Efficacy of Risk-Reduction Counseling to Prevent Human Immunodeficiency Virus and Sexually Transmitted Diseases

A Randomized Controlled Trial

Mary L. Kamb, MD, MPH; Martin Fishbein, PhD; John M. Douglas, Jr, MD; Fen Rhodes, PhD; Judy Rogers, MS; Gail Bolan, MD; Jonathan Zenilman, MD; Tamara Hoxworth, PhD; C. Kevin Malotte, DrPH; Michael Iatesta, MA; Charlotte Kent, MPH; Andrew Lentz, MPA; Sandra Graziano, PhD; Robert H. Byers, PhD; Thomas A. Peterman, MD, MSc; for the Project RESPECT Study Group

Context.—The efficacy of counseling to prevent infection with the human immunodeficiency virus (HIV) and other sexually transmitted diseases (STDs) has not been definitively shown.

Objective.—To compare the effects of 2 interactive HIV/STD counseling interventions with didactic prevention messages typical of current practice.

Design.—Multicenter randomized controlled trial (Project RESPECT), with participants assigned to 1 of 3 individual face-to-face interventions.

Setting.—Five public STD clinics (Baltimore, Md; Denver, Colo; Long Beach, Calif; Newark, NJ; and San Francisco, Calif) between July 1993 and September 1996.

Participants.—A total of 5758 heterosexual, HIV-negative patients aged 14 years or older who came for STD examinations.

Interventions.—Arm 1 received enhanced counseling, 4 interactive theory-based sessions. Arm 2 received brief counseling, 2 interactive risk-reduction sessions. Arms 3 and 4 each received 2 brief didactic messages typical of current care. Arms 1, 2, and 3 were actively followed up after enrollment with questionnaires at 3, 6, 9, and 12 months and STD tests at 6 and 12 months. An intent-to-treat analysis was used to compare interventions.

Main Outcome Measures.—Self-reported condom use and new diagnoses of STDs (gonorrhea, chlamydia, syphilis, HIV) defined by laboratory tests.

Results.—At the 3- and 6-month follow-up visits, self-reported 100% condom use was higher (P < .05) in both the enhanced counseling and brief counseling arms compared with participants in the didactic messages arm. Through the 6-month interval, 30% fewer participants had new STDs in both the enhanced counseling (7.2%; P = .002) and brief counseling (7.3%; P = .005) arms compared with those in the didactic messages arm (10.4%). Through the 12-month study, 20% fewer participants in each counseling intervention had new STDs compared with those in the didactic messages arm (P = .008). Consistently at each of the 5 study sites, STD incidence was lower in the counseling intervention arms than in the didactic messages intervention arm. Reduction of STD was similar for men and women and greater for adolescents and persons with an STD diagnosed at enrollment.

Conclusions.—Short counseling interventions using personalized risk reduction plans can increase condom use and prevent new STDs. Effective counseling can be conducted even in busy public clinics.
viation depend on reliable efficacy data, preferably based on the results of well-conducted randomized controlled trials measuring disease outcomes. However, there are limited data supporting the impression that current HIV prevention strategies, including HIV/STD counseling, are effective in reducing new infections. In the case of HIV counseling, studies that have attempted to evaluate counseling efficacy have been limited by inadequate experimental designs, interventions, and outcomes.

Considerable debate has occurred on the content and duration of counseling necessary to achieve meaningful change in risk behaviors. Many HIV counseling programs focus on collecting risk data and providing general information about HIV/AIDS. However, a number of health professionals have argued that, for greatest benefit, counseling should be an interactive process aimed at personal risk reduction. Brief intervention strategies have been successfully applied in behavioral interventions for other health risks such as alcohol use, but other experts maintain that changing sex behaviors requires multiple (ie, ≥10) intervention sessions.

Project RESPECT was a randomized controlled trial specifically designed to assess the efficacy of HIV prevention counseling in reducing high-risk sexual behaviors and preventing new sexually transmitted infections. We studied counseling approaches believed by experts to have the highest likelihood for success and, thus, evaluated risk reduction counseling models that used an interactive process between counselor and client. We were also concerned about feasibility and coverage of the interventions, and thus, we studied interventions that were acceptable to participants and able to be replicated in busy public clinic settings. This project evaluated one-on-one HIV/STD prevention counseling models—one with 4 sessions (200 minutes total) and the other with 2 sessions (40 minutes total). We compared the counseling models with each other and with brief, didactic messages that approximate the one-on-one prevention approach typically used in STD clinics and other HIV test sites.

METHODS

Study Design

The trial was conducted from July 1993 through September 1996 among patients from public, inner-city STD clinics in Baltimore, Md; Denver, Colo; Long Beach, Calif; Newark, NJ; and San Francisco, in collaboration with the Centers for Disease Control and Prevention (CDC), Atlanta, Ga. Eligible participants were HIV-negative men and women aged 14 years or older who came to one of the clinics for a full diagnostic STD examination and agreed to have an HIV test. Men who reported having a male sex partner in the past 12 months or who identified themselves as bisexual or homosexual were excluded from the study. All potential participants whose command of English would limit full participation in the interventions and those who had declined to participate in the study at earlier clinic visits were excluded also. All participants gave written, informed consent, and the institutional review boards at each site reviewed and approved the protocol.

Participants were assigned randomly to 1 of 4 intervention arms (Figure 1). Those assigned to arms 1, 2, or 3 were asked to return for follow-up appointments 3, 6, 9, and 12 months after enrollment. We included arm 4 to assess the possible intervention effects of repeated follow-up contacts, because it was speculated that these might be of sufficient magnitude to obscure differences between the interventions. Arm 4 participants had no follow-up visits scheduled after the intervention but results for syphilis and gonorrhea tests (routinely done at all 5 clinics) were obtained each time they voluntarily returned to the clinic during the 12-month study interval. To assess the effects of repeated contact, we excluded from the analysis STDs diagnosed for arm 3 participants at study-prompted follow-up visits, and we compared participants in arm 3 with arm 4 on the proportion for whom syphilis or gonorrhea was diagnosed at voluntary (unscheduled) visits. In addition, 12 months after enrollment, arm 4 participants were sought and, if located, interviewed. Their recent condom use was compared with arm 3 participants.

Randomization

Random assignment took place after enrollment and before the baseline interview and examinations. Allocation concealment procedures were defined by protocol and complied with published recommendations. A data management company provided each site with computer-generated random assignments. To ensure the numbers in arms were roughly equal, random assignments were made within blocks that varied in size from 4 to 20 and were done separately for men and women at each site. Once a number was assigned, it was not reassigned even if participants dropped out of the study.

Figure 1.—Study visits were calculated from the enrollment date to occur at 3-month intervals. The first visit occurring during each calculated 3-month interval was considered as the follow-up visit. For the first follow-up visit (3-month visit), the interval began 7 days before the calculated date 3 months after enrollment and may have occurred up to 7 days before the calculated date 6 months after enrollment. HIV indicates human immunodeficiency virus.
Interventions

Participants were assigned to 1 of 3 individual face-to-face HIV prevention strategies that each involved an HIV test. All interventions encouraged consistent condom use for vaginal and anal sex with all partners; however, interventions were tailored to each individual’s personal risks.20 For arm 1, the 4 sessions were completed within 4 weeks of enrollment. For arms 2, 3, and 4, both sessions were completed within 10 days. Whenever possible, the same counselor conducted all of a participant’s sessions. The counselor conducting an intervention never collected outcome data for that participant. No interactive counseling was provided at follow-up visits; however, regardless of assigned intervention, whenever HIV tests were obtained counselors provided brief information about the test and answered any questions.

Patients assigned to arm 1 received enhanced counseling.20 This 4-session intervention, based on the theory of reasoned action and social cognitive theory,14-16 sought to change key theoretical elements (eg, self-efficacy, attitudes, and perceived norms) underlying condom use. Session 1 lasted 20 minutes and was conducted during the initial clinic visit; the remaining sessions were 60 minutes each. Test results for HIV were given during session 3. Each session built on lessons from the preceding session. The first 3 sessions concluded with a behavioral goal-setting exercise in which the participant arrived at a small behavioral risk-reduction step that could be achieved before the next session. At the final session, a longer-term, risk-reduction plan for each participant was agreed on.

Participants assigned to arm 2 received brief counseling, a 2-session intervention modeled after CDC’s recommended HIV counseling for patients attending public clinics and HIV test sites.17,18 Session 1 (20 minutes) was conducted during the initial clinic visit and was identical to the first session of enhanced counseling. Session 2 (20 minutes) included a discussion of the HIV test result as well as additional counseling. The objectives of brief counseling were to assess actual and self-perceived HIV/STD risk, to help the participant recognize barriers to risk reduction, to negotiate an acceptable and achievable risk-reduction plan, and to support patient-initiated behavior change. The first session concluded with a behavioral goal-setting exercise in which the participant arrived at a small risk-reduction step that could be achieved before the second session. At the second session, progress in completing the behavioral step was reviewed, barriers and facilitators to completing the behavioral step were discussed, and a longer-term risk-reduction plan was developed.

Participants assigned to arms 3 and 4 received didactic messages. This 2-session informational intervention was designed to approximate what was being done in most STD clinics.10 Two brief messages about HIV and STD prevention were delivered, explicitly not engaging the participant in interactive counseling. Session 1 (5 minutes) was conducted by the clinician who had examined and treated the participant during the STD clinic visit. In session 2 (5 minutes), participants were informed about their HIV test results and limitations of the test and were given didactic prevention messages about HIV and STD pertinent to their reported risks. Participants were asked whether they had questions.

To ensure the quality and consistency of interventions, counselors and clinicians received a standard training course from a single trainer, used structured intervention protocols, and had routine observation and feedback by on-site supervisors and an outside observer who traveled to all sites (6% of the sessions were observed). In addition, process evaluations assessing intervention content and client satisfaction with the interventions were performed periodically by surveying participants, counselors, and clinicians.20

Study Outcomes

Principal outcomes were defined before the trial. Incident STDs were defined by laboratory tests, with gonorrhea defined as a positive culture for Neisseria gonorrhoeae or, for men, gram-negative intracellular diplococci on a Gram stain of a urethral swab; chlamydia as a positive Chlamydia trachomatis polymerase chain reaction from an endocervical (women) or a urine (men) specimen; syphilis as a suggestive history and physical examination with supportive treponemal and nontreponemal antibody test results; and HIV infection as a repeatedly reactive enzyme immune assay for HIV antibody with a positive confirmatory test result. Study clinicians collected specimens necessary for each of these tests from participants assigned to arms 1, 2, or 3, at the baseline, at 6- and 12-month visits, and at all voluntary (unscheduled) clinic visits. Specimens were also obtained at 3- and 9-month visits if participants or their sex partners had symptoms of an STD or if participants requested tests. Study clinicians used standard procedures to collect the study specimens and used an order specified by protocol. Specimen collection procedures were periodically monitored. Arm 4 participants returning to the clinic during a self-initiated visit underwent only tests routinely performed at the clinic.

Incentives

For intervention sessions, participants were offered free condoms at every visit and $15 for each session attended after the first session (ie, for enhanced counseling, a maximum of $45, and for brief counseling and didactic messages, a maximum of $15). For collection of outcome data, participants who returned for scheduled follow-up visits were offered $15 for each questionnaire and $25 for each STD examination. No incentives were given for voluntary (unscheduled) STD examinations, including those completed at the 3- and 9-month visits.

Data Analysis

Assuming 15% per year cumulative incidence of STD among didactic messages participants,20 we calculated a recruitment goal of 6000 (1500 per arm) for 80% power to detect a 25% reduction in STDs between counseling and control arms. For preliminary analyses of principal outcomes, analysts were blinded to intervention arm. For all analyses, any patient as...
signed a random number was included except for 75 persons whose baseline HIV test result was positive (Figure 1). Outcome analyses were performed using data on all participants, whether or not they completed their assigned intervention (intent to treat).20,21 For STD outcomes, we compared the cumulative percentage of participants with any STD from enrollment until the end of a specified visit interval. For behavioral outcomes, we compared the proportion of subjects reporting the behavior during the 3 months before each scheduled visit. For behavioral outcomes, we compared the proportion of subjects reporting the behavior during the 3 months before each scheduled visit. Return for follow-up visits every 3 months, 71% returned for the 3-month, 70% for the 6-month, 64% for the 9-month, and 66% for the 12-month visits. Of all 4328 participants, 51% returned for at least 1 of the 4 follow-up visits; 73% for at least 2 visits; 63% for 3 visits; and 51% for all 4 scheduled visits. Return for follow-up visits did not differ significantly between intervention arms.

### RESULTS

#### Participants

From July 1993 through June 1995, 13,471 eligible patients were invited, and 5833 (43%) agreed to participate. After excluding 75 patients with positive baseline HIV test results, there were 3269 men and 2489 women (Figure 1). Study participants resembled the clinics’ total populations in that they were young (median age, 25 years), minority (50% black, 19% Hispanic, 16% white, 6% other races), and low income (54% unemployed, 42% with annual income < $20,000). Study participants and those who had refused were similar in age, racial and ethnic background, and education (median, 12 years). But compared with those who had refused, participants were more likely to be women (relative risk [RR], 1.12; 95% CI, 1.08-1.17) and to have been previously tested for HIV (RR, 1.14; 95% CI, 1.09-1.18). The intervention arms were similar at baseline with respect to demographic characteristics, risk behaviors, condom use, and STD diagnoses at enrollment (Table 1).

### Coverage at Follow-up Visits

Of the 4328 participants assigned to follow-up visits every 3 months, 71% returned for the 3-month, 70% for the 6-month, 64% for the 9-month, and 66% for the 12-month visits. Of all 4328 participants, 51% returned for at least 1 of the 4 follow-up visits; 73% for at least 2 visits; 63% for 3 visits; and 51% for all 4 scheduled visits. Return for follow-up visits did not differ significantly between intervention arms.

### Intervention Adherence

Of 5758 patients enrolled, 82% completed all assigned intervention sessions. Completion was lower ($P<.001$) for those in the 4-session enhanced counseling arm (72%) than for those in either of the 2-session interventions (brief counseling, 85%; didactic messages, 85%). For the enhanced counseling arm, 99% of participants completed the first session, 80% completed the second session, 72% completed the third session, and 72% completed all 4 sessions. Regardless of assignment, most participants (>85%) surveyed about the interventions reported that the sessions were “informative,” “good,” and “helpful.”

### Table 1.—Baseline Characteristics of Participants According to Intervention Arm (N = 5758)*

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Arm 1 Enhanced Counseling (n = 1438)</th>
<th>Arm 2 Brief Counseling (n = 1447)</th>
<th>Arm 3 Didactic Messages (n = 1443)</th>
<th>Arm 4 Didactic Messages (n = 1430)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>43</td>
<td>43</td>
<td>43</td>
<td>43</td>
</tr>
<tr>
<td>Male</td>
<td>57</td>
<td>57</td>
<td>57</td>
<td>57</td>
</tr>
<tr>
<td>Site, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baltimore, Md</td>
<td>19</td>
<td>19</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td>Denver, Colo</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>Long Beach, Calif</td>
<td>18</td>
<td>19</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Newark, NJ</td>
<td>21</td>
<td>21</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>San Francisco, Calif</td>
<td>18</td>
<td>18</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Report of previous HIV test, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STD at enrollment, %</td>
<td>33</td>
<td>31</td>
<td>30</td>
<td>33</td>
</tr>
<tr>
<td>STD at enrollment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injected drugs, %</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Ever had a sex partner who had injected drugs, %</td>
<td>16</td>
<td>14</td>
<td>14</td>
<td>18</td>
</tr>
<tr>
<td>Ever had a known HIV-positive sex partner, %</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Ever gave (men) or took (women) money for sex, %</td>
<td>8</td>
<td>7</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Sex partners last 3 mo, mean/median No.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>12</td>
<td>13</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex partners last 3 mo, mean/median No.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At least 1 new sex partner in last 3 mo, %</td>
<td>49</td>
<td>46</td>
<td>48</td>
<td>48</td>
</tr>
<tr>
<td>Have a primary partner, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>76</td>
<td>75</td>
<td>77</td>
<td>76</td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have a nonprimary partner, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>61</td>
<td>60</td>
<td>59</td>
<td>61</td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal sex episodes with a condom in last 3 mo, %</td>
<td>38</td>
<td>38</td>
<td>38</td>
<td>38</td>
</tr>
<tr>
<td>1-49</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-99</td>
<td>23</td>
<td>25</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>100</td>
<td></td>
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</tr>
</tbody>
</table>

HIV indicates human immunodeficiency virus; STD, sexually transmitted disease.  
*For arm 4, screening demographic data were collected on all participants, but full behavioral questionnaires were collected only on a sample (484 [84%]) of the 1430 participants.

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frequently than at enrollment, but there were no significant differences among interventions. Considering only the 2732 participants who came to all 4 follow-up visits, we observed similar results. Using generalized estimating equations, we found enhanced counseling participants were more likely to report “no unprotected sex” than participants in the other interventions at 12 months (P = .02).

The interventions focused on consistent condom use, but we observed modest differences among them for some other “safe” behaviors (Table 2). At the 3- and 6-month visits, more participants in each counseling intervention reported safe behaviors compared with those in the didactic messages arm. For measures of condom use (eg, “any use” and “condoms with last sex”), enhanced counseling participants tended to report safe behaviors most often, followed by those who were assigned to the brief counseling arm and then those who were assigned to the didactic messages arm. For safe behaviors unrelated to condoms (eg, “no casual partners” and “no new partners”), brief counseling interventions had very similar cumulative incidence of STD through the 6- and 12-month visits. The number of participants counseled per STD averted during the preceding 3 months, baseline, and 3-, 6-, 9-, and 12-month visits.

Sexually Transmitted Diseases

Through the 12-month visit, a total of 549 participants (12.7%) were diagnosed as having a new STD, including 314 men (12.8%) and 235 women (12.6%). There were 271 participants (6.3%) diagnosed as having gonorrhea; 315 (7.3%) as having chlamydia; 25 (0.6%) as having syphilis; and 8 (0.2%) as having HIV. Some participants had multiple diagnoses.

Fewer participants assigned to either of the interactive counseling intervention arms developed new STDs compared with participants assigned to the didactic messages control arm (Figure 3). Through the 3-month visit, 149 participants (10.4%) in the didactic messages arm had new STDs compared with 103 (7.2%) in the enhanced counseling arm (RR, 0.78; 95% CI, 0.58-0.98) and 107 (7.3%) in the brief counseling arm (RR, 0.71; 95% CI, 0.58-0.89). Through the 12-month visit, 211 participants (14.6%) in the didactic messages arm had developed new STDs, compared with 165 (11.5%) in the enhanced counseling arm (RR, 0.87; 95% CI, 0.64-0.94) and 173 (12.0%) in the brief counseling arm (RR, 0.81; 95% CI, 0.67-0.98). The 2 interactive counseling interventions had very similar cumulative incidence of STD through the 6- and 12-month visits. The number of participants counseled per STD averted during the 12-month study interval was 31 for the enhanced counseling arm and 98 for the brief counseling arm.

The STD reduction associated with the interactive counseling interventions was similar among men and women, that is, about 30% fewer participants had new STDs at the 6-month visit and 20% fewer participants had new STDs at the 12-month visit, respectively. Consistently at all 5 study sites fewer participants in the counseling intervention arms had new STDs compared with those in the didactic messages arm. Considering specific STDs as outcomes, counseling was equally effective for gonorrhea and chlamydia. For HIV, there were 4 new infections among those in the didactic messages arm, 4 in those assigned to the enhanced counseling arm, and none in those assigned to the brief counseling arm (P = .06) through the 12-month visit. In the subgroup analyses, efficacy was highest in the subgroups with highest risk (ie, highest STD incidence), although differences were not significant at P < .05. The relative effectiveness of counseling was greatest for patients aged 20 years or younger (vs those older), patients reporting no prior HIV test (vs those reporting a test), and patients who had an STD diagnosed at the enrollment visit (vs those with no STD).

Effect of Repeated Contact

Gonorrhea and syphilis were diagnosed at voluntary clinic visits less often among arm 3 participants (3.3%) than arm 4 participants (4.1%), although observed differences may have been due to chance (RR, 0.80; 95% CI, 0.55-1.17). At 12 months, only 462 arm 4 participants (32%) were found and interviewed. However, compared with these, arm 5 participants were more likely to report “no episodes of unprotected vaginal sex” during the previous 3 months (39% vs 34%; RR, 1.15; 95% CI, 0.99-1.33). Although some biases are possible, these analyses were consistent in suggesting that repeated contact with study personnel, instruments, or both may have themselves had a modest intervention effect.

COMMENT

Project RESPECT demonstrated that interactive, client-centered HIV/STD counseling resulted in an overall reduction in STD incidence of about 30% after 6 months and 20% after 12 months of follow-up. The STD reduction occurred among both men and women and was observed consistently at all 5 study sites. Since 1994, CDC has recommended client-centered HIV prevention counseling for persons determined to be at risk for HIV infec-

Figure 2.—Percentage of participants reporting condom use with vaginal sex during the preceding 3 months, baseline, and 3-, 6-, 9-, and 12-month visits.

Figure 3.—Percentage of participants with a new sexually transmitted disease through the 3-, 6-, 9-, and 12-month visits.
A stated counseling benefit has been reduction in HIV or other sexually transmitted infections. In addition to reducing new infections, counseling in reducing HIV or other STDs had not been shown. This large randomized controlled trial evaluating interactive risk reduction counseling among STD clinic patients is the first to report that counseling leads to reduction in sexually transmitted infections. In addition to concerns about efficacy, concerns that interactive counseling is not feasible for busy, publicly funded clinics, or cannot be conducted by the personnel currently employed by health departments, should now be put to rest.

The follow-up results indicate that interactive counseling had greatest disease reduction benefit during the first 6 months after intervention completion but suggest that some counseling benefits continued over time. Even if the counseling benefits wane, a 20% STD reduction over 12 months is important for several reasons. A 20% STD reduction in these clinic patients will diminish disease prevalence in the community. In addition, reducing or eliminating STDs such as syphilis, gonorrhea, chlamydia, and herpes may directly reduce new HIV infections, as the presence of these STDs we studied here and HIV are similar, client-centered counseling is likely to have the same disease prevention benefits. Human immunodeficiency virus seroconversion is relatively rare in the United States, even among this high-risk population. To find a 20% reduction in HIV transmission in this population with incidence of 0.5% per year would require a study size of 241 000 in order to have an 80% likelihood of detecting a difference. The cost of such a study would be prohibitive. But the cost of counseling programs for 241 000 people (which we estimate at $8 per patient over current costs) would be easily recovered in savings from preventing an expected 145 new AIDS cases, which cost an estimated $100 000 to $200 000 per case.2

The finding that the 4-session enhanced counseling and the much shorter 2-session brief counseling had equivalent STD reduction was surprising and is good news for public health programs. Conventional wisdom has suggested that multiple-session interventions are needed for effective change of sexual behavior,2 but our results challenge this viewpoint. Timing may be an important element for intervention success; it is possible that individuals who seek STD testing and treatment are particularly amenable to behavior change. However, this is not the first study indicating that brief interventions may be as effective as longer therapies. Recently published results of a large alcohol treatment study indicate that a brief motivational intervention was as effective in achieving alcohol cessation as a longer, more intensive counseling intervention.11 A brief intervention in active drug users has also been reported as being effective as a longer intervention in changing risk behaviors.28 We studied 4-session counseling because we were not convinced that CDC’s recommended 2-session counseling would have such a powerful disease reduction impact. Although long recommended and supported by counselors, client-centered HIV prevention counseling is seldom done in STD clinics, probably because program managers also have not believed that a 2-session intervention could have a significant impact. However, this brief counseling model was designed for implementation, at low cost and with existing personnel, in the context of routine health care services. The intervention adherence we found suggests that 2-session counseling would have at least the same retention as the didactic approach that is currently used and would have greater retention than longer therapies.

This study has several strengths. The randomized controlled design, if well conducted, permits the most unbiased comparison of effects. In conducting this trial, we sought to comply with recommended procedures that have since been published as guidelines for conducting and reporting randomized controlled trials.27 The use of disease as an outcome measure can help validate self-reported data. More important, measuring disease outcomes allowed us to measure directly the interventions’ disease reduction effects, and thus permit counseling to be directly compared with other HIV/STD prevention strategies. Losses to follow-up could be an important source of bias if those not returning differed in risk from those who returned for follow-up. Our 66% follow-up after 12 months (81% with at least 1 follow-up visit) is within an acceptable range for prospective studies. Follow-up was similar for all intervention arms, and our study population rarely sought STD care at other locations,20 so the differences between interventions are unlikely to be caused by loss to follow-up. We also attempted to minimize biases in the analysis by identifying principal outcomes before the trial and by masking investigators to intervention strategies during preliminary analyses. An additional strength of this study was the use of several quality-control procedures, helping ensure that the counseling interventions were conducted by counselors at all sites consistently and as conceived.30 Also, the long follow-up period allowed us to measure the interventions’ effects over time.

We were unable to avoid some potential biases. One limitation mentioned earlier was the use of STDs as a surrogate for HIV infection. Although STDs inform about unprotected sex and partner risk, they may not be an accurate measure of heterosexual HIV risk.29 Generalizability of results is also of concern. We studied 5 widely located STD clinics that we believe

### Table 2.—Proportion of Participants With Selected Safe Behaviors by Intervention Arm at the 3-Month and 6-Month Visits *

<table>
<thead>
<tr>
<th>Safe Sex Behavior Last 3 Mo</th>
<th>Arm 1 Enhanced Counseling</th>
<th>Arm 2 Brief Counseling</th>
<th>Arm 3 Didactic Messages</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 mo, % 6 mo, %</td>
<td>3 mo, % 6 mo, %</td>
<td>3 mo, % 6 mo, %</td>
</tr>
<tr>
<td>Any condom used</td>
<td>83†‡ 78†‡ 79 73 76 73</td>
<td>71‡ 70 72‡ 70 66 66</td>
<td>70 69 73‡ 70 66 66</td>
</tr>
<tr>
<td>≤1 Sex partner</td>
<td>70 69 73‡ 70 66 66</td>
<td>63† 59 61 59 58 54</td>
<td>79† 78 80† 77 73 74</td>
</tr>
<tr>
<td>No casual partners</td>
<td>72 71 75 73 71 70</td>
<td>58 56 61† 50 50 52</td>
<td>44 46 50† 41 41 38</td>
</tr>
<tr>
<td>Condoms last sex, primary partner</td>
<td>40 39 41 38 35 35</td>
<td>40 39 41 38 35 35</td>
<td>40 39 41 38 35 35</td>
</tr>
<tr>
<td>Condoms last sex, other partner</td>
<td>40 39 41 38 35 35</td>
<td>40 39 41 38 35 35</td>
<td>40 39 41 38 35 35</td>
</tr>
<tr>
<td>Tested for STDs</td>
<td>44 46 50† 41 41 38</td>
<td>40 39 41 38 35 35</td>
<td>40 39 41 38 35 35</td>
</tr>
<tr>
<td>Ever injected drugs</td>
<td>44 46 50† 41 41 38</td>
<td>40 39 41 38 35 35</td>
<td>40 39 41 38 35 35</td>
</tr>
</tbody>
</table>

* HIV indicates human immunodeficiency virus; STD, sexually transmitted disease. 
† P < .05 compared with arm 3 (didactic messages) at same study visit. 
‡ P < .05 compared with arm 2 (brief counseling) at same study visit. 
§ For those reporting a primary sex partner. 
| For those reporting a nonprimary (‘other’) sex partner. 

12 Several observational studies and a few randomized trials using behavioral outcomes support that direct, personalized (“client-centered”) counseling is likely to initiate the behavior changes that might lead to reduction in new HIV infections.5,6,22,23 However, the efficacy of such counseling in reducing HIV or other STDs had not been shown. This large randomized controlled trial evaluating interactive risk reduction counseling among STD clinic patients is the first to report that counseling leads to reduction in sexually transmitted infections. In addition to concerns about efficacy, concerns that interactive counseling is not feasible for busy, publicly funded clinics, or cannot be conducted by the personnel currently employed by health departments, should now be put to rest.

The follow-up results indicate that interactive counseling had greatest disease reduction benefit during the first 6 months after intervention completion but suggest that some counseling benefits continued over time. Even if the counseling benefits wane, a 20% STD reduction over 12 months is important for several reasons. A 20% STD reduction in these clinic patients will diminish disease prevalence in the community. In addition, reducing or eliminating STDs such as syphilis, gonorrhea, chlamydia, and herpes may directly reduce new HIV infections, as the presence of these STDs has been found to enhance HIV acquisition and transmission.2,26 Furthermore, even transient reduction in risk for an individual may have large effects on lifetime risk if the behavior changes occur when the likelihood of infection is high (eg, during adolescence). As for whether the STD reduction found with counseling would hold true for HIV as well, we cannot say this with certainty. To the extent that sexual transmission of the condom-preventable STDs we studied here and HIV are similar, client-centered counseling is likely to have the same disease prevention benefits. Human immunodeficiency virus seroconversion is relatively rare in the United States, even among this high-risk population. To find a 20% reduction in HIV transmission in this population with incidence of 0.5% per year would require a study size of 241 000 in order to have an 80% likelihood of detecting a difference. The cost of such a study would be prohibitive. But the cost of counseling programs for 241 000 people (which we estimate at $8 per patient over current costs) would be easily recovered in savings from preventing an expected 145 new AIDS cases, which cost an estimated $100 000 to $200 000 per case.1

The finding that the 4-session enhanced counseling and the much shorter 2-session brief counseling had equivalent STD reduction was surprising and is good news for public health programs. Conventional wisdom has suggested that multiple-session interventions are needed for effective change of sexual behavior,2 but our results challenge this viewpoint. Timing may be an important element for intervention success; it is possible that individuals who seek STD testing and treatment are particularly amenable to behavior change. However, this is not the first study indicating that brief interventions may be as effective as longer therapies. Recently published results of a large alcohol treatment study indicate that a brief motivational intervention was as effective in achieving alcohol cessation as a longer, more intensive counseling intervention.11 A brief intervention in active drug users has also been reported as being effective as a longer intervention in changing risk behaviors.28 We studied 4-session counseling because we were not convinced that CDC’s recommended 2-session counseling would have such a powerful disease reduction impact. Although long recommended and supported by counselors, client-centered HIV prevention counseling is seldom done in STD clinics, probably because program managers also have not believed that a 2-session intervention could have a significant impact. However, this brief counseling model was designed for implementation, at low cost and with existing personnel, in the context of routine health care services. The intervention adherence we found suggests that 2-session counseling would have at least the same retention as the didactic approach that is currently used and would have greater retention than longer therapies.

This study has several strengths. The randomized controlled design, if well conducted, permits the most unbiased comparison of effects. In conducting this trial, we sought to comply with recommended procedures that have since been published as guidelines for conducting and reporting randomized controlled trials.27 The use of disease as an outcome measure can help validate self-reported data. More important, measuring disease outcomes allowed us to measure directly the interventions’ disease reduction effects, and thus permit counseling to be directly compared with other HIV/STD prevention strategies. Losses to follow-up could be an important source of bias if those not returning differed in risk from those who returned for follow-up. Our 66% follow-up after 12 months (81% with at least 1 follow-up visit) is within an acceptable range for prospective studies. Follow-up was similar for all intervention arms, and our study population rarely sought STD care at other locations,20 so the differences between interventions are unlikely to be caused by loss to follow-up. We also attempted to minimize biases in the analysis by identifying principal outcomes before the trial and by masking investigators to intervention strategies during preliminary analyses. An additional strength of this study was the use of several quality-control procedures, helping ensure that the counseling interventions were conducted by counselors at all sites consistently and as conceived.30 Also, the long follow-up period allowed us to measure the interventions’ effects over time.

We were unable to avoid some potential biases. One limitation mentioned earlier was the use of STDs as a surrogate for HIV infection. Although STDs inform about unprotected sex and partner risk, they may not be an accurate measure of heterosexual HIV risk.29 Generalizability of results is also of concern. We studied 5 widely located STD clinics that we believe...
to be fairly representative of the range of public clinics in the United States. However, the 45% enrollment rate was low (although not unexpected, given the length and intensity of the follow-up that participants were asked to complete). Intervention enrollment may be higher in practice because participants would not need to return for the study-related follow-up. However, participation may be lower than the $15 incentive used in this study. Perhaps more important, results may not pertain to other populations or settings. Since we studied only heterosexual STD clinic patients, we cannot know whether similar counseling sessions would be effective in other settings where HIV tests are performed, such as alternative test sites (where many gay men go for testing), among injection drug users, or at managed care plans (where many adolescents and young women receiving Medicare obtain health care). However, the individually tailored approach used in the counseling models studied here could be easily adapted to different settings.

We conclude that brief, interactive HIV/STD prevention counseling prevents new STDs and, by inference, HIV infections. This quality of counseling can be successfully conducted in busy public clinic settings. These results have several implications for existing programs, particularly those serving populations with a high HIV/STD prevalence. First, most clinics already employ HIV counselors who collect risk data, discuss the HIV test, and provide didactic prevention messages.30 These counselors could prevent new infections if they adopted interactive HIV/STD prevention counseling aimed at risk reduction. The Project RESPECT counselors were health department staff members who were motivated and enthusiastic but typically did not have advanced degrees or long experience in interactive counseling. Second, quality-control measures are critical to intervention success and are feasible for most programs.30 Quality assurance should be approached as an integral part of the process and as a means of providing a better product. Third, some programs might consider targeting counseling to higher-risk clients, such as adolescents and adults with previous STDs, to reduce costs while retaining large effects on disease reduction. Finally, given our finding that counseling benefits may wane over time, we wonder if an additional interactive counseling session done some months after brief 2-session counseling might be beneficial and might sustain or even enhance the risk-reduction benefits observed in this trial.

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The members of the Project RESPECT Study Group are as follows: Baltimore: Carolyn ErwinJohnson, MA; Bec Gudmundson; Mary A. Staat, MD, MPH; Dawn Sweet, PhD; Jonathan M. Zenilman, MD (Principal Investigator [PI]). Denver: John M. Douglas, Jr, MD (PI); Tamara Boxworth, PhD; Ken Miller, MPH; William McGill, PhD; Long Beach: Euth Bundy, PhD (co-PI); Laura A. Hoyt, MPA; C. Kevin Malotte, DrPH; Fen Rhodes, PhD (PI). Newark: Michael Iatesta, MA; Eileen Napolitano (co-PI); Kim Schula, PhD; Ken Spojitaya, MD (PI). San Francisco: Gail A. Bolan, MD (PI); Coleen LeDrew; Kimberly A. Coleman; Luna Hanslan, MSW; Charlotte K. Kent, MPH, NOVA, Inc; Bethesda, Md (PI); Christopher Gordon; Nancy Roneshine, MA (PI); Car- nita Signes. CDC: Sevgi Aral, PhD; Robert H. By- ers, PhD; Beth Dillon, MSW, MPH; Martin Fishbein, PhD; Sandra Graziano, PhD; Mary L. Kam, MD, MPH; William Killeen; James Newhall, PhD; Daniel Newman, MS; Thomas A. Peterman, MD, MSc; Karen L. Willis, RN.

References