

Is HIV/Sexually Transmitted Disease Prevention Counseling Effective Among Vulnerable Populations?

A Subset Analysis of Data Collected for a Randomized, Controlled Trial Evaluating Counseling Efficacy (Project RESPECT)

OMOTAYO O. BOLU, MBBS, MSc,* CATHERINE LINDSEY, MPH,* MARY L. KAMB, MD, MPH,* CHARLOTTE KENT, MPH,† JONATHAN ZENILMAN, MD,‡ JOHN M. DOUGLAS, JR., MD,§ C. KEVIN MALOTTE, DRPH,|| JUDY ROGERS, MS,¶ AND THOMAS A. PETERMAN, MD, MSc* FOR THE PROJECT RESPECT STUDY GROUP

Objective: The objective of this study was to evaluate counseling efficacy among high-risk groups.

Study: We conducted a subset analysis of data collected from July 1993 through September 1996 during a randomized, controlled trial (Project RESPECT). Participants (n = 4328) from 5 public U.S. sexually transmitted disease (STD) clinics were assigned to enhanced counseling, brief counseling, or educational messages. For 9 subgroups (sex, age, city, education, prior HIV test, STD at enrollment, race/ethnicity, injection drug use, exchanging sex for money/drugs), we compared STD outcomes for those assigned either type of counseling with STD outcomes for those assigned educational messages.

Results: After 12 months, all subgroups assigned counseling (brief or enhanced) had fewer STDs than those assigned educational messages. STD incidence was similar for most subgroups assigned enhanced or brief counseling. All subgroups had an appreciable number of STDs prevented per 100 persons counseled, especially adolescents (9.4 per 100) and persons with STD at enrollment (8.4 per 100).

Conclusions: HIV/STD prevention counseling (brief or enhanced counseling) resulted in fewer STDs than educational messages for all subgroups of STD clinic clients, including high-risk groups such as adolescents and persons with STDs at enrollment.

HIV COUNSELING AND TESTING have been the cornerstone of HIV prevention efforts in the United States since the development of an HIV antibody test in 1984.¹ Although HIV counseling and testing are widely supported, their efficacy for changing behaviors or preventing sexually transmitted diseases (STDs) has only recently been

*From the *Division of HIV/AIDS Prevention–Surveillance and Epidemiology, National Center for HIV, STD & TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia; †San Francisco Health Department, San Francisco, California; ‡Baltimore City Health Department and Johns Hopkins University, Baltimore, Maryland; §Denver Public Health and Colorado Department of Health and Environment, Denver, Colorado; ||Long Beach Health Department and California State University, Long Beach, California; and the ¶New Jersey Health Department, Trenton, and Newark STD Clinic, Newark, New Jersey*

demonstrated.^{2–8} Until recently, brief HIV counseling models, such as the Centers for Disease Control and Prevention's (CDC's) client-centered HIV prevention counseling model,¹ were believed to be too brief to have an effect on preventing HIV. On the other hand, longer multisession interventions, believed more likely to be effective, were often impractical in public health settings.

In 1998, results from Project RESPECT, a multicenter, randomized, controlled trial showed that CDC's brief HIV prevention counseling model and a longer enhanced HIV prevention counseling model based on behavior change theory were both effective at changing high-risk sexual behaviors and reducing new STDs.² Participants in the trial were sexually active heterosexual men and women who enrolled from 1 of 5 participating STD clinic sites.

Although overall efficacy was similar for the 2 counseling approaches (30% STD reduction at 6 months and 20% reduction at 12 months), the efficacy of counseling in subsets of vulnerable populations is not clear. Some studies suggest that the effect of counseling could be limited in women compared with men^{4,7,9–13} and that adolescents are resistant to counseling efforts.¹⁴ It is also sometimes believed that persons who have been previously HIV tested and counseled are resistant to additional counseling.^{13,15} Our objective, therefore, was to use data collected from a large prevention counseling and testing trial to estimate counseling efficacy among certain subpopulations.

Materials and Methods

Study Design and Procedures

For this subgroup analysis, we used data collected from July 1993 through September 1996 for a randomized, controlled trial of

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Informed consent was obtained from all clients participating in the study. Human experimentation guidelines of the US Department of Health and Human Services and those of participating institutions were followed in the conduct of this research.

Correspondence: Omotayo O. Bolu, MBBS, MSc, Global AIDS Program, National Center for HIV/STD and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Rd., NE, Mail Stop E-04, Atlanta, GA 30333. E-mail: obb3@cdc.gov

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counseling efficacy (Project RESPECT). The trial methods have been previously described.² In brief, the multisite study was conducted among clients attending 5 public STD clinics (Baltimore, MD; Denver, CO; Long Beach, CA; Newark, NJ; and San Francisco, CA). English-speaking clients aged 14 years or older who came for STD examinations during the study period and reported vaginal sex during the preceding 3 months were asked to participate in the study. Men who identified themselves as homosexual or who reported having had a male sex partner during the preceding 12 months were excluded.

Participants were randomized to 4 arms with varying intensities of 1-on-1 safer-sex counseling with a trained HIV counselor or clinician.

Arm 1: Enhanced Counseling. Participants (n = 1438) were assigned to receive 4 counseling sessions with a counselor (1 20-minute session followed by 3 1-hour sessions) aimed at changing attitudes, self-efficacy, social norms regarding condom use and other safe sex behaviors, as well as assisting clients to develop a realistic risk-reduction plan). The enhanced counseling model was based on behavior change theories.¹⁶

Arm 2: Brief Prevention Counseling. Participants (n = 1447) were assigned to receive 1 20-minute session (which included a personalized risk assessment aimed at developing an incremental, realistic behavior change step) followed by a second 20-minute session conducted when HIV test results were provided 7 to 10 days later. Based on successes or challenges to the behavior change step negotiated in the first session, a risk-reduction plan was developed in the second session. This counseling model was based on CDC's client-centered HIV counseling, first recommended for use with HIV testing in 1993.¹

Arm 3: HIV Prevention Education. Participants (n = 1443) were assigned to receive 2 didactic sessions with a clinician. The first session (5 minutes) was a brief, personalized educational message about HIV and STD; the second posttest counseling session (5 minutes) was another personalized educational message when HIV test results were provided. This session was a standardized version of the educational messages that were typically provided with HIV testing at the time of the trial.

Arm 4: HIV Prevention Education. Participants (n = 1430) were assigned to receive the same intervention as those in arm 3, but because arm 4 was developed to measure only the behavioral and STD prevention efficacy of repeated interviews, these participants were not followed.

Participants in arms 1, 2, and 3 were actively followed and asked to respond to questionnaires at 3, 6, 9, and 12 months and be tested for STDs at 6 and 12 months after enrollment. All participants could return at any time for an STD examination if they wanted a checkup, had symptoms, or had a partner with symptoms. Because arm 4 participants had no scheduled follow up and did not consistently undergo screening, they were excluded from this analysis.

At the enrollment visit, participants were interviewed to obtain information on sociodemographic characteristics, sexual behavior, and STD history. Genital examinations and laboratory testing for STDs were performed for all participants. The main outcomes were self-reported condom use, number of sex partners, and incident STDs defined by laboratory tests. For STD outcomes, infection with *Neisseria gonorrhoea* was defined as a positive culture or, for men, Gram-negative intracellular diplococci on a Gram stain of a urethral swab; *Chlamydia trachomatis* was defined as a positive polymerase chain reaction assay result for endocervical swabs

(women) and urine samples (men). Syphilis was diagnosed on the basis of suggestive history and physical examination with supportive treponemal and nontreponemal antibody test results. HIV infection was diagnosed as repeatedly reactive enzyme immune assay results for HIV antibody with a confirmatory test result. The Project RESPECT protocol was reviewed and approved by the Institutional Review Boards at the CDC and each participating site.

Subset Analysis

For this analysis, we used an intent-to-treat approach; that is, data on all participants were included in the analysis, regardless of whether they completed their assigned intervention. We stratified participants on 9 subgroups. Five a priori subgroups were identified in the study's initial protocol: 1) sex (male, female); 2) age (<20, 20–25, >25 years); 3i) site (Baltimore, Denver, Newark, Long Beach, San Francisco); 4) (intravenously) STD diagnosis at enrollment (no, yes); and 5) report at enrollment of a prior HIV test (no, yes). These subgroups were selected because there could be differences in counseling efficacy for these subgroups. Four additional subgroups that were not considered a priori were included because recent literature or experience of principal investigators suggested a possible effect on counseling, and these are considered as more exploratory. The additional 4 subgroups considered later included: 5) race/ethnicity (black, white, Hispanic, other); 6) education (<12th grade, 12th grade, >12th grade); 7) reported history of injection drug use (never, ever); and 8) reported history of exchanging sex for money or drugs (never, ever).

Statistical Analyses

The outcome of interest was STD incidence, based on laboratory diagnosis during the 12 months after the date of enrollment. We used SAS software version 8.2 (SAS Institute, Inc., Cary, NC) for statistical analysis. For each subgroup, we estimated the STD incidence during the 12 months after intervention and compared interventions using chi-squared tests and odds ratios (ORs) with 95% confidence intervals (CIs). The sample size for the trial was chosen to detect overall differences in interventions but not differences in specific subgroups. Thus, statistically significant differences were not expected because the sample size was too small for most subgroups. To control for potential confounding effects, we used multiple logistic regressions and created separate models for each of the subgroups. We entered potential confounders (the other subgroups) into each model and determined the adjusted ORs and 95% CI. To determine the number of STDs prevented per year per 100 persons counseled for each subgroup, we subtracted STD incidence in the counseling interventions from that in the educational intervention.

Results

From July 1993 through June 1995, 13,471 eligible clients were asked to participate in Project RESPECT, and 5833 (43%) agreed to enroll. Those who participated and those who refused to participate in Project RESPECT were similar in age, racial/ethnic background, and education level, although compared with those who refused, participants were more likely to be women (OR, 1.49; 95% CI, 1.44–1.55), to have had an STD at enrollment (OR, 1.19; 95% CI, 1.14–1.24), and to have been previously tested for HIV (OR, 1.13; 95% CI, 1.08–1.18).² After excluding clients with positive HIV test results at enrollment (n = 75) and arm 4 participants who did not routinely receive STD screening (n = 1430), 4328 enrollees remained for the subset analysis.²

Of 4328 participants in the subset analysis, 2457 (57%) were

TABLE 1. STD Incidence by Subgroup and Intervention

Subgroup	Intervention					
	Enhanced (n = 1438) Counseling		Brief (n = 1447) Counseling		Educational (n = 1443) Messages	
	STD Incidence [†]		STD Incidence		STD Incidence	
	No.	Percent	No.	Percent	No.	Percent
Sex						
Male	815	11.4	824	12.6	818	14.3
Female	623	11.6	623	11.1	625	15.0
Age (yrs)						
<20 (adolescents)	256	17.2	252	17.5	256	26.6
20–25	473	13.1	501	13.8	494	14.8
>25	709	8.3	694	8.7	693	10.1
Race						
White	266	3.4	274	6.9	277	7.6
Black	875	15.3	835	15.5	873	18.7
Hispanic	202	7.0	258	7.8	215	8.4
Others	93	8.6	80	6.3	78	11.5
Education (grade)						
<12th	428	13.8	389	14.9	421	19.2
12th	586	12.4	622	13.2	622	15.3
>12th	424	7.8	436	7.5	400	8.8
Prior HIV test						
No	386	11.4	414	11.1	437	14.7
Yes	1041	11.6	1029	12.3	1001	14.7
STD at enrollment						
No	1010	7.6	1040	7.5	1065	9.7
Yes	428	20.6	407	23.3	378	28.6
Exchange of sex for money/drugs						
Never	1135	11.4	1141	12.7	1135	14.5
Ever	292	12.3	297	9.4	300	15.3
Injection drug use						
Never	1318	11.6	1332	12.4	1312	15.2
Ever	109	11.0	104	7.7	122	9.8
Site						
Baltimore	271	12.5	274	11.7	277	19.1
Denver	349	9.5	348	8.9	349	11.8
Long Beach	264	10.2	270	10.7	264	12.1
Newark	295	20.0	297	22.6	291	21.3
San Francisco	259	4.6	258	5.4	262	8.8

STD = sexually transmitted disease.

*No. indicates number of participants in each subgroup.

[†]STD incidence indicates percentage of participants with an STD in each subgroup.

male and 1871 (43%) were female. Participants were mostly young (median age, 25 years) and of minority race/ethnicity (59% black, 19% white, 16% Hispanic, 6% other races). Less than one third had an education beyond high school (12th grade). Most participants had had a prior HIV test (71%), did not have an STD at enrollment (73%), had never exchanged sex for money or drugs (79%), had never injected drugs (92%), and completed all intervention sessions for their assigned study arm (80%). This overall distribution was similar for participants in each intervention group (Table 1) except for intervention completion rates, which were higher for participants assigned to brief counseling than for those assigned to enhanced counseling.

During the 12-month follow-up period, 549 (13%) of the participants had new STDs: 7.3% had chlamydia, 6.3% gonorrhea, 0.6% syphilis, and 0.2% HIV. Some participants had multiple diagnoses.

For nearly every subgroup analyzed, there were fewer incident STDs among those in the enhanced and brief counseling groups

than those in the educational messages group (Table 1). In subgroups by age, for example, 68 (26.6%) adolescents (<20 years old) assigned to the educational intervention had new STDs compared with 44 (17.2%) assigned to enhanced counseling (OR, 0.57; 95% CI, 0.37–0.90), and 44 (17.5%) assigned to brief counseling (OR, 0.58; 95% CI, 0.37–0.92). Similarly, older participants (>20 years old) assigned to enhanced and brief counseling interventions had fewer STDs than those assigned to the educational intervention (Table 1). In subgroups by sex, 117 (14.3%) men assigned to the educational intervention had new STDs compared with 92 (11.4%) men assigned to enhanced counseling (OR, 0.77; 95% CI, 0.57–1.04) and 104 (12.6%) men assigned to brief counseling (OR, 0.84; 95% CI, 0.63–1.12). The findings were similar for women.

All other subgroups assigned counseling interventions (enhanced or brief) also had fewer STDs than those assigned educational messages (Table 1). In crude analysis, differences between brief counseling and educational messages were statistically significant ($P < 0.05$) for adolescents, persons from Baltimore, and persons who had ever

TABLE 2. Multivariate Analysis Comparing STD Incidence by Intervention in Each Subgroup

Subgroup	Enhanced Counseling vs. Educational Messages	Brief Counseling vs. Educational Messages	Enhanced Counseling vs. Brief Counseling
	OR (95% CI)	OR (95% CI)	OR (95% CI)
Sex			
Male	0.73 (0.53–1.01)	0.76 (0.56–1.04)	1.0 (0.70–1.34)
Female	0.76 (0.53–1.08)	0.73 (0.51–1.04)	1.0 (0.71–1.50)
Age (years)			
<20 (adolescent)	0.54 (0.33–0.88)*	0.53 (0.32–0.86)*	1.1 (0.63–1.78)
20–25	0.82 (0.56–1.2)	0.91 (0.62–1.3)	0.9 (0.60–1.32)
>25	0.79 (0.54–1.16)	0.78 (0.53–1.13)	1.0 (0.70–1.55)
Race			
White	0.41 (0.18–0.95)*	0.84 (0.42–1.65)	0.57 (0.24–1.37)
Black	0.78 (0.60–1.0)	0.72 (0.55–0.96)*	1.0 (0.80–1.38)
Hispanic	0.69 (0.30–1.5)	0.71 (0.35–1.48)	0.97 (0.46–2.50)
Others	0.65 (0.19–2.1)	0.46 (0.12–1.81)	1.1 (0.17–7.1)
Education (grade)			
<12th	0.79 (0.53–1.19)	0.73 (0.50–1.1)	1.1 (0.7–1.64)
12th	0.69 (0.48–0.99)	0.74 (0.52–1.04)	0.94 (0.65–1.34)
>12th	0.79 (0.46–1.34)	0.78 (0.46–1.32)	0.95 (0.55–1.63)
Prior HIV test			
No	0.76 (0.48–1.2)	0.73 (0.47–1.14)	1.0 (0.66–1.71)
Yes	0.75 (0.57–1.0)	0.76 (0.58–1.0)	0.96 (0.72–1.3)
STD at enrollment			
No	0.86 (0.63–1.19)	0.77 (0.56–1.05)	1.1 (0.78–1.53)
Yes	0.64 (0.45–0.91)*	0.70 (0.50–1.0)	0.90 (0.63–1.3)
Exchange sex for money/drugs			
Never	0.74 (0.56–0.97)	0.83 (0.64–1.1)	0.90 (0.68–1.17)
Ever	1.45 (0.83–2.52)	0.50 (0.29–0.85)*	1.45 (0.83–2.52)
Injection drug use			
Never	0.73 (0.60–0.94)*	0.76 (0.60–1.00)	1.0 (0.74–1.22)
Ever	1.4 (0.50–3.87)	0.40 (0.11–1.49)	3.9 (0.97–15.5)
Site			
Baltimore	0.67 (0.39–1.12)	0.57 (0.34–0.95)*	1.2 (0.67–2.0)
Denver	0.76 (0.45–1.28)	0.74 (0.44–1.26)	1.1 (0.64–1.9)
Long Beach	0.92 (0.51–1.64)	0.94 (0.53–1.66)	1.0 (0.53–1.73)
Newark	0.78 (0.50–1.22)	0.94 (0.61–1.44)	0.85 (0.56–1.3)
San Francisco	0.53 (0.24–1.16)	0.55 (0.26–1.15)	1.0 (4–2.3)

*Significant $P < 0.05$.

STD = sexually transmitted disease; OR = adjusted odds ratio; CI = confidence interval; HIV = human immunodeficiency virus.

exchanged sex for money or drugs. Similarly, differences between those in the enhanced counseling groups and the educational messages group were significant only for persons who never inject drugs and persons with an STD at enrollment.

When we conducted our multivariate analysis by controlling for potential confounders using separate models for each of the subgroups, the adjusted ORs (Table 2) were similar to the crude ORs for most subgroups, suggesting there was little confounding in the groups we compared. The subgroups that had had statistically significant differences in STD incidence in the crude analyses also had statistically significant differences in the adjusted (multivariate) analyses (Table 2). In addition, significant differences in STD incidence were found between blacks in the brief counseling group compared with blacks in the educational messages group (Table 2). Overall, statistically significant differences between counseling (brief or enhanced) and educational messages were observed for adolescents, persons from Baltimore, persons who exchange sex for money or drugs, persons with STD at enrollment, persons who never inject drugs, and blacks (Table 2).

For most subgroups, the efficacy of brief counseling was similar to enhanced counseling (Table 1), with crude and adjusted ORs at or near 1.0 (Table 2). There were a few possible exceptions, although the differences were not statistically sig-

nificant. Participants who were white and who were assigned to enhanced counseling had fewer STDs than those who were assigned to brief counseling (OR, 0.57) (Table 2). Conversely, persons who reported having ever exchanged sex for money and/or drugs (OR, 1.45) and persons who had reported having ever injected drugs (OR, 3.9) had more STDs if they were assigned to the enhanced counseling group than to the brief counseling group (Table 2).

The numbers of STDs prevented per 100 persons counseled were appreciable for most subgroups assigned to brief and enhanced counseling (Table 3), particularly adolescents (9.4) and persons with an STD at enrollment (8.4). The subgroups with greater numbers of STDs prevented had the highest STD incidence overall: persons with STD at enrollment (24%), adolescents (20%), and blacks (16.5%).

Discussion

Our findings in this study were unexpected. HIV/STD prevention counseling (brief or enhanced) resulted in fewer STDs for many subgroups for whom counseling was not found to be effective previously, including adolescents,¹⁴ persons who had an STD,^{17–19} and blacks.^{13,20} We also found counseling had similar

TABLE 3. Number of STDs Prevented per 100 Persons Assigned to Enhanced and Brief Counseling, by Subgroup

Subgroup	No. of STDs Prevented per 100 Persons Counseled*	
	Enhanced Counseling	Brief Counseling
Sex		
Male	2.9	1.7
Female	3.4	3.9
Age (yrs)		
<20 (adolescent)	9.4	9.1
20–25	1.7	1.0
>25	1.4	1.3
Race		
White	4.2	0.7
Black	3.4	3.2
Hispanic	1.4	0.6
Others	2.9	5.2
Education (grade)		
<12th	5.4	4.3
12th	2.9	2.1
>12th	1.0	1.3
HIV test		
No	3.3	3.6
Yes	3.1	2.4
STD at enrollment		
No	2.1	2.2
Yes	8.0	5.3
Exchange of sex for money/drugs		
Never	3.1	1.8
Ever	3.0	5.9
Injection drug use		
Never	3.6	2.8
Ever	–1.2	2.1
Site		
Baltimore	6.6	7.4
Denver	2.3	2.9
Long Beach	1.9	1.4
Newark	1.3	–1.3
San Francisco	4.2	3.4

STD = sexually transmitted diseases; HIV = human immunodeficiency virus.

*Calculated by subtracting STD incidence in education—STD incidence in counseling.

efficacy for women and men, although earlier studies have suggested that counseling could be of limited value for women.^{4,11,12,17,21} However, some of these earlier studies^{11,12,16} were based on reported behavior change rather than incident STDs. These differences could be because our study measured STD incidence, whereas the others measured sexual behaviors; these 2 outcomes are not always highly correlated.²² An interesting finding was that the brief interactive counseling was similar to enhanced counseling in reducing new STDs for most (92%) subgroups. This was also observed among all participants in the original trial (Project RESPECT), but we did not expect this to be the case for all subgroups. Studies have suggested that certain groups such as adolescents^{14,20} and persons with STDs or repeated STDs could require multisession counseling. This could occur because people with repeat STDs are sometimes characterized as recidivists and being resistant to using condoms or reducing risky behaviors.^{19,21} Adolescents have also been characterized as needing specialized counseling^{14,20} because of their high-risk behaviors and particular vulnerabilities (eg, peer pressure, lack of knowledge). Some re-

searchers have hypothesized that some women might not insist on condom use with male partners or engage in other safe sex practices as a result of power imbalances and the need to minimize disruption in their relationships.^{23–26} People who have been previously counseled and tested for HIV are sometimes believed not to benefit from additional counseling (even though many are engaging in high-risk behaviors). Our results suggest otherwise; most participants (regardless of situation) benefited more from the enhanced counseling or the brief risk-reduction counseling than from the educational messages. The brief counseling approach and the enhanced counseling approach both prevented similar numbers of STDs, regardless of subgroup.

However, there were a few exceptions, in which the STD reduction in brief counseling was more than in enhanced counseling for persons who exchanged sex for money or drugs and who used injection drugs. This was particularly surprising because conventional thinking is that multiple interventions are required to change highly evolved, long-practiced behaviors. These differences were not statistically significant and could have been the result of chance. On the other hand, ours is not the first study showing that brief intervention can benefit such high-risk individuals; one recent study found that a brief intervention for changing risky behaviors among injection drug users was as effective as a longer session.²⁷ Another study among patients who abused alcohol found that a brief, motivational intervention was as effective as a longer intervention in achieving alcohol cessation.²⁸ Furthermore, a recent metaanalysis on the effect of HIV prevention interventions on the sex behaviors of drug users in the United States found that additional sessions did not appear to increase the effect of the interventions.²⁹

To determine which subgroups would benefit most from prevention counseling, we calculated the number of STDs prevented per 100 persons counseled; an appreciable number of STDs were prevented for all subgroups. However, more STDs were prevented for adolescents and persons with an STD at enrollment than for participants in other subgroups. These 2 subgroups had the highest STD incidence in this trial and also benefited the most from the counseling interventions; thus, those at highest risk benefited the most from counseling.

Our study has some limitations. First, the study was powered to detect differences between interventions and not differences among specific subgroups; thus, we had insufficient sample size in most subgroups to ensure that suggestive findings were statistically significant, so some findings could have been the result of chance. Second, because the eligibility criteria for the study required that all participants get HIV counseling and testing, we do not know if those who refused to enroll were less receptive to counseling than those who agreed to be in the study; this could limit generalizability. Third, because HIV seroconversions were unusual, it is not certain the STD reduction found with counseling would hold true for HIV. Fourth, because we studied subgroups in STD clinics, we do not know if the findings are generalizable to other settings such as private clinics or adolescent clinics. Finally, not all subgroups assessed in the subset analysis were considered a priori; findings from post-hoc subset analysis should be interpreted with caution. This is true especially if the intervention might influence whether a participant becomes a member of a particular subgroup.³⁰ In this analysis, the subgroups that were not considered a priori (education, race/ethnicity, history of exchanging sex for money or drugs, and history of injection drug use) were clearly defined groups that were determined from baseline data and unrelated to the intervention assignment.

In summary, the results of our subset analysis indicate that HIV/STD prevention counseling prevents new STDs for almost all

types of STD clinic clients. More importantly, the counseling interventions prevented new STDs for many subgroups commonly felt to be resistant to counseling such as adolescents, persons who already have an STD, blacks, persons who have been previously tested for HIV, injection drug users, and persons who exchange sex for money or drugs. Both counseling interventions had similar efficacy for women and men. These results have important implications for STD programs. Counseling clients in STD clinics can contribute significantly to reducing new STDs if counselors use interactive, risk-reduction counseling that engages clients in an exploration of personal risk and encourages them to develop and commit to a realistic, risk-reduction plan. Clinics with limited resources could focus on members of the 2 groups that benefited the most from counseling: adolescents and persons with an STD. Ideally, interactive risk-reduction counseling approaches would be provided to all persons because counseling is beneficial to all subgroups of STD clinic clients.

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