Reduction of High-Risk Sexual Behavior among Heterosexuals Undergoing HIV Antibody Testing: A Randomized Clinical Trial

ABSTRACT

Background. We evaluated the effect of HIV antibody testing on sexual behavior and communication with sexual partners about AIDS risk among heterosexual adults at a clinic for sexually transmitted diseases.

Methods. We randomized 186 subjects to receive either AIDS education alone (the control group) or AIDS education, an HIV antibody test, and the test results (the intervention group). These subjects were then followed up 8 weeks later.

Results. At follow-up, mean number of sexual partners decreased, but not differently between groups. However, compared with controls, HIV antibody test intervention subjects, all of whom tested negative, questioned their most recent sexual partner more about HIV antibody status ($P < 0.01$), worried more about getting AIDS ($P < 0.03$), and tended to use a condom more often with their last sexual partner ($P = 0.05$): 40% of intervention subjects vs 20% of controls used condoms, avoided genital intercourse, or knew their last partner had a negative HIV antibody test ($P < 0.005$).

Conclusion. HIV antibody testing combined with AIDS education increases concern about HIV and, at least in the short term, may promote safer sexual behaviors. Additional strategies will be necessary if behaviors risky for HIV transmission are to be further reduced. (*Am J Public Health.* 1991;81:1580–1585)

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Introduction

Antibody testing for human immunodeficiency virus (HIV) has been proposed as part of the effort to control transmission of acquired immunodeficiency syndrome (AIDS).[1,2] Such testing is now routine for military personnel, federal prisoners, immigrants, and, in some states, those applying for marriage licenses.[3] Voluntary HIV antibody testing also is becoming more commonplace in special testing centers, medical practices, and clinics. The question of who should be tested has been debated by physicians,[4] ethicists,[5] activist groups, and presidential candidates,[6] but it remains controversial. Although HIV testing has become widespread, we are only beginning to understand its effects.[7]

Descriptive studies of high-risk individuals (homosexual men and intravenous [IV] drug users) requesting HIV testing and receiving positive test results have demonstrated some decrease in sexual activity among those tested.[8] However, almost no data have been published on the impact of testing on lower-risk populations, such as heterosexual adults sexually active with multiple partners, the overwhelming majority of whom will have negative test results. Yet such information is essential in developing public policy. A negative result on an HIV antibody test could be used either to justify resumption of a high level of sexual activity or to stimulate more cautious behavior.

No randomized trials of HIV testing have been reported to date. Thus, to evaluate the impact of HIV antibody testing on sexually active heterosexual adults, we conducted a randomized trial in a Los Angeles clinic for sexually transmitted disease (STD).

Methods

Consecutive individuals attending an urban STD clinic between January and March 1988 were approached to participate in a randomized trial of HIV antibody testing. The clinic did not offer HIV antibody testing at the time of this study.

Of 724 consecutive patients, 224 were judged ineligible according to preset criteria: they had been previously approached about study participation (21%) or they were younger than 18 years of age (14%), unable to speak English (46%), of homosexual or bisexual orientation (4%), unavailable due to constraints of the clinic (i.e., sequestered by peace officers or primarily participating in other clinic areas [10%]), unable to give informed consent (4%), or unable to give a follow-up address (1%). Of the 500 eligible patients, 259 (52%) were interested in receiving free, confidential HIV antibody testing and 256 (51%) were willing to participate in the randomized trial. Those attending the clinic, those eligible for the study, and those participating were similar in gender and age; there were more Blacks in the study sample than among clinic attendees (84% vs 72%) due to the exclusion of non-English speakers (all of whom were Hispanic).

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Upon entering the clinic, patients were informed of the possibility of receiving free, confidential HIV antibody tests along with the routine clinic blood draw for syphilis serology. The nature of the randomized trial was explained to eligible patients who wished to receive the HIV antibody test. Signed consent was obtained for the study and for HIV antibody testing.

Subjects then completed a self-administered questionnaire that included items to elicit (1) demographic information; (2) knowledge about AIDS (six true/false questions); (3) mental health (a five-item global mood inventory);[9] (4) worry about general health (a four-item "health/worry" index);[10] and (5) information about their last sexual partner, including length of relationship, perceived sexual experience, and chance of carrying HIV. Communication with sexual partners was evaluated by inquiring as to whether subjects had *asked* either partner in the past month or their most recent partner (1) whether that partner had been tested for antibody to HIV and, if so, what the result was; (2) whether that partner had used IV drugs; and (3) how many previous sexual partners that partner had. Subjects' sexual behavior was measured as (1) the number of sexual partners in the past month, (2) the number of episodes of vaginal and anal intercourse and of oral sex with and without a condom in the past month with all sexual partners, and (3) the number of sexual acts with their most recent partner.

After completing the questionnaire, all subjects participated in an educational module in which they (1) received a written pamphlet that explicitly discussed safer and unsafe sexual acts and explained condom use;[11] (2) watched a 15-minute videotape that discussed behavior risky for contracting AIDS and promoted condom use and discussion of risk with sex partners;[12] and (3) participated in a 10-minute, one-on-one counseling session with a physician blinded to randomization status. The counseling focused on assessing personal risk, discussing the elements of the HIV test, and answering any questions about AIDS or HIV testing. All aspects of usual HIV pretest and posttest counseling were covered with every subject.

After completing the educational module, subjects were called for the usual clinic blood draw by the clinic nurse, who opened the sealed randomization envelope. Subjects randomized to HIV testing (the intervention group) were informed of that fact and had an extra tube of blood drawn. Subjects randomized not to receive the test (the control group) were offered a list of locations for free, anonymous HIV antibody testing.

Serum samples underwent enzyme-linked immunosorbent assay (ELISA) for HIV. Repeat positive results on ELISA tests were submitted for confirmatory western blot analyses. Negative test results were revealed to subjects, in person or by telephone, approximately 2 weeks after study entry and were accompanied by the same risk reduction message that all intervention and control subjects received during the pretest counseling. Subjects testing positive received face-to-face, in-depth counseling with analysis of risk factors. Long-term medical and psychological follow-up was arranged.

Follow-up questionnaires were mailed to all subjects 8 weeks after study entry. In addition to the names, addresses, and telephone numbers they had provided, subjects were traced by using public health and social service resources, canvassing nearby hospitals and penal institutions, and monitoring the clinic. In addition to the questions on the first questionnaire, subjects were asked whether they were worried about getting AIDS, whether they had been HIV tested, and what their responses were to testing. If the questionnaire was not returned after repeat mailings and telephone calls, a trained research assistant administered it over the telephone. The number of responses obtained by telephone did not differ between the two groups.

Of the 256 individuals consenting to participate, 125 were randomized to the intervention group and 131 to the control group. Every effort was made to follow up each subject. However, follow-up efforts revealed that 22 intervention subjects (18%) and 23 control subjects (18%) had provided untruthful names, addresses, and telephone numbers when they entered into the study—before randomization. These subjects were thus excluded from the study. The excluded subjects in the two groups were similar with regard to demographic characteristics, communication with partners about AIDS, and sexual behavior (Table 1).

Of the 103 remaining intervention subjects, 11 (11%) could not be followed up (1 left the clinic before blood could be drawn, 2 could not be reached to receive test results, 1 refused to be informed of his [positive] result, and 7 could not be located or refused to complete follow-up questionnaires). Similarly, of the remaining 108 control subjects, 14 (13%) did not complete follow-up questionnaires. Those subjects not followed up were similar at baseline between the two groups except for small differences in age and knowledge about AIDS. Compared with those who were followed up, they were somewhat less likely to be Black (Table 1). Overall, the 70 subjects who were not followed up in this trial did not differ significantly from those who were followed up in terms of demographics (except race), knowledge about AIDS, number of sexual partners last month, or previous episodes of STD. The remaining 92 subjects in the intervention group and 94 subjects in the control group make up the longitudinal sample for this study.

Three of the 124 subjects receiving an HIV antibody test through this study tested positive for HIV on ELISA. All were confirmed on western blot analysis. At follow-up counseling, one revealed that he had denied his homosexual contact to enter the study. The second was a woman with two children and an IV drug–using ex-husband; she received follow-up care but refused to complete the follow-up questionnaire. The third was a male who declined to receive his test result, fearing that he might become depressed if he were positive; he also declined to complete the follow-up questionnaire. Thus, all subjects who were followed up in the intervention group received a negative HIV antibody test result approximately 6 weeks prior to completing the follow-up questionnaire. Among the 94 control group subjects completing the follow-up survey, 10 (11%) obtained HIV antibody tests elsewhere. (Nine reported a negative result and one never obtained the result.)

Analyses were performed only on prespecified hypotheses using an intention-to-treat protocol in which subjects were analyzed in their original randomized groups, regardless of whether persons in the control group obtained the HIV test from an outside source. Baseline differences between intervention and control groups for continuous variables were assessed with t tests or Wilcoxon tests, depending on the variable's underlying distribution; differences for dichotomous variables were assessed with chi-square tests. Repeated measures analysis of variance for continuous variables (using SAS Proc GLM) and log-linear models for dichotomous variables (using SAS Proc CATMOD) were used to evaluate the effects of group differences, changes over time, and interactions.

TABLE 1—Baseline Comparison of the Study Sample to Those Providing No Follow-up Information and Those Lost to Follow-up

	No Follow-up Information		Lost to Follow-up		
	Randomized to Intervention Group	Randomized to Control Group	Randomized to Intervention Group	Randomized to Control Group	Followed-up
	(n = 22)	(n = 23)	(n = 11)	(n = 14)	(n = 186)
Age (mean ± standard deviation [SD])	25 ± 5	27 ± 5	24 ± 8*	31 ± 9*	27 ± 8
Male (%)	68	61	73	64	67
Black, %**	82	74	73	71	88
Unmarried, %	96	100	91	93	86
Education, median in years	13	13	12	12	13
Employed, %	68	52	55	50	57
Number of sexual partners:					
In the last month, mean ± SD	2.9 ± 4.3	3.2 ± 2.2	1.6 ± 1.1	1.6 ± 1.5	1.8 ± 1.5
Lifetime, median	20	39	18	18	14
Number of episodes of sexually transmitted diseases, mean ± SD	3.1 ± 2.8	3.6 ± 3.2	2.8 ± 3.1	2.1 ± 2.2	2.7 ± 2.6
AIDS knowledge index score, mean number correct of six questions ± SD	5.1 ± 1.0	4.9 ± 1.1	4.3 ± 1.0*	5.4 ± 0.9*	5.0 ± 1.1
Mental health scale score, mean ± SE	4.5 ± 0.2	4.5 ± 0.2	4.5 ± 0.2	4.1 ± 0.2	4.6 ± 0.1
Health/worry scale score, mean ± SE	4.2 ± 0.2	3.8 ± 0.1	3.7 ± 0.3	4.1 ± 0.2	4.1 ± 0.1
Number of AIDS risk questions asked of last partner, mean ± SD	0.4 ± 0.7	0.8 ± 1.0	0.6 ± 0.7	0.9 ± 1.0	0.9 ± 1.0
Unprotected vaginal or anal intercourse with last partner, %	82	83	100	79	90

*$P < 0.05$ for t-test comparison of means of intervention and control groups.
**$\chi^2 = 4.6$, $P < 0.04$ for comparison between lost to follow-up (n = 70) and followed-up (n = 186) groups.

TABLE 2—Baseline Characteristics of the Intervention and Control Groups

	Intervention Group	Control Group
	(n = 92)	(n = 94)
Demographic Characteristics		
Age, range 18, 66; mean in years ± SD	28 ± 8	27 ± 8
Male, %	71	63
Black, %	93*	82*
Completed high school, %	85	83
Unmarried, %	84	88
Employed, %	55	60
Income, % less than $1000 per month	73	73
Knows person with AIDS, %	5	7
Previous HIV antibody test, %	5	9
Age at first intercourse, range 3, 26; median in years	15	15
Previous episodes of sexually transmitted disease, range 0, 13; mean ± SD	2.6 ± 2.6	2.8 ± 2.6
Sexual Behavior		
Number of sexual partners		
Past 30 days, range 0,15; mean ± SD	1.9 ± 1.7	1.7 ± 1.2
Same month last year, range 0,20; mean ± SD	3.1 ± 3.4	2.6 ± 2.3
Lifetime, range 1, 1000; median	16	13
Vaginal or anal intercourse without a condom with last sexual partner, %	90	89

*$\chi^2 = 4.7$, $P = 0.03$ for difference between groups.

Results

The characteristics of subjects completing the study are shown in Table 2. The mean age was 27 years. Most were male, Black, and high school graduates and were unmarried, employed, and reported an income of less than $1000 per month; 6% reported knowing someone with AIDS, 5% used IV drugs, and 7% had been previously tested for antibody to HIV. Only race differed significantly between the groups ($P = 0.03$). Baseline scores for knowledge about AIDS, mental health, and health/worry were similar.

At baseline, subjects reported a mean of 1.8 sexual partners in the past month compared with 2.9 for the same month the previous year ($P < 0.001$). They reported a median of 14 lifetime sexual partners, age at first sexual intercourse of 15, and a mean of 2.7 previous episodes of STD. The groups did not differ in these baseline values or in the proportion engaging in various sexual acts with all partners over the past month (Table 2).

The two groups did not differ in length of sexual relationship with the last partner, in estimated number of previous sexual partners that this last partner had had, or in estimates of this partner's chance of carrying HIV. Nearly half reported having asked if their last partner had used injected drugs, 14% had asked if that partner had been tested for HIV, and 26% had asked how many previous sexual partners this partner had had. There were no significant differences between groups at study entry in these measures of communication either with the last partner or with all partners in the past month. Re-

garding their last sexual encounter, 88% reported vaginal intercourse without condoms (12% with condoms) and 9% reported anal intercourse without condoms (1% with condoms). The groups did not differ in baseline measures of sexual activity (Table 3).

At follow-up, there were no differences between intervention and control groups or from baseline in measures of AIDS knowledge, mental health, or health/worry (Table 4). However, when specifically asked at follow-up if they were concerned about AIDS, intervention subjects expressed greater concern than controls ($P < 0.03$). Comparing those who were more worried with those who were not, intervention group subjects were significantly more likely to be *more* worried about getting AIDS than they had been 1 month previously (45% vs 26%, $P = <0.01$).

Intervention subjects were more likely than control subjects to report at follow-up that they had asked their last sexual partner about their risk of carrying HIV (Table 5). Inquiries about that partner's HIV status rose from 13% to 41% in the intervention group, significantly more than the 15% to 24% rise in the control group ($P < 0.01$, difference = 18%, 95% confidence interval [CI]: 7.4%, 29%). This difference was due to two effects: 29% of intervention subjects *had not* asked about HIV status at baseline but did so at follow-up, compared with 17% in the control group ($P = .01$), and only 1% of intervention subjects who *had* asked about HIV status at baseline "backslid" and failed to do so at follow-up, compared with 9% of control subjects ($P = .01$).

The proportion of subjects who reported having asked their most recent sexual partner about that person's number of prior sexual partners increased in both groups: from 23% to 57% in the intervention group and from 29% to 53% in the control group. Fifty percent of intervention subjects asked about IV drug use at follow-up compared with 34% of control subjects; however, differences between groups were not significant (Table 5).

Overall, 51% of intervention subjects and 32% of control subjects asked their last sexual partner more questions at follow-up than at baseline about their risk of carrying HIV (difference = 19%, 95% CI: 5%, 33%).

As might be expected after a visit to an STD clinic, the last sexual partner was a first-time partner for only 14% of subjects at follow-up (vs 24% at baseline, $P < 0.05$). There were no differences at follow-up between groups in the percentage for whom the most recent sex partner was a new partner, in the length of sexual relationship with that sexual partner, in the subject's perception of that partner's prior sexual experience, or in the subject's perception of that partner's risk of carrying HIV.

Subjects in both groups decreased their total number of sexual partners per month from 1.9 and 1.7 partners in the intervention and control groups, respectively, at study entry to 1.4 and 1.3 partners, respectively, at follow-up ($P < 0.01$), though the groups did not differ (Table 5).

Although the decline in the number of partners with whom the subjects had vaginal, oral, or anal sex was similar between the two groups, 27% of intervention subjects avoided vaginal or anal intercourse *without a condom* with their most recent sexual partner compared with 13% of control subjects. This approached statistical significance ($P = 0.05$) for a difference between groups. Analyzed separately, the

TABLE 3—Baseline Sexual Behavior with Last Sexual Partner

	Intervention Group (n = 92)	Control Group n = 94)
Last encounter was first sexual experience with this partner (%)	20	28
Estimate of partner's lifetime number of previous sexual partners, range 1, 15; median	6.1	7.5
Percentage estimating partner's risk of carrying HIV as being less than one in a million	39	46
Sexual activity with last partner (%)		
Vaginal intercourse		
Without condom	89	88
With condom	13	12
Oral-vaginal sex	24	23
Oral-penile sex		
Without condom	33	29
With condom	1	2
Anal intercourse		
Without condom	9	9
With condom	1	0

TABLE 4—AIDS Knowledge, Mental Health, Health/Worry and AIDS Worry Baseline vs Follow-up

	Intervention Group (n = 92)	Control Group (n = 94)
AIDS Knowledge Index Score, mean correct of six questions ± SD		
Baseline	5.0 ± 1.1	5.0 ± 1.0
Follow-up	4.8 ± 1.1	4.9 ± 1.0
Mental health scale score mean ± SE		
Baseline	4.5 ± 0.1	4.6 ± 0.1
Follow-up	4.4 ± 0.1	4.5 ± 0.1
Health/worry scale score, mean ± SE		
Baseline	4.1 ± 0.1	4.1 ± 0.1
Follow-up	4.1 ± 0.1	3.9 ± 0.1
Worry about getting AIDS compared with 1 month earlier (%)*		
More worried	45	26
About the same	37	51
Less worried	18	23

*$\chi^2 = 7.3$, $P < 0.03$ for difference between groups.

TABLE 5—Sexual Behavior and Communication about AIDS Baseline vs Follow-up

	Intervention Group (n = 92)	Control Group (n = 94)
Number of Sexual Partners in the Past 30 Days		
Baseline	1.9 ± 1.7	1.7 ± 1.2
Follow-up	1.4 ± 1.0*	1.3 ± 0.8*
Asked Last Sexual Partner:		
If tested for HIV, %:		
Baseline	13	15
Follow-up	41**	24**
If used injected drugs, %:		
Baseline	47	45
Follow-up	50	34
About number of previous sexual partners, %:		
Baseline	23	29
Follow-up	57	53
Avoided Vaginal or Anal Intercourse without a Condom with Last Sexual Partner, %:		
Baseline	10	11
Follow-up	27***	13***
Avoided Vaginal or Anal Intercourse without a Condom *or* Knew Last Sexual Partner's HIV Test Result Was Negative, %:		
Baseline	13	17
Follow-up	40****	20****

*$P < 0.01$ for change over time.
**$P < 0.01$ for group differences in change over time.
***$P = 0.05$ for group differences in change over time.
****$P < 0.003$ for group differences in change over time.

intervention group avoided intercourse without a condom more at follow-up than at baseline ($P < 0.0001$), whereas the control group did not ($P = 0.34$). Three subjects in the intervention group and none in the control group reported having only oral sex; all other subjects in both groups used condoms for vaginal or anal intercourse (Table 5).

The difference between the groups in the rate of "protected" sexual activity was greater when knowledge of a partner's risk factors was taken into account. Among those having vaginal or anal intercourse without condoms with their last partner, 13 intervention subjects (14%) and 6 control subjects (6%) had asked about this partner's HIV serostatus and had been told the partner was seronegative. Thus, at follow-up, fully 40% (37 of 92) of intervention subjects used a condom, had only oral sex, or stated that they knew their partner's HIV serostatus was negative, whereas only 20% (19 of 94) of control subjects did so ($P < 0.003$, difference = 20%, 95% CI: 7.1%, 33%).

Discussion

Nonrandomized interventions that are intended to change sexual behavior are difficult to evaluate because of the underlying trend toward decreasing rates of activities at risk for transmission of HIV. In this study, all subjects received AIDS education and the components of pre- and posttest counseling, and all were randomized to receive or not receive an HIV antibody test. Compared with individuals in the control group, intervention subjects worried more about getting AIDS (even though they received *negative* HIV test results) and were more likely to have asked partners about AIDS risk factors. HIV testing also was associated with a decrease in unprotected vaginal and anal intercourse. The intervention did not affect our measures of knowledge about AIDS, health/worry, or mental health status.

The behaviors protective for HIV seen among the intervention group in this study are consistent with findings in some observational studies of homosexual men. For example, in an observational study of homosexual men apprised of negative HIV antibody status,[13] van Griensven and colleagues found fewer sexual partners, more communication with partners about HIV serostatus, and increased condom use. Coates et al. found that homosexual men who reported a negative HIV status were more likely to reduce unprotected anal intercourse than those choosing not to be tested.[14,15] Three other observational studies, however, found no substantive behavioral change associated with knowledge of a negative test result in homosexual men.[16–18]

The findings in the current study of greater worry about AIDS and decreased risky sexual behavior among individuals testing negative for HIV are particularly important in light of speculation that a negative test result would adversely affect perceived risk of HIV infection and would be viewed as license to continue "business as usual."[19,20]

While condom use is generally regarded as protective against HIV transmission, some contend that communication with partners about their risk of carrying HIV often is not very useful[21] and might be deleterious if a partner lies.[22] On the other hand, Hearst and Hulley suggest that the sexual partner's probability of HIV infection is "by far the most important" predictor of infection risk; they state that "the best advice we can give our patients is to choose their partners carefully."[23] In this study, intervention subjects increased questioning of partners about HIV testing significantly more than controls did. As with changes in condom use, this may reflect heightened concern about becoming infected with HIV. However, it also may be a result of having been tested; perhaps individuals who know their personal test result are more willing to ask about HIV serostatus.

There is a danger that individuals at STD clinics might fail to understand the "window period" before seroconversion and be incorrectly reassured of negative serostatus in pursuing future unprotected sexual behavior. Although intervention subjects were more likely to use condoms, the majority still had unprotected vaginal or anal intercourse with their last partner. Educational efforts need to stress the meaning of a negative HIV test result, especially during this period after an STD.

The findings of this study need to be interpreted with caution. While intervention subjects significantly decreased risky behavior compared with controls, a large proportion continued to engage in activities at risk for transmission of HIV. The sexual behavior reported in this study is self-reported; subjects may have been untruthful, but it is doubtful that the propensity to lie differed between groups. In addition, 27% of the original sample could not be followed up. Finally, multiple comparisons were performed; however, each was a preplanned analysis, and the fact that 4 of 10 were associated with P values

of .05 or less, all in a similar direction, is more than would have been expected by chance alone.

Furthermore, this study was conducted among a predominantly Black, unmarried, low socioeconomic status population attending an STD clinic. Although this group is of considerable importance because their behaviors may promote the spread of HIV infection among the general heterosexual population,[24–26] findings may not be generalizable to other heterosexuals at lower risk of HIV infection. Half the clinic population was unwilling to receive an HIV test. Indeed, this study compares only the 26% of the STD clinic population that met inclusion criteria, were willing to receive an HIV test and participate in a clinical trial, and were followed up. Results of the trial may apply only to this select group. Lastly, the follow-up period for this study was short. Behavior alterations found at 2 months of follow-up may not have persisted.

This study was carried out as a research project offering free, confidential HIV testing. The fact that subjects accepted testing under such circumstances does not predict the acceptance of testing under other conditions.[27] Perhaps the benefits of testing would be diminished if strict confidentiality could not be assured.[28] Discrimination resulting from reporting of positive HIV test results may produce negative effects not seen in this trial.[29] Confidentiality, sensitivity, and efforts to reduce the stigma of positive HIV test results must be part of effective testing programs.

The findings of this study provide assurance that HIV testing in at-risk heterosexuals is safe: subjects, all of whom tested negative for HIV, did not increase risky sexual behavior and did not suffer adverse psychological consequences of testing. The findings also suggest that, for this heterosexual population, HIV antibody testing is effective in reducing certain risky sexual behaviors, perhaps through the mechanism of increasing the level of worry about acquiring HIV infection. Further studies of testing are needed to assess its long-term effects and to examine its effects in other heterosexual populations with different risk profiles. Finally, although one-time interventions such as that described here may reduce at-risk activities, they do not eliminate them. Additional interventions may well be required to reduce further the risk of HIV transmission. □

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