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Project REACH: a provider-delivered dual protection intervention for women using family planning services in New York City

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Abstract

High rates of unintended pregnancies and sexually transmitted infection (STI), including HIV, highlight the importance of promoting dual protection (DP) -- i.e., methods that offer concurrent protection against unintended pregnancies and STI -- during contraceptive counseling. Using a Phase II quasi-experimental design, this study compared an individualized, clinic-based, nurse-delivered intervention designed to increase DP against standard of care among 101 HIV-negative women accessing contraceptive services in medically under-served areas of New York City. Participants were evaluated at baseline, post-counseling, and six months later. Findings indicated that the intervention has possible benefit. At six-month follow-up, there was greater perceived susceptibility to STI and fewer condom-unprotected vaginal sex occasions in the intervention arm. Women in the intervention also had five times the odds of reporting female condom use. Results suggest that this intervention has the potential for a larger population impact and should be more rigorously evaluated in a Phase III trial.

Keywords

Dual protection; HIV intervention; women; pregnancy prevention; New York City

INTRODUCTION

The integration of family planning and sexually transmitted infection (STI) services has rapidly gained momentum in global reproductive health following the 1994 International Conference on Population and Development (ICPD) in Cairo. The 2009 Berlin NGO Forum on Sexual and Reproductive Health and Development further underscored the importance of access to integrated services (Greer, Chau, Hinz, & Thanenthiran, 2009). Family planning providers are seen as well-positioned to assume a more influential role in increasing women's safer sex practices and thereby reducing the rate of STIs, including HIV. In the

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United States (US), there has been an effort, supported by Title X funding, to incorporate STI diagnosis, treatment, and prevention into traditional family planning settings (Dailard, 1999). More than 4,400 family planning clinics currently receive Title X funding via the US Public Health Service Act for the purpose of fulfilling the goals proposed by the ICPD (1994), reaching more than five million women (U.S. Department of Health & Human Services, Office of Public Health and Service, & Office of Population Affairs, 2008). Among women whose family income is at or below the 2008 federal poverty level, 67% access reproductive services at family planning clinics, and these clinics are the usual source of family planning services for six out of 10 women served by publically funded centers (National Women's Law Center, 2009). Family planning settings, therefore, are an efficient and natural setting for addressing women's STI as well as pregnancy prevention needs.

The increasing global rates of unintended pregnancies and STI, including HIV, suggest that dual protection (DP), or concurrent protection against unintended pregnancies and STI, is an ideal concept for family planning clinicians to promote (Cates & Steiner, 2002). DP can be achieved in three ways: by use of a male or female condom alone, by use of two methods including a condom and some non-barrier contraceptive, or by use of an effective contraceptive in the context of long-term mutual monogamy. DP is a sensible strategy because it asks clients to consider the inherent connection between unintended pregnancies and STI. Cates and Steiner (2002) highlight two key elements to the DP approach: (1) the promotion of being dually protected for every occasion of sex; and (2) in-depth risk assessments around unintended pregnancies and STI. DP requires the family planning setting to integrate their services; women who receive counseling only on fertility control will not know if DP is a suitable approach for them or if they are at substantial risk for infection. Where STI and pregnancy prevention services are both offered, counseling is often compartmentalized, with pregnancy and HIV/STI issues discussed sequentially (rather than concurrently) and conceptually integrated.

Motivational interviewing, an effective theory-based, client-centered counseling approach (Miller & Rollnick, 2002), is a promising strategy for addressing the complex issues at play when counseling women about pregnancy and STI risks. It provides a one-on-one, individualized approach to counseling, providing feedback on the potential risks posed by behavior, empowering a person to make choices about behavior change, guiding and supporting the initiation of change, and suggesting specific behavior change strategies using cognitive-behavioral techniques. A recent review by the Centre for Review and Dissemination (Rubak, Sandbaek, Lauritzen, & Christensen, 2005) of 72 controlled studies evaluating this brief treatment model found evidence for the effectiveness of motivational interviewing in reducing substance abuse, injection risk behavior, eating disorders, and gambling, and in enhancing adherence to diet and exercise and treatment.

In the US, data from the 2002 National Survey of Family Growth indicate that contraceptive use is near universal, with 98% of sexually active women aged 15–44 years reporting ever having used at least one contraceptive method (Mosher, Martinez, Chandra, Abma, & Wilson, 2004). However, in terms of current contraceptive use, about 38% of women were not using contraception. About 11.1% of women reported using the male condom as their most effective method, but 14.7% reported dual method use, i.e., they were using a condom use with another contraceptive method. In the month of interview, the proportion of all women using two or more methods of contraception was approximately 10% and the proportion among all contraceptors was about 15%. Thus, these small percentages suggest there may be a need for increasing DP among at-risk women in the US.

In this paper, we report on results from “Project REACH” – Research and Education about Contraceptive Health, a Phase II trial comparing the potential efficacy of a Risk and

Decision-Making (RAD) intervention, grounded in motivational interviewing, to standard-of-care (SoC) counseling, in increasing DP.

METHODS

Study Overview and Research Setting

Project REACH is an individualized, clinic-based, provider-delivered intervention to promote DP with family planning clients. This approach efficiently exploits routine provider-client contact during family planning visits, and is intended to be practical and replicable in these time and resource-constrained settings.

Using a quasi-experimental design, a one-session manualized RAD intervention was compared against standard of care (SoC) immediately post-counseling and six months later. The study was undertaken collaboratively with the Community HealthCare Network (CHN), a New York City consortium of nine freestanding clinics and two mobile health clinics offering family planning, reproductive health, pediatric, general medical and HIV primary care services in medically under-served areas. The study was conducted in four of the nine freestanding clinics, with two sites located in Brooklyn, one in the Bronx, and one in Manhattan. Institutional Review Board approval was obtained from the New York State Psychiatric Institute-Columbia University Department of Psychiatry and the CHN.

Participants and Recruitment Procedures

Clients enrolled in the study were 101 low-income, primarily African American, Caribbean, and Latina 15–32 year-old HIV-seronegative women. To be eligible, women had to be between the ages of 15 and 32, report at least one occasion of vaginal sex without a condom in the last three months, be HIV- seronegative or untested by self-report, not be pregnant or desiring to become pregnant within the next year, and be attending the clinic for routine (6 month or yearly) counseling and check-ups. Eligible and interested participants completed informed consent prior to study participation.

A total of 482 women were approached in the waiting areas of the respective study sites and escorted to a private office to be screened for eligibility. Of this total, 298 were found to be ineligible, 53 were eligible but declined study participation, and 30 either did not complete the baseline assessment, declined, or were found ineligible at the time of the baseline assessment interview. Clients were assigned to condition based on day of visit to see either the study nurse, who rotated on a variable schedule to each of the clinics, or one of the SoC nurses available at that clinic. Clients were evaluated pre- and post-nurse counseling, and six months later using a structured assessment instrument.

Nurses

Fifteen Licensed Practical Nurses (LPNs), all female and already working at the clinics, were involved in the study. Of these, 11 self-identified as African-American or Black, two as Latina, one as White, and one as Asian-Pacific Islander. Only one of the 15 nurses, who was Black, was trained in RAD counseling. Since the salary of the nurse administering this untested counseling approach was partially supported by grant funds, it was only possible to hire one study nurse. The choice of the nurse was not random, but based on pre-implementation discussions with our collaborators at CHN. The criteria for selection were the nurse's willingness to participate in the study and openness to try a different form of counseling.

Intervention

The RAD is a manualized intervention that is DP-focused and grounded in motivational interviewing (Miller & Rollnick, 2002) and relapse prevention (Marlatt & Gordon, 1985). The study nurse was intensively trained over a one-week period prior to launching the study. HIV/STI risk assessment followed a standard protocol, with normalizing prefaces (e.g., “most people have times when they don’t use a condom”) and targeted probes designed to increase client comfort and enhance evaluation of risk. The importance of condom use for STI prevention during anal as well as vaginal sex was discussed. The study nurse used a semi-structured counseling and decision-making guide to help clients simultaneously select both a method of contraception and HIV/STI prevention. The nurse prompted women to consider both the female and male condom when considering DP. The client’s values framed the decision-making process, and provided both standardization of the counseling script for the nurse and a counterweight to the nurse’s own values (Fischhoff, 1992; Swartz & Parks, 1994).

Once a preferred option was identified by the client during the consultation, the study nurse discussed the positive and negative aspects of use. She also helped clients anticipate difficulties they might encounter in consistently and correctly using the selected method and helped them brainstorm solutions. These challenges and solutions were incorporated into “Action Plans”; the client left with a written copy of her individualized plan. At the end of the session, the study nurse also scheduled clients for subsequent phone or in-person follow-up appointments to reinforce method use. The counseling sessions ranged from 10 to 30 minutes in length, with an average of 16 minutes.

The remainder of the clinic nurses followed the clinic’s SoC counseling. The SoC policy in the clinics required that all clients seen for their initial, semi-annual, or annual exam visits be screened for HIV risk by the nurse, using a structured checklist that conformed to New York State mandated pre-test counseling guidelines. The checklist assessed risks of clients and their partners (e.g., IV drug use, commercial sex) with response options of “Yes”, “No” or “Don’t Know”, and was essentially a tool to determine if HIV testing was warranted. Contraceptive and STI diagnostic and treatment needs of the clients also were addressed at each visit. SoC nurses did not use a standard protocol when counseling clients on method selection; HIV risk assessment and method selection were discrete components of counseling. Table 1 provides an overview of RAD and SoC counseling content.

Assessment

Clients were evaluated pre- and post-nurse counseling, and six months later using a structured, interviewer-administered assessment instrument. Sexual risk behavior and contraceptive use were evaluated using an adaptation of the Sexual Risk Behavior Assessment Schedule for Adults (SERBAS-A; Meyer-Bahlburg, Ehrhardt, Exner, Calderwood, & Gruen, 1988), an instrument with demonstrated reliability in diverse populations (Exner et al., 2002; McKinnon et al., 1993; Meyer-Bahlburg et al., 1993; The NIMH Healthy Living Project Team, 2007; Rotheram-Borus et al., 1992; Susser et al., 1995). Areas assessed included number of partners, number of occasions of vaginal intercourse, and number of vaginal intercourse occasions protected by male or female condoms, as well as use of other contraceptive methods. Practice of anal sex was assessed as well. The time frame for assessing current behavior was the past three months; lifetime partner numbers, abortion, and STI and HIV testing were evaluated as well. The a priori main outcome was reduction in the number of male or female condom unprotected sex occasions between baseline and six-month follow-up.

Attitudinal variables also were assessed. Self-efficacy to practice safer sex was assessed with a 17-item scale that asked women to rate *How sure are you that you could do each of the following behaviors if it was important to you?* Typical items included *buying a condom; using a condom; convincing a partner to wear a condom; using the female condom; and refusing to engage in unsafe sex*. The six-point response scale ranged from *very sure* to *very unsure*; thus mean scores range from 1 to 6. Cronbach's alpha reliability was 0.84 and 0.85 at baseline and follow-up, respectively. Attitude toward condoms was assessed by a single item: *considering what you know about male condoms, how do you feel about it as a method for you - positive, neutral or negative?* Women also indicated whether or not they felt they would be susceptible to STIs *if you and your partner(s) were not doing anything at all to protect you against disease*, with zero reflecting *no risk* and 1 *some likelihood of risk*.

Background variables included age, ethnicity, education, country of origin, marital status, whether working, and whether receiving public assistance.

Quality Control of the Intervention and Assessment

With participant consent, we audio-taped 78% of counseling sessions. Initially, every session of the RAD nurse was reviewed and feedback provided; following review of the third session tape, approximately every fourth session was reviewed, with bi-weekly or as needed supervision. Interviews were audio-taped as well; 98% of participants provided consent for this. After the first three field interviews were reviewed, approximately every fourth tape was reviewed and discussed during bi-weekly supervision. Tapes were also reviewed at the request of an interviewer when an unusual or challenging interview occurred.

Statistical Analysis

In this Phase II study, we used a non-superiority (or futility) design. We chose this design because we considered it most important to control for Type I error – the possibility of falsely rejecting the hypothesis that the intervention is truly beneficial. In this design, the null hypothesis states that the intervention meets or exceeds some criterion of potential benefit, in this case, 20% or better than SoC, in reducing mean unprotected vaginal sex occasions. It is tested against the non-superiority alternative that the intervention group reduces the mean number of unprotected sex occasions by less than 20% compared to the SoC group which, if true, would be too small to warrant further testing (i.e., would be “futile”). We reject this primary null hypothesis if there is enough evidence of non-superiority at $\alpha = .10$ level (one-sided). If H_0 is rejected, then we conclude that there is no evidence of a potential benefit of this intervention and a more rigorous test should not be undertaken. If H_0 is not rejected, then we have failed to rule out the possibility that there may be some benefit and further research is warranted.

The intention-to-treat principle was used in the primary analysis. To ensure group balance on demographic variables and the primary outcome variable, the intervention and SoC participants were compared using chi-square tests for categorical variables and t-tests and the Mann-Whitney U for continuous variables (with normal and non-normal distributions, respectively). Baseline values were entered into the primary analysis model and in secondary analyses to adjust for any differences.

In secondary analyses, we tested the conventional null hypothesis that the intervention had no effect on secondary outcomes. The secondary outcomes included self-efficacy for safer sex, attitude toward condoms, and perceived risk for STI (evaluated pre- and post-test and at six-month follow-up), and HIV testing and female condom use (evaluated at baseline and

six-month follow-up). There were too few women engaging in anal sex (seven at baseline and 11 at follow-up) to warrant analysis.

For both primary and secondary analyses, the Generalized Estimating Equation (GEE; Zeger & Liang, 1986) methodology was used to account for the within-subject correlation between the baseline and follow-up data. Analyses of number of unprotected occasions were conducted using Poisson regression and an overdispersion parameter was included to account for heterogeneity between subjects. We used logistic regression for dichotomous outcomes (such as ever used the female condom) and linear regression for continuous variables (such as percent of condom-protected vaginal occasions).

RESULTS

Participants

Baseline data on participant demographics, sexual attitudes and behavior appear in Table 2. Most women self-identified as African-American or Black, Caribbean, or Latina, and 71% were born in the US. The mean age of participants was 21 years. Most (84%) were single and never married. Slightly fewer than one in five received public assistance, and slightly less than half were currently in school, with a mean of 13 years of formal education. More than half ($n=63$) did not have children. Most (59.4%) had a high school education or less. Women reported fairly high self-efficacy for safer sex (4.87 out of a possible 6), and held positive attitudes toward male condoms (mean of 4.34 out of a possible 5). Median number of lifetime partners was five, and median number of current partners was one. Women reported a median of 12 unprotected vaginal intercourse occasions at baseline, and seven women had engaged in anal sex, all but one reporting a single unprotected anal sex occasion. Slightly fewer than half felt that they would be at risk for STI were they to have sex without using condoms, and 56.7% reported a prior STI. Almost all had experience with a male condom, and about 13% had used the female condom. Follow-up interviews were completed by 93% of participants.

Primary Outcome

At baseline, the intervention group had a lower mean number of unprotected occasions than the comparison group (difference = 6.06, $p = 0.17$). Since this was the major outcome and the direction of the difference was potentially biased in favor of the intervention, we accounted for the baseline difference by entering baseline mean number of unprotected occasions in our primary analysis model. The result shows that for a given number of unprotected occasions at baseline, relative to the comparison group, the intervention group had a greater reduction of about 3 unprotected occasions ($\beta = -2.97$, one-sided p -value = 0.56). Here β is the difference between the mean reduction for the intervention and 1.2 times the mean reduction for the comparison group. Therefore, we do not reject the superiority null hypothesis at the one-sided 0.10 level.

Secondary Outcomes

Although there were no differences between groups when women were asked about perceived STI risk immediately post-counseling, at six-month follow-up, women in the intervention had 2.5 times greater odds of seeing themselves as at risk for STI than comparison group women (see Table 3). There also was a significant difference in female condom use six months post-counseling ($\beta = 1.71$, $p = 0.02$). Women who received RAD counseling had five times the odds of reporting female condom use in the prior three months at follow-up (OR = 5.02, 95% CI = 1.39, 18.11). Among women who had never used female condoms prior to counseling, the intervention group had significantly higher odds of trying it at follow-up than the comparison group (OR = 8.55, 95% CI = 1.71, 42.83, $p < 0.02$). In a

trend finding, women who first initiated female condom use post-counseling reported a higher proportion of condom-protected sex occasions than those who did not use the female condom (60% vs. 39%; Mann-Whitney U = 254.0, $p=0.100$).

There were no significant differences between the two study groups on other secondary outcomes.

DISCUSSION

Promotion of DP by integrating STI with family planning services as part of routine care has the potential to concurrently address women's STI and pregnancy prevention needs. The RAD was designed to be used by LPN-level nurses to efficiently help women to simultaneously address both needs. Findings indicate that women who received RAD counseling reported fewer unprotected vaginal intercourse occasions at follow-up, and the null hypothesis for the test of non-superiority was not rejected. This indicates that the intervention has possible benefit and should be more rigorously evaluated in a Phase III trial. In addition to influencing risk-reduction, the RAD also sensitized women to their risk for STI: a greater proportion of intervention than comparison women felt at risk for STI six months post-counseling.

Although the RAD intervention was not specifically designed to promote the female condom, but rather DP, this counseling approach resulted in higher rates of client female condom use, perhaps because the RAD nurse routinely discussed it as an option. Findings suggest that the FC can be successfully promoted within the context of routine risk-reduction counseling. Given that this and other research suggests that promoting the female condom in addition to the male condom can increase the overall number of protected intercourse occasions (Artz et al., 2000; Latka, Gollub, French, & Stein, 2000; Musuba, Morrison, Sunkutu, & Wong, 1998), the RAD counseling approach, provided as part of routine family planning services, offers the potential for a broader public health impact.

There are several limitations to this study. A biological outcome was not feasible due to power issues, so the outcome relied on self-report. Given substantial attention to quality assurance and previous reports on the validity of self-report measures (Jaccard et al., 2004; Pequegnat et al., 2000), we are confident of the reported study findings. Since there was only one RAD nurse, it is possible that the nurse, not the RAD, was the critical factor. There is evidence to support that the RAD was a critical factor, given changes in perceived STI risk, a predicted mediator targeted by the RAD, and in female condom initiation. In addition, based on random review of audio-taped counseling sessions using a monitoring tool developed for this project, we found that the RAD nurse exhibited significantly more behaviors reflecting motivational interviewing techniques than the SoC nurses (Adams-Skinner, Exner, Pili, Wallace, & Hoffman, 2009).

Family planning counseling provides a natural venue in which to screen for sexual risk and promote DP. Unfortunately, women at-risk for STI often do not self-identify and frequently remain unidentified due to cursory clinic screening procedures.

Historically, family planning centers have counseled women about contraceptive options. Although many family planning clinics now offer HIV counseling and testing, STI risk counseling is typically not well integrated with pregnancy counseling, in spite of the dual risks of many family planning clients. Many women using contraception to prevent unintended pregnancy do not adequately take into account or are unaware of their partner(s)' sexual risk behaviors and therefore do not perceive the need for disease protection, and providers may not adequately address the gap between the client's risk and her assessment.

Encouraging women to use barrier methods that are less effective for preventing unintended pregnancy, though more effective for HIV/STI prevention, runs counter to the fundamental practice of family planning, which emphasizes high acceptance and continuation rates and low fertility rates (Hardon, 1992). Even in those family planning programs where DP has become a policy, in actual practice this may not be done consistently or effectively, and usually means two methods. The presence of an official SoC policy does not necessarily ensure provider adherence, as has been found in other settings (Kautz, Dickey, & Stevens, 1990).

Family planning providers are uniquely situated to play a pivotal role in helping women to frame their contraceptive choices in a context that considers concurrently their needs for pregnancy prevention as well as protection against HIV and other STI. As gatekeepers of contraception, family planning providers' acceptance, and endorsement of contraceptive methods are critical to their clients' adoption and continued use.

To effectively capitalize on the potential of family planning providers to increase DP in at-risk and underserved communities, there is an immediate need for practical, feasible interventions that effectively identify at-risk women in family planning settings and promote informed method choices which balance HIV/STI and pregnancy prevention needs. Helping women to increase awareness of their dual risks for HIV and pregnancy can result in increased condom use with their partners. The RAD intervention is a standardized counseling tool that may help sensitize more family planning clients to their STI risks and incorporate DP into their contraceptive practices. Even with a modest effect size, the RAD intervention has the potential for a large population impact: it is inexpensive, theory-based, easy-to-administer, and applicable to large numbers of sexually active reproductive-aged women who use family planning services both in the US and globally.

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REFERENCES

- Adams-Skinner J, Exner TM, Pili C, Wallace B, Hoffman S. The development and validation of a tool to assess nurse performance in dual protection counseling. *Patient Education and Counseling*. 2009; 76:265–271. [PubMed: 19216047]
- Artz L, Macaluso M, Brill I, Kelaghan J, Austin H, Fleenor M, Robey L, Hook EW 3rd. Effectiveness of an intervention promoting the female condom to patients at sexually transmitted disease clinics. *American Journal of Public Health*. 2000; 90:237–244. [PubMed: 10667185]
- Cates W, Steiner M. Dual protection against unintended pregnancy and sexually transmitted infections: what is the best contraceptive approach. *Sexually Transmitted Diseases*. 2002; 29:168–174. [PubMed: 11875378]
- Dailard C. Title X family planning clinics confront escalating costs, increasing needs. *Guttmacher Report on Public Policy*. 1999; 2:1–2. 14.
- Exner TM, Hoffman S, Parikh K, Leu CS, Ehrhardt AA, Clayton J. HIV counseling and testing: Women's experiences and the role of testing as a prevention strategy. *Perspectives on Sexual & Reproductive Health*. 2002; 34:76–83. [PubMed: 12043712]
- Fischhoff B. Giving advice: Decision theory perspectives on sexual assault. *The American Psychologist*. 1992; 47:577–588. [PubMed: 1595985]

- Greer G, Chau K, Hinz C, Thanenthiran S. Sex, rights, and politics--from Cairo to Berlin. *Lancet*. 2009; 374:949. [PubMed: 19766868]
- Hardon AP. The needs of women versus the interests of family planning personnel, policy-makers and researchers: Conflicting views on safety and acceptability of contraceptives. *Social Science & Medicine*. 1992; 35:753–766.
- International Conference on Population and Development. International Conference on Population and Development Secretariat; 1994. Retrieved from: <http://www.iwhc.org/index.php?option=comcontest&task=view&id=3565&Itemid=824>.
- Jaccard J, McDonald R, Wan CK, Guilamo-Ramos V, Dittus P, Quinlan S. Recalling sexual partners: The accuracy of self-reports. *Journal of Health Psychology*. 2004; 9:699–712. [PubMed: 15367750]
- Kautz DD, Dickey CA, Stevens MN. Using research to identify why nurses do not meet established sexuality nursing standards. *Journal of Nursing Quality Assurance*. 1990; 4(3):69–78. [PubMed: 2324236]
- Latka M, Gollub E, French P, Stein Z. Male condom and female-condom use among women after counseling in a risk-reduction hierarchy for STD prevention. *Sexually Transmitted Diseases*. 2000; 27:431–437. [PubMed: 10987447]
- Marlatt, AG.; Gordon, JR. Relapse prevention: Maintenance strategies in the treatment of addictive behaviors. New York, NY: Guilford Press; 1985.
- McKinnon K, Cournos F, Meyer-Bahlburg HFL, Guido JR, Caraballo LR, Margoshes ES, Herman R, Exner TM. Reliability of sexual risk behavior interviews with psychiatric patients. *American Journal of Psychiatry*. 1993; 150:972–974. [PubMed: 8494081]
- Meyer-Bahlburg, HFL.; Ehrhardt, AA.; Exner, TM.; Calderwood, M.; Gruen, RS. Sexual Risk Behavior Assessment Schedule - Adult (SERBAS-A). New York, NY: Columbia University, Department of Psychiatry; 1988. Unpublished instruments.
- Meyer-Bahlburg HFL, Nostlinger C, Exner TM, Ehrhardt AA, Gruen RS, Lorenz G, Gorman JM, Sorrell SJ. Sexual functioning in HIV+ and HIV-injected drug-using women. *Journal of Sex & Marital Therapy*. 1993; 19(1):56–68. [PubMed: 8468710]
- Miller, WR.; Rollnick, S. Motivational interviewing: Preparing people for change. 2nd ed. New York, NY: Guilford Press; 2002.
- Mosher WD, Martinez GM, Chandra A, Abma JC, Wilson SJ. Use of contraception and use of family planning services in the United States: 1982–2002. *Advance Data from Vital Health and Statistics*. 2004; 350:1–36.
- Musuba E, Morrison C, Sunkutu M, Wong E. Long-term use of the female condom among couples at high risk of human immunodeficiency virus infection in Zambia. *Sexually Transmitted Diseases*. 1998; 25:260–264. [PubMed: 9587178]
- National Women's Law Center. Increase funding for the Title X family planning program. Help low-income women access quality, affordable family planning services and other preventive health care. 2009. Retrieved from: http://www.nwlc.org/pdf/title_x_fact_sheet_09.pdf
- Pequegnat W, Fishbein M, Celentano D, Ehrhardt AA, Garnett G, Holtgrave D, Jaccard J, Zenilman J. NIMH/APPC workgroup on behavioral and biological outcomes in HIV/STD prevention studies: A position statement. *Sexually Transmitted Diseases*. 2000; 27:127–132. [PubMed: 10726643]
- Rotheram-Borus MJ, Meyer-Bahlburg HFL, Koopman C, Rosario M, Exner TM, Henderson R, Matthieu M. Lifetime sexual behaviors among runaway males and females. *Journal of Sex Research*. 1992; 29:15–29.
- Rubak S, Sandbaek A, Lauritzen T, Christensen B. Motivational interviewing: a systematic review and meta-analysis. *British Journal of General Practice*. 2005; 55:305–312. [PubMed: 15826439]
- Susser E, Valencia E, Miller M, Tsai WY, Meyer-Bahlburg H, Conover S. Sexual behaviors of homeless mentally ill men at risk for HIV. *American Journal of Psychiatry*. 1995; 152:583–587. [PubMed: 7694908]
- Swartz, R.; Parks, S. Infusing the teaching of critical and creative thinking into content instruction. Pacific Grove, CA: Critical Thinking Press and Software; 1994.
- The NIMH Healthy Living Project Team. Effects of a behavioral intervention to reduce risk of transmission among people living with HIV: The Healthy Living Project randomized controlled

study. *Journal of Acquired Immune Deficiency Syndromes*. 2007; 44:213–221. [PubMed: 17146375]

U.S. Department of Health & Human Services, Office of Public Health and Science, Office of Population Affairs. Fact Sheet. 2008 January. Retrieved from:
http://www.opaclearinghouse.org/pdf/TitleX-FactSheet_1-21-08.pdf

Zeger S, Liang KY. Longitudinal data analysis for discrete and continuous data. *Biometrics*. 1986; 42(1):121–130. [PubMed: 3719049]

Table 1**Standard of Care versus Risk and Decision-Making (RAD) Content**

SOC Content	RAD Content
Reproductive Health Assessment: Includes exploration of reason for visit, other reproductive health issues	Reproductive Health Assessment: Includes exploration of reason for visit, other reproductive health issues
Risk Assessment: Asks clients about their own and partner(s)' risk behaviors as delineated in the standard New York State HIV pretest counseling check list	Risk Assessment: Explores client's and partner(s)' past and current risk behavior and contraceptive practices using a semi-structured interview with built-in prefaces, expanded response options and probes
Motivational Assessment: Discusses pregnancy and HIV/STI prevention needs and the client's experience with previous methods and prior consistency of use	Motivational Assessment: Interactively assesses client satisfaction and concerns with methods previously used, as well as client and partner sexual practices, client motivations for pregnancy and STI/HIV prevention, and relationship and other impediments/facilitators of method use
Method Options: Elicits information on the client's initial method preference, including method characteristics that are important to her. It is standard-of-care policy to review all available options that fit the woman's interest, providing descriptions of the method and contraindications.	Methods Options Individualized, interactive counseling. Six major use factors are reviewed: STI/HIV risk-reduction, pregnancy risk-reduction, health contraindications, method-related costs, methods features, and client and partner satisfaction with previously used methods. The discussion of method options is tailored using a decision tree that takes these issues into account. Education materials, including flip charts, are used to aid this process.
Client Method Selection: Clients select methods of choice and proper method explained, with universal recommendations for the use of male condoms in addition to any other method selected.	Client Method Selection: Client select method of choice and proper method is explained. For all clients who choose the male or female condom, its use is demonstrated by the provider and practiced by the client using models.
Identification of Barriers to Method Use Not Applicable	Identification of Barriers to Method Use: Elicits problems the client may encounter in enacting initial and consistent use of the method selected, including practical problems (e.g., not having a condom, forgetting to take pill), personal objections to methods (e.g., interrupting sex), and relationship/partner issues (e.g., partner objection to method, fear of partner reaction).
Problem-Solving Solutions Not Applicable	Problem-Solving Solutions: Helps clients brainstorm solutions that will address barriers to method use and identifies and reinforces client and relationship strengths, or other resources that can help client successfully enact use. When partner negotiation is an issue, strategies are modeled through role-playing.
Triage of Women with Referral Needs: All clients who identify as having psychosocial referral needs (e.g., depression, partner abuse) on their medical history forms or in the counseling session are referred to the clinical social worker for triage	Triage of Women with Referral Needs: All clients who identify as having psychosocial referral needs (e.g., depression, partner abuse) on their medical history forms or in the counseling session are referred to the clinical social worker for triage

Table 2

Characteristics of the Sample by Condition (N=101)

	SoC Comparison (N=64)	RAD Intervention (N=37)	Total (N=101)
	%	%	%
Demographics *			
Race/ethnicity			
Black/African American	45.3	37.8	42.6
Caribbean or American	28.1	24.3	26.7
Latina	18.8	27.0	21.8
White/European	3.1	0	2.0
Asian/Pacific Islander	0	2.7	1.0
Other	4.7	8.1	5.9
Born in the US	71.9	70.3	71.3
Currently in school	48.5	62.2	53.5
Never married	82.8	86.5	84.2
Receives public assistance	14.1	27.0	18.8
	Mean	Mean	Mean
Age	21.28	22.43	21.7
Years of education	13.14	13.14	13.14
Sexual attitudes and behavior*			
HIV safer-sex self efficacy	4.85	4.90	4.87
Attitude toward male condoms	4.23	4.51	4.34
Number of male partners, lifetime (median)	5.0	4.0	4.50
Number of male partners, last 3 months (median)	1.0	1.0	1.0
Number of male partners, last 3 months (mean)	1.2	1.2	1.2
Number of unprotected vaginal sex occasions, 3 mos (median)	11.0	12.0	12.0
	%	%	%
If practiced anal sex, last 3 months	6.3	8.1	6.9
Perceives self as susceptible to STI	45.3	51.4	47.5
Ever had an STI	57.8	54.1	56.4
Ever had an abortion	40.3	50.0	43.9
Ever tested for HIV	84.4	78.4	82.2
Ever used female condoms	14.1	10.8	12.9
Ever used male condoms	93.8	94.6	94.0

*
p values >0.10

Table 3

Secondary Outcomes: Comparison Versus Intervention at Follow-up¹

	SoC (N=58)	RAD (N=36)	Unadjusted		Controlling for baseline	
	Mean	Mean	β	p	β	p
HIV safer-sex self efficacy	4.95	4.93	-0.01	0.93	-0.03	0.74
Attitude toward male condoms	4.23	4.51	0.11	0.31	0.06	0.39
	%	%	OR	95% CI	OR	95% CI
Perceives self as susceptible to STI post-counseling	51.6	54.1	1.11	0.49, 2.49	1.01	0.42, 2.43
Perceives self as susceptible to STI at 6 month follow-up	24.1	44.4	2.51	1.03, 6.13*	2.51	1.03, 6.14*
Tested for HIV post-counseling	82.5	83.3	0.85	0.37, 1.98	0.89	0.38, 2.10
Female condom use at 6 month follow-up	3.1	21.6	8.55 ²	1.71, 42.8**	5.02 ³	1.39, 18.11**

¹ 94 of the 101 enrolled women returned for follow-up

² Among women who had never used FC at baseline

³ Includes women who had used FC at baseline

* p <0.05;

** p <0.01