

Behavioral Counseling to Prevent Sexually Transmitted Infections: A Systematic Review for the U.S. Preventive Services Task Force

Jennifer S. Lin, MD, MCR; Evelyn Whitlock, MD, MPH; Elizabeth O'Connor, PhD; and Vance Bauer, MA

Background: Despite advances in prevention and treatment, sexually transmitted infections (STIs) remain an important cause of morbidity and mortality in the United States.

Purpose: To systematically review the evidence for behavioral counseling interventions to prevent STIs in adolescents and adults (nonpregnant and pregnant).

Data Sources: English-language articles in MEDLINE, PsycINFO, the Centers for Disease Control and Prevention's Prevention Synthesis Research Project database, and Cochrane databases (1988 through December 2007), supplemented with expert recommendations and the bibliographies of previous systematic reviews.

Study Selection: Reviewers included 21 articles representing 15 fair- or good-quality randomized, controlled trials that evaluated behavioral counseling interventions feasible in primary care and 1 fair-quality and 1 good-quality controlled trial with study samples representative of primary care populations in English-speaking countries. Comparative effectiveness trials that did not include a true control group were excluded.

Data Extraction: Investigators abstracted, critically appraised, and synthesized 21 articles that met inclusion criteria.

Data Synthesis: Most evidence suggests a modest reduction in STIs at 12 months among high-risk adults receiving multiple intervention sessions and among sexually active adolescents. Evidence also suggested that these interventions increase adherence to treatment recommendations for women in STI clinics and general contraceptive use in male adolescents and decrease nonsexual risky behavior and pregnancy in sexually active female adolescents. No evidence of substantial behavioral or biological harms for risk reduction counseling was found.

Limitation: Significant clinical heterogeneity in study populations, interventions, and measurement of outcomes limited the reviewers' ability to meta-analyze trial results and to suggest important intervention components.

Conclusion: Good-quality evidence suggests that behavioral counseling interventions with multiple sessions conducted in STI clinics and primary care effectively reduces STI incidence in "at-risk" adult and adolescent populations. Additional trial evidence is needed for both lower-intensity behavioral counseling interventions and lower-risk patient populations.

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For author affiliations, see end of text.

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Despite advances in both prevention and treatment, sexually transmitted infections (STIs) remain an important cause of morbidity in the United States. The Centers for Disease Control and Prevention estimate that 19 million new STIs occur each year, almost half of which are among persons 15 to 24 years of age (1). Rates of STIs in the United States exceed those in all other industrialized countries, as well as goals set by Healthy People 2010. In 2005, rates of bacterial and viral STI acquisition continued to increase in the United States, with the exception of HIV, which has remained relatively stable over the last 5 years. Sexually transmitted infections cause a substantial economic burden—the direct medical costs associated with STIs in the United States are estimated at \$15 billion annually (2).

Individual risk factors for STI acquisition are based on risky behaviors (for example, sex with multiple or new partners, sex with high-risk partners, unprotected sex, sex while intoxicated, and sex in exchange for money). These behaviors are theoretically influenced by an individual's preexisting knowledge, attitudes, skills, and self-efficacy and the presence of environmental factors that promote, reinforce, or inhibit change (3). Therefore, risk factors based on an individual's risky behavior are generally considered modifiable. Population risk factors are based on the higher-than-average incidence of STIs in a particular group (for example, adolescents and young adults; black, Hispanic, American Indian, and Alaskan Native persons; men

who have sex with men; mentally ill persons; and persons living in low-income urban areas). Population risk factors also lead to increased morbidity of STIs in particular groups, such as pregnant women (2, 4).

Several national organizations, including the U.S. Preventive Services Task Force (USPSTF) and the Centers for Disease Control and Prevention, recommend periodic sexual risk assessment to determine which patients are most likely to benefit from STI screening or risk reduction counseling (5–7). There remains, however, great variability in taking a sexual history and risk assessment in clinical practice, ranging from 15% to 90% in primary care (8). In addition, STI and condom use counseling in primary care is low, documented in only about one third to one half of appropriate encounters (8). In a random digit-dialing telephone survey of low-income adolescents, only 50% re-

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Conversion of graphics into slides

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ported being counseled on preventing STIs (9). A survey of primary care physicians showed that only 40% of physicians reported screening all their adolescent patients for sexual activity, and only 31% reported educating their adolescent patients about STI transmission (10).

In 1996, the USPSTF recommended that all adolescent and adult patients be advised about risk factors for STIs and counseled about effective measures to reduce risk for infection, which was based on the proven efficacy of risk reduction, although the effectiveness of clinical counseling in a primary care setting had not been adequately evaluated. Thus, we examined the evidence for the benefits and harms of counseling primary care patients to prevent STIs, including HIV. Using the USPSTF's methods (11), we developed an analytic framework (Figure 1) that included 5 updated questions to guide the current systematic review:

1. Is there direct evidence that primary care counseling to reduce risky sexual behavior can reduce STI incidence or related morbidity and mortality?
2. Does primary care behavioral counseling to prevent STI result in safer sexual behaviors among those counseled?
3. Does primary care behavioral counseling to prevent STI result in benefits other than safer sexual behaviors and reductions in STI incidence?
4. Are there harms from primary care behavioral counseling to prevent STI?
5. Do sexual behavior changes lead to a reduced incidence of STI or related morbidity and mortality?

METHODS

Data Sources

We searched MEDLINE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and PsycINFO from 1988 through December 2007,

as well as the Centers for Disease Control and Prevention's Prevention Research Synthesis Project database through August 2006. We examined the literature since 1988 because that was the initial year for published studies on sexual behavioral counseling in the post-HIV era. We supplemented literature searches with outside source material from experts in the field and the bibliographies of existing relevant systematic reviews.

Study Selection

We included trials that evaluated behavioral counseling interventions conducted in primary care or judged to be feasible for delivery in primary care. We defined *behavioral counseling* as any intervention that included some provision of education, skills training, and guidance on how to change sexual behavior, delivered alone or in combination with other interventions intended to promote sexual risk reduction or risk avoidance. Table 1 summarizes inclusion and exclusion criteria.

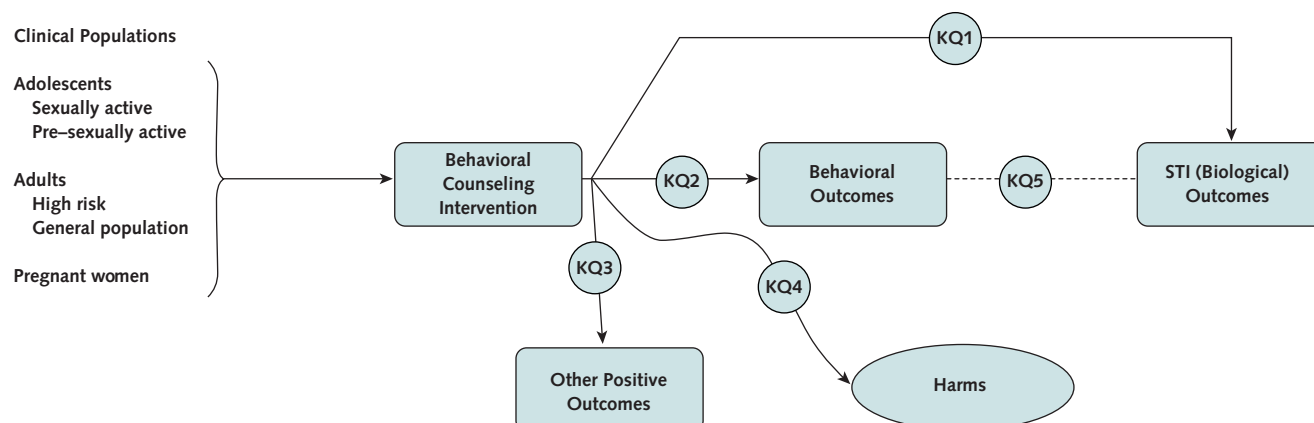
Data Extraction and Quality Assessment

Two investigators independently screened all abstracts for inclusion. We reviewed a total of 3197 abstracts and 287 complete articles for key questions 1 through 4. Two investigators independently rated all articles meeting inclusion criteria for quality assessment by using the USPSTF's study design-specific quality criteria (11, 12). This review included 21 articles representing 15 unique trials for key questions 1 through 4 (Figure 2). One primary reviewer abstracted relevant information into standardized evidence tables for each included article. A second reviewer checked the abstraction process.

Data Synthesis

Because of the heterogeneity in study populations, settings, interventions, and outcomes, we did not attempt

Figure 1. Analytic framework.



KQ = key question. Key question 5 (Do sexual behavior changes lead to a reduced incidence of STI, or related morbidity and mortality?) is not addressed in this article; please see the full evidence report (available at www.ahrq.gov/clinic/uspstfix.htm).

Table 1. Summary of Inclusion and Exclusion Criteria for Key Questions 1 through 4

Study Characteristic	Inclusion Criteria	Exclusion Criteria
Clinical conditions	Sexual transmission of bacteria or virus (e.g., HIV, hepatitis B and C, herpes simplex virus, human papillomavirus, chlamydia, gonorrhea, syphilis, and trichomonas)	Other modes of transmission for bloodborne STIs (e.g., maternal–fetal transmission, transfusions, inadvertent needlesticks, and sharing needles or injection equipment)
Study design	English-language RCTs and non-RCTs; control group with no intervention (e.g., wait-list control, usual care), minimal intervention (e.g., usual care limited to no more than 15 min of information), or attention control (e.g., similar format and intensity intervention on a different content area)	Comparative effectiveness trials without a control group; all observational studies
Population	Adults (pregnant and nonpregnant); adolescents (sexually active and pre–sexually active)	Persons with HIV
Setting	Primary care settings (e.g., pediatric, OB/GYN, internal medicine, family practice, family planning, military, adolescent and school-based health clinics) Specialty clinics (e.g., STI, genitourinary clinics, HIV testing sites, mental health clinics) considered because of limited trials in primary care	Correctional facilities, school-based programs, substance abuse treatment facilities, HIV clinics, and inpatient hospital units Nonindustrialized countries, as defined by the UN Human Development Index
Intervention	1. Conducted in primary care 2. Judged to be feasible in primary care: a) involve individual-level identification; b) usually involve primary care staff, or the intervention will be seen as connected to the health care system by the participant; c) delivered to individuals or small groups; d) group-level interventions generally do not involve >8 group sessions and the intervention period is no longer than 12 mo 3. Referable from primary care: conducted as part of a health care setting, or be widely available in the community at a national level	Community-based programs (e.g., worksite programs, school programs); social marketing interventions (e.g., media campaigns); policy-level interventions (e.g., local and state public or health policy)
Outcomes	Minimum of a 3-mo outcome assessment of biological (laboratory-tested or self-reported) or self-reported behavioral outcomes	Self-reported measures of attitude, knowledge, beliefs, ability, and self-efficacy

OB/GYN = obstetrics/gynecology; RCT = randomized, controlled trial; STI = sexually transmitted infection; UN = United Nations.

quantitative synthesis of study results, but report our qualitative synthesis. Given the large variation in intensity of behavioral counseling interventions studied, we use the term *low intensity* to describe single-visit counseling interventions lasting less than 30 minutes or any intervention that could be added to usual primary care without significant additional visit time; *moderate intensity* to describe interventions lasting longer than 30 minutes but less than 2 hours in total; and *high intensity* to describe multiple-visit interventions requiring more than 2 hours in total.

Role of the Funding Source

The authors worked with 4 USPSTF liaisons at key points throughout the review process to develop and refine the scope, analytic framework, and key questions; to resolve issues around the review process; and to finalize the evidence synthesis. Staff from the Agency for Healthcare Research and Quality (AHRQ) provided project oversight, reviewed the draft report, and assisted in external review of the draft evidence report. The draft report was subsequently revised after review by 5 experts, including representatives of federal agencies. The final evidence report is available at www.ahrq.gov/clinic/uspstfix.htm. Interested readers can refer to the full report for further details on methods and results. However, this article includes 2 additional trials that were identified (13, 14), but not yet published, at the time we prepared the final evidence report.

RESULTS

Key Question 1

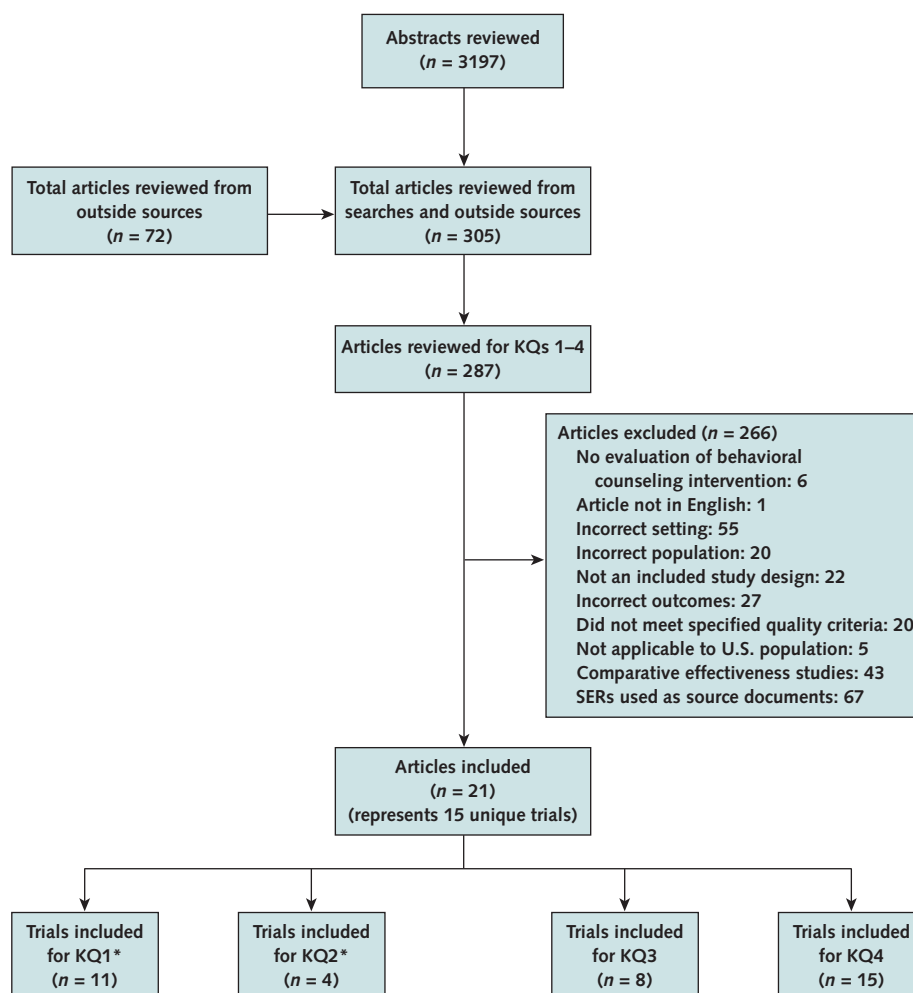
Is there direct evidence that primary care counseling to reduce risky sexual behavior can reduce STI incidence or related morbidity and mortality?

Adults

We identified 8 fair- or good-quality trials in adults examining the effect of behavioral counseling interventions on reducing STI incidence (Table 2) (13–20). Only 3 randomized, controlled trials (RCTs) were conducted in a primary care setting (13, 14, 20). Five trials included only women (13–16, 20). All trial populations, except for one (14), were considered at high risk for STIs on the basis of sociodemographic population risk factors or individual risk factors, including participants with a history of current or previous STI ranging from 20% to 100%. Behavioral counseling interventions ranged from low intensity (for example, distribution of tailored self-help materials) to high intensity (for example, multiple-session counseling interventions up to 10 sessions).

Most evidence (5 RCTs; $n = 8122$) suggests a modest reduction in bacterial STIs at 12 months among high-risk adults receiving moderate- to high-intensity counseling interventions (13, 15–17, 19). Only 1 of these 5 trials was conducted in a primary care setting, which was identified after the completion of the final evidence report for the

Figure 2. Study flow diagram.



KQ = key question; SER = systematic evidence review.

* Articles for KQ3 and KQ4 were reviewed from articles from KQ1 and KQ2.

USPSTF (13). This good-quality trial, by Jemmott and colleagues ($n = 564$), showed that women receiving either low-intensity individual counseling or high-intensity group counseling had fewer incident bacterial STIs than did control participants (14% to 15% vs. 27%, respectively). The results are reported only for the low-intensity and high-intensity intervention groups combined, probably because the counseling intervention groups were not independently statistically significant. Three trials conducted in STI clinics ($n = 7150$) showed a moderate decrease in bacterial STI incidence at 12 months, compared with usual care that included only minimal counseling. The largest STI clinic trial, Project RESPECT (Review, Enhance, Situations, Plan, Examine, Challenge, Tell), by Kamb and colleagues ($n = 5758$) (17), showed that individuals receiving either moderate- or high-intensity individual HIV counseling with testing, compared with usual care with 10-minute education, had fewer incident bacterial or viral

STIs (11.5% to 12.0% vs. 14.6%, respectively) (17). The moderate-intensity and high-intensity counseling interventions did not seem to differ in effect. However, Project RESPECT, otherwise a well-done RCT, had only 70% follow-up at 6 months and 66% follow-up at 12 months. In the remaining trial ($n = 408$) showing a treatment benefit, psychiatric clinic outpatients who received very-high-intensity group counseling (10 sessions) had a lower incidence of any self-reported STI at 6 months than did those receiving similarly formatted substance abuse counseling (19). However, this trial used self-reported, as opposed to laboratory or clinically diagnosed, STI.

In contrast, 3 treatment trials—1 trial in high-risk persons attending an STI clinic and 2 trials in primary care patients—showed no benefit. A fair-quality trial by Boyer and colleagues (18) conducted in an STI clinic ($n = 393$) did not show a reduction in incident bacterial or viral STIs at 6 months in participants receiving high-intensity indi-

vidual counseling; however, this trial had a shorter duration and suboptimal follow-up (70% at 6 months). Two fair-quality trials in young women attending primary care clinics showed no statistically significant difference in self-reported or laboratory-tested STIs (14, 21). In both trials, the women had relatively low rates of STI outcomes, and 1 of the trials, by Scholes and colleagues (20), used self-reported outcomes and a shorter duration of follow-up. Thus, all 3 trials had limitations in study design that may have limited their ability to detect statistically significant differences in STI incidence.

Adolescents

We identified 4 fair- or good-quality RCTs that examined the effect of behavioral counseling interventions on reducing STI incidence in adolescents, one of which is an a priori subgroup analysis from Project RESPECT (Table 2) (17, 21–23). Three of the 4 trials included only sexually active adolescents (17, 22, 23), and 1 included both sexually active and pre-sexually active adolescents (age 12 to 15 years) (21). Interventions ranged from low to high intensity and from 1 to 4 sessions and were in either an individual or a small-group format.

Most evidence (3 RCTs; $n = 1998$) showed a modest reduction in STI incidence at 12 months in sexually active adolescents receiving moderate- to high-intensity counseling. Two of these trials were exclusively in adolescent girls receiving high-intensity group counseling (22, 23). In a subgroup analysis of participants younger than age 20 years from Project RESPECT ($n = 764$), those receiving HIV counseling and testing had lower rates of STIs at 12 months than did those receiving usual care (approximately 17% to 18% vs. 26.6%, respectively) (24).

We found only 1 fair-quality RCT that included pre-sexually active young adolescents ($n = 219$), in which a low-intensity counseling did not reduce the incidence of self-reported STI (21). This trial, by Boekeloo and colleagues (21), was probably not powered to show a difference in STI incidence, given the small sample size, relatively short follow-up, and low percentages of incident STI.

Pregnant Women

We found no studies specifically addressing pregnant women that met our inclusion criteria. Project SAFE (Sexual Awareness for Everyone), which found a moderate reduction in incident gonorrhea and chlamydial infections at 12 months using a high-intensity group counseling intervention, included about 30% pregnant women. Their results, however, were not reported separately for this subgroup (16).

Key Question 2

Does primary care behavioral counseling to prevent STI result in safer sexual behaviors among those counseled?

Adults

We identified 3 fair- or good-quality trials that examined the effect of behavioral counseling interventions on reducing self-reported risky sexual behaviors or increasing protective sexual behaviors in adults but did not report biological health outcomes (Appendix Table 1, available at www.annals.org) (25–27). All of these RCTs were conducted in primary care or equivalent clinic settings. Behavioral counseling interventions in these studies ranged from low intensity (brief single-session counseling) to high intensity (multiple-session counseling up to 18 hours).

Only 1 good-quality trial, by Ehrhardt and colleagues ($n = 360$) (25), showed a decrease in self-reported unprotected sexual intercourse and an 18% increase in self-reported condom use in women receiving an extremely intensive counseling intervention consisting of nine 2-hour group sessions (25). These women attending a family planning clinic were at similar risk to those attending STI clinics (almost 60% with a history of an STI). Two fair-quality trials did not show a reduction in self-reported risky sexual behaviors (unprotected sexual intercourse or multiple sex partners) or an increase in consistent condom use (26, 27). An RCT in Australia ($n = 312$) by Proude and colleagues (26) evaluated a low-intensity physician-counseling intervention but had limited follow-up (3 months). The other RCT ($n = 370$), conducted at a university health clinic, did not show any changes in condom use or number of sex partners with moderate-intensity counseling but also had relatively limited follow-up (6 months) (27).

Measures of self-reported behavioral outcomes (for example, unprotected sexual intercourse, condom use, and number of sexual partners) and methods of data collection (for example, interview or questionnaire) varied among trials, further limiting comparisons across trials.

Adolescents

We identified 1 fair-quality trial that examined the effect of general safe sex counseling in primary care among high school-age male adolescents (28). This trial did not show an increase in condom use or abstinence with a single 1-hour counseling intervention, compared with the wait-list control group.

Pregnant Women

We found no studies meeting our inclusion criteria that specifically addressed pregnant women.

Key Question 3

Does primary care behavioral counseling to prevent STIs result in benefits other than safer sexual behaviors and reductions in STI incidence?

In general, few studies reported on other behavioral or biological outcomes (for example, self-reported measures of reduction in other risky behaviors, or reduction in unwanted pregnancy or pregnancy in adolescents). For adults, we found evidence from Project SAFE ($n = 617$) that

Table 2. Effectiveness of Behavioral Counseling Interventions to Reduce STIs in Adults and Adolescents Based on Randomized, Controlled Trials (Key Question 1)

Study, Year (Reference)	Study Quality	Study Sample	Setting	Counseling Intervention
Adults				
Petersen et al., 2007 (14)	Fair	<i>n</i> = 737; age range, 16–44 y; 0% male	PC clinics	Pregnancy and STI risk reduction based on motivational interviewing IG: moderate or high—unknown duration; 2 individual sessions CG: single-session general health promotion counseling
Jemmott et al., 2007 (13)	Good	<i>n</i> = 564; mean age, 27 y; 0% male	PC clinic	Culturally tailored, skills-based intervention based on social cognitive behavioral theory IG1: high—200 min total; 1 group session IG2: low—20 min total; 1 individual session CG: matched general health promotion counseling
Shain et al., 2004 (15); Project SAFE 2	Fair	<i>n</i> = 775 (690 in analysis); mean age, 21 y; 0% male	STI clinic	Culturally tailored ARRM IG1 and IG2: high—9 h total; 3 group sessions ± optional support group sessions CG: usual care, 15-min counseling
Shain et al., 1999 (16); Project SAFE	Good	<i>n</i> = 617 (549 in analysis); mean age, 21 y; 0% male	STI clinic	Culturally tailored ARRM IG: high—9 to 12 h total; 3 group sessions CG: usual care, 15-min counseling
Kamb et al., 1998 (17); Project RESPECT	Fair	<i>n</i> = 5758; median age, 25 y; 57% male	STI clinics	Enhanced CDC's client-centered HIV prevention counseling model IG1: high—200 min total; 4 individual sessions IG2: moderate—40 min total; 2 individual sessions CG: usual care, 10-min information only
Boyer et al., 1997 (18)	Fair	<i>n</i> = 393; age range, 18–35 y; 67% male	STI clinic	ARRM IG: high—4 h total; 4 individual sessions CG: usual care, 15-min counseling
Carey et al., 2004 (19)	Fair	<i>n</i> = 408; median age, 36 y; 46% male	Psychiatric clinic	HIV harm reduction model and motivational techniques IG: high—unknown total hours; 10 group sessions CG1 and CG2: matched substance abuse counseling or usual care
Scholes et al., 2003 (20)	Fair	<i>n</i> = 1210; mean age, 21 y; 0% male	PC clinics	Individually tailored self-help printed materials based on multiple social science theories IG: low—2 mailings: 12-page booklet and booster newsletter CG: usual care, details NR
Adolescents				
Jemmott et al., 2005 (22)	Good	<i>n</i> = 682; mean age, 15 y; 0% male	PC clinic	Culturally tailored, skills-based intervention based on cognitive behavioral theories IG1 and IG2: high—250 min total; 1 group session ± skills training CG: matched general health promotion counseling
DiClemente et al., 2004 (23)	Good	<i>n</i> = 522; mean age, 16 y; 0% male	PC clinics	Culturally tailored social cognitive theory and theory of gender and power; with peer co-facilitators IG: high—4 h total; 4 group sessions CG: matched nutrition and exercise counseling
Kamb et al., 1998 (17); Bolu et al., 2004 (24); Project RESPECT	Fair	<i>n</i> = 764 (subgroup analysis of 5758); subgroup age <20 y	STI clinics	Enhanced CDC's client-centered HIV prevention counseling model IG1: high—200 min total; 4 individual sessions IG2: moderate—40 min total; 2 individual sessions CG: usual care, 10-min information only
Boekeloo et al., 1999 (21)	Fair	<i>n</i> = 219; age 12–15 y (mean NR); 50% male	PC clinics	Physician counseling based on 15-min audiotape risk assessment done in waiting period IG: low—unknown total duration; "brief" individual session CG: usual care, details NR

ARRM = AIDS risk reduction model; CDC = Centers for Disease Control and Prevention; CG = control group; IG = intervention group; NR = not reported; NS = not significant; OR = odds ratio; PC = primary care; RESPECT = Review, Enhance, Situations, Plan, Examine, Challenge, Tell; RR = relative risk; SAFE = Sexual Awareness For Everyone; STI = sexually transmitted infection.

* Or longest follow-up if otherwise specified.

high-intensity behavioral counseling can increase adherence to treatment recommendations for women in an STI clinic setting (15, 16, 25). For adolescents, we found evidence that moderate- to high-intensity behavioral counseling may decrease other risky behavior and pregnancy in sexually active female adolescents (19, 20, 22) and may

increase general contraceptive use in male adolescents (21–23, 28). Jemmott and colleagues' study (*n* = 682) showed that a high-intensity group counseling intervention decreased the mean number of days of sex while intoxicated (22). DiClemente and associates' study in adolescent black girls (*n* = 522) showed that a high-intensity group coun-

Table 2—Continued

STI Outcome at 12-mo Follow-up*

STI-positive (for chlamydia):

Total: 1%; NS differences between groups, data not shown

STI-positive (for any other STI by self-report or chart review):

Total: 8%; NS differences between groups, data not shown

STI-positive (for gonorrhea, chlamydia, trichomonas), adjusted:

IG1: 15%

IG2: 14%

CG: 27%; $P = 0.03$ (IG1 and IG2 vs. CG)

STI-positive (for gonorrhea, chlamydia), adjusted:

IG1: 15.7%; $P = 0.006$; OR, 0.51 (95% CI, 0.31–0.83)IG2: 15.4%; $P = 0.004$; OR, 0.50 (CI, 0.31–0.80)

CG: 26.8%

STI-positive (for gonorrhea, chlamydia), adjusted:

IG: 16.8%; $P = 0.004$; OR, 0.52 (CI, 0.34–0.81)

CG: 26.9%

STI-positive (for gonorrhea, chlamydia, syphilis, HIV), adjusted:

IG1: 11.5%; RR, 0.78 (CI, 0.64–0.94)

IG2: 12.0%; RR, 0.81 (CI, 0.67–0.98)

CG1: 14.6%

STI-positive at 6 mo (for any STI):

IG: 6.8% (male); 21.8% (female); $P = NS$

CG: 7.0% (male); 22% (female)

Self-report at 6 mo of new STI diagnosis, adjusted:

IG: 2%

CG1: 8%; $P < 0.013$ CG2: 5%; $P < 0.046$

Self-report (at 6 mo) of STI diagnosis in past 3 mo, adjusted:

IG: 3.5%; $P = 0.93$; OR, 0.97 (CI, 0.48–1.96)

CG: 3.6%

STI-positive (for gonorrhea, chlamydia, trichomonas), adjusted:

IG1: 10.5%; $P = 0.05$ IG2: 14.4%; $P = 0.44$

CG: 18.2%

STI incidence per 100 person-months (crude) and OR (adjusted):

Chlamydia:

IG: 2.1; CG: 2.0

OR, 0.17 (CI,
0.03–0.92)

Gonorrhea:

IG: 0.9; CG: 0.7

OR, 0.14 (CI,
0.01–3.02)

Trichomonas:

IG: 0.9; CG: 1.2

OR, 0.37 (CI,
0.09–1.46)

STI-positive (for gonorrhea, chlamydia, syphilis, HIV), adjusted:

IG1: 17.2%; RR, 0.57 (CI, 0.37–0.90)

IG2: 17.5%; RR, 0.58 (CI, 0.37–0.92)

CG1: 26.6%

Self-report at 9 mo of STI (told by physician/nurse):

IG: 0%; $P = NS$

CG: 2.9%

Self-report at 9 mo of treatment for STI:

IG: 1.1%; $P = NS$

CG: 5.8%

individual intervention can increase general contraception among high-school boys (28).

Key Question 4

Are there harms from primary care behavioral counseling to prevent STI?

Adults

Overall, the 11 trials ($n = 11\,826$) evaluating risk reduction counseling in adult populations did not show any increased incidence of STIs or self-reported risky behaviors, including increased unprotected sex or increased number of sexual partners (Appendix Table 1, available at www.annals.org) (13–20, 25–27). The 8 trials ($n = 10\,462$) that reported biological outcomes did not show an increased incidence of STIs, either by self-report or laboratory testing (13–20). Ten trials showed no evidence of self-reported increased unprotected sex (or decreased use of condoms) (13, 14, 16–20, 25–27). Six trials showed no evidence of self-reported increase in the number of sexual partners.

Adolescents

Overall, the 5 trials ($n = 3382$) evaluating risk reduction counseling in adolescents did not show an increased incidence of STIs or self-reported risk behaviors, including increased unprotected sex, increased number of sexual partners, or earlier sexual debut (Appendix Table 1, available at www.annals.org) (21–23, 28). The 4 trials ($n = 2187$) that reported on biological outcomes did not show any increased incidence of STIs, either by self-report or laboratory testing. Five trials did not show an increase in self-reported unprotected sex (or decrease in self-reported use of condoms). Two trials showed no increase in the participants' self-reported number of sexual partners.

Boekeloo and colleagues' trial ($n = 219$) showed a transient increase in self-reported vaginal sex at 3 months, but not at 9 months, in adolescents age 12 to 15 years (21). Self-reported overall sexual intercourse (vaginal, oral, or anal sex), however, did not increase.

DISCUSSION

On the basis of primary care–relevant trial data, good evidence suggests the effectiveness of moderate- to high-intensity behavioral counseling in reducing the incidence of overall STIs (excluding herpes simplex virus) in high-risk adult and sexually active adolescent populations, with more robust evidence for common bacterial STIs (such as gonorrhea and chlamydia) (Table 3). In general, the body of evidence from trials using self-reported behavior outcomes supports the interpretation of the evidence using biological outcomes. We found no trials evaluating the effectiveness of behavioral counseling interventions to prevent STIs in truly low-risk populations, because even trials conducted in primary care settings included only persons

selling intervention reduce self-reported pregnancy (23). Boekeloo and colleagues' trial in young adolescents ($n = 219$) showed that a low-intensity counseling intervention may reduce self-reported pregnancy, although the trial's results were not statistically significant (21). Danielson and colleagues ($n = 1195$) showed that a moderate-intensity

at higher risk (for example, sexually active adolescents or young adults age <25 years) (Figure 3).

On the basis of 11 trials, no substantial harm is evident in counseling interventions for adults or adolescents (Table 3). In young adolescents, low-intensity risk reduction behavioral counseling transiently increased self-reported vaginal sexual intercourse in young adolescents. The importance of this transient finding is unclear, however, given that no change in overall sexual activity or vaginal sexual activity was apparent by the end of the trial at 9 months (21). Only 1 study reported on sexual debut, and it found that risk reduction counseling did not increase sexual activity in participants who were previously not sexually active (28). We found no trials for risk avoidance or abstinence-only counseling that met our inclusion criteria. Therefore, we could not assess potential harms or benefits associated with these types of counseling interventions. Our findings are consistent with a recent meta-analysis that included all studies examining a deliberate HIV risk reduction counseling intervention in a nonperinatal context, which found no inadvertent increase in the number of sexual occasions or sexual partners (29).

Given the clinical heterogeneity among these trials, we could not draw definitive conclusions about the differential effect of interventions on specific populations or the differential effect of specific intervention elements (for example, theory, content, format, and intensity). On the basis of this body of evidence, however, population risk and intervention intensity seem to be the biggest predictors of a counseling intervention's effect on STI incidence and self-reported behavior change. In general, there is more trial evidence in female than in male adults and adolescents. In adults, evidence for specific high-risk populations is strong: black and Hispanic populations, low-income urban populations, populations with a high baseline prevalence of STIs or history of STIs (20% to 100%), and persons with major psychiatric disease and comorbid recent history of substance abuse. Evidence for sexually active adolescents is also strong, specifically for ethnically diverse and low-income, urban adolescent populations.

Intervention intensity, more than format or a particular behavioral model, may also be an important factor in the effectiveness of counseling interventions. However, no low-intensity or single-visit counseling interventions were used in the highest-risk populations (that is, trials conducted in STI clinics). The range of intensity for effective interventions was 40 minutes delivered in 2 sessions with HIV testing (17) to 18 hours over 9 sessions (25). One trial showed potential benefit of a low-intensity (20-minute, one-to-one counseling) intervention to decrease laboratory-tested STIs at 12 months, but it did not include separate analysis of the low-intensity intervention group, probably because of statistical power limitations (13). Two trials in high-risk populations conducted in primary care ($n = 1429$) did not show a reduction in the incidence of self-reported STIs using low-intensity interventions (13,

20, 21). All effective interventions were based on individual risk-based counseling and included tailored risk reduction plans. Most of these interventions were developed with some amount of formative research within the targeted population. For adolescents, 2 of the effective interventions also included instruction on condom skills. In 1 of Jemmott and colleagues' studies, only the condom skills intervention group showed an effect on STI reduction (22). All effective interventions were based on common behavioral models, including the AIDS risk reduction model, cognitive-behavioral theories, harm reduction, stages of change theory and motivational techniques, theory of reasoned action, and social cognitive theory. These behavioral models and social theories, however, were also the basis for interventions that did not show a risk reduction in STIs or behavioral change in high-risk populations seen in primary care (20, 21, 28).

This body of evidence has several limitations. First, trials reporting STI incidence with non-statistically significant intervention effects do not imply that the interventions are ineffective (14, 18, 20, 21). The overall incidence of even common bacterial STIs is relatively low. These studies, therefore, are subject to type II measurement error (such as inadequate power). Second, trials for key question 2 using self-reported behavioral outcomes should be interpreted with caution, especially if there is no consistency in direction or magnitude of effect among different behavioral outcomes. Self-reported STI incidence and self-reported behavioral outcomes are particularly subject to both assessment and reporting bias (30), although methodological improvements in measurement can reduce these biases. Third, as a result of our stringency around internal validity and scope of interventions, our findings have limitations in generalizability. Many high-risk populations are not addressed. For some of these populations, sexual risk reduction is addressed elsewhere. In men who have sex with men and intravenous drug users, for example, good evidence indicates that community-based and community-level interventions can reduce risky behaviors (31–34). We found limited rigorous trial evidence for many high-risk groups. In addition, some types of counseling interventions (for example, HIV counseling and testing, risk avoidance counseling) are not adequately represented in our review, although they were recently reviewed elsewhere (34, 35).

Even more important than the limitations of applicability to different populations or interventions types, however, are the translational issues of delivering behavioral counseling interventions in practice. These issues are particularly pertinent for this body of evidence, because all identified effective counseling interventions were moderate to high intensity and, at minimum, involved multiple sessions and trained counselors. All trials had dedicated research staff for recruitment (screening), intervention, and assessments.

Evidence is lacking for the effectiveness of low-intensity behavioral counseling interventions, especially in lower-

Table 3. Summary of Evidence

Studies	Limitations; Consistency	Validity	Summary of Findings
Key question 1: biological outcomes			
Adults			
8 RCTs	Heterogeneity in settings, populations, and interventions; inconsistency of findings by trial setting, population risk, and intensity of intervention	Internal: Fair to good External: Fair High-risk populations; trials mainly conducted in urban settings and specialty settings, and in women and minorities	Four ($n = 7714$) of the 6 trials that used laboratory-tested outcome measures showed a moderate reduction in STI incidence at 12 mo among high-risk adults receiving moderate- to high-intensity counseling interventions. One trial ($n = 737$) did not show a reduction in STI incidence at 12 mo in women attending PC receiving a moderate- or high-intensity counseling intervention. One trial ($n = 393$) did not show a reduction in STI incidence at 6 mo in adults attending an STI clinic and receiving a high-intensity counseling intervention. One trial in a psychiatric clinic ($n = 408$) showed a moderate reduction in self-reported STI incidence using a high-intensity counseling intervention. One trial ($n = 1210$) did not show a reduction in self-reported STIs in adults receiving a low-intensity counseling intervention. Self-reported measures of STI outcomes should be interpreted cautiously.
Adolescents			
4 RCTs	Heterogeneity in populations and interventions; inconsistency of findings between sexually active adolescents and general adolescent population and by intensity of intervention	Internal: Fair to good External: Fair Trials mainly conducted in urban settings and in girls and minorities	Sexually active adolescents: All 3 trials ($n = 1998$) showed a modest reduction in laboratory-diagnosed STI incidence at 12 mo in sexually active adolescents receiving moderate- to high-intensity counseling interventions. Pre-sexually active and sexually active adolescents: One trial ($n = 219$) did not show a reduction in self-reported STI incidence at 3 or 9 mo in young adolescents receiving a low-intensity counseling intervention. Self-reported measures of STI outcomes should be interpreted cautiously.
Key question 2: behavioral outcomes			
Adults			
3 RCTs	Heterogeneity in populations and interventions; inconsistency of findings by population risk and intervention intensity	Internal: Fair External: Fair High-risk populations; 1 trial conducted in Australia	Two of the 3 trials did not show a decrease in self-reported risky sexual behavior (i.e., unprotected sexual intercourse or multiple sex partners) or an increase in self-reported male condom use in adults receiving low- to high-intensity counseling interventions. Only 1 trial showed a decrease in self-reported unprotected sexual intercourse and increase in self-reported (male and female) condom use at 12 mo in women with a high percentage of previous STI who were receiving a very-high-intensity counseling intervention (18 h) but not a high-intensity counseling intervention (10 h).
Adolescents			
1 RCT	Only 1 study	Internal: Fair External: Fair Conducted in high school-age boys	Pre-sexually active and sexually active adolescents: This study did not show an increase in condom use or abstinence at 12 mo in male adolescents receiving a moderate-intensity counseling intervention.
Key question 3: other positive outcomes			
Adults			
4 RCTs	Limited number of trials reporting additional positive outcomes; no serious inconsistencies	Internal: Fair External: Fair High-risk populations; mainly conducted in urban settings and in women and minorities	Two trials conducted in STI clinics found that women receiving high-intensity group counseling also had increased STI treatment adherence. One trial in an urban family-planning clinic did not show an increase in self-reported "alternative risk reduction" strategies with high-intensity group counseling at 12 mo. One trial in PC did not show an increase in overall contraceptive use or decrease in unintended pregnancy at 12 mo.
Adolescents			
4 RCTs	Limited number of trials reporting additional positive outcomes; no serious inconsistencies	Internal: Fair External: Fair Trials mainly conducted in urban settings and minorities	Sexually active adolescents: One trial showed a decrease in self-reported sex while intoxicated at 3 and 6 mo, but not at 12 mo, in female adolescents receiving high-intensity group counseling. Another trial showed a decrease in self-reported pregnancy at 6 mo, but not at 12 mo, in female adolescents receiving high-intensity group counseling. The significance of transient findings is unclear. Pre-sexually active and sexually active adolescents: One trial did not show a statistically significant decrease in self-reported pregnancy in adolescents receiving a low-intensity counseling intervention, which also had a smaller sample size and fewer reported pregnancies. Another trial showed an increase in general contraception use in male adolescents receiving a moderate-intensity counseling intervention.

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Table 3—Continued

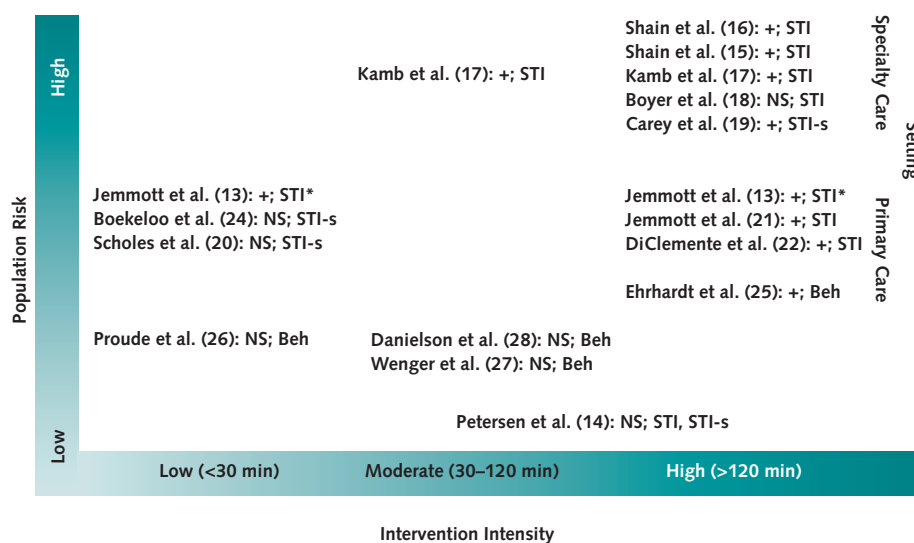
Studies	Limitations; Consistency	Validity	Summary of Findings
Key question 4: adverse effects			
Adults			
11 RCTs	No significant limitations or inconsistencies	Internal: Fair to good External: Fair High-risk populations	Overall, no increase in number of sexual partners, unprotected sexual intercourse, or STI incidence by testing or self-report with low- to high-intensity counseling interventions.
Adolescents			
4 RCTs	Heterogeneity in populations, interventions, and measurement of outcomes limiting ability to make comparisons between trials; however, no serious inconsistencies	Internal: Fair to good External: Fair Trials mainly conducted in urban settings and minorities; only 2 trials included pre-sexually active adolescents	Sexually active adolescents: Overall, no increase in number of sexual partners, unprotected sexual intercourse, or STI incidence by testing or self-report with high-intensity counseling interventions. Pre-sexually active and sexually active adolescents: One study showed a transient increase of vaginal sex in young adolescents receiving a low-intensity counseling intervention at 3 mo (OR, 2.46 [95% CI, 1.04–5.84]), but no increase at 9 mo and no increase in overall sexual activity at either follow-up. Another study in PC showed no evidence of earlier sexual debut in male adolescents receiving a moderate-intensity counseling intervention.

OR = odds ratio; PC = primary care; RCT = randomized, controlled trial; STI = sexually transmitted infection.

risk populations. The few trials that evaluated low-intensity interventions had study design factors that may have contributed to their non-statistically significant intervention effect findings (13, 20, 21, 26). Thus, we need trials that evaluate low-intensity counseling interventions, which may be applicable to primary care. **Appendix Table 2** (available at www.annals.org) lists trials that are currently in progress. From rigorous trials evaluating behavioral counseling interventions, we conclude that population risk and intervention intensity seem to be the strongest predictors of inter-

vention effect. Good evidence suggests that moderate- to high-intensity behavioral counseling is effective in reducing STI incidence in high-risk populations in both STI clinics and primary care settings. Rigorous trials that replicate the effectiveness of proven counseling interventions in other populations are needed to demonstrate the feasibility and generalizability of primary care behavioral counseling interventions to prevent STIs. In addition, methodologically rigorous trial evidence on the effectiveness of primary care behavioral counseling to prevent STIs is lacking—particu-

Figure 3. Summary of findings: intervention intensity vs. population risk and setting.



+ = positive findings; Beh = behavioral outcomes; NS = non-statistically significant findings; STI = sexually transmitted infection (biological outcomes); STI-s = self-reported STI.

* Low- and high-intensity intervention groups were not analyzed separately.

larly for men and male adolescents, pregnant women, and certain high-risk populations.

From the Center for Health Research, Kaiser Permanente Northwest, Portland, Oregon.

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Corresponding Author: Jennifer S. Lin, MD, MCR, Center for Health Research, Kaiser Permanente Northwest, 3800 North Interstate Avenue, Portland, OR 97227; e-mail, jennifer.s.lin@kpchr.org.

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Current author addresses are available at www.annals.org.

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Current Author Addresses: Drs. Lin, Whitlock, and O'Connor and Mr. Bauer: Center for Health Research, Kaiser Permanente Northwest, 3800 North Interstate Avenue, Portland, OR 97227.

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Appendix Table 1. Effectiveness of Behavioral Counseling Interventions							
Study, Year (Reference)	Study Quality	Setting	Study Sample	Counseling Intervention	Follow-up, %	Outcome at 12-mo Follow-up*	Outcomes
Adults with biological outcomes							
Petersen et al., 2007 (14)	Fair (minor concerns about reporting)	PC (FP) clinics	<i>n</i> = 737; age range, 16–44 y; 0% male; 27% black	Pregnancy and STI risk reduction based on motivational interviewing IG: moderate or high—unknown duration; 2 (individual) sessions CG: single-session general health promotion counseling	8 mo: 91; 12 mo: 87	STI-positive (for chlamydia): Total: 1%; NS differences between groups, data not shown STI-positive (for any other STI by self-report or chart review): Total: 8%; NS differences between groups, data not shown	No increase in unprotected sex or decrease in condom use; no increase in STI incidence (by self-report, chart review, or testing)
Jemmott et al., 2007 (13)	Good	Women’s health clinic (hospital-based)	<i>n</i> = 564; mean age, 27 y; 0% male; 100% black; 20% with STI (current)	Culturally tailored, skills-based intervention based on social cognitive-behavioral theory IG1: high—200 min total; 1 group session IG2: low—20 min total; 1 individual session CG: matched general health promotion counseling	6 mo: 90; 12 mo: 87	STI-positive (for gonorrhea, chlamydia, trichomonas), adjusted: IG1: 15% IG2: 14% CG: 27%; <i>P</i> = 0.03 (IG1 and IG2 vs. CG)	No increase in unprotected sex or decrease in condom use; no increase in STI incidence (by testing)
Shain et al., 2004 (15); Project SAFE 2	Fair (groups slightly different at baseline, minor concerns about reporting)	STI clinic	<i>n</i> = 775 (690 in analysis); mean age, 21 y; 0% male; 23% black; 77% Hispanic; 100% with STI (current)	Culturally tailored ARRM IG1 and IG2: high—9 h total; 3 group sessions ± optional support group sessions CG: usual care, 15-min counseling	12 mo: 91; 24 mo: 91	STI-positive (for gonorrhea, chlamydia), adjusted: IG1: 15.7%; <i>P</i> = 0.006; OR, 0.51 (95% CI, 0.31–0.83) IG2: 15.4%; <i>P</i> = 0.004; OR, 0.50 (CI, 0.31–0.80) CG: 26.8%	No increase in number of sex partners; no increase in STI incidence (by testing)
Shain et al., 1999 (16); Project SAFE	Good	STI clinic	<i>n</i> = 617 (549 in analysis); mean age, 21 y; 0% male; 31% black; 69% Hispanic; 100% with STI (current)	Culturally tailored ARRM IG: high—9 to 12 h total; 3 group sessions CG: usual care, 15-min counseling	6 mo: 82; 12 mo: 89	STI-positive (for gonorrhea, chlamydia), adjusted: IG: 16.8%; <i>P</i> = 0.004; OR, 0.52 (CI, 0.34–0.81) CG: 26.9%	No increase in unprotected sex or decrease in condom use; no increase in STI incidence (by self-report)
Kamb et al., 1998 (17); Project RESPECT	Fair (suboptimal follow-up)	STI clinics	<i>n</i> = 5758; median age, 25 y; 57% male; 59% black; 19% Hispanic; 6% other nonwhite; 32% with STI (current)	Enhanced CDC client-centered HIV prevention counseling model IG1: high—200 min total; 4 individual sessions IG2: moderate—40 min total; 2 individual sessions CG: usual care, 10-min information only	6 mo: 70; 12 mo: 66	STI-positive (for gonorrhea, chlamydia, syphilis, HIV), adjusted: IG1: 11.5%; RR, 0.78 (CI, 0.64–0.94) IG2: 12.0%; RR, 0.81 (CI, 0.67–0.98) CG1: 14.6%	No increase in number of sex partners; no increase in unprotected sex or decrease in condom use; no increase in STI incidence (by testing)
Boyer et al., 1997 (18)	Fair	STI clinic	<i>n</i> = 393; age range, 18–35 y; 67% male; 46% black; 15% Hispanic; 10% other nonwhite; 62% with STI Hx	ARRM IG: high—4 h total; 4 individual sessions CG: usual care, 15-min counseling	Within 6 mo: 72	STI-positive at 6 mo (for any STI): IG: 6.8% (male); 21.8% (female); <i>P</i> = NS CG: 7.0% (male); 22% (female)	No increase in number of sex partners; no increase in unprotected sex acts; no increase in STI incidence (by self-report)
Carey et al., 2004 (19)	Fair (minor concerns about reporting)	Psychiatric clinic	<i>n</i> = 408; median age, 36 y; 46% male; 21% black; 38% with STI Hx	HIV harm reduction model and motivational techniques IG: high—unknown total hours; 10 group sessions CG1 and CG2: matched substance abuse counseling or usual care	6 mo: 89; 9 mo: 88	Self-report at 6 mo of new STI diagnosis, adjusted: IG: 2% CG1: 8%; <i>P</i> < 0.013 CG2: 5%; <i>P</i> < 0.046	No increase in number of sex partners; no increase in unprotected sex or decrease in condom use; no increase in STI incidence (by self-report)
Scholes et al., 2003 (20)	Fair (minor concerns about reporting)	Medical clinics (managed care practice)	<i>n</i> = 1210; mean age, 21 y; 0% male; 19% black; 12% other nonwhite; 27% with STI Hx	Individually tailored self-help printed materials based on multiple social science theories IG: low—2 mailings: 12-page booklet and booster newsletter CG: usual care, details NR	6 mo: 86	Self-report (at 6 mo) of STI diagnosis in past 3 mo; adjusted: IG: 3%; <i>P</i> = 0.93; OR, 0.97 (CI, 0.48–1.96) CG: 3.6%	No increase in unprotected sex or decrease in condom use; no increase in STI incidence (by self-report)
Adolescents with biological outcomes							
Jemmott et al., 2005 (22)	Good	Adolescent medicine clinic (hospital-based)	<i>n</i> = 682 (235 in IG1); mean age, 15 y; 0% male; 68% black; 32% Hispanic; 22% with STI (current)	Culturally tailored, skills-based intervention based on cognitive-behavioral theories IG1 and IG2: high—250 min total; 1 group session ± skills training CG: matched general health promotion counseling	6 mo: 93; 12 mo: 89	STI-positive (for gonorrhea, chlamydia, trichomonas), adjusted: IG1: 10.5%; <i>P</i> = 0.05 IG2: 14.4%; <i>P</i> = 0.44 CG: 18.2%	No increase in number of sex partners; no increase in unprotected sex or decrease in condom use; no increase in STI incidence (by testing)
DiClemente et al., 2004 (23)	Good	Community health clinics	<i>n</i> = 522; mean age, 16 y; 0% male; 100% black; 17% with chlamydia (current)	Culturally tailored social cognitive theory and theory of gender and power, with peer co-facilitators IG: high—4 h total; 4 group sessions CG: matched nutrition and exercise counseling	6 mo: 90; 12 mo: 88	STI incidence per 100 person-months (crude) and OR (adjusted): Chlamydia: IG: 2.1; CG: 2.0 OR, 0.17 (CI, 0.03–0.92) Gonorrhea: IG: 0.9; CG: 0.7 OR, 0.14 (CI, 0.01–3.02) Trichomonas: IG: 0.9; CG: 1.2 OR, 0.37 (CI, 0.09–1.46)	No increase in unprotected sex or decrease in condom use; no increase in STI incidence (by testing)
Kamb et al., 1998 (17); Bolu et al., 2004 (24); Project RESPECT	Fair (suboptimal follow-up)	STI clinics	<i>n</i> = 764 (subgroup analysis of 5758); subgroup age <20 y	Enhanced CDC client-centered HIV prevention counseling model IG1: high—200 min total; 4 individual sessions IG2: moderate—40 min total; 2 individual sessions CG: usual care, 10-min information only	NR	STI-positive (for gonorrhea, chlamydia, syphilis, HIV), adjusted: IG1: 17.2%; RR, 0.57 (CI, 0.37–0.90) IG2: 17.5%; RR, 0.58 (CI, 0.37–0.92) CG1: 26.6%	No increase in STI incidence (by testing)
Boekeloo et al., 1999 (21)	Fair (minor concerns about reporting)	Pediatric clinics (HMO)	<i>n</i> = 219; age 12–15 y (mean age NR); 50% male; 64% black; 3% Hispanic; 14% other nonwhite; 6% with STI Hx (past 3 mo)	Physician counseling based on 15-min audiotape risk assessment done in waiting period IG: low—unknown total duration; “brief” individual session CG: usual care, details NR	9 mo: 90	Self-report at 9 mo with STI (told by physician/nurse): IG: 0%; <i>P</i> = NS CG: 2.9% Self-report at 9 mo of treatment for STI: IG: 1.1%; <i>P</i> = NS CG: 5.8%	Increase in percentage having vaginal sex at 3 mo but not at 9 mo; no increase in any (vaginal, oral, or anal) sex; no increase in unprotected sex or decrease in condom use; no increase in STI incidence (by self-report)

Continued on following page

Appendix Table 1—Continued

Study, Year (Reference)	Study Quality	Setting	Study Sample	Counseling Intervention	Follow-up, %	Outcome at 12-mo Follow-Up*	Outcomes
Adults with behavioral outcomes only							
Ehrhardt et al., 2002 (25); Hoffman et al., 2003 (36); Melendez et al., 2003 (37); Project FIO	Good	Planned Parenthood clinic	<i>n</i> = 682; mean age, 22.3 y; 0% male; 73 black; 17% Hispanic; 58.3% with STI (previous)	Culturally tailored ARRM IG1: high—10 h total; 4 group sessions plus booster at 9 mo IG2: high—18 h total; 8 group sessions plus booster at 9 mo CG: usual care, assessment only	6 mo: 91 12 mo: 97	Condom use in past 3 mo: IG1: NR IG2: 18% increase (<i>P</i> = 0.06) CG: NR Model predicted mean number of unprotected acts in past 3 mo: IG2: On average, 4 fewer UVI/UAI than control group (<i>P</i> = 0.00) Maintaining or improving safer sex behavior, adjusted: IG1: 66.4% IG2: 72.7% CG: 61.7% OR (IG2 to CG), 1.65 (CI, 0.94–2.90)	No increase in unprotected sex or decrease in condom use
Proude et al., 2004 (26)	Fair (suboptimal follow-up, minor concerns about reporting)	FPs; Australia	<i>n</i> = 312; age range, 18–25 y; 29% male	Physician counseling based on brief risk assessment done by FP during visit; theory not specified IG: low—unknown total duration; “brief” individual session CG: usual care, details NR	3 mo: 68	At 3 mo, new sex partners over past 3 mo (calculated): IG1: 7.1% (11/156) CG: 8.3% (13/156) At 3 mo, condom use on first sex occasion with new partner: IG: 73% (8/11) CG: 77% (10/13) <i>P</i> = 0.813	No increase in number of sex partners; no increase in unprotected sex or decrease in condom use
Wenger et al., 1992 (27)	Fair (minor concerns about reporting)	University health clinic	<i>n</i> = 370; mean age, 23 y; 28% male; 61% white; 23% with STI (previous)	“Education” or “education” plus HIV testing; theory not specified IG1 and IG2: moderate—1 h total; 1 group session ± HIV testing CG: wait-list control	6 mo: 88	At 6 mo, patients with UVI/UAI with last sex partner: IG1: 68% IG2: 63% CG: 61% <i>P</i> > 0.15 At 6 mo, mean number of sex partners in last mo: IG1: 0.70 IG2: 0.84 CG: 0.72 <i>P</i> > 0.15	No increase in number of sex partners; no increase in unprotected sex or decrease in condom use
Adolescents with behavioral outcomes only							
Danielson et al., 1990 (28)	Fair (minor concerns about reporting)	HMO	<i>n</i> = 1195; age range, 15–18 y; 100% male; <5% black; <4% Asian	Slide tape program followed by session with health practitioner; theory not specified. IG: moderate—1 h total; 1 individual session CG: wait-list control	12 mo: 81	Condom use at most recent intercourse: IG: 33.3% CG: 35.8% Sexually active male teenager: IG: mean, 90% CG: mean, 91% Sexually active male teenager (of those not previously sexually active): IG: mean, 30% CG: mean, 34% Any contraceptive use at most recent intercourse: IG: 69.9% CG: 65.8% Adjusted OR, 1.51; <i>P</i> < 0.05 Adjusted (for those who had not been sexually active at baseline) OR, 2.53; <i>P</i> < 0.01	No increase in unprotected sex or decrease in condom use; no earlier sexual debut

ARRM = AIDS risk reduction model; CDC = Centers for Disease Control and Prevention; CG = control group; FIO = Future Is Ours; FP = family practice; Hx = history; IG = intervention group; NR = not reported; NS = not significant; OR = odds ratio; PC = primary care; STI = sexually transmitted infection; RR = relative risk; UAI = unprotected anal intercourse; UVI = unprotected vaginal intercourse.
* Or longest follow-up if otherwise specified.

Appendix Table 2. Studies in Progress						
Study Chair(s) or Principal Investigator(s)	Title	Setting	Population	Intervention and Control	Outcomes	Status
Patterson TL	STD Risk Reduction for Heterosexual Methamphetamine Users	Specific setting, NR; study conducted in San Diego, CA	Both sexes, age ≥18 y, current user of methamphetamine	1) No maintenance counseling intervention program; 2) maintenance counseling program; or 3) diet and exercise attention control group	Sexual risk behaviors, HIV serologic status, STDs	Completed
Stark MJ	Reducing HIV and Domestic Violence Risk in Women Offenders	Specific setting, NR; study conducted in Portland, OR	Women age ≥18 y who had been in jail or prison in the past year or are currently on parole or probation; history of HIV-related behaviors in past year	1) Information on local HIV prevention resources; 2) up to 10 supportive counseling sessions based on motivational interviewing aimed to reduce HIV risk; or 3) up to 10 supportive counseling sessions based on motivational interviewing aimed to reduce HIV and domestic violence	Biological testing for HIV and STIs, HIV risk behavior, experiences of domestic violence	Completed
Williams SP, Sperling C	An STD Prevention Intervention for Men Newly Released From Jail	Specific setting, NR; study conducted in Decatur, GA	Men age 18–60 y, ≤45 days after release from jail, self-reported HIV negative with substance use histories	5-session intervention vs. control	STD infections, sexual risk behaviors, condom use, substance use behavior	Completed
Kyung-Hee C	Education Program to Promote Female Condom Use	Specific setting, NR; study conducted in San Francisco, CA	African-American, Asian-American, Latina, or white women age 18–39 y	4-session female condom skills training vs. 4-session women’s general health promotion	Female condom use (primary), male or female condom use (secondary)	Currently recruiting
Morrison-Beedy DC	Maintaining HIV Prevention Gains in Female Adolescents	Urban family-planning clinics	Sexually active females age 15–19 y	HIV risk reduction intervention based on the Information-Motivation-Behavioral Skills model or equivalent health promotion control, both with booster sessions at 3 and 6 mo	Biological test for STIs (chlamydia and gonorrhea), sexual behaviors	Currently recruiting
O'Donnell L	Testing the Effectiveness of VOICES as Implemented by STD and HIV Prevention Agencies in the United States and Puerto Rico	Urban STD clinics (New York and San Juan, Puerto Rico)	Both sexes, STD-positive at baseline, age ≥18 y	Brief, culturally specific, single-session intervention in small groups	STD incidence as determined by medical chart review and/or surveillance data	Currently recruiting
Rose ES, Sales J	HIV Prevention for African American Teens	Urban family-planning clinic	Sexually active African-American females age 14–20 y	Sexual health education program, with periodic telephone contacts designed to either reinforce sexual health promotion (intervention) or reinforce dietary practices (control)	HIV prevention behaviors; unclear whether study includes biological assessment of STIs at follow-up (these are noted to be done at baseline)	Currently recruiting
Bull SS	A Tailored Interactive Website for Promoting Condom Use Among Young Adults	Patients recruited from urban health clinic or Planned Parenthood	Both sexes age 18–25 y	Tailored interactive online risk reduction program vs. standard online risk reduction program (on reproductive health—not specific to condoms or STDs)	Condom use	No longer recruiting
Gold MA	The S.A.F.E. Study: Computer-Aided Counseling to Prevent Teen Pregnancy/STDs	Inner-city, hospital-based clinic	Females age 13–21 y	Computer-assisted motivational intervention vs. didactic educational control	Protective sexual behaviors (for both pregnancy and STIs); abstinence	No longer recruiting
Klausner JD, Rietmeijer CA, Malotte K, O'Donnell LN	Video-Based Intervention Study to Prevent HIV/Sexually Transmitted Diseases (STDs) Among STD Clinic Patients	Urban STD clinics	Sexually active adults age ≥18 y	Brief 23-min waiting room educational video vs. standard waiting room experience	STD incidence as determined by medical record review and STD surveillance registry data; sexual behavior assessed in a random sample of patients	No longer recruiting
Morokoff P	Increasing Condom Use in People at Risk for HIV Infection	Health clinics serving local ethnic minority communities	At-risk heterosexual men and women age 18–44 y	Computer-delivered individualized intervention vs. HIV information comparison group	Condom use, risk behaviors	No longer recruiting

NR = not reported; S.A.F.E. = Sexual Awareness For Everyone; STD = sexually transmitted disease; STI = sexually transmitted infection.