival analysis. Analysis of pregnancy incidence was performed across the three intervention arms and by the initial method of contraception chosen by the couple.

## RESULTS

Couples randomized to all three groups were similar in age, educational level, prior contraceptive use and knowledge, fertility desires, current number of children, baseline condom use, and HIV status (Table 1). Follow-up rates were not significantly different for couples in any of the three groups, and there was no evidence of differential death rates from AIDS across the three groups. Fifty-one (19%) women had used a hormonal contraceptive or IUD before study entry (OC had been used by 45, injectables by 4, and an IUD by 2 women). Reasons given for stopping the method included wanting to get pregnant (20), side effects (11), method not available (8), concerns that the method was bad for her health (7), switching to condoms (5), husband wanting her to stop using the method (2), and other/no reason (12). The majority of enrolled couples (92%) were HIV discordant (124 M+/F-, 107 F+/M-), but 16 (6%) were concordant positive couples and 4 (2%) were concordant negative couples. Approximately half the couples eventually wanted to have more children (Table 1). Fertility decisions were most often perceived as being made by the husband alone (44% of men and 54% of women) or the couple together (46% of men and 36% of women) and only very rarely by the wife alone (3% of men and 5% of women). Baseline knowledge of contraceptive methods, particularly condoms and OCs, was high among couples in all arms of the RCT.

Within 3 months of the intervention, 33% (27) of control couples, 80% (89) of intervention 1 couples, and 76% (44) of intervention 2 couples had adopted a nonbarrier contraceptive method (Table 2). Method initiation was significantly greater in the intervention 1 and intervention 2 groups than in the control group ( $p < 0.001$  in each case). However, contraceptive use was not statistically significantly different between the intervention 1 and intervention 2 groups ( $p = 0.52$ ). In each arm, OCs and injectables were the most commonly chosen contraceptive method; only 2 women in the RCT initially elected to use Norplant, and none chose the IUD.

At 12 months, pregnancies had occurred in 22% of control, 22% of intervention 1, and 16% of intervention 2 group couples (Table 2). Survival analysis for time to pregnancy showed a slight trend toward decreasing pregnancy incidence

TABLE 1. BACKGROUND CHARACTERISTICS OF STUDY PARTICIPANTS BY INTERVENTION GROUP<sup>a</sup>

	Control group n = 82 couples		Intervention 1 n = 111 couples		Intervention 2 n = 58 couples	
	Men	Women	Men	Women	Men	Women
Mean age, years	32	26	33	26	33	27
Age range, years	20–47	18–38	22–57	17–38	23–56	19–38
Highest educational level						
Primary school	43%	57%	48%	60%	31%	69%
Secondary school	46%	26%	45%	25%	62%	21%
Prior hormonal/IUD contraceptive use	—	20%	—	19%	—	19%
Prompted contraceptive knowledge						
Condom	100%	100%	99%	99%	100%	100%
Oral contraceptives	94%	96%	95%	95%	97%	98%
Injectibles	78%	91%	80%	89%	89%	96%
IUD	76%	88%	83%	82%	82%	88%
Tubal ligation	71%	84%	78%	77%	67%	84%
Vasectomy	65%	60%	59%	63%	57%	75%
Norplant	54%	73%	62%	71%	55%	70%
Fertility desires						
Ideal number of children per family	4.4	4.2	4.3	4.3	4.5	4.4
Percent wanting more children	54%	54%	54%	50%	40%	38%
Mean additional children desired	2.6	2.1	2.3	2.2	2.8	2.3
			<i>Couple together</i>	<i>Couple together</i>	<i>Couple together</i>	
Mean (range) children with study partner		2.3 (0–7)	2.3 (0–10)		2.5 (0–6)	
Mean (range) surviving children with study partner		2.0 (0–6)	2.0 (0–10)		2.3 (0–5)	
HIV status						
Discordant (M + F–)		55%	42%		55%	
Discordant (M – F+)		34%	51%		38%	
Concordant positive (M + F+)		10%	4%		7%	
Concordant negative (M – F–)		1%	3%		0%	
Percent of sexual acts using condoms during the last 3 months		79%	80%		90%	

<sup>a</sup>None of the differences in background characteristics across couples in the three groups are statistically significant.

across the three arms (Fig. 1), but the difference between the control group and the intervention groups did not achieve significance ( $p = 0.24$ ). The survival analysis for time to pregnancy was repeated separately for HIV-positive and HIV-negative women. There was no statistical difference in pregnancy incidence across the three RCT arms in either HIV-positive or HIV-negative women.

Contraceptive switching, stopping, and user failure all contributed to pregnancies among women who initiated nonbarrier contraception. Of 83 women who initiated OC use at entry, only 30 (36%) were still using OC without a pregnancy at the end of their follow-up period. Thirty-eight (46%) became pregnant (25 of whom reported continued OC use until the pregnancy was detected), 3 switched to injectable contraception, and 12 abandoned method use. Of 73 baseline in-

jectable users, only 28 (38%) were still using injections without a pregnancy at the end of the follow-up period. Twenty-two (30%) became pregnant (4 within 3–4 months of their first injection, 5 after switching to OC, and 13 after stopping method use), 7 switched to OC, and 16 abandoned all methods. The pregnancy rate in women who did not initiate method use at enrollment was 43% (38 of 91). Compared with nonusers, pregnancy incidence was significantly lower among women who initiated injectable contraception at baseline ( $p = 0.02$ ), but not among baseline OC users (Fig. 2). Stratifying the analysis by HIV status showed that among HIV-negative women, the choice of baseline contraceptive method was not significantly associated with incident pregnancy ( $p = 0.37$ ); however, among HIV-positive women, pregnancy incidence was significantly lower among those who adopted in-

TABLE 2. CONTRACEPTIVE INITIATION AND PREGNANCY INCIDENCE AFTER INTERVENTIONS

	Control group n = 82 couples n (%)	Intervention 1 n = 111 couples n (%)	Intervention 2 n = 58 couples n (%)
Nonbarrier contraceptive initiation within 3 months of intervention			
Injectable	13 (17)	40 (36)	20 (34)
Pill/minipill	13 (16)	47 (42)	23 (40)
Norplant	0	1 (1)	1 (2)
IUD	0	0	0
Tubal ligation	0	1 (1)	0
No nonbarrier method	55 (67)	22 (20)	14 (24)
Total initial acceptors	27 (33)	89 (80)*	44 (76)**
Pregnancy incidence at 12 months			
Pregnant			
Not pregnant	45 (55)	64 (58)	33 (57)
Dropped/died	19 (23)	23 (21)	16 (28)
% of follow-up intervals during which a condom was used	63	62	58

\* $p < 0.001$  compared with control group.

\*\* $p < 0.001$  compared with control group;  $p = 0.52$  compared with intervention 1 group.

jectable contraceptives ( $p = 0.02$ ) (Fig. 3). Additionally, rates of injectable discontinuation were lower among HIV-positive women: 27% of HIV-positive women who adopted injectable contraceptives discontinued use compared with 39% of HIV-negative users.

Perfect (100%) condom use, as measured by self-report of the number of coital acts for which a condom was and was not used during each 3-month follow-up interval, was reported in 63% of control group follow-up intervals, 62% of intervention 1 group intervals, and 58% of intervention 2 group intervals. Similarly, perfect condom

use was reported in 61% of intervals during which OCs were used and 59% of intervals when injectables were used. None of these differences reached statistical significance.

### DISCUSSION

Enhancing access to nonbarrier contraceptives in our intervention groups dramatically increased the initiation of OCs and injectables but did not significantly decrease pregnancy after 1–2 years of follow-up overall. High discontinuation rates

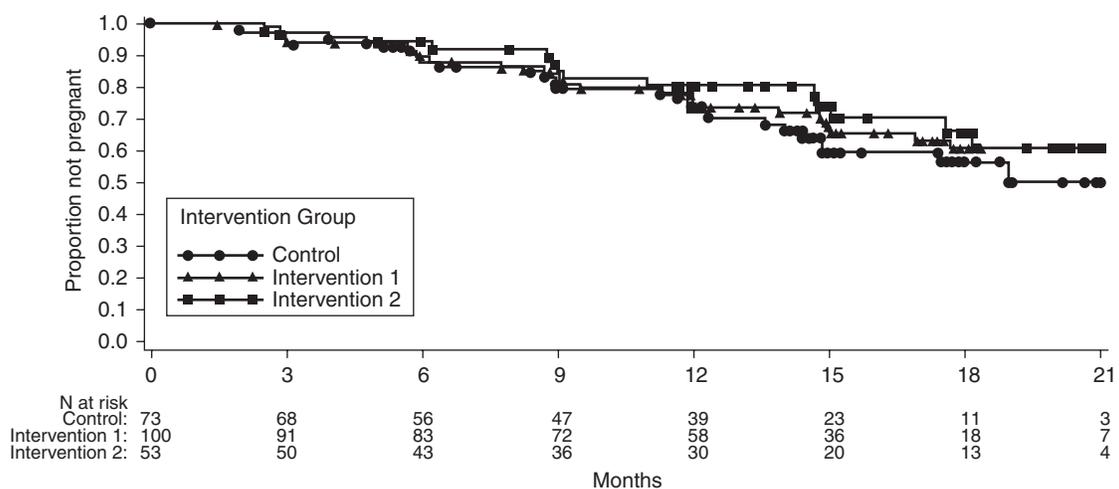


FIG. 1. Pregnancy incidence by intervention group ( $n = 236$  couples).

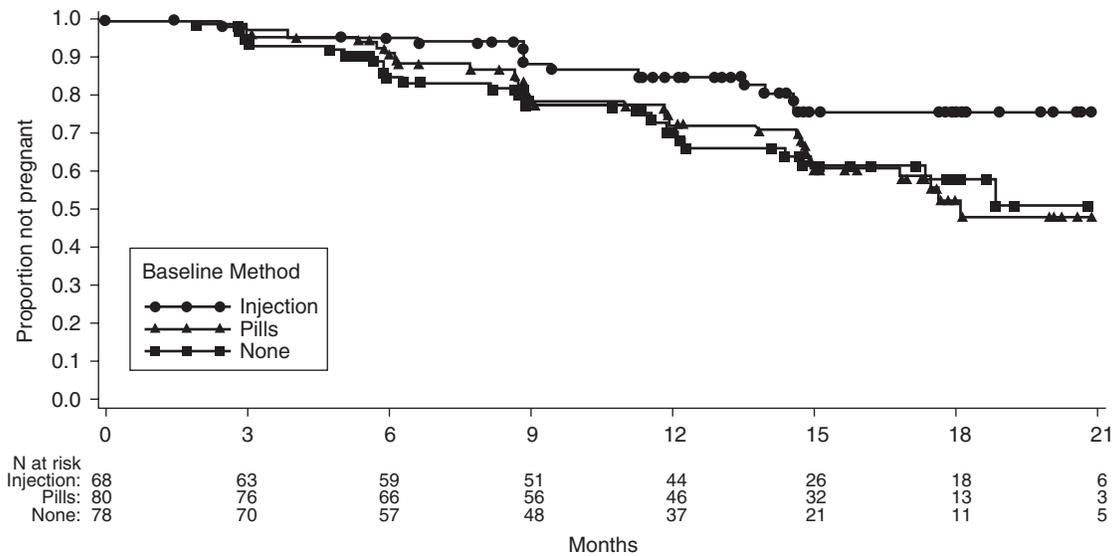


FIG. 2. Pregnancy incidence by initial contraceptive choice ( $n = 226$  couples).

with both methods and OC user failure were common. Pregnancy incidence was significantly lower among women who adopted injectable contraceptives, but the adoption of OCs did not significantly lower pregnancy incidence relative to those who chose to use only condoms. Similarly, for HIV-positive women, pregnancy incidence was significantly lower among those who adopted injectable contraceptives but not among those who adopted OCs.

Concerns about the use of hormonal contraceptives increasing a woman's risk of HIV infec-

tion or the risk of her transmitting HIV to her partner<sup>11,12</sup> have been raised previously. In our study, use of nonbarrier contraceptives was not associated with decreased condom use; the reporting of condom use was consistent across all three RCT arms, suggesting that the adoption of nonbarrier methods was not replacing condom use in any one of the three groups. That is, condom use was similarly high among couples given access to alternative contraceptive methods as it was among those in the control group. At baseline, we measure the percentage of coital acts that

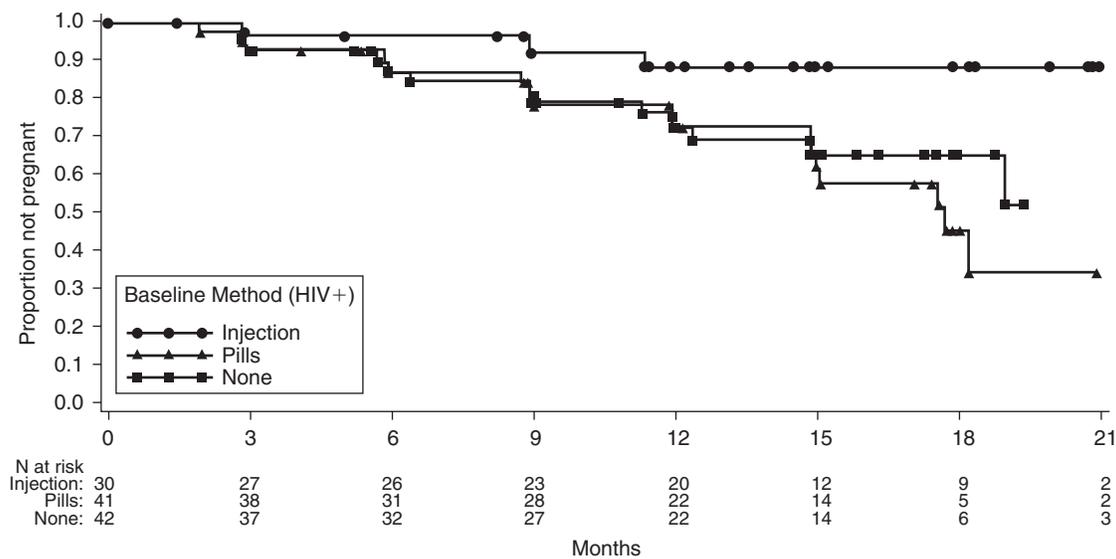


FIG. 3. Pregnancy incidence among HIV-positive women by method of family planning adopted.

used a condom, and postintervention we measure the percentage of follow-up intervals during which 100% condom use was reported; hence, we would expect the latter figure to be lower. Our previous work in this same population has correlated self-reported condom use with incidence of STDs and HIV seroconversion.<sup>10</sup> Although one older study found that OC use was independently associated with HIV seroconversion in commercial sex workers,<sup>13</sup> most other studies have found no independent association between hormonal contraceptive use and HIV seropositivity.<sup>14-17</sup> Like this study, our previous research in Rwanda showed no decrease in condom use among women who initiated OC or injection use.<sup>10</sup> Therefore, we believe that emphasizing the dual-method approach to unplanned pregnancy/HIV/STD prevention is the most responsible approach. Previous studies support our findings, which suggest that integration of family planning and HIV/STD prevention services encourages dual-method use, thus mutually reinforcing the goals of prevention of heterosexual HIV transmission, unplanned pregnancy, and pediatric AIDS.<sup>14-25</sup>

In many developing countries, family planning and HIV services traditionally have been offered separately, with little or no integration.<sup>26</sup> The rationale for the division of family planning and HIV services lies in the intended target population of each service: family planning services primarily target married women of reproductive age, whereas HIV services have focused attention on individuals at high risk of infection. However, the changing shape of the HIV epidemic over the last decade has seen a shift toward infection among women of reproductive age. In developing countries, most new HIV infections take place through heterosexual transmission between married or cohabiting couples.<sup>3</sup> Approximately one half of the 40 million people now living with HIV are women of reproductive age.<sup>27</sup> Countries with a high prevalence of HIV are often countries with a high unmet need for family planning.<sup>28,29</sup> Thus, the integration of family planning and HIV services has the potential to meet dual-service demands while also reducing the spread of HIV through heterosexual and mother-to-child transmission. Additionally, integration of services in resource-poor settings has the potential to provide a cost-effective mechanism for delivering services to a large in-need population.<sup>6,30</sup>

With an estimated 700,000 new HIV infections occurring in children each year,<sup>31</sup> stemming mother-to-child transmission of HIV is an important public health goal. Cates<sup>32</sup> suggests that prevention of mother-to-child transmission is best achieved through a combination of two strategies: preventing unwanted pregnancies among HIV-infected women and preventing HIV infection among women of reproductive age. The integration of family planning and HIV services has the potential to achieve these two goals. Promotion of condom use can aid in the reduction of heterosexual transmission, and promotion of family planning can reduce unwanted pregnancies and thus limit mother-to-child transmission. Previous studies have suggested that contraceptive use among HIV-positive women is low, with pressure to bear children, fears of health effects of contraception, and the availability of antiretroviral therapy offering a better quality of life all influencing a woman's decision not to adopt a method of family planning.<sup>32</sup>

The integration of family planning and HIV services has several potential formats. When the HIV epidemic first gained prominence in the 1980s, some of the first HIV prevention programs in developing countries were linked to family planning services.<sup>26</sup> Such assimilation of services involved integration of diagnosis and treatment for STDs, sexual risk-reduction counseling, and condom promotion into existing family planning services.<sup>33-35</sup> Despite efforts to link HIV services and family planning services, in 2003 the World Health Organization, in a review of the contribution of reproductive health services to HIV prevention, found that there had been few cases of successful integration of family planning and HIV services.<sup>6,26</sup> In recent years, however, the opposite form of integration has begun to emerge, with family planning services added to existing HIV services. For example, VCT centers provide a mechanism for reaching populations in need of family planning services: those who are sexually active, yet may not normally visit a family planning clinic.<sup>36</sup> The assimilation of family planning into existing HIV services is growing. Strachan et al.,<sup>37</sup> in an analysis of the family planning content of 12 international VCT and Preventing Mother-to-Child Transmission (PMTCT) guidelines, found that all but one addressed issues of family planning. Despite this growth in attempts to integrate services, little is known of the impact

of service integration on reproductive health and HIV indicators. Such evidence is needed to inform the future direction of family planning and HIV service integration.

These results demonstrate the potential for future family planning educational interventions to encourage the adoption of nonbarrier contraceptive methods among HIV concordant and discordant couples while not reducing the use of condoms. All couples received family planning education, but the adoption of nonbarrier contraceptive methods was significantly higher among couples who were also given free on-site access to contraceptive methods, highlighting the benefit that providing integrated family planning and HIV services can have for improving contraceptive use.

Pregnancy incidence was significantly lower among injectable users than among those who used condoms only. Similar findings for a greater protective effect of injectables against pregnancy than OCs have been shown previously.<sup>38</sup> When the sample was stratified by HIV status, we found that pregnancy incidence was significantly lower among HIV-positive injectable users than among HIV-positive OC and condom only users but not among HIV-negative injectable users compared with HIV-negative OC and condom only users. This difference was due partly to greater method discontinuation among HIV-negative users, perhaps suggesting that HIV-positive users were more determined than their negative counterparts not to get pregnant and, thus, were more likely to tolerate the side effects of injectable contraceptives.

The finding that the intervention did not lower incident pregnancy is disappointing. High levels of contraceptive discontinuation and user failure diluted the effect of the intervention on incident pregnancy. We were successful in increasing nonbarrier use, but we were not successful in translating this use into lower pregnancy overall, although injectable users did have lower pregnancy rates than OC users or women using only condoms. Clearly, more than simply education and on-site provision of contraceptives is needed to lower pregnancy incidence. Unfortunately, pregnancy intention was not assessed, making it difficult to determine if our intervention designed to reduce outside pressures to conceive was effective in decreasing unintended pregnancies even if it was not effective in decreasing overall

pregnancy incidence. Perhaps further ongoing family planning counseling, particularly for those couples who opt to use OCs, is needed to encourage the use of longer-acting injectable methods and to provide help with adherence and continued dual-method use as long as pregnancy is not desired.

Our study has several limitations. First, the pilot study nature of this RCT meant that sample size was constrained by the need to recruit couples only from those already involved in other studies at the research center. As a result, we may have had insufficient statistical power to detect differences between groups when differences actually do exist. However, the nearly identical pregnancy rate at 12 months among the three groups suggests that lack of statistical power did not cause our negative findings. Second, our randomization process led to a discrepancy in the number of couples allocated to each arm. This discrepancy was most likely due to chance, as there was no systematic bias in the randomization procedure. The nature of the intervention required randomization by day rather than by couple, which may have accentuated the different accrual rates in each group. In addition, lack of block randomization meant that an equal number of days randomized to each group were not guaranteed. However, the distribution of days in each of the randomized groups did not differ significantly; thus, it is unlikely that this introduced bias into the analysis. Although we have examined our randomization process and outcome in detail and see no systemic bias in our randomization procedures, we can never definitively rule out some unknown bias that may have affected our results.

Finally, study participants were drawn from one sub-Saharan African city where affordable chemoprophylaxis to prevent vertical HIV transmission was not available, raising the question of generalizability of our findings. Levels of family planning knowledge and access, as well as societal influences on family planning and the availability of chemoprophylaxis for vertical HIV transmission, differ among populations. However, we believe that advocating the dual-method approach to HIV/STD/pregnancy prevention can be beneficial in preventing unplanned pregnancies and, therefore, pediatric AIDS wherever heterosexual (and, therefore, vertical) HIV transmission is occurring.

## CONCLUSIONS

Antiretrovirals can reduce perinatal HIV transmission and offer hope to HIV-positive women in developing countries who wish to bear children.<sup>39</sup> However, chemoprophylaxis to prevent vertical transmission does not address the needs of HIV-positive women who do not wish to become pregnant, is still not available in many areas of many developing countries, and does not address the growing problem of AIDS orphans. Advocating the dual-method approach to HIV/STD/pregnancy prevention is feasible and safe. HIV discordant couples already at risk for HIV transmission and using condoms for protection can and do accept additional nonbarrier contraception for added protection against pregnancy without decreasing condom use. Our randomized, controlled study demonstrates that increasing access to nonbarrier contraceptives dramatically increases rates of dual-method initiation, but high rates of method discontinuation and OC failure led to no difference in pregnancy incidence at 1–2 years of follow-up. HIV-positive women who initially chose injectable contraception were more successful at not becoming pregnant than those who chose pills or condoms alone.

We acknowledge that this study took place in a highly controlled, intensive environment that does not represent a typical service delivery environment. In terms of study replicability, however, the most successful elements of this study were the simple integration of free family planning and HIV services in one site, which allowed couples access to multiple services. Reducing provider bias against injectables and other barriers to injectable use might allow more HIV-positive women to freely choose injections as their contraceptive method and, therefore, decrease unplanned pregnancy and pediatric AIDS. The integration of HIV and family planning services can be effective in promoting dual-method use, but further research is needed to assess ways to translate increased method uptake into lower pregnancy incidence.

## ACKNOWLEDGMENT

We thank the staff and study participants of the Zambia-Emory HIV Research Project.

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