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A Randomized Controlled Trial to Evaluate a Structural Intervention to Promote the Female Condom in New York State

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INTRODUCTION

The female condom (FC) remains the only physical barrier method in addition to the male condom that has both contraceptive efficacy (1-2) and high likelihood of STI prevention efficacy (3-6). Findings from several use-effectiveness studies have indicated that the FC was at least as effective as the male condom in preventing STIs (5, 7-9), and there is no evidence of migration away from the male condom when individuals are offered both male and female condoms (10-12). Furthermore, several longer-term intervention studies suggest that promoting the FC in addition to the male condom can increase the overall number of protected intercourse occasions within a partnership (8, 12-15). A preponderance of studies shows that short-term acceptability of the FC is high among diverse groups of women and men in many settings, with the proportion trying the method ranging from 37% to 96% (16-17). With the March 2009 FDA approval of FC2 -- the second-generation product made of synthetic latex -- cost should be less of an impediment to use. In 2010, FC2 was distributed in 114 countries, mainly by public health organizations and donor groups (18).

Global demand for FC2 has continued to increase, with sales in more than 100 countries. In the US, there are signs of renewed interest in the female condom where the number of FC2s distributed more than tripled in 2010 (19). Following the approval of FC2, the Female Health Company initiated FC reintroduction programs in partnership with health departments in cities with high rates of HIV/AIDS and sexually transmitted diseases (18). Paradoxically, even with indications of high efficacy, use-effectiveness and acceptability, female condoms have been under-funded and under-utilized as a pregnancy/HIV/STI prevention method. Integration of FC2 into comprehensive condom programming in the US is critical given that in 2009, heterosexuals accounted for 27% of estimated new HIV infections, and 23% of those newly infected were women (20). Women also represent 20% of AIDS diagnoses cumulatively reported in the US (20). In light of gender inequalities being an important driver of the feminization of HIV/AIDS, women's challenges in negotiating for safer sex, and the reluctance or refusal of many men (and women) to use the male condom, methods that offer women and men alternative protection options urgently

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need to be promoted. Universal access to female condoms can potentially increase the number of protected sex encounters and thus contribute to reducing new HIV infections.

Nearly all FC studies have focused on the determinants of user acceptability and uptake. Individual-level barriers, including insertion difficulties and partner resistance, have been identified, and some effective strategies to reduce these impediments have been implemented (10-13, 21-23). However, as noted by the World Health Organization, acceptance of new contraceptive technologies may be influenced by the complex interplay of individual, partner, provider and health-system factors (24).

Providers of direct sexual risk-reduction counseling often are the primary sources of HIV/STI information for their clients and are in a position to either promote or marginalize the FC. Some research suggests that provider bias against the FC may restrict promotion of the method. In a study conducted in four types of settings in New York City, most of the 78 providers involved in “hands-on” HIV/STI and/or pregnancy counseling believed that the FC was as effective as or better than the male condom (25-26). However, they were reluctant to recommend it to their clients due to limited knowledge of and experience with the method. Few counselors appeared to use pro-active counseling techniques to counteract clients’ initial reluctance, viewing the FC as a method of last resort to be suggested only when a woman lacks other options. Similar provider resistance noted in the promotion of other contraceptive methods suggests that negative attitudes of health care providers limit women’s access to and adoption of methods (27-28). This presents a major structural barrier to FC promotion.

With limited exceptions (29-32), there have been few large-scale, system-wide FC promotion interventions that systematically explore the interplay of the method, agency service delivery system, provider, and user, and how these factors may promote or constrain adoption and continued use of the FC. Provider training is considered an essential component of FC promotion by UNAIDS (33), but evaluation of such training on providers’ behavior and on client acceptance of the FC is rare. This is key in light of the pivotal role that providers, as gatekeepers of HIV/STI prevention technologies, can play in promoting or impeding clients’ access to the FC.

No intervention has yet aimed to modify structural factors, such as agency policies and widespread counseling practices, that may impede adoption and continued use of the FC. Testing system-level interventions designed to alter the environmental context and structural factors (34) to facilitate FC programming and increase institutional capacity for delivery of effective HIV prevention services (25) is essential. In this paper, we report on a multi-level multi-component structural intervention (using a randomized controlled design) targeted primarily at the level of organization and service providers in 44 agencies in New York State to develop, support and sustain policies and programs that increase clients’ access to and use of the FC.

METHODS

Overview

We used a randomized controlled design to test the efficacy of an *Enhanced Intervention* [EI] for FC promotion targeting both directors of agencies and HIV sexual risk-reduction counselors against a *Minimal Intervention* [MI] that provided agency access to FCs and directors with a rationale for their promotion, but no intervention for counselors. We opted for a MI condition instead of a no-treatment control because we believed that the EI would achieve a substantial improvement over doing nothing at all. Therefore, we set a higher bar for the more resource-intensive EI by including a MI. The comparison of a low-cost MI

against a more labor-intensive *EI* enables us to ascertain the degree of impact that can be achieved with each. We hypothesized that the *MI* would result in improved agency FC policies, counselor practices, and client FC intention over those in place at the baseline assessment, and that the *EI* would result in significantly greater improvements than the *MI*.

We also nested a serial cross-sectional case study of clients in 8 agencies (four *MI* and four *EI*) in New York City and the Albany area, with one *MI* and one *EI* agency randomly selected from those participating in consecutive recruitment waves). This case study aimed to ascertain client risk behavior and intention to use the FC in the coming 3 months. Since we lacked the resources to enroll a longitudinal cohort, and, given that clients utilizing services at one time point were not necessarily going to re-access services during a follow-up period, we believed that a cross-sectional cohort would enable us to capture the impact of the intervention on a broader sample of clients. We also observed counselors in these agencies (on average one session per counselor at baseline (N=48 observations on 36 counselors) and follow-up (N=31 observations on 25 counselors) to ascertain the counseling content, whether the counselors were implementing what they learned in their FC training workshop, and whether the behavior of counselors was associated with clients' reported intention to use the FC.

Theoretical Model

The *EI* was guided by findings from empirical work on provider attitudes (30,36), and empirical studies that identified two critical areas to FC adoption: partner negotiation (37-38) and insertion skills (39). We relied on techniques identified by Social Learning Theory (40-41): increasing self-efficacy for FC promotion through cognitive restructuring of impeding beliefs and behavioral skills rehearsal; using structured practice with feedback; increasing positive expectancies for FC use by fostering positive peer norms; and providing encouragement and reinforcement through social support. The intervention also was informed by elements from Bruce's (42) quality of care model, and Green and Kreuter's (43) PRECEDE/PROCEED planning model that delineates three categories of factors that influence behavior: (1) predisposing (knowledge, attitudes, and beliefs); (2) enabling (requisite skills and environmental resources); and (3) reinforcing (feedback, reminders, and rewards).

Recruitment and Assessment of Participants

To be eligible to participate, agencies had to receive New York State Department of Health (NYSDOH) AIDS Institute funding for prevention or treatment initiatives, work with heterosexually-active at-risk populations, and have a client base comprised of at least 60% women. Using the NYSDOH Contract Management System database, we identified 182 agencies who met these criteria. These agencies constituted the sampling frame for the study. The bulk of these agencies (58%) were located in NYC, with the remainder in the NYC metropolitan area (19%) and in Upstate urban areas (Albany, Buffalo, Rochester and Syracuse (23%). The agencies included medical institutions, and both small and large community-based organizations (CBOs). Agencies provided a broad spectrum of HIV-prevention activities, including substance abuse and syringe-exchange programs, education/outreach initiatives with at-risk populations, HIV counseling and testing (C&T), primary care, and case management and support services for HIV-seropositive clients. We surveyed the agencies in order to enumerate the number and type of staff who were potentially eligible for the intervention, and to determine the size of the agency, as reflected in number of clients who receive sexual risk-reduction counseling per month. We pair-matched these programs on four factors: agency size, type of services (medical vs. non-medical), population served (primary ethnic/racial groups; risk profile of patients (IDUs/partners of IDUs, STI patients, HIV+ persons), high-HIV prevalence census tract clientele), and

geographic location (upstate vs. NYC metropolitan area). Experience augmented this data-driven approach to matching. Senior NYSDOH personnel with oversight of AIDS Institute-funded programs drew on their experiences with those agencies to make final decisions on the appropriateness of a match; 23 agencies were matched using these methods.

Agencies—We contacted agencies through their director (or designated authority) by phone, following receipt of an explanatory letter which provided a description of the study. Directors were invited to attend a two-hour meeting to introduce them to the study, garner support, and serve as a means of recruitment. Regionally-specific HIV/STI prevalence data and information on the FC and barriers/facilitators of use were presented, possible promotional activities discussed, and agency-specific ‘Action Plans’ for FC promotion were generated. Following the meeting, directors were contacted by phone regarding their interest in participation, with all but one agreeing, meaning that the match for that agency also could not participate. Directors provided a signed letter of agreement to participate, and indicated either authorization to use the NYSDOH Institutional Review Board (IRB) or their own agency’s IRB. After IRB approval was obtained, directors were mailed a brief baseline survey to complete, and we recruited counselors, as described below. Agencies were randomized by our study statistician using a random numbers table after a matched pair agreed to participate and we received completed baseline information from both directors and counselors at the paired agencies. Directors and counselors were surveyed again 12 months post-intervention. Participating agencies received a \$100 gift certificate for office supplies.

Counselors—Directors provided the names and work contact information of counselors, who following receipt of an explanatory letter, were recruited by phone. To be eligible to participate, counselors had to be at least 18 years of age, speak and read English, conduct sexual risk-reduction counseling with heterosexually-active clients as part of routine duties, have received training on HIV sexual risk-reduction counseling, have worked at least 6 months in their current position, and expect to be at the agency one year hence. We screened 250 counselors in order to enroll 223. Among the 27 who were not enrolled in the study, 13 refused to participate, six were under age 18, four did not routinely provide sexual risk-reduction counseling, one was uncomfortable with spoken English, and the remainder did not anticipate being at the agency for the next year. In the few cases where a counselor either refused to participate or was ineligible due to anticipated relocation and his/her agency was subsequently randomized to the *EI*, those counselors were invited to attend the in-person *EI* training in order to mask their refusal or reason for ineligibility. Those eligible who agreed to participate provided written consent and were mailed a self-administered baseline survey, which took about 20 minutes to complete. Counselors received \$15 for completing the baseline survey, and \$35 for completing the follow-up survey one year later.

Clients—In the eight case study agencies, we conducted brief, anonymous exit interviews post risk-reduction counseling coinciding with the baseline and 12-month follow-up assessments for the main trial, with an average of four clients of 36 counselors (N=143 clients at baseline; N=134 at follow-up). To be eligible for the case study, clients had to be a client of a counselor who agreed to participate in the case study, at least 18 years of age, speak English, and have no evident sign of cognitive impairment. Written client consent was obtained. Clients participating in the observational component were told about this aspect of the study by their counselor, and a session with the first client providing formal consent when study staff were on premises was observed. Observers were blind to condition at baseline; randomization occurred after baselines were completed. Since we did not inquire about knowledge or suspicion about assigned condition post-observation, it is less certain

that they remained so at follow-up due to direct or inadvertent disclosure by a counselor. Clients were paid \$10 for the exit interview and \$10 for observation.

Interventions

Table 1 provides an overview of the components of the *EI* and *MI* conditions.

Minimal Intervention—The *MI*, targeted to the agency-level only, consisted of a regional directors' meeting and provision of free female condoms to the agencies.

Enhanced Intervention—The *EI*, targeted to both the agency- and counselor-levels, consisted of the same two components as the *MI*, but also included (1) at the agency-level, the distribution of a "Female Condom Program and Policy Tool-Kit" to directors and 12 months of technical support; and (2) at the counselor-level, a one-day FC training workshop, 12 months of technical support, and provision of FC materials for use with clients.

The Tool-Kit sent to directors of agencies in the *EI* contained materials (posters, pamphlets, information sheets) to assist with creation of intra-agency FC promotional policies and practices, as well as pelvic models to be used by sexual risk-reduction counselors to demonstrate correct FC use with clients. The content and use of these Tool-Kits were reviewed via phone. Further technical support calls were scheduled monthly to check on Action Plans and support continued FC promotional activities.

Counselors in the *EI* attended a 6-hour training provided in groups in a local setting, and received their own Tool-Kit with posters, pamphlets and a DVD used in a trial (10) that promoted the FC to heterosexual couples. Training was conducted in groups of approximately 20, with multiple training dates to allow agencies to free counselors on alternate days. Technical support calls were scheduled monthly.

Measures

Agency-level—Directors provided, via baseline and follow-up surveys, information on services, staffing, number of clients served, and policies and practices regarding FC promotion. The primary outcome at the agency-level was a composite measure (Cronbach's $\alpha=.75$) reflecting *FC Policy and Practices*, which adds one point for each of the following: (1) a formal agency policy about FCs; (2) prioritization of FC promotion is regarded as a priority; (3) mention of the FC in the agency mission statement; (4) training of new staff on the FC; (5) mechanism for monitoring FC supply; (6) mechanism for monitoring FC promotion; (7) integration of the FC into existing programs and services; and (8) availability of FC educational materials.

Counselor-level—Counselors provided background information on gender, age, race/ethnicity, educational level, number of years in current position, and job title. The major outcome, assessed separately for heterosexually active male and female clients, asked "In the past 3 months, how many of your clients did you counsel about the efficacy, negotiation and proper use of the FC?" with categories '1=none,' '2=less than half,' '3=half,' '4=more than half,' and '5=all.'

Secondary outcomes included *Knowledge of the FC*, assessed via 11 items (Cronbach's $\alpha=.76$; sample item: "Any type of lubricant can be used with the FC"). To measure *Attitudes toward the FC*, we included all 30 candidate items used to construct the Likert-scaled FC Attitudes Scale (44). Factor analysis in this sample yielded two reliable 8-item scales: *Negative Aspects of the FC* (Cronbach's $\alpha=.82$; sample items: "FCs are weird"; "FCs are not convenient") and *Sexual Pleasure* (Cronbach's $\alpha=.78$; sample item: "FCs take all the fun out

of sex”; “FCs make sex more enjoyable for the woman than male condoms”). Higher scores reflect more positive attitudes. *Intention to Counsel Clients on FCs* was assessed by an item rating likelihood of routinely recommending the FC to clients in the next three months, rated on a seven-point-Likert-scale; 1=‘Not likely at all’ to 7=‘Extremely likely’. *Peer Norms for Promoting the FC with Clients* assessed the proportion (from ‘1=none’ to ‘5=all’) of counselors in one’s network perceived to recommend the FC regularly to female and male clients (Cronbach’s $\alpha=.88$). *Self-efficacy for FC Promotion* was assessed via six Likert-scaled items (1=‘Extremely unsure’ to 7= ‘Extremely sure’) that asked how certain the counselor was that he/she could mention, counsel on effectiveness, demonstrate, counsel on use-related issues, and assist clients in negotiating FC use and mastering insertion (Cronbach’s $\alpha=.93$).

Observations of counselors in the eight case-study agencies, conducted using a check-list, allowed us to ascertain how many of 27 pre-coded FC-related discussion points and counseling activities were covered by those counselors (Cronbach’s $\alpha=.95$; sample items: “discussed the effectiveness of the FC”; “mentioned that any lubricant can be used”; “counseled on how to negotiate with partner”; role-played negotiation”; “modeled insertion on a pelvic model”).

Client-level—In addition to background information (gender, age, race/ethnicity, education, injection drug use in the prior year), we obtained data on number of partners in the past 12 months and male and female condom use during vaginal and anal sex in the prior year. *Intention for FC Use* was measured by the item “How likely are you to use the female condom in the next three months?” rated from ‘1=extremely unlikely’ to ‘6=extremely likely.’ *Attitude toward the FC* was assessed by an item “How do you feel about the female condom as a method for you?” rated from ‘1 extremely negative’ to ‘6 extremely positive’, while *Self-efficacy for FC use* was assessed by the item: “How confident are you that you could use a female condom correctly?” rated from ‘1 extremely unlikely’ to ‘6 extremely likely.’ Knowledge was assessed via seven items using true/false/unsure response categories (Cronbach’s $\alpha=.66$).

Statistical Analysis

Descriptive statistics were generated on all agency-, counselor-, and client-level variables. To test the first hypothesis -- whether the *MI* and *EI* resulted in improved FC policies and practices, counselor behaviors and attitudes, and client intention for FC use over those in place at the start of the trial -- we compared baseline to follow-up values in each group separately. To test the second hypothesis (primary analysis), we examined differences in the magnitude of change from baseline to follow-up between the *MI* and *EI* groups for each of the major outcomes. The agency-level outcome analysis compared *MI* and *EI* agencies on the composite measure reflecting FC policies and practices. The counselor-level outcome analyses compared counselors on the proportion of heterosexually active female and male clients counseled on the FC, as well as on the secondary outcomes (knowledge of the FC, attitudes toward the FC). We also examined differences in number of observed FC-related discussion points and counseling activities addressed by a sub-sample of counselors from the nested case-study whose counseling sessions were observed both at baseline and 12 months later. For the client-level analysis (in the nested case study), we evaluated the intervention effect on the cross-sectional client-level outcomes (intention to use the FC, knowledge of the FC) comparing the difference in clients recruited at baseline and 12-month follow-up in the four *MI* and four *EI* agencies. The criterion for statistical significance was specified a priori as $\alpha = 0.05$ (two-tailed).

Because earlier work by our team had suggested that family planning clinic providers compared with community-based agency providers have more negative attitudes toward the female condom, in secondary exploratory analyses we examined whether facility type (medical vs. non-medical) modified the effect of the intervention (i.e., whether the intervention had a different effect according to facility type). We stratified analyses by facility type and conducted formal tests of interaction (condition*time*facility type). For tests of interaction, we set the critical p-value to $< .10$. Finally, among case-study participants whose counseling sessions were observed, secondary analysis examined the association between client intention to use the FC and number of FC-related discussion points and counseling activities covered during the session.

We used the generalized linear model (GLM) with an identity link function and identity working correlation matrix for continuous variables and the logit link function for dichotomous outcomes. To test the first set of hypotheses, the model included a constant term and a 12-month follow-up indicator. These models were run separately in the *MI* and *EI* groups. In these models, the regression coefficient for the 12-month follow-up indicator represents the degree of change over time in the outcome of interest. To test the second set of hypotheses, the model included a constant term, the intervention indicator (vs. control), 12-month follow-up indicator (vs. baseline), and the interaction between the two indicators. In these models, the regression coefficient for the interaction of the intervention indicator and the 12-month follow-up indicator represents the efficacy of the *EI* over the *MI*. For continuous outcomes, this regression coefficient is the mean difference in change over time between *EI* and *MI*, and for dichotomous outcomes, it is the logarithm of the ratio of two odds ratios. The generalized estimating equation (GEE) methodology was employed to account for correlations due to clustering within levels (e.g., counselors nested within agencies) and multiple assessments over time on the same participants. For the client-level analyses, GEE was used (even though baseline and 12-month follow-up client-level data were collected from different participating clients) because the outcomes were correlated among those served by the same counselor, whose measures also were correlated within agency (45). The Pearson product-moment correlation was used to evaluate the association between client intention to use the FC and counselor behavior during observed sessions among a subsample of participants in the nested case-study.

RESULTS

Of the 44 participating agencies, 5% were substance abuse treatment facilities or syringe exchange programs, 7% were family planning clinics, 38% were other medical settings (hospital or STD clinic), and the remainder were CBOs or outreach organizations (See Table 2 for counselor characteristics).

Results for the primary *agency-level* outcome, FC Policy and Practices, are shown in Table 3. There was no significant change from baseline to follow-up in *MI* agencies. Although there were increases in the *EI* agencies in mean change over time in their incorporation of the FC into policies and practices, these changes did not reach statistical significance ($\beta=.77$; $p=.09$), and *MI* and *EI* agencies did not differ significantly in mean change over time. In analyses stratified by facility type (not shown), there were no significant intervention effects in either type of facility.

In the primary *counselor-level* outcome analysis (Table 4), both groups reported significant increases in clients counseled on the FC from baseline to follow-up, for both heterosexually active women and men clients. However, there were no significant differences between *MI* and *EI* in change over time. In exploratory tests of differential intervention effects according to facility type, the proportion of women who have sex with men counseled on the FC did

not differ by type of facility, although there was a significant interaction between facility type and condition ($\beta=1.62$; interaction $p=.049$), indicating that *EI* intervention effects were greater in medical facilities. In the respective analyses for men who have sex with women, stratified analyses revealed a significant intervention effect in both medical ($\beta=1.30$; $p=.003$) and non-medical ($\beta=1.08$; $p=.06$) settings, with the effect being stronger among *EI* in medical facilities ($\beta=2.68$; interaction $p=.002$).

For secondary counselor-level outcomes, both *MI* and *EI* counselors showed significant increases in knowledge of the FC, with a significantly greater gain among *EI* counselors at follow-up. Those assigned to the *EI* but not the *MI* showed significant increases in self-efficacy for FC promotion and more positive attitudes toward the FC's effect on sexual pleasure, with significant group differences in change over time on these two outcomes. While counselors in the *MI* but not the *EI* reported significant increases in Peer Norms for FC Promotion from baseline to follow-up, there were no significant differences between groups in change over time. Exploratory tests of differential effects according to type of facility showed that intervention effects for the FC pleasure variable were significant in medical ($\beta=.24$; $p=.01$) but not in non-medical facilities, and that this was stronger among *EI* counselors in medical facilities ($\beta=.19$; interaction $p=.07$). Likewise, counselors showed significant knowledge gains in medical ($\beta=2.45$; $p<.0001$) but not non-medical facilities ($\beta=.17$; $p=.01$), with *EI* intervention effects stronger in medical facilities as well ($\beta=2.29$; interaction $p=.001$).

Due both to attrition among counselors participating in the nested cross-sectional case study and to reassignment of duties, we were able to observe only 25 of the 36 counselors (69% retention) both at baseline and 12 months later. Although the increase in number of FC-related discussion points and counseling activities was greater among *EI* ($N=15$; mean increase = 3.9) than *MI* counselors ($N=11$; mean increase = 0.90), this difference was not significant, possibly due to limited power.

At the client-level, clients counseled in *EI* but not *MI* agencies, had a significant increase in intention to use the FC in the coming 3 months from baseline to follow-up, and this increase was significantly greater in *EI* vs. *MI* agency clients (Table 5). There was no interaction by facility type for that variable. *EI*-counseled clients also displayed increases in FC knowledge and self-efficacy for FC use; the effect was significantly greater in the *EI*- versus *MI*-counseled clients for knowledge, but not for self-efficacy. There were no intervention effects on clients' attitudes about the FC. With respect to these outcomes, secondary analyses indicated that there was a significant interaction between facility type and condition: clients in non-medical *EI* facilities reported greater knowledge gains than those in medical facilities ($\beta=1.44$; interaction $p=.049$). Tests of differential effects by facility type also showed that intervention effects on client self-efficacy were stronger in non-medical *EI* facilities ($\beta=.66$; interaction $p=.081$). Exploratory analyses among nested case-study participants where observational data from counselors were available both at baseline and follow-up indicated that client FC intention scores correlated with the number of discussion points on the FC covered by the counselor in observed counseling sessions ($N=26$; $r=.31$; $p=.004$). These findings buttress confidence in the construct validity of counselors' and clients' self-report measures.

DISCUSSION

Findings suggest that making subsidized FCs available and assisting agency directors to understand the need for and potential of the FC, and to formulate action plans, may lead to increased FC promotion. There was substantial change over time on the part of counselors in both conditions in their counseling practices with women and men. At follow-up, over 70%

of sexual risk-reduction counselors discussed the FC with more than half of heterosexually active women clients. More than 50% of counselors with heterosexually active male clients discussed the FC with most of them as well. Although the FC was designed to give women greater control over their own protection without having to rely on their male partners to use a condom, evidence consistently suggests that the male partner's response to the method has a substantial impact on its acceptability to women. Many studies confirm that partner cooperation is necessary to use the FC successfully (11-12, 18-20), underscoring the importance of the finding that counselors promoted it to men as well as women.

Compared to the *MI*, the *EI* resulted in greater positive change over time in counselors' knowledge and attitudes about the FC, including attitudes about the effect of the FC on sexual pleasure. How a contraceptive or STI-protection method affects both women's and men's sexual pleasure is now understood to be one of the most important factors determining its consistent use (11, 46-47). Notably, secondary analysis indicated that the positive changes over time in counselors' FC counseling practices, FC attitudes, and knowledge were greater for counselors in medical (than in non-medical) facilities, settings in which prior research suggests that the FC is often a marginalized method (25,26,30,36). In addition, case-study findings indicate that clients from *EI* sites reported greater change in intention to use the FC and greater increase in knowledge of the FC than clients from *MI* sites.

Interpreting findings is complicated by several important limitations. Retention rates were not ideal (85% of agencies and 74% of counselors), in part due to the disbanding of two agencies and counselor job and location changes. Although we did not find significant increases over time in agencies' FC policies and practices, this may in part result from a design flaw. While baseline data were obtained from agency directors prior to randomization, the baseline assessment was completed up to 4 weeks after they had attended the Director's Meeting - a critical intervention component targeting both *MI* and *EI* agencies, and during which they developed agency-specific plans to foster FC promotion. We cannot rule out the possibility that some of the relatively high baseline rates on several of the elements comprising the FC Policies and Practices Index (such as 50% of agencies indicating that FC promotion was a strong priority, and over 40% reporting training new staff on the FC) may reflect changes made after the Directors Meeting.

Volunteer bias, i.e., that volunteers (and perhaps the agencies selected) are primed to change, may have influenced findings as well. Matching agencies can involve art as well as science. AIDS Institute personnel's insights regarding agencies' staffing, stability, and operations, derived from grant oversight, was the final element in vetting a 'match'. This approach could result in atypically 'optimal' matches of 'optimal' agencies, compromising generalizability. Alternately, we may have failed to understand underlying unevaluated or unanticipated factors that could compromise the quality of matching. It also seems reasonable to assume that agencies opting to participate in this initiative share characteristics of 'early adopters' of other innovations - more in need, more aware of the need, and more motivated to address the need (48-49). Support for this possibility comes from the fact that one agency randomized to the *MI* launched a well-designed FC promotional campaign at the same time this study was in the field.

The outcomes relied on self-report data, so they should be interpreted cautiously. They are nonetheless informative, assuming inflated reporting occurred in both conditions, and that counselors in both conditions were aware that they were participating in a study providing free FC access and that clients were unaware of condition. Our client-level outcome measured self-reported intention to use the FC, not behavior, since data were cross-sectional and we thus, unfortunately, could not examine longitudinal changes in use. The association between client intention to use the FC and number of FC-related discussion points and

counseling activities covered during observed sessions provides some evidence for the construct validity of the intention variable – i.e., intention to use the FC was significantly related in the expected direction to a theoretically-relevant predictor variable in the nomological net (50-51). Future studies would be strengthened if they include “harder”, non-self-report outcomes.

The study was not designed to evaluate the differential effect of specific intervention components, so it is unclear which aspects of the intervention contributed to findings, and to what extent – was identifying the need for the FC and barriers to promotion critical? developing action plans? subsidizing FCs? The fact that FCs were Medicaid-reimbursable in New York State before the study began, and that both the New York City and State Departments of Health offered agencies free FC access suggests that FC availability itself was not the single most critical factor in expanded FC promotion on the part of counselors.

Widespread promotion of the FC has faced numerous barriers in the social and political environment. In the US, these barriers include ridicule in the press, limited advertising and promotion, higher cost relative to the male condom, inadequate training of health care providers and others who counsel on sexual risk, and limited distribution in the public health system (52). Latka (53) offers a hopeful analogy, noting possible parallels between the trajectory of the tampon and FC. First introduced in the 1930s for menstrual hygiene, the tampon experienced little uptake despite mass-marketing. Like the FC now, early tampon users tended not to use them exclusively. Eventually tampons caught on, in large part through endorsement by the medical field.

In spite of limitations, the study has significant merit as the first to examine a multi-level approach to FC promotion in the US. Both interventions were intentionally modest and designed to be sustainable in the public health sector, and in fact, the *EI* was designed to be able to fit into the menu of trainings provided by the New York State AIDS Institute's Division of Education and Training. Our intervention capitalized on the organizational infrastructure, training, and capacity-building mechanisms in place for HIV/STI counselors of the AIDS Institute, which coordinates all HIV public health initiatives in a state with one of the highest number of HIV/AIDS cases among women. Interest in roll-out of the intervention has already been expressed by representatives of Departments of Health from several states.

What lessons have been learned from this initiative, and what are the implications for future structural intervention efforts? Conducting randomized trials of interventions and examining relevant outcomes is not enough. Real-world contingencies that can influence an intervention's uptake, implementation and sustainability, and the processes involved in successfully – or unsuccessfully - achieving these, need to be better understood. The caveats that hedge our understanding of findings underscore the importance of more fully exploiting emerging implementation science theory and practice to inform the execution and monitoring of intervention development, evaluation and eventual roll-out.

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TABLE 1

INTERVENTION FORMAT AND OBJECTIVES

FORMAT	SPECIFIC OBJECTIVES
REGIONAL DIRECTORS' MEETING	
Target: Agency Directors (MI and EI)	
Meetings with directors of agencies that receive AIDS Institute funds	Acquaint agency directors with the proposed FC promotion activities, generate enthusiasm for the program, enlist their support, develop 'action plans'
FEMALE CONDOM AVAILABILITY INITIATIVE (6 MONTHS PRE-WORKSHOP & 12 MONTHS LATER)	
Target: All Enrolled Agencies (MI and EI)	
Availability of FCs	Provide adequate numbers of FCs to sustain promotion throughout the trial
FEMALE CONDOM PROGRAM AND POLICY TOOL KIT	
Target: Agency Directors (MI only)	
Provision of materials modeling FC promotional policies and practices	Acquaint agency directors with materials that can assist with creation of intra-agency FC promotional policies and practices
TRAINING WORKSHOP FOR COUNSELORS (6 hours)	
Target: Counselors (EI only)	
Importance of FC promotion	Set the stage for the importance of HIV/STI sexual risk-reduction Increase counselors' awareness of the FC as a prevention option
Efficacy, acceptability and factors that influence barrier methods	Increase awareness of efficacy, acceptability and factors affecting use Increase awareness of the impact of counselors on client method uptake
Understanding and clarifying personal values	Confront personal biases about barrier methods and male and female condoms Increase awareness of beliefs, values and behaviors regarding clients
Comfort with sex and sexuality	Increase counselors' comfort in communicating explicitly with clients about sex
Female condom: real-world use	Enhance appreciation of the need for FCs and other woman-initiated methods Increase counselors' knowledge about the FC Enhance counselors' understanding of clients' obstacles to FC adoption and use
Female condom insertion and removal	Develop counselors' technical competence with the FC Enhance counselors' comfort with the FC Increase self-efficacy that they can teach clients to use the FC correctly
Motivational enhancement interviewing and problem-solving techniques	Enhance ability to assist clients to prioritize concurrent STI and pregnancy prevention needs Enhance skills for assisting clients to anticipate and confront possible obstacles Enhance counselors' client-centered counseling skills
Partner negotiation strategies, including managing abusive responses from partners	Strengthen counselors' ability to improve their clients' condom negotiation and decision-making skills Increase ability to help their clients manage abusive partner responses
Developing a FC plan of action	Enable counselors to introduce the FC effectively into their programs
POST-WORKSHOP TECHNICAL ASSISTANCE & SUPPORT (12 MONTHS)	
Target: Directors and Counselors (EI only)	
Monthly and as needed technical support phone call	Provide ongoing support services to reinforce the FC policy tool-kit (directors) and training (counselors) and ensure that problems are addressed and resolved rapidly
IEC MATERIALS FOR CLIENTS AND COUNSELORS	
Target: Counselors (EI only)	
Videos, brochures, pamphlets, intervention manuals	Provide print materials to assist clients with FC insertion and use Provide counselors with video and supportive print materials to introduce women and their partners to the FC and motivate use Provide supportive print materials for clients on negotiating with partners (including addressing issues of possible abuse)

Table 2

Counselor Characteristics (N=223)

Variable	
	Mean (range)
Age	41.2 (18-64)
	%
Race	
Black/African American	40.5
Hispanic	35.5
Caucasian	22.7
Other	1.4
Education	
< High school	3.2
High school/GED	12.7
Some college	38.9
College degree	30.3
Post-graduate degree	14.9
Position	
Educator/outreach worker	36.8
Case manager/social worker	22.0
HIV test counselor	15.7
Supervisor	13.0
Medical provider	8.5
Harm-reduction personnel	4.0

Table 3

Agency-Level Major Outcome: FC Policy and Practices

	MINIMAL INTERVENTION			ENHANCED INTERVENTION			<i>MI</i> vs.
	Baseline (N=22)	Follow-Up (N=17)	BL to FU	Baseline (N=22)	Follow-up (N=19)	BL to FU	<i>EI</i>
Whether...	%	%	β^1	%	%	β^1	β^2
There is formal agency policy about FCs	9.1	6.7		0	5.0		N/A
The FC is a strong priority	50.0	76.5		50.0	63.2		-1.62
The FC is mentioned in the agency's mission statement	14.6	13.3		13.6	12.1		.10
New staff are trained on the FC	47.6	62.5		40.9	52.9		-.12
There is a mechanism for monitoring FC supply	63.6	76.5		63.6	83.3		.43
There is a mechanism for monitoring FC promotion	31.8	35.3		27.3	68.4		1.60
There is integration of the FC into existing programs and services	50.0	37.5		27.3	68.7		1.78
FC educational materials are available	40.0	6.7		38.9	66.7		3.38**
Mean Score	4.0	4.0	0.0	4.2	5.0	.77	.77

¹ Represents the slope of the baseline to follow-up change over time in number of FC-friendly policies and practices for the indicated condition.

² Represents the slope of the baseline to follow-up difference in number of FC-friendly policies and practices between agencies in the *EI* and *MI* conditions.

**
p < .001

Table 4

Counselor-Level: Major and Secondary Outcomes

	MINIMAL INTERVENTION			ENHANCED INTERVENTION			
	Baseline (N=103)	Follow-up (N=78)	BL to FU	Baseline (N=120)	Follow-up (N=88)	BL to FU	MI vs. EI
<i>Major Outcome</i>							
Women clients counseled	%	%	β^1	%	%	β^1	β^2
1. None	11.8	1.4		16.2	3.8		
2. Less than half	19.6	15.1		17.8	12.5		
3. About half	12.7	6.8		6.8	11.3		
4. More than half	17.6	26.0		25.4	20.0		
5. All	38.2	50.7		33.9	52.5		
Mean Score	3.5	4.1	.67***	3.4	4.1	.63**	-.03

Men clients counseled	Baseline (N=95)	Follow-up (N=85)		Baseline (N=115)	Follow-up (N=75)		
1. None	22.1	14.7		29.6	13.3		
2. Less than half	26.3	16.2		22.6	18.7		
3. About half	12.6	7.4		9.6	13.3		
4. More than half	13.7	26.5		12.2	13.3		
5. All	25.3	35.3		26.1	41.3		
Mean Score	2.9	3.5	.67***	2.8	3.5	.71**	.04

<i>Secondary Outcomes</i>							
	Mean	Mean	β^1	Mean	Mean	β^1	β^2
Knowledge of the FC (possible range:1-11)	6.6	6.3	.41*	7.0	8.1	1.81***	1.41***
Attitudes: negative aspects of the FC (possible range:1-4)	2.8	2.7	-.04	2.7	2.9	.15*	.20*
Attitudes: sexual pleasure inhibition (possible range:1-4)	2.9	2.9	-.04	2.9	3.0	.13*	.17**
Intention to counsel clients on the FC (possible range:1-7)	5.1	5.2	.13	5.2	5.1	-.08	-.21
Peer norms for promoting the FC (possible range:1-5)	3.2	3.5	.25*	3.1	3.3	.21	-.03
Self-efficacy for promoting the FC (possible range:1-7)	5.2	5.5	.29	5.0	5.5	.50	.21

¹ Represents the change over time in mean counselor scores from baseline to follow-up for the indicated group (MI or EI).

² Represents the difference in mean score change over time (from baseline to follow-up) between counselors in the MI and EI conditions.

* p < .05

** p < .01

*** p < .001

Table 5

Client-Level Outcomes

	MINIMAL INTERVENTION			ENHANCED INTERVENTION			<i>MI vs. EI</i>
	Baseline (N=74)	Follow-up (N=76)	BL to FU	Baseline (N=69)	Follow-up (N=58)	BL to FU	
	Mean	Mean	β^1	Mean	Mean	β^1	β^2
Intention to use the FC, next 3 months (possible range:1-6)	3.7	3.4	-.44	3.3	4.5	.55*	.99**
Knowledge of the FC (possible range:1-7)	4.4	4.0	-.30	4.1	4.9	.91**	1.20**
Self-efficacy for FC use (possible range:1-6)	4.3	4.5	-.00	4.3	4.8	.28*	.28
Attitude toward the FC (possible range:1-6)	4.4	4.5	.22	4.7	4.8	.33	.04

¹ Represents the slope of the baseline to follow-up difference between counselors in the EI and MI conditions.

* p < .10

** p < .05