Clinician-Delivered Intervention During Routine Clinical Care Reduces Unprotected Sexual Behavior Among HIV-Infected Patients

Jeffrey D. Fisher, PhD, William A. Fisher, PhD,*† Deborah H. Cornman, PhD,* Rivet K. Amico, PhD,* Angela Bryan, PhD,‡ and Gerald H. Friedland, MD§*

Objective: To evaluate the effectiveness of a clinician-delivered intervention, implemented during routine clinical care, in reducing unprotected sexual behavior of HIV-infected patients.

Design: A prospective clinical trial comparing the impact of a clinician-delivered intervention arm vs. a standard-of-care control arm on unprotected sexual behavior of HIV-infected patients.

Setting: The 2 largest HIV clinics in Connecticut.

Participants: A total of 497 HIV-infected patients, aged ≥18 years, receiving HIV clinical care.

Intervention: HIV clinical care providers conducted brief client-centered interventions at each clinical encounter that were designed to help HIV-infected patients reduce unprotected sexual behavior.

Main Outcome Measures: Unprotected insertive and receptive vaginal and anal intercourse and unprotected insertive oral sex; unprotected insertive and receptive vaginal and anal intercourse only.

Results: HIV-infected patients who received the clinician-delivered intervention showed significantly reduced unprotected insertive and receptive vaginal and anal intercourse and insertive oral sex over a follow-up interval of 18 months ($P < 0.05$). These behaviors increased across the study interval for patients in the standard-of-care control arm ($P < 0.01$). For the measure of unprotected insertive and receptive vaginal and anal sex only, there was a trend toward a reduction in unprotected sex among intervention arm participants over time ($P < 0.09$), and a significant increase in unprotected sex in the standard-of-care control arm ($P < 0.01$).

Conclusions: A clinician-delivered HIV prevention intervention targeting HIV-infected patients resulted in reductions in unprotected sex. Interventions of this kind should be integrated into routine HIV clinical care.

Key Words: HIV/AIDS, HIV prevention, clinician-delivered intervention, HIV-infected patients, sexual risk behavior, unprotected sex

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New HIV infections have not declined significantly in the United States[1] and many other nations[2] in recent years, in large part owing to the continuing risky sexual behavior and injection drug use practices of a proportion of HIV-positive persons.[3–11] Failure to reduce the incidence of HIV risk behavior among HIV-infected persons has arguably been an outcome of nearly exclusive focus on delivering HIV prevention interventions to HIV-negative as opposed to HIV-positive persons[12] throughout most of the history of the HIV pandemic.

To address the lack of HIV prevention interventions designed to support HIV-positive persons' practice of HIV-preventive behavior, efforts to develop effective prevention interventions for HIV-infected persons have now become a major clinical and public health focus.[7,13–22] The implementation of HIV prevention interventions for HIV-positive persons is particularly relevant in the current context of effective and potent antiretroviral therapy that has transformed HIV into a chronic disease with an extended period of potential infectiousness with both sensitive and resistant virus.[23–25]

Although many HIV-infected individuals avoid risky behaviors that can transmit the virus to others, substantial numbers of HIV-infected persons continue to engage in HIV transmission-risk behaviors.[5–7,9,10,26–29] Research indicates that approximately 33% of HIV-positive persons engage in behaviors that place uninfected individuals at risk for infection,[4–6,8,11] and HIV transmission-risk behavior rates appear to be similar across HIV-infected men who have sex with men, HIV-infected injection drug users, HIV-infected heterosexual men and women, and HIV-infected individuals who are and who are not seeking health services.[8]

The challenge of developing effective and feasible interventions to promote safer sex and drug injection practices among HIV-infected individuals has been designated by the Centers for Disease Control,[13] National Institutes of Health,[30] and the Global HIV Prevention Working Group[14] as a critical priority at this point in the HIV pandemic. In this respect, it has

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From *Department of Psychology, Center for Health/HIV Intervention and Prevention, University of Connecticut, Storrs, CT; †Departments of Psychology and Obstetrics and Gynaecology, University of Western Ontario, London, Ontario, Canada; ‡Department of Psychology, University of Colorado, Boulder, CO; and §AIDS Program, Yale University School of Medicine, New Haven, CT.
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Reprints: Jeffrey D. Fisher, Center for Health/HIV Intervention and Prevention, 2006 Hillside Rd., Unit 128, University of Connecticut, Storrs, CT 06269-1248 (e-mail: jeffrey.fisher@uconn.edu).

been specifically recommended that HIV prevention interventions be integrated into clinical care for HIV-infected patients.[13,14] It has been noted that "clinicians providing medical care to HIV-infected persons can play a key role in helping their patients reduce risk behaviors and maintain safer practices and can do so with a feasible level of effort, even in constrained practice settings. Clinicians can greatly affect patients' risks for transmission of HIV to others by performing a brief screening for HIV transmission-risk behaviors; communicating prevention messages; discussing sexual and drug-use behavior; positively reinforcing changes to safer behavior; referring patients for such services as substance abuse treatment; facilitating partner notification, counseling, and testing; and identifying and treating other STDs"[13] (see also Gayle et al[14]).

The HIV clinical care setting may be an efficient and effective context in which to situate HIV prevention interventions for HIV-infected persons because it provides repeated opportunities for supportive prevention contacts between clinicians and patients and capitalizes on the often trusting relationship between them. The HIV clinical care setting also affords the most complete access possible to the population of HIV-infected individuals who are capable of transmitting the virus to uninfected others. At present, however, very few HIV prevention interventions have been systematically implemented and evaluated in the HIV clinical care setting.[12,15,17–19]

The current research involves the design, implementation, and evaluation of a clinician-delivered HIV risk reduction intervention, targeting HIV-infected patients' risky sexual and drug use behaviors, and delivered in the context of routine HIV clinical care. This approach exploits the efficiencies and strengths of the HIV clinical care setting and the opportunities it affords for repeated clinician–patient prevention interactions and is designed to be amenable to widespread and cost-effective dissemination.

METHODS

Participants

HIV-infected participants were recruited at the 2 largest HIV clinics in Connecticut, including 1 site in New Haven and 1 in Hartford. Inclusion criteria for the study protocol were documented HIV infection; receiving HIV clinical care; and age $\geq$18 years. Exclusion criteria were physical or mental disability sufficient to interfere with involvement in the research protocol.

Subjects were recruited with poster displays in examination and waiting rooms soliciting participation; brochures that contained similar information; solicitation from nurses and clinic staff; and by way of clinicians who described the study to their patients. Interested patients were introduced to research staff who described study details and obtained informed consent. Participation in this study was voluntary. Institutional review boards at the University of Connecticut, Yale University School of Medicine, and Hartford Hospital approved the research protocol.

Study Design

This prospective clinical trial employed a quasi-experimental research design[31–33] in which clinics were assigned to intervention (New Haven) or standard-of-care control (Hartford) arms. This design was selected to avoid cross-contamination between intervention and control arms had both conditions been implemented within the same clinical site. Moreover, implementing both the experimental and control conditions of this study at a single site could have potentially caused patients in the control group to feel disadvantaged and resentful. The intervention and control sites were selected on the basis of their similarity in population served (eg, both serve approximately 800 HIV-positive patients from inner city populations) and structure of services (eg, both are hospital-based comprehensive HIV clinics staffed by clinicians and nurses, with social work and mental health services available, and assign patients to individual practitioners who provide HIV primary care services to their own panel of patients). We note that the intervention and standard-of-care control sites were carefully compared and found to be similar on several potential confounders, including clinic environments and procedures, overall characteristics of patient populations, standards of care, lack of preexisting HIV prevention efforts, and modes of HIV transmission. To further assess for bias in outcome measures associated with preexisting differences between sites, we conducted tests for pretest equivalence and were prepared to statistically adjust for any measured variable on which the clinics differed and that was related to our primary outcome measures.[31–33]

Procedures

On average, at the intervention and control arm sites, patients saw their providers for regularly scheduled visits about every other month. Standardized sexual and injection drug use behavior assessments[4,34,35] and measures of other relevant factors were conducted at baseline and at approximately 6-month intervals for a follow-up period of approximately 18 months (4 assessments). Computer-administered self-interviews (CASI)[36] assessed patients' demographics, HIV prevention information, motivation, behavioral skills, and sexual and injection drug use behaviors. Measures were administered in either English or Spanish, at the patient's choice, with an accompanying audio track to assist those who had difficulty reading. On average, 2 HIV prevention intervention sessions were delivered per patient between each assessment of patient behavior. Subjects were compensated $25 for each CASI assessment but received no compensation for participating with their HIV care provider in the clinician-delivered HIV prevention intervention. Study participants were informed that their HIV care providers would at no time have access to data from their CASI assessments.

The clinician-initiated intervention protocol, known as the "Options/Opciones Project," was based on the information–motivation–behavioral skills model, an empirically validated approach to HIV risk reduction.[37–40] It was delivered using techniques drawn from motivational interviewing,[41] an empirically validated, brief, patient-centered strategy for promoting risk behavior change in clinical settings. Intervention content was also informed by focus group discussions with

HIV-infected patients (n = 20) and HIV care clinicians (n = 17) who reviewed and commented upon this intervention approach while it was under development. Details of intervention development have been described elsewhere.[42]

The Options/Opciones Project HIV risk reduction intervention consisted of brief (5- to 10-minute), collaborative, patient-centered discussions between clinician and patient, conducted during routine clinical visits and repeated at each visit, over a study interval of approximately 18 months. Clinicians verbally assessed HIV-positive patients' sexual and injection drug use behaviors, evaluated patients' readiness to change risky (or maintain safer) behaviors, sought to understand patient ambivalence about change, and elicited strategies from patients for moving toward change or maintaining safer behavior. Clinician and patient then negotiated an individually tailored behavior change (or maintenance) goal or plan of action, and sessions ended with the patient being given a "prevention prescription," written on a prescription pad, which summarized the agreed-upon-goal to be reached by the next visit. Clinicians were directed to attempt to implement the intervention at the end of every regular clinical visit with every enrolled patient unless pressing medical concerns precluded intervention delivery.

Participants in the standard-of-care control arm met with their clinicians for scheduled visits and received standard medical care, which did not systematically include discussion of HIV prevention. Such discussions were not prohibited during the study, however, and occurred on an ad hoc basis.

Clinician Training

Over the course of this research, 23 HIV care clinicians (20 physicians, 2 physician assistants, and 1 nurse-practitioner) were trained to deliver the Options/Opciones Project intervention to criterion. Intervention training consisted of 3 hours of didactic teaching and interactive practice in intervention delivery with HIV-infected standardized patient volunteers. A 1-hour one-on-one follow-up session with role plays was also conducted with each clinician, after the core intervention training, and before he or she began to deliver the intervention. In addition, clinicians participated in a 2-hour workshop on sexual and injection drug use behavior and risk reduction strategies. Clinicians were provided with a complete intervention manual and had access to an intervention "cheat sheet," outlining intervention procedures, attached to each intervention arm patient's medical chart.

Intervention Fidelity

Intervention fidelity was assessed with clinicians' reports of their delivery of 9 specific intervention protocol steps at each visit and via patient completion of exit questionnaires following intervention visits. These findings are discussed in detail in a separate report[42] that provides convergent evidence of intervention fidelity from clinician and patient reports and indicates that the intervention was delivered in 73% of all HIV clinical care visits. Most of the cases in which it was not delivered were due to the presence of pressing medical concerns.

Outcome Measures

Several intervention outcome measures were used in this research. As a broad measure of potential HIV transmission-risk sexual behavior, the total number of unprotected vaginal and anal sexual events (receptive and insertive) together with the total number of unprotected insertive oral sexual events (participant's penis in a partner's mouth) over the prior 3-month period was calculated. (Unprotected receptive oral sex by an HIV-infected person is associated with minimum HIV transmission risk[43,44] and was not included in this index.) We also constructed a more rigorous and conservative measure of HIV transmission-risk sexual behavior that included only unprotected vaginal and anal sexual events. We label this transmission-risk measure as "more rigorous and conservative" for 2 reasons. First, HIV transmission via unprotected oral insertive behavior by an HIV-infected person is relatively inefficient, especially when ejaculation is unknown. Second, because of its relative inefficiency, some respondents may view engaging in oral sex (to the exclusion of other unprotected acts) as a risk reduction measure. Our intervention's motivational interviewing techniques recognize the importance of such individual subjectivities in determining respondent risk reduction goals.

In addition to considering the behavior itself, transmission risk is by implication based on the assumption of HIV being transmitted from an infected to a noninfected individual. Despite the fact that respondents' perceptions and assumptions regarding their partner's serostatus may be highly inaccurate and speculative,[5,6,26,45] we decided to include this variable in constructing additional exploratory risk measures. Presumed partner serostatus and sexual risk behavior were combined in 4 different ways: number of unprotected vaginal, anal, and insertive oral sexual acts with an HIV-negative or HIV status-unknown partner; number of unprotected vaginal and anal sexual acts with an HIV-negative or HIV status-unknown partner; number of HIV-negative and HIV status-unknown sexual partners with whom the respondent reported unprotected vaginal, anal, or insertive oral sex; and number of HIV-negative and HIV status-unknown sexual partners with whom the respondent reported unprotected vaginal or anal sex. Current injection drug use behavior was too infrequent in this sample for use as an intervention outcome measure.

Analytic Approach

At each wave of data collection, unprotected sexual events were summed for each participant. We analyzed baseline unprotected sexual behaviors (both unprotected vaginal, anal, and insertive oral sexual events *and* unprotected vaginal and anal sexual events) to assess possible differences between participants who were in the intervention vs. standard-of-care control arms as well as to determine whether there were differences between participants who were retained vs. not retained across all 4 waves of data collection. Analyses of variance for continuous measures[46] and logit modeling (PROC CATMOD)[47] analyses for categorical measures[48] were conducted to examine whether pretest differences between study arms or differential attrition between arms had taken place.

To assess intervention outcomes, we modeled 2 primary measures of unprotected sexual behavior (unprotected vaginal,

anal, and insertive oral sex events *and* unprotected vaginal and anal sex events) as a function of study arm (intervention or control), time, and the study arm × time interaction. Preliminary analyses supported this approach as individual providers appeared to have no independent effects on outcomes and there were no "dosing" effects. Generalized estimating equations (GEE) were used to account for the correlated nature of the longitudinal data (ie, repeated observations across subjects)[49] as well as the Poisson distribution of our outcome measure.[50–52] In these analyses we specified a lag-1 autoregressive error structure on the repeated observations and included an overdispersion parameter to improve the fit of the model, as GEE can underestimate standard errors when overdispersion is present.[50,51]

We estimated 2 primary models, and as described earlier, one was more broadly based and the other more rigorous and conservative. The former involved total number of unprotected vaginal, anal, and insertive oral sexual events, and the latter involved total number of unprotected vaginal and anal sexual events. Moreover, we estimated 4 exploratory models (total number of unprotected vaginal, anal, and insertive oral sexual events with HIV-negative and HIV status-unknown partners; total number of unprotected vaginal and anal sexual events with HIV-negative and HIV status-unknown partners; total number of HIV-negative and HIV status-unknown partners involved in unprotected vaginal, anal, and insertive oral sexual events; and total number of HIV-negative and HIV status-unknown partners involved in unprotected vaginal and anal sexual events). These analyses employed SAS version 8.02 (SAS, Inc., Cary, NC) using the PROC GENMOD procedure, with missing observations estimated via the all-possible-pairs method associated with PROC GENMOD.[49,52,53]

RESULTS

Patient Characteristics

Between October 2000 and August 2003, 497 patients participated in this study. Research at both sites occurred over the same interval. Mean age of participants was 43 years (range: 22–70 years); 288 (58%) were male and 209 (42%) were female; 187 (38%) were African American, 174 (35%) Hispanic, and 107 (22%) were white. A total of 219 participants (44%) had some high school education; 180 (36%) had a high school diploma or equivalent; and 97 (20%) had some college education or a college degree. The majority of participants, 344 (69%), had yearly family incomes of <$10,000. Most participants had stable housing, although 39 (8%) were living in homeless shelters, on the street, or in abandoned buildings.

Self-reported routes of HIV infection (valid n = 488) included acquiring HIV through heterosexual sex (n = 223, 46%), sharing contaminated injection paraphernalia (n = 194, 40%), male same-sex contact (n = 56, 12%), and blood transfusion (n = 12, 3%). Nearly half (n = 235, 47%) of study participants reported that they had known about their HIV status for ≥10 years, and 323 of the 483 participants queried (67%) indicated that they were currently prescribed antiretroviral medications. One or more biologic measures were available for 419 participants (84%). Median CD4 count for these participants was 356 cells/mm^3, with a range of 0–1705 (SD = 308); 266 (78%) of the 342 participants for whom viral load data were available had virus detectable at ≥400 copies/mL; and >¾ (n = 228, 86%) of those with detectable viral loads had viral loads of ≥1500 copies/mL.

Baseline Unprotected Sexual Behavior

At baseline assessment, 114 (23%) of 490 participants in this HIV clinical care sample reported unprotected vaginal, anal, or insertive oral sex during the preceding 3 months (7 participants had missing values on this variable). Aggregate number of such unprotected sexual events was substantial: HIV-infected study participants reported a total of 2408 unprotected vaginal, anal, or insertive oral sexual events during the past 3 months, with 1785 of these being unprotected vaginal or anal sexual events. Aggregate number of partners involved in unprotected vaginal, anal, or insertive oral sexual events over the past 3 months was also substantial: HIV-infected study participants reported engaging in such unprotected sexual acts with a total of 351 partners during this interval.

Baseline Differences Between Intervention and Control Arms

Statistical tests were conducted to detect possible baseline differences between patients in the intervention compared with the standard-of-care control arm (Table 1). There were significant differences ($P < 0.05$) between intervention and control arm participants at baseline on race, whether participants received public assistance, whether participants had education beyond high school, route of HIV infection, CD4 counts, and whether they were prescribed antiretroviral therapy. None of these variables were associated with number of reported unprotected vaginal, anal, and insertive oral sexual events, nor were any significantly associated with the more conservative sexual risk measure (unprotected vaginal and anal sex). For completeness, we also tested a series of models in which these variables served as moderators of treatment effects on the broader and the more conservatively defined primary outcome measures, and in all cases the test of the time × condition × covariate was nonsignificant (all P values ≥0.25). Therefore, no covariates are included in any of the intervention outcome analyses.

Attrition Analyses

Of 497 patients completing baseline assessments, 490 provided complete baseline data. A total of 403 of these participants provided data at the second risk behavior assessment; 321 provided complete assessments for 3 waves of data; and 231 provided assessments at all 4 time points. Thus, a total of 1445 separate assessments were collected over the course of the study, leaving 543 missing data points. We examined the reasons for missing data, and its potential impact on the evaluation of treatment outcome, understanding that attrition in a population in which there is substantial health status, geographic, and resource instability is to be expected.[19,54,55] For the 266 participants who were unable to complete

TABLE 1. Tests for Baseline Differences Between Intervention and Control Arms

Variable	Intervention (n = 252)	Control (n = 245)	Test of Pretest Equivalence
Gender (female)	45%	39%	χ^2 (1, n = 497) = 2.13, P = 0.14
Race			χ^2 (3, n = 495) = 80.46, $P < 0.001$
African American	51%	25%	
Hispanic	17%	53%	
White	28%	15%	
Other	4%	7%	
Age	43.24 (7.5)	43.51 (7.9)	F (1,489) = 0.14, P = 0.71
Income (making ≤$10,000 per year)	72%	74%	χ^2 (1, n = 472) = 0.46, P = 0.50
Receiving welfare or public assistance	77%	63%	χ^2 (1, n = 497) = 11.07, $P < 0.001$
Education (completed high school or less)	24%	15%	χ^2 (1, n = 496) = 6.11, P = 0.01
Route of HIV Infection			χ^2 (3, n = 488) = 8.07, P = 0.04
Heterosexual sex	46%	45%	
IDU	35%	44%	
Homosexual sex	15%	10%	
Blood transfusion	4%	1%	
Sexual Orientation			χ^2 (2, n = 497) = 2.36, P = 0.31
Heterosexual	79%	77%	
Homosexual	11%	15%	
Bisexual	10%	8%	
On antiretroviral therapy	73%	60%	χ^2 (1, n = 484) = 8.04, P = 0.005
$CD4^+$ cell counts	471 (326)	368 (290)	F (1,405) = 11.232, P = 0.001
Detectable viral load	77%	79%	χ^2 (1, n = 342) = 0.194, P = 0.660

IDU, intravenous drug use.

assessments for all 4 time points, 101 (38%) terminated their care at the clinic, 70 (26%) received no further assessment because of conflicting schedules or failure to appear for scheduled visits; 43 (16%) could not complete a final assessment before the study terminated; 39 (15%) died during the study period; and a few withdrew because they were too sick to continue (3 participants, 1%), objected to the personal nature of the assessment items (3 participants, 1%), or for no stated reason (7 participants, 3%).

Attrition analyses were performed to statistically determine whether any systematic attrition by study arm had occurred. Based on these analyses, there was no differential attrition by study arm noted for either of the 2 primary baseline sexual risk behaviors (unprotected vaginal, anal, and insertive oral sexual events, or vaginal and anal events), HIV transmission route, age, gender, sexual orientation, race, education, income, or housing status (all P values >0.15). Those who dropped out of the study did not differ from those who remained on any of these factors, and attrition was also consistent within the intervention and control populations. Individuals who were engaging in risky behavior at baseline were no more likely to leave the study than those who were not and were no more likely to leave the intervention than the control arm of this research.

Intervention Outcome Analyses

Analysis of intervention impact on the broad outcome measure of total number of unprotected vaginal, anal, and insertive oral sexual events revealed a significant study arm effect (b = 0.62, SE = 0.24, P = 0.01; intervention arm participants reported more unprotected sexual events at baseline assessment than did standard-of-care control arm participants), modified by a significant study arm × time interaction ($b = -0.51$, SE = 0.15, $P < 0.001$). Notably, as can be seen in Figure 1 and Table 2, unprotected vaginal, anal, and insertive oral sexual events decreased significantly over time among HIV-infected patients who received the clinician-delivered HIV prevention intervention ($b = -0.51$, SE = 0.23, $P < 0.05$). In contrast, unprotected vaginal, anal, and insertive oral sexual events increased steadily and significantly over

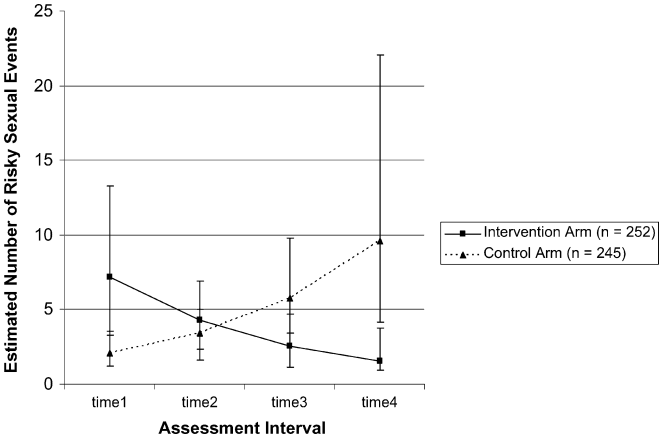

FIGURE 1. Estimated mean number of unprotected anal, vaginal, and insertive oral sexual events in intervention vs. control arms over time.

TABLE 2. Estimated Mean* Unprotected Sexual Events Within Study Arms Over Time†

Measure	Study Arm	Time 1	Time 2	Time 3	Time 4	Time by Condition	Time Effect Within Condition
Unprotected vaginal, anal, and insertive oral sexual events	Intervention	7.15 (0.31)	4.27 (0.24)	2.56 (0.31)	1.53 (0.46)	$b = -0.51$, SE = 0.15, $P < 0.001$	$b = -0.51$, SE = 0.23, $P < 0.05$
	Control	2.06 (0.28)	3.44 (0.20)	5.75 (0.27)	9.61 (0.42)		$b = 0.51$, SE = 0.19, $P < 0.01$
Unprotected vaginal and anal sexual events	Intervention	5.33 (0.35)	3.50 (0.28)	2.30 (0.33)	1.51 (0.47)	$b = -0.52$, SE = 0.16, $P = 0.002$	$b = -0.42$, SE = 0.25, $P = 0.09$
	Control	1.49 (0.29)	2.74 (0.20)	5.06 (0.28)	9.34 (0.45)		$b = 0.61$, SE = 0.21, $P < 0.01$
Unprotected vaginal, anal, and insertive oral sexual events with HIV-negative or HIV status-unknown partners	Intervention	10.56 (0.25)	8.57 (0.16)	6.96 (0.15)	5.65 (0.23)	$b = -0.22$, SE = 0.09, $P < 0.01$	$b = -0.20$, SE = 0.13, $P = 0.11$
	Control	5.66 (0.18)	7.21 (0.16)	9.19 (0.20)	11.72 (0.26)		$b = 0.24$, SE = 0.12, $P < 0.05$
Unprotected vaginal and anal sexual events with HIV-negative or HIV status-unknown partners	Intervention	8.20 (0.28)	7.16 (0.18)	6.24 (0.16)	5.45 (0.23)	$b = -0.21$, SE = 0.09, $P = 0.02$	$b = -0.14$, SE = 0.13, $P = 0.30$
	Control	4.52 (0.19)	6.00 (0.16)	7.97 (0.20)	10.58 (0.28)		$b = 0.28$, SE = 0.13, $P < 0.05$
Number of HIV-negative or HIV status-unknown partners involved in unprotected vaginal, anal, and insertive oral sexual events	Intervention	1.78 (0.31)	1.14 (0.19)	0.72 (0.14)	0.46 (0.21)	$b = -0.27$, SE = 0.16, $P = 0.09$	$b = -0.44$, SE = 0.25, $P = 0.08$
	Control	1.18 (0.34)	1.30 (0.28)	1.43 (0.34)	1.58 (0.48)		$b = 0.10$, SE = 0.20, $P = 0.62$
Number of HIV-negative or HIV status-unknown partners involved in unprotected vaginal or anal sexual events	Intervention	0.49 (0.49)	0.21 (0.25)	0.09 (0.32)	0.04 (0.60)	$b = -0.61$, SE = 0.32, $P = 0.06$	$b = -0.87$, SE = 0.58, $P = 0.14$
	Control	0.31 (0.58)	0.44 (0.38)	0.63 (0.47)	0.90 (0.75)		$b = 0.36$, SE = 0.27, $P = 0.19$

*Data derived from GEE models (see "Methods").
†Time points separated by an average 7.9 months.

time for HIV-infected patients in the standard-of-care control arm of this research ($b = 0.51$, SE = 0.19, $P < 0.01$). Note that this interaction remains significant when these analyses are performed separately for male ($P = 0.002$) and female ($P = 0.04$) patients. Means displayed in Figure 1 and Table 2 are predicted group means from the GEE analysis, with missing observations estimated via the all-possible-pairs method associated with PROC GENMOD. Trimming outliers from the control group at the final wave of measurement did not change the significance of this interaction effect.

We repeated this intervention outcome analysis with our more conservative measure, focusing on unprotected vaginal and anal sexual events only. Number of unprotected vaginal and anal sexual events showed a significant effect of study arm ($b = 0.64$, SE = 0.28, $P < 0.05$), similar to the study arm effect reported for the broader measure, and a significant study arm × time interaction ($b = -0.52$, SE = 0.16, $P = 0.002$). This interaction indicates a marginally significant reduction in unprotected vaginal and anal sex among intervention arm patients over time ($b = -0.42$, SE = 0.25, $P = 0.09$) and a significant increase in unprotected vaginal and anal sex among standard-of-care control arm patients ($b = 0.61$, SE = 0.21, $P < 0.01$). As can be seen in Table 2, unprotected vaginal and anal sexual events for HIV-infected intervention arm patients decreased steadily over the study period. In contrast, HIV-infected control arm participants showed steady increases in unprotected vaginal and anal sex over the study interval.

In additional, exploratory analyses, we examined intervention impact on number of unprotected sexual events reported with partners who were perceived to be HIV negative or HIV status unknown. For number of unprotected vaginal, anal, and oral insertive sexual events with partners perceived to be HIV negative or HIV status unknown, there was a significant study arm effect ($b = 0.31$, SE = 0.15, $P = 0.04$), similar to that reported for the broad measure reported earlier, and a significant study arm × time interaction ($b = -0.22$, SE = 0.09, $P = 0.01$). The study arm × time interaction indicates that HIV-positive intervention arm patients tended to reduce their number of unprotected vaginal, anal, and insertive oral sexual events with HIV-negative or HIV status-unknown partners over time ($b = -0.20$, SE = 0.13, $P = 0.11$). Conversely, standard-of-care control arm patients significantly increased unprotected vaginal, anal, and insertive oral sexual events with partners perceived to be HIV negative or HIV status unknown over the study interval ($b = 0.24$, SE = 0.12, $P < 0.05$) (Table 2). When conducting this analysis for the number of unprotected vaginal and anal sexual events only, with partners thought to be HIV negative or HIV status unknown, there was a marginal effect of study arm ($b = 0.30$, SE = 0.16, $P < 0.07$) and a significant study arm × time interaction ($b = -0.21$, SE = 0.09, $P = 0.02$). The pattern of this interaction indicated a nonsignificant trend for reduction in unprotected vaginal and anal sex among intervention arm patients with partners perceived to be HIV negative or unknown ($b = -0.14$, SE = 0.13, $P = 0.30$) and a significant increase in unprotected vaginal and anal sex

among standard-of-care control arm patients with partners perceived to be HIV negative or HIV status unknown (b = 0.28, SE = 0.13, $P < 0.05$) (Table 2).

Exploratory analysis of the number of partners perceived to be HIV negative or HIV status unknown with whom the patient was involved in unprotected vaginal, anal, and insertive oral sexual events did not show a study arm effect (b = 0.21, SE = 0.16, P = 0.38) but did reveal a marginal study arm × time interaction (b = −0.27, SE = 0.16, P = 0.09). The study arm × time interaction indicates a nonsignificant trend for intervention patients to decrease the number of HIV-negative and HIV status-unknown partners with whom they were involved in unprotected vaginal, anal, and insertive oral sexual events over time (b = −0.44, SE = 0.25, P = 0.08). In contrast, there was no change in the number of HIV-negative or HIV status-unknown partners involved in this type of event reported by patients in the standard-of-care control condition (b = 0.10, SE = 0.20, P = 0.62). For number of HIV-negative or status-unknown partners with whom the patient was involved in unprotected vaginal or anal sex only, no study arm effect was observed (b = 0.23, SE = 0.36, P = 0.53), although there was a trend for a study arm × time interaction (b = −0.61, SE = 0.32, P = 0.06). Whereas neither the intervention nor the standard-of-care control arm participants demonstrated significant change in the number of HIV-negative or status-unknown partners with whom they were involved in unprotected vaginal or anal sex events over time (b = −0.87, SE = 0.58, P = 0.14 and b = 0.36, SE = 0.27, P = 0.19, respectively), the direction of these effects (Table 2) was consistent with those described above. Intervention arm participants tended to reduce the number of HIV-negative and HIV status-unknown partners with whom they had unprotected vaginal or anal sex, whereas control arm participants tended to increase the number of HIV-negative and HIV status-unknown partners with whom they had unprotected vaginal or anal sex.

DISCUSSION

The current findings are among the first to demonstrate that a clinician-delivered HIV prevention intervention, implemented during the course of routine clinical care, can be effective in reducing a broad measure of HIV-infected patients' unprotected vaginal, anal, and insertive oral sexual behavior. The pattern of results reported for a more conservative and rigorous measure, involving unprotected vaginal and anal intercourse only, showed a similar trend toward a reduction in unprotected sex for HIV-positive patients in the intervention arm of this study. The current research also demonstrates that this clinician-delivered intervention approach is both feasible to implement and acceptable to patients. Numerous HIV care clinicians were readily trained in the intervention protocol, which is brief to deliver (5–10 minutes) and which was successfully implemented during the majority of patients' routine clinical visits in a high-volume, inner city HIV care setting. (For further information about the intervention development, clinician training, and intervention implementation, see Fisher et al.[42])

The clinician-delivered intervention under study resulted in a significant reduction in total unprotected vaginal, anal, and insertive oral sexual events reported by HIV-positive patients and a trend for reductions in a more conservative outcome measure of unprotected vaginal and anal sexual events only. In contrast, standard-of-care control patients showed significant increase in unprotected sexual behavior, whether defined both broadly (unprotected vaginal, anal, and insertive oral events) or conservatively (unprotected vaginal and anal sexual events). Primary analyses thus demonstrated a consistent pattern of results in which intervention participants decreased unprotected sexual events and standard-of-care control participants increased unprotected sexual activity. An identical pattern of results appeared in each of our exploratory analyses of intervention outcome. Examination of reported outcome measure means (Table 2) shows a consistent pattern of reduced unprotected sex for intervention participants and increased unprotected sex for standard-of-care controls that is repeated for each outcome measure assessed: unprotected vaginal, anal, and insertive oral sex for all partners; unprotected vaginal and anal sex for all partners; unprotected vaginal, anal, and insertive oral sex with partners perceived to be HIV negative or HIV status unknown; unprotected vaginal and anal sex with partners perceived to be HIV negative or HIV status unknown; number of HIV-negative or HIV status-unknown partners involved in unprotected vaginal, anal, or insertive oral sex; and number of HIV-negative or HIV status-unknown partners involved in unprotected vaginal and anal sex.

Although we believe our finding for an intervention-induced reduction in total unprotected vaginal, anal, and insertive oral sex events is of both statistical and clinical significance (the mean of such unprotected events declined from an estimated 7.5 per HIV-positive patient at baseline to an estimated 1.5 such unprotected events per patient at follow-up), we have no ready explanation for why statistical significance of intervention effects was inconsistent for the remaining outcome measures, other than to speculate that this is potentially an artifact reflecting a lack of power or large standard errors due to the variability of risk in the sample. Future research replicating this type of clinician-delivered intervention over time, exploring new types of interventions that can be implemented by other types of clinicians (eg, nurses, social workers), and directly assessing reasons for increases in unprotected sexual behavior among HIV-positive persons not in such interventions, is needed to strengthen our understanding of intervention impact and of the natural history of safer sexual behavior.

With the welcome success of antiretroviral therapy, there is a growing cohort of relatively healthy and long-lived HIV-infected persons who are nonetheless capable of transmitting both sensitive and antiretroviral-resistant virus to uninfected others.[7,13,30,56,57] At the same time, there is a paucity of empirically validated strategies for assisting HIV-infected persons to maintain safer sexual behavior and a lack of identified delivery channels that could effectively reach large numbers of HIV-infected persons.[12,17–19] The only published study to date involving safer sex interventions for HIV-infected patients in a clinical care setting[19] found that counseling by providers emphasizing the negative effects of unsafe sex can reduce unprotected sexual behavior in patients with high levels of risk

behavior. Taken together, the current and the existing study suggest the value of incorporating HIV prevention elements into routine clinical interactions between HIV-infected patients and providers. Because the clinical care setting provides the most universal access possible to HIV-infected persons and offers repeated opportunities for clinician–patient HIV prevention interactions,[13,14] it appears to be both desirable and potentially effective to integrate HIV care and HIV prevention. The finding that HIV-infected persons in our standard-of-care control setting significantly *increased* their unprotected sexual behavior across time is consistent with recent observations of increases in unprotected sexual behavior[58–61] and so-called safer sex fatigue among HIV-positive individuals,[62] and underscores the cost of failing to intervene and the urgency of linking HIV prevention with HIV care on a broad basis.

Limitations of the current research include the use of a limited number of clinical settings, a relatively small sample size, reliance on self-reports of unprotected sexual behavior, and characteristics of quasi-experimental research approaches. Systematic efforts were made to address and minimize each of these potential limitations. Specifically, clinical sites for the current research were chosen on the basis of their broad representativeness of high-volume, inner city HIV clinical care settings. Assessments of sexual behavior were computer based and completely confidential, and patients were directly assured that their clinical care providers would never see reports of their sexual behavior. A considerable literature, moreover, attests to the validity of reports of safer and unprotected sexual behavior.[63–66] Finally, we note that the quasi-experimental approach we adopted, deemed most appropriate to this research, resulted, as is often the case, in instances of initial nonequivalence between control and intervention research arms. Statistical tests to detect effects of such initial inequivalence clearly indicate that there was no differential effect on intervention outcome of any of the factors on which intervention and control arms initially differed, including Hispanic/Latino ethnicity or gender, age, income, being on welfare, education, sexual orientation, CD4 count, detectability of viral load, or being on highly active antiretroviral therapy. Moreover, concerns about initial nonequivalence on risk behavior are greatly lessened by the crossover interaction pattern consistently observed in our results across 4 waves of assessment and on several outcome variables.

Overall, it appears that our clinician-delivered HIV prevention intervention targeting HIV-infected patients has potential to reduce unprotected sexual behavior in this population and that consideration should be given to incorporating this type of intervention into clinical care. There has recently been a widespread call for the integration of prevention and clinical care,[13,14] and our work has demonstrated that such an approach can be both feasible and effective (see also Richardson et al[19]). Nonetheless, we recognize the importance of conducting additional research on the development and validation of means for promoting HIV prevention among HIV-infected individuals both within and outside of the clinical care setting. This research could ultimately involve large, randomized clinical trials including additional clinical sites and biologic outcomes, now that initial work has shown that this approach has promise.

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