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Behavioral Counseling to Prevent Sexually Transmitted Infections

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Structured Abstract

Background: Despite advances in prevention and treatment, sexually transmitted infections (STIs) remain a significant cause of morbidity and mortality in the United States. There are an estimated 19 million new infections each year in the US costing about $13 billion.

Purpose: This systematic review supports the USPSTF in updating its prior recommendation on behavioral counseling to prevent STI.

Data Sources: For four key questions, we searched Medline (ML), Cochrane Central Registry of Controlled Trials (CCRCT), Cochrane Database of Systematic Reviews (CDSR), PsycINFO (PI), and the CDC's Prevention Synthesis Research (PRS) Project's database from 1988 through December 2006. For the fifth key question, we searched ML and CCRCT from 1988 to August 2006. Literature searches were supplemented with outside source material from experts in the field and from examining the bibliographies of existing systematic reviews on these topics.

Study Selection: This review included 19 articles representing 13 unique trials of counseling interventions and three trials for evaluating the effectiveness of female condoms. Included trials evaluated a primary care feasible behavioral counseling intervention addressing sexual behavior change to prevent the transmission of STIs.

Data Extraction: Two investigators independently screened all abstracts and rated all articles meeting inclusion criteria. One primary reviewer abstracted relevant information into standardized evidence tables. A second reviewer checked the abstraction process.

Data Synthesis and Results: Due to the heterogeneity of intervention methods, populations, and settings, we conducted a qualitative synthesis of our findings. The majority of evidence suggests a modest reduction in STIs at 6 or 12 months among "at-risk" adults in STI clinics receiving multiple intervention sessions, and at 12 months among sexually active adolescents. We also found evidence for increased compliance with treatment recommendations for adult women in STI clinics, general contraception use in male adolescents, and decreased nonsexual risky behavior and pregnancy in sexually active female adolescents. Overall, we found no evidence of significant behavioral or biological harms for risk-reduction counseling.

Limitations: We did not find sufficient trials evaluating primary care feasible behavioral counseling interventions to prevent STIs in a general-risk population or certain "at-risk" groups.

Conclusions: There is fair to good evidence suggesting that moderate- to high-intensity behavioral counseling conducted in STI clinics effectively reduces STI incidence in "at-risk" populations. Among sexually active adolescents, there is fair to good evidence that high-intensity behavioral counseling effectively reduces STI incidence in a primary care setting. There is a need for additional evidence for both lower-intensity behavioral counseling interventions and studies in lower-risk populations.

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I. Introduction

Scope and Purpose

This systematic review was undertaken to support the USPSTF in updating its prior recommendation on sexually transmitted infection (STI) counseling.[1]

We examined the evidence for the benefits and harms of counseling primary care patients to prevent sexually transmitted infections (STIs), including Human Immunodeficiency Virus (HIV). Our review includes studies evaluating behavioral counseling interventions conducted in primary care, or judged to be feasible for delivery in primary care. We defined behavioral counseling interventions as any intervention that included some provision of education, skills training, and support providing guidance to clients/patients on how to change sexual behavior, delivered alone or in combination with other interventions intended to promote sexual risk reduction or risk avoidance. We included studies targeting adults (e.g., general and "at-risk" populations), adolescents (e.g., sexually active and pre-sexual debut), and pregnant women. This review summarizes the current state of the evidence relevant to primary care clinicians and identifies key gaps in this scientific literature.

Condition Definition

An STI is any bacterial or viral illness that is transmitted through sexual contact, including, but not limited to, anal, vaginal, or oral sex. Common STIs in the US include HIV, Hepatitis B, Hepatitis C, Herpes simplex virus 1 and 2 (HSV 1 and 2), Human papillomavirus (HPV), Chlamydia trachomatis, Neisseria gonorrhea, Treponema pallidum (Syphilis), and Trichomonas vaginalis.

In addition to sexual contact, there are other methods by which the bloodborne STIs (HIV, Hepatitis B and C) can be acquired, including maternal-fetal transmission, transfusions, inadvertent needlesticks, and sharing needles or injection equipment with an infected person. This report does not address these methods of transmission or the counseling measures that could potentially reduce them.

Burden of Preventable Illness

Despite advances in both prevention and treatment, STIs remain a significant cause of morbidity and mortality in the United States. The Center for Disease Control and Prevention (CDC) estimates that 19 million new infections occur each year, almost half of which occur among people ages 15 to 24 years.[2] STI rates in the US exceed those in all other industrialized countries, including countries in western and northern Europe, Canada, Japan, and Australia. The rates also exceed the US benchmarks set by Healthy People 2010 goals. Of the reported bacterial STIs, chlamydia is currently acquired at a rate of 320 new cases per 100,000 persons a year; gonorrhea at 114 new cases per 100,000 persons a year; and, syphilis at 2.8 new cases per 100,000 persons. This is complicated by the fact that these rates are likely an underestimate given underreporting of STIs. Of the reported viral STIs, an estimated forty-five to fifty million Americans have herpes simplex virus (HSV), with about one million new cases occurring each year. High risk human papillomavirus (HPV) infections (e.g., types 16 and 18) currently affect about 22 percent of women, and it is estimated that 50 percent of all sexually active persons will

acquire some form of HPV during their lifetime.[3] While the annual number of new HIV cases has been relatively stable over the past five years, this number remains high at 40,000 per year. These rates are more troubling when viewed with the fact that an estimated 25 percent of these individuals are unaware of their positive status.[4] STIs reap significant economic cost, as the direct medical costs associated with STIs in the United States are estimated at $13 billion annually.[5]

Risk Factors

Level of risk and risk factors for STI acquisition can be divided into individual risk factors and population risk factors. Individual risk factors are based on an individual's engagement in risky behaviors (e.g., sex with multiple or new partners, sex with high-risk partners, unprotected sex, sex while intoxicated, sex in exchange for money). These behaviors are theoretically influenced by an individual's preexisting knowledge, attitudes, skills, self-efficacy, and the presence of environmental factors that promote, reinforce, or inhibit change. 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 epidemiologic group, or the increased morbidity of STIs in a particular group (e.g., pregnant women). Higher-risk population groups for STIs in the US include adolescents and young adults, African Americans, Hispanics, men who have sex with men (MSM), military recruits, inmates and former inmates, intravenous drug users (IVDUs) and former IVDUs, sex workers, mentally ill persons, mentally disabled persons, persons living in low-income urban areas, persons living in the southern United States, persons with a history of an STI, and pregnant women.

Current Practice

Several national organizations, including the USPSTF and the CDC, recommend periodic sexual risk assessment to determine which patients are most likely to benefit from STI screening or prompt risk-reduction counseling. There remains great variability, however, in taking a sexual history and risk assessment in clinical practice. From individual studies, it appears that the proportion of providers taking sexual histories or documenting sexual histories ranges from less than 50 percent to about 90 percent. Two national population surveys indicated that only 28 percent of adults aged 18-64 years reported being asked about STIs during routine visits, and only 15 percent of women of reproductive age said they discussed STIs at their first obstetric and gynecologic visit.[6]

In general, sexual-risk-reduction counseling in primary care appears to be low. In one primary care practice, an independent, random sample of charts showed that only 45 percent of all patients under 45 years old had received counseling on condom use. In other studies conducted in the private sector setting, STI counseling was only documented for about one third of all visits in which HIV or other STI testing was performed, although lack of documentation could be a factor in these studies.[6] In a random-digit-dialing phone survey of low-income adolescents, only 50 percent reported being counseled on STIs.[7] A survey of primary care physicians showed that only 40 percent of physicians reported screening all their adolescent patients for sexual activity, and only 31 percent reported educating their adolescent patients about STI transmission.[8] In a survey of colleges and universities, about 60 percent of schools had health centers, most of which provided "some" STI prevention education.[9]

Perhaps the most pervasive provider-based barriers to sexual risk assessment and sexual-risk-reduction counseling for STIs in primary care include lack of time, lack of support staff, and low confidence in the effectiveness of their STI prevention message. In a survey of primary care

providers in the private sector, about one third reported lack of time to elicit sexual histories or address STIs and limited number of staff members to counsel patients.[6] In another survey of primary care providers, while 89 percent felt comfortable discussing sex-related issues with patients, 70 percent believed that their counseling was ineffective, 48 percent believed their medical school STI training was inadequate, and 43 percent believed they were not responsible for STI preventive services.[10] Other commonly cited barriers include patient concerns and discomfort around discussing sexual issues with health care providers; provider discomfort discussing sexual issues; insufficient or nonconfidential reimbursement methods for risk assessment and counseling; difficulty keeping up with revised recommendations for STI screening and treatment; lack of explicit policies and protocols for STI care in general; lack of provider feedback and reminder systems; legal concerns about reporting sexual activity of minors; and lack of demand for quality improvement of STI care.[6]

Previous USPSTF Recommendation

In 1996, the USPSTF presented the following recommendations about counseling for HIV and other STIs:

> *All adolescent and adult patients should be advised about risk factors for human immunodeficiency virus (HIV) infection and other sexually transmitted diseases (STDs), and counseled appropriately about effective measures to reduce the risk of infection. Counseling should be tailored to the individual risk factors, needs, and abilities of each patient. This recommendation is based on the proven efficacy of risk reduction, although the effectiveness of clinician counseling in the primary care setting is uncertain....*
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> *All adolescent and adult patients should be advised about risk factors for STDs and counseled appropriately about effective measures to reduce risk of infection (B recommendation). This recommendation is based on the proven efficacy of risk reduction, although the effectiveness of clinical counseling in the primary care setting has not been evaluated adequately (C recommendation).*[1]

The USPSTF used a different methodology and rating system to evaluate evidence for recommendations in 1996. Using the USPSTF's current methodology, this B/C recommendation might have received an "I" rating for insufficient evidence to recommend for or against routinely providing counseling.

II. Methods

Update Key Questions and Analytic Framework

Using the USPSTF's methods,[11] we developed an analytic framework (Figure 1) that included five updated key questions (KQs) to guide our literature search and systematic review. KQ1 examined the direct evidence that primary care feasible behavioral counseling interventions to reduce risky sexual behaviors or increase protective sexual behaviors reduce the incidence of STIs, including HIV, or their related morbidity and mortality. KQ2 examined if these behavioral counseling interventions reduce risky behaviors or increase protective sexual behaviors that impact the transmission of STIs. Trials that met inclusion for KQ1 (i.e., reported on STI incidence as an outcome measure), were not included in KQ2, even if they reported on behavioral outcome measures. KQ3 examined if these behavioral counseling interventions have other positive behavioral or biologic outcomes, other than change in sexual behaviors and STI incidence. KQ4 examined if these behavioral counseling interventions can cause any adverse behavioral or biologic outcomes. For KQ3 and KQ4, we did not consider outcome measures of knowledge, attitudes, self-esteem, ability changes, or self-efficacy. KQ5 examined if any behavioral change outcomes identified in KQ2 were associated with a decrease in STI incidence. Based on our findings in KQ2, we focused KQ5 on the evidence for female condoms use. We did not reconsider the evidence for male condom use or abstinence, both of which the USPSTF previously judged as adequate in 1996.

In addition to our systematic review of the above key questions, we also address two contextual questions that the USPSTF defined as important to interpreting the evidence. These included: what are possible socio-cultural or health care system factors that mediate the effect of these behavioral counseling interventions, and what is the cost-effectiveness of these behavioral counseling interventions. In contrast to key questions, evidence for contextual questions were not systematically reviewed.

Literature Search Strategy

We developed literature search strategies and terms for each KQ (Appendix A, Table 1) and conducted two separate literature searches (Search one was for KQ1, KQ2; and Search two was for KQ5). For behavioral counseling interventions that met our inclusion criteria for KQ1 and KQ2, we examined if there were other positive (KQ3) or potentially harmful (KQ4) behavioral or biological outcomes. Because we limited our search for potential adverse effects to behavioral or biological outcomes, which are the paradoxical effects of beneficial outcomes (i.e., increase in risky sexual behavior rather than a decrease in risky sexual behavior), we used the same study design criteria for beneficial (KQ1, 2, 3) and harmful (KQ4) outcomes. Therefore, we were able to use a single, broad search strategy for KQ1, 2, 3, and 4.

For KQs 1 and 2, we searched Medline (ML), Cochrane Central Registry of Controlled Trials (CCRCT), Cochrane Database of Systematic Reviews (CDSR), PsycINFO (PI), and the CDC's Prevention Synthesis Research (PRS) Project's database from 1988 to December 31, 2006. We explicitly chose to examine the literature since 1988 because it marks the initial year for published studies on sexual behavioral counseling in the post-HIV era. Our approach is consistent with both the CDC's Guide to Community Preventive Services and the PRS Project. For KQ5, we searched ML and CCRCT from 1988 to August 2006. KQ5 focused on the

effectiveness of female condoms, which were first manufactured in 1988. Literature searches were supplemented with outside source material from experts in the field and from examining the bibliographies of existing systematic reviews on this topic (Appendix A Table 4).

While we did not conduct systematic searches for contextual questions, we searched the National Health Service Economic Evaluation Database (NHSEED) through October 2006 for any articles related to cost-effectiveness.

Article Review and Data Abstraction

We reviewed all abstracts for potential inclusion for any of the KQs using the inclusion/exclusion criteria described in Appendix A, Table 2. To be included, a study had to evaluate a primary care feasible behavioral counseling intervention addressing sexual behavior change (e.g., sexual risk reduction or sexual risk avoidance) with the primary intention of preventing STI transmission. Consistent with the USPSTF's scope, behavioral counseling interventions needed to be conducted in primary care settings, or judged to be feasible for delivery in primary care based. In general, primary care feasible counseling interventions had to involve individual-level participant identification; a primary care practitioner or related clinical staff; and individual or small-group format, with a limited number of sessions, or at a minimum be viewed as connected to the health care system. Behavioral counseling interventions that included an active component of community outreach, use of community members (e.g., opinion leaders, peer facilitators), use of community programs (e.g., worksite programs, school programs), use of social marketing, or use of public policy changes were not considered primary care feasible. School- and university-based trials were excluded unless conducted in a school- or university-based health clinic. (see Appendix A Table 2 for criteria details).

We also required that studies evaluating primary care feasible behavioral counseling interventions be conducted in populations representative of primary care patients. Therefore, we excluded studies that exclusively enrolled participants from correctional facilities, substance-abuse-treatment facilities, HIV clinics, and inpatient hospital units.

For inclusion, studies had to report either biological (e.g., STI incidence) or behavioral outcomes at 3 months after the counseling intervention or later. We excluded studies only reporting outcomes centered around knowledge, attitudes, self-esteem, and ability changes (skills).

All included studies were limited to those reported in English language. For KQs 1, 2, 3, and 4, studies were also limited to those conducted in English-speaking countries with cultural similarity to the US (e.g., Australia, Canada, New Zealand, and United Kingdom). For KQ5, studies were not limited to English-speaking countries. The study design was limited to randomized controlled trials (RCTs) and controlled clinical trials (CCTs). For KQ5, however, we included comparative observational research designs in addition to RCTs and CCTs. We excluded trials of comparative effectiveness (i.e., trials without a control arm). Trials had to include a control arm with no intervention (e.g., wait-list control, usual care), minimal intervention (e.g., usual care limited to no more than 15 minutes of information), or matched control (e.g., similar format and intensity intervention on a different content area).

Two investigators independently screened all abstracts for potential inclusion. We reviewed a total of 2776 abstracts and 278 complete articles for KQs 1, 2, 3, and 4. We reviewed 190 abstracts and 15 complete articles for KQ5. Two investigators independently rated all articles meeting inclusion criteria for quality assessment (30 articles) using the USPSTF's study-design specific quality criteria (Appendix A Table 3). All poor-quality studies were excluded. Listings of all excluded articles are included in Appendix C. Aside from quality, the most

common reasons for articles exclusion included interventions not judged to be primary care feasible or relevant and comparative effectiveness designs. A QUORUM tree of reviewed abstracts and articles is included in Appendix A Figure 1.

This review included 19 articles representing 13 unique trials for KQs 1, 2, and 3, and three articles for KQ 4. One primary reviewer abstracted relevant information into standardized evidence tables for each included article (Appendix B). A second reviewer checked the abstraction process.

Literature Synthesis

We were unable to conduct quantitative synthesis for any key question due to the heterogeneity of intervention methods, populations addressed, and settings. Instead, we qualitatively synthesized our results within categories focusing first on the population(s) addressed, and second on the setting in which the population was identified and the counseling intervention delivered. The results text and corresponding summary tables reflect these qualitative summaries.

USPSTF Involvement

The authors worked with four 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. The Agency for Healthcare Research and Quality (AHRQ) funded this research under a contract to support the work of the USPSTF. AHRQ staff provided project oversight, reviewed the draft report, and assisted in external review of the draft evidence synthesis.

III. Results

Key Question 1. Is there direct evidence that behavioral counseling interventions to reduce risky sexual behaviors and increase protective sexual behaviors reduce STI incidence and/or related morbidity and mortality?

Summary of results.

Adults. We identified six fair-to-good quality trials in adults examining the impact of primary care feasible behavioral counseling interventions on reducing STI incidence (Table 1).[12-17] One RCT was conducted in a psychiatric outpatient clinic;[13] four RCTs were conducted in STI clinics,[12,14,16,17] and only one RCT was conducted in a primary care setting.[15] Behavioral counseling interventions ranged from low intensity (e.g., distribution of tailored self-help materials) to high intensity (e.g., multiple session counseling interventions up to 10 sessions). All trials focused on urban and ethnically diverse patient populations (20-60 percent African American). All trials conducted in STI clinics used laboratory or clinically diagnosed STI as their outcome measure, while the other two trials not conducted in STI clinics used self-reported measures of STI.

The majority of evidence (four RCTs, n=7558)[13,14,16,17] suggests a modest reduction in STI at 6 or 12 months among "at-risk" adults receiving multiple intervention sessions. Three of the four trials conducted in STI clinics (three RCTs, n=7150)[14,16,17] showed a moderate decrease in bacterial STI incidence at 12 months, compared to usual care that included only minimal counseling. One of these trials, Project SAFE 2, reported a similar magnitude of reduction in STI incidence at 2 years. One trial, Project RESPECT, combined HIV counseling with testing.[14] In contrast, one fair-quality trial conducted in an STI clinic (n=393) did not show an effect on STI incidence at 6 months.[12] In a fair-quality RCT (n=408), psychiatric clinic outpatients with a history of alcohol or other substance abuse who received 10 sessions of group counseling on sexual risk reduction had a lower incidence of self-reported STI at 6 months, compared to those receiving similarly formatted substance abuse counseling.[13]

In the single fair-quality RCT conducted in an HMO primary care setting (n=1210), young nonmonogamous women receiving two rounds of tailored printed materials did not show a significant difference in self-reported STIs at 6 months, compared with usual care.[15]

In general, all trials were well conducted RCTs. Project RESPECT, however, had only 70 percent followup at 6 months, and 66 percent followup at 12 months. Similarly, an RCT by Boyer et al. with non-significant intervention effects had approximately 70 percent followup at 6 months. Two trials, one by Carey et al. and one by Scholes et al., used self-reported measures of STI incidence.

Adolescents. We identified four fair-to-good-quality RCTs that examined the impact of primary care feasible behavioral counseling interventions on reducing STI incidence explicitly in adolescents (Table 2).[14,18-21] Three of the four trials focused on sexually active adolescents,[14,19,21] and one included both sexually active and pre-sexually active adolescents (aged 12 to 15 years old).[18] All trials focused on urban and ethnically diverse patient populations (60 to 100 percent African American). Two trials included only female adolescents. Interventions ranged from one to four sessions in an individual or small-group format. The three trials in sexually active adolescents used laboratory or clinically diagnosed STIs as their outcome measure, while the one trial with both sexually active and pre-sexually active adolescents used self-reported STI measures.

The majority of evidence (three RCTs, n= 1998) showed a modest reduction in STI incidence at 12 months in sexually active adolescents. All three RCTs in sexually active adolescents, who had much higher baseline risks for STIs, showed a decrease in laboratory positive STIs at 12 months. One of these trials, Project RESPECT, combined HIV counseling with testing. We only found one fair-quality RCT that included pre-sexually active adolescents (n=219), in which those who received a low-intensity counseling intervention (15 minute standardized risk assessment and discussion of risk with pediatrician) did not have a significant difference in self-reported STIs at 3 or 9 months.[18]

The RCT by Boekeloo et al. with non-significant intervention effects was likely not powered to show a difference in STI incidence, given the small sample size and low percentages of incident STI. In addition, this RCT used self-reported measures of STI incidence.

Pregnant women. We found no studies that met our inclusion criteria specifically addressing pregnant women. One study by Shain et al. included about 30% pregnant women. Their results, however, were not reported separately for this subgroup.[16]

Study Details.

Adults: laboratory diagnosed STIs. The four trials that used laboratory diagnosed STIs were all conducted in STI clinics. Shain et al[16,17] conducted two trials, Project SAFE and Project SAFE 2, in an urban STI clinic that included low-income Hispanic and African American women, aged 15 to 45 years, who were nonviral STI positive. However, results were not reported separately for the adolescent age group. In Project SAFE (n=617), women were randomized to either a three-session, small-group counseling intervention that was a cultural adaptation of the AIDS Risk Reduction Model (ARRM) or standardized usual care consisting of 15 minute counseling by CDC guidelines.[16] At baseline, women were on average about 21 years old, about 70 percent were Hispanic, and about 30 percent were pregnant. At 6 months, with about 80 percent followup, 11.3 percent in the intervention group and 17.2 percent in the control group had laboratory diagnosed gonorrhea or chlamydia, adjusted OR 0.58, 95 percent CI (0.34, 0.99). At 12 months, with about 90 percent followup, 16.8 percent in the intervention group and 26.9 percent in the control group were STI positive, adjusted OR 0.52, 95 percent CI (0.34-0.81). In Project SAFE 2 (n=775), women were randomized to the same culturally tailored ARRM intervention, an enhanced intervention with the option of five additional monthly support-group sessions or a usual care control group.[17] Women at baseline were on average about 21 years old, about 75 percent were Hispanic, and about 25 percent were African American. This trial had about 90 percent followup at 1 and 2 years and reported on laboratory diagnosed gonorrhea or chlamydia. Similar to their previous trial, this trial showed a similar magnitude of risk reduction for the standard intervention at 1 year, adjusted OR 0.51 (0.31-0.83), and at 2 years, adjusted OR 0.57, 95 percent CI (0.34-0.96). There was no difference in re-infection rates between the two intervention groups, standard versus enhanced.

Kamb et al.[14] conducted Project RESPECT, a multi-center, fair-quality RCT in four urban STI clinics serving predominantly low-income and minority populations. Project RESPECT randomized heterosexual persons age 14 or older (n=5758) into one of two intervention groups or one of two control groups. One intervention group received enhanced HIV counseling and testing based on the theory of reasoned action and social cognitive theory delivered in four individual sessions (total of 200 minutes). The second intervention group was the CDC's client-centered HIV prevention counseling model delivered in two brief individual sessions (total of 40 minutes). The control groups also consisted of two similar individual sessions, only lasting a total of 10 minutes. At baseline, participants had a median age of 25 years, 57 percent were men, 84 percent were nonwhite, and about one-third had a current STI. At 6 months, with about 70 percent followup, the standard intervention group had a reduction in

those testing positive for a new STI (including gonorrhea, chlamydia, syphilis, or HIV), compared with those in the primary control group, RR 0.71, 95 percent CI (0.58-0.89). At 12 months, with about 66 percent followup, the RR was 0.81, 95 percent CI (0.67-0.98). There was no significant difference in risk reduction between the two intervention groups, standard versus enhanced.

A trial conducted by Boyer et al.[12] in STI clinics focused on heterosexual young adults with either a previous/current STI or a partner diagnosed with an STI. Participants (n=393) were randomized to four sessions of ARRM-based individual counseling, or usual care consisting of a brief 15-minute standard risk-reduction. At baseline, 67 percent were men, 71 percent were nonwhite, and 62 percent had a history of an STI. At 6 months, with about 70 percent followup, there was no difference in newly detected STIs by laboratory testing (gonorrhea, chlamydia, syphilis, trichomonas, or HIV), sequelae of STIs (e.g., PID, cervicitis, urethritis), or chronic/possible STIs (e.g., HSV, HPV, BV).

Adults: self-reported STIs. The only trial in a general primary care setting that examined the impact of behavioral counseling intervention on STI incidence in adults was by Scholes et al.[15] This fair-quality RCT focused on nonmonogamous women, aged 18 to 24 years, who received care in an HMO. Women (n=1210) were randomized to receive either tailored self-help intervention materials consisting of a 12-page magazine style booklet aimed at increasing condom use, plus a booster newsletter at 3 months, or to usual care. At baseline, about 31 percent of the women were nonwhite, about 42 percent were employed fulltime, and about 26 percent had a history of an STI. At 6 months, with 85 percent followup, there was no difference in any self-reported STIs over the past 3 months. Overall, there was a low percent of self-reported STIs at the 6-month followup (3.5 percent in the intervention group and 3.6 percent in the usual care group).

A fair-quality RCT by Carey et al.[13] was the only study focusing on mentally ill patients meeting our inclusion criteria. This study focused on patients attending an outpatient psychiatric clinic who had comorbid drug or alcohol use. Participants (n=408) were randomized into one of three groups: an intervention group receiving 10 group sessions on HIV risk reduction based on harm reduction and motivational techniques to enhance readiness to change; a control group receiving 10 group sessions on substance use reduction; and a second control group receiving usual care only. At baseline, the median age was 36 years, 46 percent were men, 21 percent were nonwhite, 17 percent were employed, and about 38 percent had a history of an STI. At 6 months, with 89 percent followup, only 2 percent in the intervention group self-reported a newly diagnosed STI, compared to 8 percent in the substance use reduction control group, $p<0.013$ adjusted for STI at baseline.

***Adolescents: laboratory diagnosed STIs*.** Three trials were exclusively conducted in sexually active adolescents. One good-quality trial by Jemmott et al.[20] focused on African American and Hispanic girls in an urban adolescent medicine clinic. Adolescents (n=682) were randomized to receive one of two culturally tailored counseling interventions based on cognitive behavioral theories or a similarly formatted general health promotion intervention. The interventions consisted of either one 250-minute, small-group session on skills based HIV/STI risk reduction or information based risk reduction delivered by a trained African American female facilitator. At baseline, the mean age was about 15 years, about 70 percent were African American, 30 percent were Hispanic, and about 20 percent had a current STI. At 6 months, with about 93 percent followup, there was no significant difference in laboratory diagnosed gonorrhea, chlamydia, or trichomonas. At 12 months, however, with about 89 percent followup, there was a significant reduction in STIs for girls who received the skills-based counseling intervention, adjusted mean 10.5 percent in the skills-based intervention, compared to 18.2 percent in the

control group, p=0.05.

Another good-quality trial that focused on a similar population, sexually active African-American adolescents aged 14-18 years, was conducted by DiClemente et al.[19] This trial randomized girls (n=552) to either receive either a culturally tailored counseling intervention on sexual risk reduction or nutrition and exercise, based on social cognitive theory and theory of gender and power. This intervention was similar in intensity to the trial by Jemmott et al., but group sessions were divided into four sessions and delivered by a trained African-American female facilitator with two peer facilitators. At baseline, these girls were on average 16 years old and about 20-30 percent had a current bacterial STI. At 12 months, with about 88 percent followup, there was a significant reduction in laboratory diagnosed chlamydia infections, adjusted OR 0.17, 95 percent CI (0.03-0.92). The reductions in gonorrhea and trichomonas infections were not statistically significant. This finding, however, may result from the relatively small number of incident gonorrhea and trichomonas infections, which occurred at about half the rate of chlamydia infections.

Project RESPECT, as discussed in the "Adult" subsection, was a fair-quality, multi-center RCT that evaluated two HIV counseling and testing interventions in STI clinics.[14,21] Bolu et al.[21] present a series of subgroup analyses that included a stratification by age groups. They report that the greatest risk reduction for newly diagnosed STIs (gonorrhea, chlamydia, syphilis, and HIV) was in adolescents (age 14 to 20 years), for both the standard and enhanced interventions. The adjusted RR for the standard intervention (CDC's client-centered HIV prevention counseling model, two sessions for a total of 40 minutes) was 0.58, 95 percent CI (0.37, 0.92), compared to control.

***Adolescents: self-reported STIs*.** Boekeloo et al[18] conducted the only trial that examined a behavioral counseling intervention's impact on STI incidence in a general population of adolescents, including presexually active adolescents. This fair-quality RCT focused on young adolescents, aged 12 to 15 years, in an urban/suburban HMO. Young adolescents (n=219) were randomized to either a 15-minute audiotape including a risk assessment and a subsequent discussion with pediatrician or usual care with their primary care pediatrician. This counseling intervention, ASSESS (Awareness, Skills, Self-efficacy/-esteem, and Social Support), based on social cognitive theory and the Theory of Reasoned Action, was designed to be incorporated into the general health exam and waiting period. At baseline, about half of the adolescents were aged 12-13 years, about half were male, about 80 percent were nonwhite, and 20 percent were sexually active during the previous 3 months, and about five to seven percent had been treated for an STI during the previous 3 months. At both 3 and 9 months, with about 90 percent followup, there was no statistically significant difference in self-reported incidents of STIs. Rates of self-reported STIs, however, were low (up to 5.8 percent).

Key Question 2. Do behavioral counseling interventions to prevent STIs in primary care reduce risky sexual behaviors or increase protective sexual behaviors?

We will not discuss studies that provide direct evidence of behavioral counseling interventions on the reduction of STI incidence in the context of their impact on behavioral outcomes. Details of behavioral outcomes for these studies, however, can be found in the evidence table (Appendix B).

Summary of results.

Adults. We identified three additional fair-to-good-quality trials that examined the impact of

primary care feasible behavioral counseling interventions on reducing self-reported risky sexual behaviors or increasing protective sexual behaviors in adults, but did not report biological health outcomes (Table 3).[22-24] All of these RCTs were conducted in primary care or primary care equivalent clinic settings (e.g., family planning clinic, university health clinic, family practice setting in Australia). All trials were conducted in urban environments and focused on young adults. Behavioral counseling interventions in these studies ranged from low intensity (e.g., brief single-session counseling) to high intensity (multiple-session counseling up to 18 hours).

Of the three trials only one showed a reduction in risk sexual behaviors (unprotected sexual intercourse, multiple sex partners) or an increase in consistent condom use. This trial by Ehrhardt et al.,[22] was conducted in a family planning clinic. The trial showed a decrease at 12 months in self-reported unprotected sexual intercourse and an increase in (male and female) condom use in the extremely intensive counseling intervention arm. The intervention consisted of nine 2-hour group sessions, but not using a less-intensive intervention consisting of five 2-hour group sessions.

Measures of self-reported behavioral outcomes (e.g., unprotected sexual intercourse, condom use, and number of sexual partners) and methods of data collection (e.g., interview or questionnaire) varied amongst trials.

Adolescents. We identified one fair-quality trial that examined the impact of primary care feasible behavioral counseling interventions on reducing self-reported risky sexual behaviors or increasing protective sexual behaviors in adolescents (Table 4).[25] This fair-quality RCT was conducted in an HMO, which included both sexually and presexually active adolescents. This RCT did not show an increase in condom use or abstinence at 12 months in male adolescents who received a single 1-hour counseling intervention, compared with those who did not.

Pregnant women. We found no studies that met our inclusion criteria that specifically addressed pregnant women. One study by Hobfoll et al. was excluded for poor quality.[26]

Study Details.

Adults. Three studies meeting our inclusion criteria examined the impact of primary care feasible behavioral counseling interventions on self-reported risky and protective sexual behavior in a nonSTI clinic population.[22-24]

Wenger et al.[24] conducted a fair-quality RCT at a university health clinic targeting heterosexual university students. Students seeking care at the clinic (n=370) were randomized into one of three arms: one session of small-group education and counseling, counseling plus HIV testing, or usual care plus a list of locations for free anonymous HIV testing. At baseline, participants' average age was 23 years, 28 percent were men, 39 percent were nonwhite, and 23 percent self-reported a history of an STI. With about 90 percent followup in the intervention groups and about 80 percent followup in the control group at 6 months, there was no significant difference between the three groups in the self-report of unprotected sex with previous partner or mean number of sex partners during the previous month.

In our hierarchical approach, we looked in non-US, English-speaking countries when there was not sufficient evidence from US-based studies. We found one article, by Proude et al.,[23] from Australia that met our inclusion criteria. This fair-quality trial randomized young adults (n=312) in family medicine practices to either receive a brief risk assessment and physician-counseling plus educational pamphlets on sexual risk reduction or tobacco use (active control). At baseline, more than half of patients were aged 22 to 25 years, about 30 percent were men, and 14 percent reported multiple partners during the previous year. At 3 months, with about two-thirds followup, there was no difference in self-reported condom use with new

partners (n=24), or in self-reported new sex partners during the previous 3 months.

This third study, Project FIO (The Future is Ours) by Ehrhardt et al., was conducted in an urban family planning clinic.[22] Women (n=360) in this good-quality trial were randomized to receive one of two risk reduction behavioral counseling interventions based on the ARRM, or an assessment-only group. The intervention consisted of either four 2-hour group sessions with a booster session at 9 months, or to an eight 2-hour group sessions plus a booster at 9 months. At baseline women were on average 22 years old, 72 percent were African American, 17 percent were Hispanic, and almost 60 percent had a history of an STI. At 12 months, with over 90 percent followup, they found that women in the eight-session intervention group had an average of four fewer unprotected sexual acts during the previous 3 months based on self-report, p=0.00. They also reported an 18 percent increase in self-reported condom (male or female) use in the eight-session intervention group. This result, however, is of borderline statistical significance (p=0.06).

Adolescents. One trial meeting our inclusion criteria examined the impact of primary care feasible behavioral counseling interventions on self-reported risky and protective sexual behavior.

This trial by Danielson et al. examined the impact of a general sexual health intervention that included risk-reduction counseling on high school boys in an urban HMO.[19] Adolescents (n=1195) were randomized to either wait-list control or a 1-hour medical appointment with 30 minutes of slide tape program on general sexual health and 30 minutes risk-reduction counseling with health practitioner. Participants at baseline were less than 10 percent nonwhite and 37 percent self-reported being sexually active during the previous year. At 12 months, with about 80 percent followup, there was no difference between the two groups in self-reported condom use or abstinence.

Key Question 3. Are there other positive outcomes besides sexual behavioral changes and reduced incidence of STI resulting from behavioral counseling interventions to prevent STIs in primary care?

Summary of results. Within the body of literature examined for KQ1 and KQ2, we looked for evidence of other positive outcomes obtained from behavioral counseling interventions. We focused on other positive behavioral or biological outcomes of primary care feasible counseling interventions. We do not discuss outcomes that are primarily psychosocial mediators of behavior (e.g., knowledge, attitude and self-esteem, and ability changes), although these measures were reported in many of our included studies.[12-15,18-20,23-25,27]

In general, few studies reported on other behavioral or biological outcomes. For adults, we found evidence that behavioral counseling increases compliance with treatment recommendations for women in an STI clinic setting (Table 5).[16,17,22] For adolescents, we found evidence that behavioral counseling may decrease other risky behavior and pregnancy in sexually active female adolescents, and increase general contraception use in male adolescents (Table 6).[18-20,25]

Study Details.

Adults. In both Project SAFE[16] and Project SAFE 2,[17] those who received group counseling had increased treatment compliance compared to those who received usual care. In Project SAFE, 15.7 percent of participants in the intervention arm reported unprotected sexual intercourse with untreated or incompletely treated sexual partners, compared with 28.5 percent ($p<0.001$) in the control arm. Likewise, in Project SAFE 2, 7.8 percent in the intervention arm ($p<0.001$) reported unprotected sexual intercourse with an untreated/incompletely treated sexual partner, versus 18.1 percent in the control arm.

The trial by Ehrhardt et al.[22] targeting women in a family planning clinic reported on other behavioral outcomes as a composite measure of "alternative risk reduction strategy." These included refusing sex, leaving/ending relationship, and mutual HIV testing. However, there was no significant difference in this composite measure at the 12-month followup.

Adolescents. The trial by Jemmott et al.[20] found a significant decrease in self-reported number of days of sex while intoxicated over the past 3 months at their 3-and 6-month followup for those girls in the skills-based counseling intervention arm, compared to those in the health promotion arm. This effect, however, was not statistically significant at the 12-month followup.

The trial by DiClemente et al.[19] found a significant decrease in self-reported pregnancy at 6 months for those girls in the intervention group, OR 0.38 (0.15, 0.96). Again, this effect was not significant at the 12 month followup, OR 0.74 (0.30, 1.82).

The trial by Boekeloo et al.[18] that targeted young adolescents in an HMO did not find a statistically significant reduction in self-reported pregnancy. This study, however, had a smaller sample size and fewer reported pregnancies.

In the Danielson et al.[25] trial, high-school boys in an HMO who received counseling self-reported an increase in any contraception use during their most recent sexual encounter, which appeared to be mediated by partner use of oral contraceptives rather than condom use.

Key Question 4. What are the adverse effects associated with behavioral counseling interventions to prevent STIs in primary care to reduce risky sexual behaviors and increase protective sexual behaviors?

Summary of results. Within the body of literature examined for KQs 1 and 2, we looked for evidence of harms of primary care feasible behavioral counseling interventions. We found no additional studies meeting our inclusion criteria that assessed behavioral or biological adverse effects of counseling interventions.

Adults. Overall, the nine trials evaluating risk reduction counseling in adult populations showed no evidence of increased incidence of STIs or self-reported risky behaviors, including increased unprotected sex or increased number of sexual partners (Table 7).[12-17,22-24] The six trials that reported on biological outcomes showed no evidence of increased incidence of STIs, either by self report or laboratory testing.[12-17] Eight trials showed no evidence of self-reported increased unprotected sex (or decreased use of condoms).[12-16,22-24] Six trials showed no evidence of self-reported increase in the number of sexual partners.

Adolescents. Overall, the five trials evaluating risk-reduction counseling in adolescents showed no evidence of increased incidence of STIs or self-reported risk behaviors including increased unprotected sex, increased number of sexual partners, or earlier onset of sexual debut (Table 8).[18-20,25] No trials evaluating abstinence-only counseling interventions met our inclusion criteria. Therefore, we could not assess potential harms or benefits associated with these types of

counseling interventions. The four trials that reported on biological outcomes showed no evidence of increased incidence of STIs, either by self-report or laboratory testing.[18-20,25] Five trials showed no evidence of an increase in self-reported unprotected sex (or decreased use of condoms). [18-20,25] Two trials showed no evidence of an increase in the participants' self-reported number of sexual partners.[14,20]

One trial by Boekeloo et al.[18] showed a transient increase in self-reported vaginal sex at 3 months, but not at 9 months, in adolescents aged 12 to 15 years. There was no increase, however, in self-reported overall sexual intercourse (vaginal, oral, or anal sex).

Study Details.

Adolescents. Only one study, by Boekeloo et al., showed possible harms for risk-reduction behavioral counseling in adolescents.[18] This fair-quality RCT, in which 12 to 15 year old adolescents (n=219) from an urban HMO were assigned to either usual care or a 15-minute, standardized, self-risk assessment, and physician discussion of risk, reported that adolescents in the intervention group self-reported more vaginal sexual intercourse at 3 months compared with adolescents receiving usual care, adjusted OR 2.46, 95 percent CI (1.04, 5.84). This effect, however, was not observed at the 9-month followup. In addition, no difference was observed in self-report of "any" sexual intercourse (including vaginal, oral or anal sex) at either followup.

Three of the five studies were conducted in sexually active adolescent populations. [19,20,25] One of the two trials conducted in a general adolescent population reported on sexual debut.[25] This fair-quality RCT of 15- to 18-year-old adolescent boys, 37 percent of whom self-reported being sexually active during the previous year, found no evidence that risk reduction counseling increased sexual activity in those previously not sexually active. The proportion of boys not sexually active at baseline, who became sexually active during the following year, was 30 percent in the intervention group, compared with 34 percent in the wait-list control group.

Key Question 5. Do sexual behavioral changes, including reducing risky sexual behaviors and increasing protective sexual behaviors, lead to a reduced incidence of STIs and/or related morbidity and mortality?

Summary of results. Based on the findings from KQ 2 that behavioral counseling can increase both male and female condom use, we examined the effectiveness of female condoms in reducing the incidence and transmission of STIs. We did not reexamine the effectiveness of male condoms for the prevention of STIs, which has been previously established.

We found four trials examining the effectiveness of female condoms in reducing the incidence of STIs (Table 9). One study by Soper et al. was excluded for poor quality.[28] The remaining three studies were RCTs comparing the effectiveness of female plus male condom use compared to male condom use alone.[29-31] Only one study was conducted in the US, the other two were conducted in Kenya and Thailand. All three studies suggest that counseling women to use female condoms and providing female condoms offers similar protection against bacterial STIs as counseling women to use male condoms. Although none of these trials were powered as non-inferiority studies, there were no statistical differences in the incidences of bacterial STIs between the women using female and male condoms versus the women only using male condoms. The percentages of women using female condoms were consistently low in the two trials that report on female condom use

Study Details. The RCT by French et al. is the only fair-quality study in the US that directly examined the effectiveness of female condom use in reducing the incidence of STIs.[31] Women attending an urban public STI clinic (n=1442) were randomized into one of two interventions, either a 20-minute, small-group, interactive counseling session on using female condoms (in which the women were instructed to use male condoms for oral sex, and not advised to stop using other methods), or a similarly formatted counseling session on using male condoms. All the women were given a free supply of their assigned condoms. Only approximately 50 percent of women returned for additional STI testing (gonorrhea, chlamydia, syphilis, and trichomonas) during the 1-year followup period. Among those who had followup, there was no statistically significant difference in STI incidence between the two groups. The percent of women using female condoms was not reported.

One good-quality study by Feldblum et al.,[29] conducted in rural Kenya, randomized twelve agricultural sites representing 1929 women to either a multi-faceted program with community level education and individual counseling to promote female and male condom use or a similar program excluding female condom information. All adults were provided with female and male condoms, or only male condoms, respectively. These communities had 82 percent followup at both 6- and 12-month followup assessments. There was no significant difference in STI prevalence (gonorrhea, chlamydia, and trichomonas) between programs at either 6 or 12 months. Only 11 percent of women at 6 months and 7 percent of women at 12 months consistently used female condoms. As female condom use declined at 12 months, however, consistent male condom use increased, from 14 percent to 22 percent in the female condom intervention communities. Overall, there was a low percentage of consistent condom use in all communities.

One fair-quality study by Fontanet et al. conducted in urban Thailand randomized four [30] commercial sex establishments, representing 548 female sex workers to either male condoms plus female condoms or only male condoms. In the female condom intervention sites, women were instructed to use female condoms when clients refused or could not use a male condom. In the male condom only sites, women were instructed not to have sex if clients refused or could not use a male condom. Again, women were provided with condoms. At 24 weeks (6 months), 96 percent of women in the female condom group versus 88 percent of women in the male condom only group had followup. There was no statistically significant difference in the STI incidence, OR (95 percent CI), for female plus male condom, versus male condom alone 0.76 (0.50, 1.16). In the female condom intervention sites, female condoms were used in only 12 percent of sex acts, and male condoms were used in about 88 percent of sex acts.

IV. Discussion

Summary of Review Findings

Variation in population risk and intervention intensity

We did not find any trials evaluating primary care feasible behavioral counseling interventions to prevent STIs in a general-risk (average) population. All the populations studied in the trials we identified address "at risk" population groups who have a higher than average STI incidence (e.g., adolescents and young adults, African Americans, Hispanics, mentally ill persons, mentally disabled persons, persons living in low-income urban areas, or persons with a previous or present history of an STI). For this discussion, therefore, we use the term *low- risk* to describe the general primary care population and *high-risk* to describe "at-risk" groups. We also stratify our discussion of populations based on trial setting (i.e., primary care setting versus STI clinic), as setting is another measure of population risk.

Given that there is a very large variation in the 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. We use *moderate intensity* to describe interventions lasting longer than 30 minutes, but less than 2 hours in total. We use *high intensity* to describe multiple-visit interventions requiring longer than 2 hours.

Effects of behavioral counseling interventions on STI incidence and self-reported sexual behavior

STI incidence. Only two trials targeting high-risk populations in primary care settings used self-reported STI incidence as an outcome measure (one in adults,[15] and one in adolescents).[18] Neither of these trials reported an intervention effect. Both of these trials used low-intensity counseling interventions and had low proportions of persons self-reporting STI incidence at followup (less than four percent). One trial targeting a high-risk population in a psychiatric clinic used self-reported STI incidence as an outcome measure.[13] This trial by Carey et al. showed an eight percent reduction in self-reported STI at 6 months in the intervention arm, as compared to a two percent reduction in the matched intensity control arm ($p<0.013$).

Six trials targeting high-risk populations– three in adults,[12,13,16,17] two in adolescents,[19,20] and one in both[14]– used STI incidence as an outcome measure. All but one of these trials (five RCTs, n= 8384) showed a reduction in STI incidence. This one trial (n=393) targeted heterosexual adults attending an STI clinic. There was no reduction, however, in STI incidence in the high-intensity counseling intervention arm.[12]

Two trials in predominantly adult women attending STI clinics, Project SAFE and Project SAFE 2, showed a similar reduction in laboratory diagnosed gonorrhea and chlamydia at 12 months, OR 0.52, 95 percent CI (0.34, 0.81) and OR 0.51, 95 percent CI (0.31, 0.83), respectively. Project SAFE 2 showed a persistent effect in risk reduction in bacterial STI incidence (OR 0.57, 95 percent CI (0.34, 0.96)) at 24 months in Project SAFE 2.[16,17] Due to the heterogeneity amongst these trials, we caution the extrapolation of the effect estimated by Project SAFE 2, which showed a similar magnitude of risk reduction at 1 and 2 years. In fact, other studies suggest some decay of effect over time, although a benefit remains for cumulative

risk reduction.[32-35]

For adolescents, both trials using high-intensity group interventions in sexually active adolescent girls— one was conducted in an adolescent medicine clinic[20] and the other was conducted in a community health center[19]— showed a reduction in bacterial STIs at 12 months. In the trial by Jemmott et al.,[20] 10.5 percent of adolescents tested positive for chlamydia, gonorrhea, or trichomonas in the skills-based counseling intervention arm, compared to 18.2 percent in the control arm (adjusted p=0.05). In the trial by DiClemente et al.,[19]there was a decrease in the incidence of chlamydia, gonorrhea, and trichomonas. This reduction, however, was only statistically significant for chlamydia, OR 0.17, 95 percent CI (0.03, 0.92), probably due to the low incidence of gonorrhea and trichomonas in this study.

One trial, Project RESPECT, which included both adults and adolescents attending STI clinics, used two individual-based interventions combined with HIV testing— a moderate-intensity intervention of two 20-minute sessions and a high-intensity intervention of four 50-minute sessions. Both the moderate- and high-intensity counseling interventions showed a similar decrease at 12 months in overall laboratory diagnosed STIs (gonorrhea, chlamydia, syphilis, and HIV), RR 0.78, 95 percent CI (0.64, 0.94) and RR 0.81, 95 percent CI (0.67, 0.98) respectively.[14] In an *a priori* subgroup analysis, this risk reduction appeared to be more exaggerated in adolescents (age 14 to 20 years), RR 0.57, 95 percent CI (0.37, 0.90).[21] In another *a priori* subgroup analysis, this risk reduction was not significant for HSV incidence(Appendix B Table 1).[36]

There is evidence for the effectiveness of moderate-to high-intensity behavioral counseling to reduce the incidence of overall STIs (not including HSV) in high-risk populations, with more robust evidence for common bacterial STIs(e.g., gonorrhea and chlamydia). Two trials in high- risk populations conducted in primary care (n=1429) did not show a reduction in incidence of self-reported STIs using low-intensity interventions. We found no trials in low-or general-risk populations (Figure 2).

Self-reported behavioral outcomes. Four of the six trials targeting high-risk populations in primary care settings only used self-reported sexual behaviors as outcome measures—three in adults[22-24,37] and one in adolescents.[25]

For adults, we found only one trial, Project FIO, that showed a beneficial effect of a high-intensity counseling intervention on self-reported sexual behaviors.[22] This trial was conducted in women attending a family planning clinic who had a relatively high baseline risk for STI (self-reported 58 percent with a history of an STI). This trial showed a beneficial effect for the nine-session (total 18 hours), group-counseling intervention, but not for the five-session (total 10 hours) intervention, compared to women receiving no intervention. At 12 months, women in the nine-session intervention group reported four fewer unprotected sexual acts during the past three months, $p<0.001$, and an 18 percent increase in self reported male or female condom of borderline statistical significance, $p=0.06$.[22]

The other two trials in high-risk adult populations in primary care settings did not show an intervention effect, including: one trial using a low-intensity individual intervention in young adults attending family practices in Australia;[23] and one trial using a moderate-intensity individual intervention with and without HIV testing in young adults attending a university health center.[24] The one trial in an adolescent population in a primary care setting using a moderate-intensity individual intervention did not increase condom use or abstinence.[25]

In general, there is no additional evidence for the effectiveness of low-, moderate-, or high-intensity behavioral counseling interventions in high-risk populations based on self-reported sexual behavior outcomes. One trial did show a benefit using a very-high-intensity

intervention, but in retrospect this population's risk was similar to those studied STI clinics, although based in a family planning clinic. We identified no trials that met our inclusion criteria in low- or general-risk populations (Figure 2).

Effect of behavioral counseling interventions on other positive outcomes and adverse outcomes

In general, few trials report on other positive outcomes in addition to psychosocial mediators of behavior (e.g., knowledge, attitudes, self-esteem, and ability changes). For adults, high-intensity counseling interventions for women in STI clinics can also increase treatment compliance (i.e. decrease unprotected sex with untreated or incompletely treated sexual partners). For sexually active adolescents, high-intensity behavioral counseling may transiently increase general contraceptive use and decrease pregnancy.

Based on nine fair-to-good-quality trials, there appears to be no significant harm in primary care feasible counseling interventions for adults (i.e., there is no increase in risky behaviors or increase in STI incidence). For adolescents, risk reduction behavioral counseling may transiently increase vaginal sexual intercourse in young adolescents. However, the significance of this transient finding is unclear, given that no change in overall sexual activity or vaginal sexual activity by the end of the trial at 9 months.[18] Only one study reported on sexual debut. This study found that risk-reduction counseling did not increase sexual activity in those previously not sexually active.[25] We found no trials for risk-avoidance or abstinence-only counseling that met our inclusion criteria. 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 the number of sexual occasions or sexual partners.[38]

Effect of behavioral counseling intervention elements

Given the heterogeneity amongst these trials and limited evidence for effective interventions, it is not possible to draw definitive conclusions about the differential effect of interventions on specific populations or the differential effect of specific intervention elements (e.g., theory and content, format, and intensity). Based on the existing body of evidence, however, it appears that population risk and intervention intensity are the biggest predictors of a counseling intervention's effect on STI incidence and self-reported behavior change. In adults, there is strong evidence for high-risk individuals, specifically for ethnically diverse populations, predominantly African American and Hispanic; low-income urban populations; populations with a high baseline prevalence of STIs or history of STIs (30-100 percent); and some evidence for persons with major psychiatric disease with comorbid recent history of substance abuse. There is also strong evidence for sexually active adolescents, and specifically for ethnically diverse and low-income urban populations.

Intervention intensity, more than format or a particular behavioral model, may also be an important factor in the effectiveness of counseling interventions. However, there were no low-intensity or single-visit counseling interventions used in the highest-risk populations. The range of intensity for effective interventions was 40 minutes delivered in two sessions with HIV testing,[14] to 10 sessions of unknown duration,[13] to 18 hours over nine sessions.[22] All effective interventions were based on individual risk-based counseling and included a tailored risk-reduction plan. Most of these interventions were developed with some amount of formative research within the targeted population. For adolescents, two of the effective interventions also included instruction on condom skills. In one study by Jemmott et al., only the condom skills intervention group showed an effect in STI reduction.[20] All effective interventions were based on

common behavioral models, including the AIDS risk reduction model (ARRM), cognitive behavioral theories, harm reduction, stages of change theory and motivational techniques, theory of reasoned action, and social cognitive theory. However, individually tailored counseling and these behavioral models and other social theories were also the basis for interventions that did not show a risk reduction in STIs or behavioral change in moderate-risk populations.[15,18,25]

Of the thirteen trials we reviewed, five of them used culturally tailored interventions.[16,17,19,20,22] Of the seven positive trials, six were conducted in predominantly nonwhite populations, and five of these six interventions were tailored to be culturally sensitive. Project RESPECT had about 84 percent nonwhite participants, but was not explicitly culturally tailored. Without direct comparisons of culturally tailored interventions versus nontailored interventions, the significance of this observation is uncertain. These trials also matched counselor gender, ethnicity, or both to participants, and one trial used adolescent peer co-facilitators. Based on Project RESPECT, however, Pealer et al. report that there is no significant association between intervention completion or new STIs and counselor characteristics (e.g., gender, ethnicity, education, and counseling experience), or counselor-client dyad characteristics (e.g., concordance or discordance of gender and ethnicity).[39] This finding is supported by a nonprimary care feasible counseling intervention trial by Jemmott et al., which found that the effects of an HIV risk-reduction intervention in adolescents did not vary as a function of the facilitator's race or gender, participant's gender, or the gender composition of the intervention group.[40]

Effectiveness of female condoms

In this report, we examined the effectiveness of female condoms in reducing the incidence and transmission of STIs. We did not reexamine the effectiveness of the consistent and correct use of male condoms (latex or polyurethane), which has previously been shown to be highly effective in preventing the sexual transmission of most STIs and HIV,[41,42] the development of PID,[43] and possibly in reducing the risk of HSV and HPV.[44,45] The FDA approved female condoms based on laboratory studies that demonstrated that polyurethane female condoms offer protection against STI pathogens.[46] Since their approval, we identified only three fair-to-good-quality studies directly examining the effectiveness of female condoms in preventing STIs.[29-31] These studies, only one of which was conducted in the US with poor followup, suggest that hierarchical counseling to use female condoms (i.e., use female condoms when male condoms are not used) and female condom availability offer a similar risk reduction in bacterial STI incidence as counseling to use male condoms only. Overall, however, the use of female condoms was low, 7 to 11 percent reporting consistent female condom use,[29] or 12 percent of all acts using a female condom.[30]

Contextual Issues

The delivery, receipt, and impact of behavioral counseling interventions are influenced by various socio-cultural and health care system factors. Unfortunately, because of the heterogeneity of populations targeted, intervention settings, and intervention designs, it is difficult to draw conclusions about potential mediating and moderating factors by comparisons between studies. Some inferences, however, can be made from the body of evidence as a whole, and some conclusions can be drawn from larger individual trials that might inform the feasibility and generalizability of behavioral counseling interventions to prevent STIs in a primary care setting.

Socio-cultural factors. All seven trials that showed a beneficial impact on STI incidence or

sexual behavior were conducted in low-income urban environments with an ethnically diverse patient population. Only the trial by Carey et al. among psychiatric outpatients was about 20 percent African American. The other six trials were predominantly or completely conducted with African Americans and Hispanics. Project SAFE, which had a subgroup analysis by ethnicity, reported similar point estimates of reduction in reinfection rate for bacterial STIs in Hispanics and African Americans. This risk reduction, however, was not statistically significant for African Americans, likely because there were about half the number of African Americans in the trial. Korte et al., therefore, concluded that the impact of the behavioral counseling intervention was comparable in both ethnic groups.(Appendix B Table 2)

Two trials in predominantly African American female adults and adolescents[19,22] had subsequent subgroup analyses among participants who self-reported a history of intimate partner violence.[47,48] Both subgroup analyses found that high-intensity behavioral counseling interventions had a similar beneficial effect (i.e., decrease in bacterial STI incidence in female adolescents and decrease in self-reported risky sexual behavior in female adults) as in the original trial analyses.(Appendix B Table 1)

Health care system factors. All studies meeting our inclusion criteria were conducted primarily in a clinic setting. For adolescents, two trials recruited patients and conducted the intervention in an HMO;[18,25] one trial recruited from and was conducted in a hospital-based adolescent clinic;[20] one trial recruited from various community health agencies and was conducted in a family medicine clinic on weekends;[19] and one multi-center trial recruited from and was conducted in STI clinics.[14] For adults, one trial recruited from a managed care clinic and the intervention was delivered through the mail;[15] one trial was recruited from and conducted in a family practices in Australia;[23] one trial was recruited from and conducted in a family planning clinic;[22] one trial was recruited from and conducted in a university based health clinic;[24] one trial recruited from and was conducted in a psychiatric clinic;[13] and four trials were recruited from and conducted in STI clinics.[12,14,16,17]

All trials had dedicated research staff for the recruitment (screening), intervention, and assessments. For adolescents, four of the five trials had trained facilitators delivering the intervention,[14,19,20,25] one of which also used peer co-faciliators.[19] For adults, six of the nine trials had trained facilitators delivering the intervention.[12-14,16,17,22] One of these nine did not report on the intervention staffing.[24]

For both adolescents and adults, only two trials used the existing primary care provider to deliver the intervention[18,23] and one trial used a mailed intervention.[15] These three trials evaluated brief interventions conducted in lower-risk settings, and none of these trials showed a consistent change in self-reported STI incidence or sexual behavior.

In most of the trials, participants were given a financial incentive as reimbursement for time and travel, which ranged from $10 to $40 per session. In most of these trials, participants were given additional financial incentives for baseline and followup assessments.

Cost-effectiveness. In our targeted search for evidence on cost-effectiveness, we identified multiple cost-effectiveness and cost-benefit analyses primarily addressing HIV prevention. Most of these analyses, however, were based on evidence not applicable to primary care feasible behavioral counseling (e.g., community- or school-based interventions). In total, we only found two relevant articles that considered primary care feasible interventions,[49,50] one of which we excluded because it was an analyses based on a trial by O'Donnell et al. evaluating a video-based intervention in an STI clinic, which we excluded for poor quality.[49,51]

We found one comparative cost-effective analysis that included a broad range of HIV-prevention interventions, ranging from individual-level counseling or partner notification to

structural interventions like condom availability.[52] For each intervention, Cohen et al. selected one particular study that demonstrated effectiveness in changing HIV incidence, STI incidence, or self-reported risk behavior (e.g., unprotected sexual intercourse). Among the 26 types of interventions they addressed, they calculate the cost-effectiveness of the interventions from Project RESPECT and Project SAFE based on their model as prototypes for client-centered HIV Counseling and Testing and multiple sessions of group counseling, respectively. In their model, cost-effectiveness is assessed from the perspective of the public health system. HIV prevalence estimates were taken directly from the study or, when not available, from published estimates based on the location in which the study was conducted. Because of the uncertainty of some cost-estimates (e.g., cost of person hours, supplies, and overhead), Cohen et al. conducted a sensitivity analysis of the various cost parameters in their model.

For Project RESPECT, based on a 20 percent STI reduction at 12 months, 1447 persons were reached at an estimated cost of $74 per person, and 1.01 HIV cases averted in 12 months, leaving a cost-effectiveness ratio of $110,000 per case averted. For Project SAFE, based on an 38 percent STI reduction at 12 months, 313 persons were reached at an estimated cost of $160 per person, and 0.29 HIV cases averted at 12 months, leaving a cost-effectiveness ratio of $170,000 per case averted. Cohen et al. estimate that interventions for which the cost-effectiveness ratio remains below $200,000 may be considered "cost-effective" compared with the lifetime costs of treatment of HIV infection. In their sensitivity analyses, prevalence of HIV infection in the target population and cost per person reached by the intervention had the greatest impact on cost-effectiveness. Therefore, Cohen et al. conclude that the interventions delivered in Project RESPECT and Project SAFE may not be cost-effective for low-incidence populations. Their analyses of cost-effectiveness is based only on incident HIV cases averted and not other averted STIs. We did not identify any cost-effectiveness or cost-benefit analyses addressing STI prevention in general.

Limitations

This body of evidence has several limitations that should be considered when interpreting this report's findings.

Interpreting results within studies. Trials reporting STI incidence with non-significant intervention effects do not imply the interventions are not effective.[12,15,18] The overall incidence of even common bacterial STIs is low. These studies, therefore, are subject to type-2 measurement error (e.g., inadequate power). In general, these trials do not report their calculation of sample size. Trials either had relatively small sample sizes, low percentages of STIs, or both. In addition, the study by Scholes et al. in adults and Boekeloo et al. in adolescents both used self-reported measures of STI incidence, which are particularly subject to assessment and reporting bias.[53,54]

Studies for KQ2 using self-reported behavioral outcomes should be interpreted cautiously, especially if there is no consistency in direction or magnitude of effect among different behavioral outcomes. Similar to self-reported STI incidence, self-reported behavioral outcomes are also particularly subject to assessment and reporting bias.[54] Measurement of these outcomes are not standardized, and improved validity and reliability of these measures require rigorous study design (e.g., extensive training of interviewer and continuous quality control monitoring) or alternative strategies, (e.g., audio computer assisted self-interview (A-CASI)) to decrease social desirability bias. In addition, there exist more permutations for selective reporting with behavioral outcomes (e.g., on different types of behavioral outcomes).

Although in the studies that reported both biological and behavioral outcomes, we generally found concordance of direction of effect of STI incidence and self-reported behavior

for both positive[13,14,16,17,19,20] and negative studies,[12,15,18] there were a few self-reported behavioral measures that were not concordant with the STI incidence. In a subsequent analysis of the Project RESPECT data, many behaviors had paradoxical associations with STI incidence.[55] The relationship between STI incidence and behavior is exceedingly complex, therefore, it is difficult to extrapolate disease prevention effectiveness from self-reported measures of behavioral outcomes without rigorous and comprehensive behavioral measurement.[56]

Interpreting results across studies. Unfortunately there is minimal conclusive information that can be gathered from comparisons between studies. In general, there are a relatively small number of trials, 13 in total, 8 in adults, 4 in adolescents, and 1 in both. This small number is further diluted by the heterogeneity of the populations studied; intervention setting, format and intensity; and comparators (e.g., wait-list or usual care control; matched health promotion intervention; usual care involving minimal STI prevention education or counseling). Therefore, we are unable to pool effect sizes or make direct comparisons of effect sizes by population or intervention characteristics. In addition, we did not include comparative effectiveness studies of counseling interventions, which were beyond the scope of this review. Therefore, we are unable to comment on the differential effect of different types of interventions or intervention elements, other than findings from the studies we included with multiple intervention arms.[14,17,20,22,24]

External validity. Our stringency around internal validity and scope of interventions, which focused primarily on whether primary care interventions are effective, affects the generalizability of our results. To minimize bias, we considered only randomized and non-randomized controlled trials and excluded all poor-quality studies and studies with limited reporting of trial details. However, we contacted first authors of articles to supplement or clarify issues around incomplete or unclear reporting of information, when appropriate. Second, we focused only on those interventions that we considered primary care feasible, and therefore excluded a large number of primarily community-based trials evaluating counseling interventions to prevent STIs, including HIV. Third, comparative effectiveness studies were beyond the scope of this review and, therefore, many trials in high risk populations (e.g., MSM, IVDU) in which HIV Counseling and Testing was considered "standard of care," were excluded from this review. Therefore, our review does not address trials on many high risk populations (e.g., pregnant women, MSM, sex workers, military recruits, inmates or former inmates, mentally disabled, or IVDUs).

For some of these populations, sexual risk reduction is addressed elsewhere. In MSM and IVDU, for example, there is good evidence that community-based and community-level interventions can reduce risky behaviors.[57-59] In general, we found limited rigorous trial evidence for other "at risk" groups (e.g., pregnant women, mentally ill and mentally disabled, military recruits, sex workers, and inmates or former inmates). One study by Shain et al. included women who were pregnant, although results were not reported separately for this subgroup. One study by Carey et al. included mentally ill persons with co-morbid substance abuse. We identified trials for military recruits and sex workers in settings not considered to be primary care feasible. We identified one trial underway in newly released inmates (Appendix D).

In addition, as a result of our stringency around internal validity and scope, only two HIV Counseling and Testing intervention trials,[14,24] and no risk-avoidance (abstinence-only) intervention trials, met criteria to be included in our review. However, the evidence for these interventions' effectiveness are addressed elsewhere. The effectiveness of HIV Counseling and Testing is covered in the USPSTF's report on HIV Screening.[60] The effectiveness of community-based risk avoidance behavioral counseling is currently under review by the CDC's Guide to Community Preventive Services in their review of STI prevention in adolescents.

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 (e.g., cost and opportunity cost of implementation and maintenance of counseling and other operational barriers). These issues are particularly pertinent for this body of evidence, since all identified effective counseling interventions were moderate- to high-intensity, and at minimum involved multiple sessions and trained counselors.

Evidence gaps and future research

In general, there still exists a paucity of methodologically rigorous trial evidence for the effectiveness of primary care feasible behavioral counseling to prevent STIs – in particular, for lower-risk populations and lower-intensity counseling interventions. Trials with biological outcomes (e.g., STI incidence) addressing readily identifiable "at-risk" populations (e.g., pregnant women, adolescents and young adults, ethnic minorities, mentally ill persons, and urban poor) in nonSTI clinics are needed to demonstrate the effectiveness of counseling in lower risk settings. Currently, there are several trials in press or in progress that may address some of these gaps (see Appendix D). If possible, trials addressing general-risk populations in primary care settings should also be conducted. We do not know of any trials underway that address a general-risk population in primary care.

There is also a need for effectiveness trials of lower-intensity counseling interventions that can more feasibly be incorporated into health care delivery. We identified several ongoing or recently completed trials that may address this evidence gap using brief single-session interventions, waiting-room interventions, or computer-delivered interventions (Appendix D).

Finally, there are few trials that replicate the effectiveness of proven counseling interventions in other populations. For example, there is a paucity of rigorous trial evidence for men, male adolescents, pregnant women, and other high-risk population groups. Similarly, there are few trials of different interventions in similar populations. Reproducibility of counseling interventions' effectiveness among different populations is important to establish both feasibility and generalizability. Evaluating different interventions in similar populations, as well as comparative effectiveness trials of counseling interventions, will help define essential elements for an effective counseling intervention for STI prevention.

Conclusions

From rigorous trials evaluating primary care feasible behavioral counseling interventions, we conclude that population risk and intervention intensity appear to correlate most strongly with intervention effect. There is fair evidence to suggest that moderate-to high-intensity behavioral counseling is effective in reducing STI incidence in high-risk populations (e.g., "at-risk" populations in STI clinics). There is no evidence for or against the extrapolation of the effectiveness of these interventions to similarly "at-risk" populations in non-STI clinics. In addition, there is fair evidence to suggest that among sexually active adolescents, high-intensity behavioral counseling is effective in reducing STI incidence in a primary care setting. All effective counseling interventions were based on individual-risk based counseling in individual or small group sessions. Within this body of evidence, we found fair evidence to suggest that risk reduction counseling interventions do not have significant behavioral or biological adverse effects.

We found surprisingly few studies evaluating the effectiveness of female condom use in preventing transmission of STIs. While female condom use in these trials was extremely low, female condom use combined with male condom use was not significantly different from male condom use alone in preventing incident STIs.

There is a lack of evidence for the effectiveness of low-intensity behavioral counseling interventions, especially in lower-risk populations. The few trials that evaluated low-intensity interventions had study design factors which may have contributed to their non-significant intervention effect findings.[15,18,23] We identified no trials conducted in a general-risk, primary care population.

Figure 1. Analytic framework

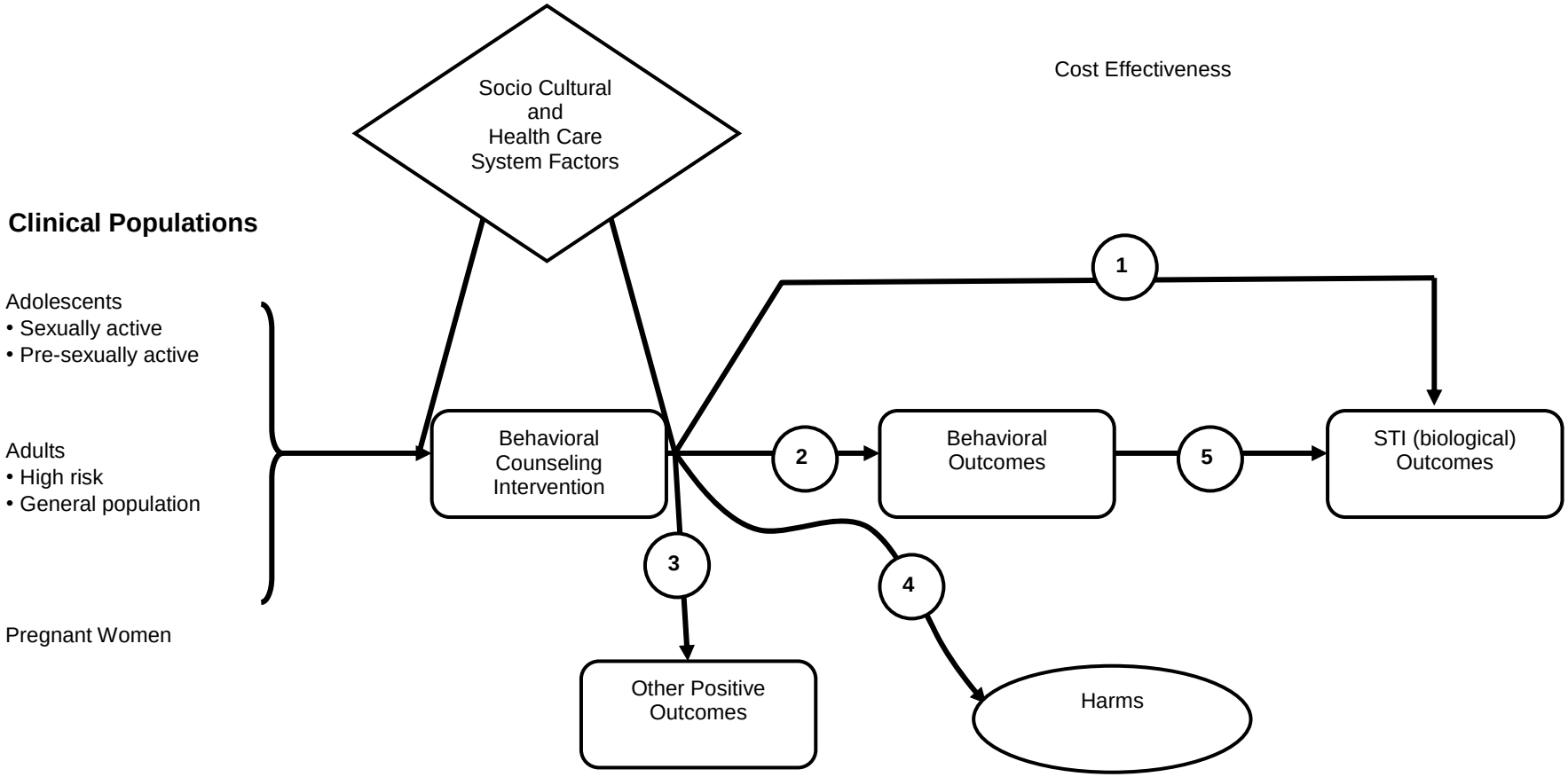
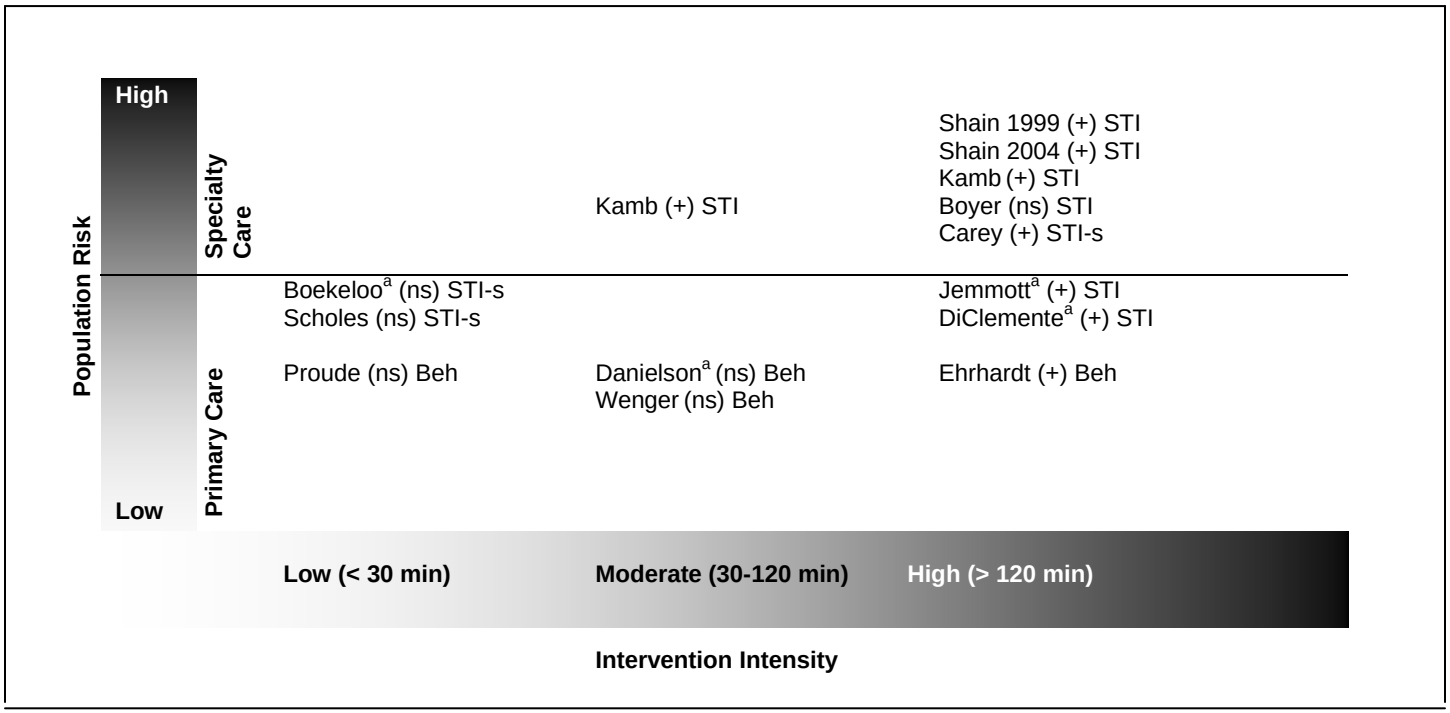


Figure 2. Intervention intensity vs. population risk



[a] Adolescent only population
(+) positive findings
(ns) statistically non-significant findings
STI STI Biological Outcomes (STI-s self reported)
Beh Behavioral Outcomes

Table 1. Biological outcomes adults (KQ1)

Study Reference Quality	Setting	Baseline Demographics	Study Intervention/Intensity	Biologic Outcomes
Shain 2004[17] Project SAFE 2 Fair	STI clinic	N: 775 (690 in analysis) 100% Female Hispanic: 77% African American: 23% with GC (c):20.6% with Chlamydia (c): 77.8% with Trichomonas (c): 15.4% with syphilis (c): 4.6%	Culturally tailored ARRM. IG1 & IG2: High- 9 hours total; 3 group sessions +/- optional support group sessions CG: usual care, 15 minute CDC standard counseling	*% Re-infection (newly dx GC, chlamydia, or both)* mean %, p values 1-year: IG1: 15.7%, p=0.006; IG2: 15.4%, p=0.004; CG: 26.8% 2-year: IG1: 14.7%, p=0.03; IG2: 14.8%, p, 0.03; CG: 23.1% OR (adjusted) with recurrent STI IG1: 0.51 (0.31-0.83); IG2: 0.50 (0.31-0.80) IG1: 0.57 (0.34-0.96); IG2: 0.58 (0.36-0.94)
Shain 1999[16] Project SAFE Good	STI clinic	N: 617 (549 in analysis) 100% Female Hispanic: 69% African American: 31% with GC (c): 22.8% with chlamydia (c): 68.7 with trichomonas (c): 23.7% with syphilis(c): 6.0%	Culturally tailored ARRM. IG: High- 9-12 hours total; 3 group sessions CG: usual care, 15 minute CDC standard counseling	*% Re-infection (newly dx GC, chlamydia, or both)* mean % at 12 mo, p=0.01 between group assignments *IG:* 16.8% (48/285) *CG:* 26.9% (71 /264) OR (adjusted) with recurrent STI 6-mo: IG: 11.3% (30/265); CG: 17.2% (42/244); OR: 0.58 (0.34-0.99), p=0.05 12-mo: IG: 16.8% (48/285); CG: 26.9% (71/264); *OR: 0.52 (0.34-0.81), p=0.004*
Kamb 1998[14] Project RESPECT Fair	STI clinics	N: 5758 Male: 57% African American: 59% Hispanic: 19% Other race: 6% with STI (c): 31.8%	CDC's client centered HIV prevention counseling model; enhanced version based on multiple social science theories. IG1: High- 200 minutes total; 4 individual sessions; IG2- Moderate- 40 minutes total; 2 individual sessions CG: usual care, 10 minute information only	*mean % with new STI (GC/chlamydia, syphilis, HIV), RR (adjusted) for new STI* 6-mo: IG1: 7.2%; RR 0.69 (0.54-0.88); IG2: 7.3%; RR 0.71 (0.58-0.89); CG1: 10.4% 12-mo: IG1: 11.5%; RR 0.78 (0.64-0.94); IG2: 12.0%; RR 0.81 (0.67-0.98); CG1: 14.6%
Boyer 1997[12] Fair	STI clinic	N: 393 African American: 46% Male (c): 67% Hispanic: 15% Other race: 10% with hx of STI (c): 62%	ARRM. IG: High- 4 hours total; 4 individual sessions CG: usual care, 15 minute standard counseling	*% New/Probable STI (GC, chlamydia, syphilis, trichomonas, HIV, HSV, HPV, BV)* Male % Mean: IG: 6.8%; CG: 7.0% Female% Mean: IG: 21.8%; CG: 22%
Carey 2004[13] Fair	Outpatient psychiatric	N: 408 Male: 46% African-American: 21%	HIV harm reduction, motivational techniques to enhance readiness to change. IG: High- unknown total hours; 10 group sessions CG1 & CG2: matched substance abuse counseling, or usual care	*% Self-report of newly dx STI* N, % at baseline, mean %, p values (adjusted) IG: 123, 10%, 2% CG1: 121, 8%, 8%, p<0.013 CG2: 110, 7%, 5%, p<0.046 OR not reported
Scholes 2003[15] Fair	Medical clinic	N: 1210 100% Female African American: 19% Other race: 12% With hx/dx of STI: 27%	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	*% Self reported STI dx in past 3 mo* Mean % IG: 3.5% CG: 3.6% OR (adjusted): 0.97 (0.48, 1.96), p=0.93

Abbreviations: GC= Gonorrhea; HSV= Herpes simplex virus; HPV= human papilloma virus; BV= bacterial vaginosis; ARRM= AIDS Risk Reduction Model; dx= diagnosed; RR= Relative Risk; OR= Odds Ratio; IG= Intervention Group; CG= Control Group; hx= history' (c)= calculated; NR= not reported; FP= family practice

Table 2. Biological outcomes adolescents (KQ1)

Study Reference Quality	Setting	Population	Study Intervention/Intensity	Biologic Outcomes
Jemmott 2005[20] Good	Adolescent medicine clinic	N: 682 100% Female African American: 68% Hispanic: 32% with any STI: 21.9%	Culturally tailored skills-based intervention based on cognitive behavioral theories. IG1 & IG2: High- 250 minutes total; one group session; +/- skills training CG: matched general health promotion counseling	*Mean % testing positive for STI (GC, chlamydia, Trichomonas),* *p value (adjusted)* 6-mo: IG1: 15.8%, p=0.80; IG2: 15.5%, p=0.89; CG: 14.8% 12-mo: IG1: 10.5%, p=0.05; IG2: 14.4%, p=0.44; CG: 18.2%
DiClemente 2004[19] Good	Community health agencies	N: 522 100% Female African American: 100% with GC: 5.2% with chlamydia: 17.4% with trichomonas: 13.0%	Culturally tailored social cognitive theory and theory of gender and power; with peer co-facilitators. IG: High- 4 hours total; 4 group sessions CG: matched nutrition and exercise counseling	*STI incidence per 100 person (crude), OR (adjusted) over 12mo* chlamydia IG: 2.1 CG: 2.0 OR: 0.17 (0.03-0.92) Gonorrhea IG: 0.9 CG: 0.7 OR: 0.14 (0.01-3.02) Trichomonas IG: 0.9 CG: 1.2 OR: 0.37 (0.09-1.46
Kamb 1998[14] Bolu 2004[21] Project RESPECT Fair	STI clinics	N: 764 Male: NR for subgroup Race: NR for subgroup with any STI: NR for subgroup	CDC's client centered HIV prevention counseling model; enhanced version based on multiple social science theories. IG1: High- 200 minutes total; 4 individual sessions; IG2- Moderate- 40 minutes total; 2 individual sessions CG: usual care, 10 minute information only	*mean % with new STI (GC/chlamydia, syphilis, HIV), RR (adjusted) for new STI at 12 mo* IG1: 17.2% RR 0.57 (0.37-0.90) IG2: 17.5% RR 0.58 (0.37-0.92) CG1: 26.6%
Boekeloo 1999[18] Fair	HMO	N: 219 Male: 50.2% African American: 64% Hispanic: 3% Other race: 14%	Physician counseling based on 15 minute audiotape risk assessment done in waiting period. IG: Low- unknown total duration; 'brief' individual session CG: usual care, details NR	*% Told by doctor/nurse they had STI (self-reported)* 3-mo: IG: 1.1%; CG: 0.9% 9-mo: IG: 0%; CG: 2.9% *% treated for an STD (self-reported)* 3-mo: IG: 2.2%; CG: 4.7% 9-mo: IG: 1.1%; CG: 5.8%

Abbreviations: GC= Gonorrhea; HSV= Herpes simplex virus; HPV= human papilloma virus; BV= bacterial vaginosis; ARRM= AIDS Risk Reduction Model; dx= diagnosed; RR= Relative Risk; OR= Odds Ratio; IG= Intervention Group; CG= Control Group; hx= history' (c)= calculated; NR= not reported; FP= family practice

Table 3. Behavioral outcomes adults (KQ2)

Study Reference Quality	Setting	Population	Study Intervention	UAI or UVI (without condom unless specified)	Use of condom (male condom unless otherwise specified)	# Of sex partners
Ehrhardt 2002[22] Hoffman 2003[61] Melendez 2003[47] Project FIO Good	Planned Parenthood clinic	N: 360 100% Female African American: 73% Hispanic: 17% with hx STI: 58.3%	Culturally tailored ARRM. IG1: High- 10 hours total; four group sessions plus booster at 9 months; IG2: High- 18 hours total; eight group sessions plus booster at 9 months CG: usual care, assessment only	*'model predicted' mean # unprotected acts in past 3 mo* text reads IG2 had on average 4 fewer UVI/UAI than control, p=0.00 *% maintaining or improving safer sex behavior, OR (adjusted)* IG1: 66.4% IG2: 72.7% CG: 61.7% OR (IG2 to CG) 1.65 (0.94, 2.90)	*% using condom (male/female) in past 3-mo* IG1: NR IG2: 18% increase, p=0.06 CG: NR	NR
Proude 2004[23] Fair	FP practices Australia	N: 312 Male: 29% Race: NR	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	NR	*% Condom use on first sex occasion with new partner* IG: 73%(8/11) CG: 77%(10/13) p=0.813	*% New sex partners over past 3 mo (c)* IG1: 11/156 CG: 13/156
Wenger 1992[24] Fair	University Health Clinic	N: 370 Male: 28% Caucasian: 61% with hx/dx STI: 23%	'Education'; or 'Education' plus HIV testing; theory not specified. IG1 & IG2: Moderate- 1 hour total; 1 group session; +/- HIV testing CG: wait list control	*% With UVI/UAI with last sex partner* 6-mo IG1: 68% IG2: 63% CG: 61% p>0.15	N	*Mean number sex partners in last mo* 6-mo IG1: 0.70 IG2: 0.84 CG: 0.72 p>0.15

Abbreviations: GC= Gonorrhea; HSV= Herpes simplex virus; HPV= human papilloma virus; BV= bacterial vaginosis; ARRM= AIDS Risk Reduction Model; dx= diagnosed; RR= Relative Risk; OR= Odds Ratio; IG= Intervention Group; CG= Control Group; hx= history' (c)= calculated; NR= not reported; FP= family practice

Table 4. Behavioral outcomes adolescents (KQ2)

Study Reference Quality	Location Population	Baseline Demographics	Study Intervention/Intensity	UAI or UVI (without condom unless otherwise specified)	Use of condom (male condom unless otherwise specified)	# Of sex partners	Abstinence
Danielson 1990[25] Fair	HMO	N: 1195 Male: 100% African American: <5% Asian pacific islander: <4%	Slide tape program followed by session with health practitioner; theory not specified. IG: Moderate- 1 hour total; 1 individual session CG: wait-list control	*% using any contraceptive at most recent intercourse* IG: 69.9% CG: 65.8% OR adjusted 1.51, p<0.05 OR adjusted for those who had not been sex active at baseline 2.53, p<0.01	*% using condom at most recent intercourse* IG: 33.3% CG: 35.8%	N	*Mean % teen male sex active* IG: 90% CG: 91% *mean % teen male sex active (of those not previously sex active*) IG: 30% CG: 34%

Abbreviations: GC= Gonorrhea; HSV= Herpes simplex virus; HPV= human papilloma virus; BV= bacterial vaginosis; ARRM= AIDS Risk Reduction Model; dx= diagnosed; RR= Relative Risk; OR= Odds Ratio; IG= Intervention Group; CG= Control Group; hx= history' (c)= calculated; NR= not reported; FP= family practice

Table 5. Other positive outcomes adults (KQ3)

Study Reference Quality	Setting	Population	Study Intervention	Other positive Outcomes
Shain 2004[17] Project SAFE 2 Fair	STI clinic	N: 775 (690 in analysis) 100% Female Hispanic: 77% African American: 23% *with GC (c):20.6%* *with chlamydia (c): 77.8%* *with trichomonas (c): 15.4%* *with syphilis(c): 4.6%* Male: 0%	Culturally tailored ARRM. IG1 & IG2: High- 9 hours total; 3 group sessions +/- optional support group sessions CG: usual care, 15 minute CDC standard counseling	% unprotected sex with untreated or incompletely treated partner at 12 mo IG1: 7.8%, p=0.001 IG2: 10.2%, p=0.01 CG: 18.1%
Shain 1999[16] Project SAFE Good	STI clinic	N: 617 (549 in analysis) 100% Female Hispanic: 69% African American: 31% with GC (c): 22.8% with chlamydia (c): 68.7% with trichomonas (c): 23.7% with syphilis (c): 6.0%	Culturally tailored ARRM. IG: High- 9-12 hours total; 3 group sessions CG: usual care, 15 minute CDC standard counseling	*% apply condoms on sex partners (relative % change)* 6-mo: IG: 2.18; CG: 1.51; 45.99% (24.66, 63.86), p<0.001 12-mo: IG: 1.97; CG: 1.59; 28.39% (12.51, 54.7), p=0.003
Ehrhardt 2002[22] Hoffman 2003[61] Melendez 2003[47] Project FIO Good	Planned Parenthood clinic	N: 360 100% Female African American: 73% Hispanic: 17% with hx STI: 58.3%	Culturally tailored ARRM. IG1: High- 10 hours total; four group sessions plus booster at 9 months; IG2: High- 18 hours total; eight group sessions plus booster at 9 months CG: usual care, assessment only	*% Alternative risk reduction strategy (# sex occasions; outercourse; refusing sex; leaving relationship; choosing not to get involved with new partner; mutual HIV testing)* - text states no difference between groups at 12-mo f/u

Abbreviations: GC= Gonorrhea; HSV= Herpes simplex virus; HPV= human papilloma virus; BV= bacterial vaginosis; ARRM= AIDS Risk Reduction Model; dx= diagnosed; RR= Relative Risk; OR= Odds Ratio; IG= Intervention Group; CG= Control Group; hx= history' (c)= calculated; NR= not reported; FP= family practice

Table 6. Other positive outcomes adolescents (KQ3)

Study Reference Quality	Setting	Population	Study Intervention/Intensity	Other positive Outcomes		
Jemmott 2005[20] Good	Adolescent medicine clinic	N: 682 100% Female African American: 68% Hispanic: 32% with any STI: 21.9	Culturally tailored skills-based intervention based on cognitive behavioral theories. IG1 & IG2: High- 250 minutes total; one group session; +/- skills training CG: matched general health promotion counseling	*mean # of days of sex while intoxicated past 3 mo* 3-mo IG1: 0.10, p=0.03 IG2: 0.29, p=0.98 CG: 0.26	6-mo IG1: 0.07, p=0.005 IG2: 0.15, p=0.10 CG: 0.31	12-mo IG1: 0.42, p=0.37 IG2: 0.53, p=0.65 CG: 0.66
DiClemente 2004[19] Good	Community health agencies	N: 522 100% Female African American: 100% with GC: 5.2% with chlamydia: 17.4% with trichomonas: 13.0%	Culturally tailored social cognitive theory and theory of gender and power; with peer co-facilitators. IG: High- 4 hours total; 4 group sessions CG: matched nutrition and exercise counseling	*% self-reported pregnancy* 6-mo IG: 3.6 CG: 7.0 OR 0.38 (0.15-0.96) *% apply condoms on sex partners (relative % change)* 6-mo IG: 2.18 CG: 1.51 45.99% (24.66, 63.86), p<0.001	12-mo IG: 6.0 CG: 8.5 OR 0.74 (0.30-1.82) 12-mo IG: 1.97 CG: 1.59 28.39% (12.51, 54.7), p=0.003	
Boekeloo 1999[18] Fair	HMO	N: 219 Male: 50.2% African American: 64% Hispanic: 3% Other race: 14%	Physician counseling based on 15 minute audiotape risk assessment done in waiting period. IG: Low- unknown total duration; 'brief' individual session CG: usual care, details NR	*% self-reported pregnancy (gotten someone or been pregnant)* baseline, 3-mo IG: 1.0%, 0% CG: 1.8%, 1.9% NS, p>0.05	baseline, 6-mo IG: 1.0%, 1.1% CG: 1.8%, 5.9% NS, p>0.05	
Danielson 1990[25] Fair	HMO	N: 1195 Male: 100% African American: <5% Asian pacific islander: <4%	Slide tape program followed by session with health practitioner; theory not specified. IG: Moderate- 1 hour total; 1 individual session CG: wait-list control	*% with partner using pill at most recent sexual intercourse* IG: 32.4% CG: 23.9% OR 1.66, p<0.05		

Abbreviations: GC= Gonorrhea; HSV= Herpes simplex virus; HPV= human papilloma virus; BV= bacterial vaginosis; ARRM= AIDS Risk Reduction Model; dx= diagnosed; RR= Relative Risk; OR= Odds Ratio; IG= Intervention Group; CG= Control Group; hx= history' (c)= calculated; NR= not reported; FP= family practice

Table 7. Adverse effects adults (KQ4)

Study Reference Quality	Setting	Baseline Demographics	Study Intervention	Adverse Outcomes
Carey 2004[13] Fair	Outpatient psychiatric	N: 408 Male: 46% African-American: 21%	HIV harm reduction, motivational techniques to enhance readiness to change. High: unknown total hours; 10 group sessions	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)
Shain 2004[17] Project SAFE 2 Fair	STI clinic	N: 690 100% Female Hispanic: 77% African American: 23%	Culturally tailored ARRM. High: 9 hours total; 3 group sessions +/- optional support group sessions	No increase in number of sex partners No increase in STI incidence (by testing)
Scholes 2003[15] Fair	Medical clinic	N: 1210 100% Female African American: 19% Other race: 12%	Individually tailored self-help printed materials based on multiple social science theories. Low: 2 mailings, 12-page booklet and booster newsletter	No increase in unprotected sex or decrease in condom use No increase in STI incidence (by self report)
Ehrhardt 2002[22] Project FIO Good	Planned Parenthood clinic	N: 360 100% Female African American: 73% Hispanic: 17%	Culturally tailored ARRM. High: 18 hours total; eight group sessions plus booster at 9 months	No increase in unprotected sex or decrease in condom use
Shain 1999[16] Project SAFE Good	STI clinic	N: 617 (n=549 in analysis) 100% Female Hispanic: 69% African American: 31%	Culturally tailored ARRM. High: 9-12 hours total; 3 group sessions	No increase in unprotected sex or decrease in condom use No increase in STI incidence (by self report)
Kamb 1998[14] Project RESPECT Fair	STI clinics	N: 5758 Male: 57% African American: 59% Hispanic: 19% Other race: 6%	CDC's client centered HIV prevention counseling model; or enhanced version using theory of reasoned action and social cognitive theory. Moderate: 40 minutes total; 2 individual sessions. High: 200 minutes total; 4 individual sessions	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 1997[12] Fair	STI clinic	N: 393 Male (c): 67% African American: 46% Hispanic: 15% Other race: 10%	ARRM. High: 4 hours total; 4 individual sessions	No increase in unprotected sex or decrease in condom use. No increase in STI incidence (by self-report) No increase in number of sex partners
Wenger 1992[24] Fair	University Health Clinic	N: 370 Male: 28% White: 61%	'Education'; or 'Education' plus HIV testing; theory not specified. Moderate: 1 hour total; 1 group session	No increase in number of sex partners No increase in unprotected sex or decrease in condom use
Proude 2004[23] Fair	FP practices Australia	N: 312 Male: 29% Race: NR	Physician counseling based on brief risk assessment done by FP during visit; theory not specified. Low: unknown total duration; 'brief' individual session	No increase in number of sex partners No increase in unprotected sex or decrease in condom use

Abbreviations: GC= Gonorrhea; HSV= Herpes simplex virus; HPV= human papilloma virus; BV= bacterial vaginosis; ARRM= AIDS Risk Reduction Model; dx= diagnosed; RR= Relative Risk; OR= Odds Ratio; IG= Intervention Group; CG= Control Group; hx= history' (c)= calculated; NR= not reported; FP= family practice

Table 8. Adverse effects adolescents (KQ4)

Study Reference Quality	Setting	Baseline Demographics	Study Intervention	Adverse Outcomes
Jemmott 2005[20] Good	Adolescent medicine clinic	N: 682 100% Female African American: 68% Hispanic: 32%	Culturally tailored skills-based intervention based on cognitive behavioral theories. High: 250 minutes total; one group session	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 2004[19] Good	Community health agencies	N: 522 100% Female African American: 100%	Culturally tailored social cognitive theory and theory of gender and power; with peer co-facilitators. High:4 hours total; 4 group sessions.	No increase in unprotected sex or decrease in condom use No increase in STI incidence (by testing)
Boekeloo 1999[18] Fair	HMO	N: 219 Male: 50.2% African American: 64% Caucasian: 19% Hispanic: 3% Other race: 14%	Physician counseling based on 15 minute audiotape risk assessment done in waiting period. Low: unknown total duration; 'brief' individual session	INCREASE in % having vaginal sex at 3mo but NOT at 9mo (at 6 mo: IG=27%, CG=20%, OR -2.46 (1.04, 5.84)) No increase in overall sex (vaginal, oral, and anal sex) No increase in unprotected sex or decrease in condom use No increase in STI incidence (by self report)
Danielson 1990[25] Fair	HMO	N: 1195 Male: 100% African American: <5% Asian pacific islander: <4%	Slide tape program followed by session with health practitioner; theory not specified. Moderate: 1 hour total; 1 individual session	No increase in unprotected sex or decrease in condom use No earlier sexual debut

Abbreviations: GC= Gonorrhea; HSV= Herpes simplex virus; HPV= human papilloma virus; BV= bacterial vaginosis; ARRM= AIDS Risk Reduction Model; dx= diagnosed; RR= Relative Risk; OR= Odds Ratio; IG= Intervention Group; CG= Control Group; hx= history' (c)= calculated; NR= not reported; FP= family practice

Table 9. Female condom effectiveness (KQ5)

Study Reference Quality	Study Design Location Target population	Population	Study Intervention	Outcomes/Results
French 2003[31] **Fair**	RCT US; urban STI clinic Adult, female; low-income, minority	N : 1442 % Female: 100% % African American: 86%	IG: small group sessions; 10-20 minutes; given free female condoms during study period. Encouraged to use the female condom during vaginal and anal sex and were instructed to purchase flavored male condoms for oral sex (not advised to stop using other methods). CG: format same as IG, encouraged to use male condoms during all types of sexual intercourse (not encouraged to stop using any other method of protection)	*STI diagnosed at follow-up (gonorrhea, chlamydia, early syphilis, trichomonas)* IG: 12.4%(106/855) CG: 15.8%(93/587) OR (unadjusted)- 0.75 (0.56-1.01), p=0.06 *STI incidence (per 100 women months) at follow-up* IG: 6.8 CG: 8.5 OR- 0.79 (0.59-1.06), p=0.11
Fontanet 1998[30] **Fair**	RCT Thailand; urban Sex establishments Adult; Female; sex workers	N: 504 % Female: 100% Race: NR	IG: male/female condom group; option of using female condom when clients refused or could not use a male condom; given free supply of condoms. CG: male condom group; if clients refused or could not use male condoms, they were instructed not to have sex; given free supply of condoms (same as IG)	*STI (gonorrhea, chlamydia, trichomonas, genital ulcer disease) Incidence (per 100 woman weeks)* IG: 2.81 CG: 3.69 Incidence rate ratio (95% CI): 0.76 (0.50-1.16) *Percent with acts female condom* IG: 12.0% CG: 0%
Feldblum 2001[29] **Feldblum 2000**[62] **Good**	Cluster RCT Kenya; rural Agricultural sites Adult, female; employed as agricultural worker	N: 1929 % Female: 100% Race: NR	IG: Outreach program with individual counseling, given male and female condoms for all adults. CG: Similar prevention program excluding information on female condoms, only given male condoms	*Crude prevalence of STI (gonorrhea, chlamydia, or trichomonas)* <u>Baseline</u> <u>6-mo</u> <u>12-mo</u> IG: 22.1% IG: 17.1% IG: 18.2% CG: 25.6% CG: 17.6% CG: 18.4% *OR (adjusted)* IG: OR- 1.1 (0.8, 1.6- 1.0) CG: OR- 1.0 *% Consistent female condom use* <u>6-mo</u> <u>12-mo</u> IG=11% IG: 7% CG=NA CG: NA

Abbreviations: GC= Gonorrhea; HSV= Herpes simplex virus; HPV= human papilloma virus; BV= bacterial vaginosis; ARRM= AIDS Risk Reduction Model; dx= diagnosed; RR= Relative Risk; OR= Odds Ratio; IG= Intervention Group; CG= Control Group; hx= history' (c)= calculated; NR= not reported; FP= family practice

Table 10. Summary of evidence

No. of studies	Design	Limitations	Consistency	Applicability	Overall Quality	Summary of Findings	Comment
KQ1. biological outcomes							
	Adults						
6[12-17]	RCT	Limited number of trials with significant heterogeneity in populations and interventions.	Inconsistency between STI clinic and non-STI clinic setting and intensity of intervention.	Trials conducted in urban areas; 4 trials in predominantly AA and/or Hispanic adults; 4 trials in STI clinics; 1 trial in a psychiatric clinic	Fair-Good	Three of the six trials (n=7150) showed a moderate reduction in STI incidence at 12 months among adults in STI clinics receiving moderate to high-intensity counseling interventions. One trial (n=393) did not show a reduction in STI incidence at 6 months in adults attending an STI clinic 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[14-18-21]	RCT	Limited number of trials with significant heterogeneity in populations and interventions.	Inconsistency between sexually active adolescents and general adolescent population and intensity of intervention.	Trials conducted in urban areas in predominantly AA and/or Hispanic adolescents	Fair-Good	<u>Sexually active adolescents</u>: All three trials (n=1998) showed a modest reduction in laboratory diagnosed STI incidence at 12 months in sexually active adolescents receiving moderate to high-intensity counseling interventions. <u>Pre-sexually and sexually active adolescents</u>: One trial (n=219) did not show a reduction in self-reported STI incidence at 3 or 9 months in young adolescents receiving a low-intensity counseling intervention.	One of the 4 trials is a subgroup analysis by age group of Project RESPECT Self-reported measures of STI outcomes should be interpreted cautiously

No. of studies	Design	Limitations	Consistency	Applicability	Overall Quality	Summary of Findings	Comment
KQ2. behavioral outcomes							
	Adults						
3[22-24]	RCT	Limited number of trials with significant heterogeneity in populations, interventions, and measurement of outcomes.	Inconsistency by intervention intensity and population risk.	Trials conducted in urban areas; 1 trials in predominantly AA and/or Hispanic adults; 1 trial in a university health clinic; 1 trial in Australia	Fair	Two of the three trials did not show a decrease in self-reported risky sexual behavior (i.e. unprotected sexual intercourse or multiple sex partners or increase in self-reported male condom use) in adults receiving low to high-intensity counseling interventions. Only one trial showed a decrease in self-reported unprotected sexual intercourse and increase in self-reported (male and female) condom use at 12 months in women with a high percentage of previous STI, receiving a very high-intensity counseling intervention (18 hours), but not a high-intensity counseling intervention (10 hours).	
Adolescents							
1[19]	RCT	Only one study.	N/A	High school boys in urban HMO setting	Fair	<u>Pre-sexually and sexually active adolescents</u>: This study did not show an increase in condom use or abstinence at 12 months in male adolescents receiving a moderate-intensity counseling intervention.	
KQ3. other positive outcomes							
Adults							
3[16,17,22]	RCT	Limited number of trials with significant heterogeneity in populations and interventions	No inconsistencies	Trials conducted in urban areas in predominantly AA and/or Hispanic adults	Fair	Two trials conducted in STI clinics found that women receiving high-intensity group counseling also had increased STI treatment compliance, as measured by self-reported unprotected intercourse with untreated or incompletely treated sex partner. Another trial did not show an increase in self-reported 'alternative risk reduction' strategies with high-intensity group counseling at 12 months.	

No. of studies	Design	Limitations	Consistency	Applicability	Overall Quality	Summary of Findings	Comment
Adolescents							
4[18-20,25]	RCT	Limited number of trials with significant heterogeneity in populations and interventions.	No serious inconsistencies	Trials conducted in urban areas; 3 trials in predominantly AA and/or Hispanic adolescents	Fair	Sexually active adolescents: One trial showed a decrease in self-reported sex while intoxicated at 3 and 6 months, but not at 12 months in female adolescents receiving high-intensity group counseling. Another trial showed a decrease in self-reported pregnancy at 6 months, but not at 12 months, in female adolescents receiving high-intensity group counseling. Pre-sexually 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.	
KQ4. adverse effects							
Adults							
9[12-17,22-24]	RCT	Limited number of trials with significant heterogeneity in populations, interventions, and measurement of outcomes.	No inconsistencies	Trials conducted in urban areas; 6 trials in predominantly AA and/or Hispanic adults; 4 trials in STI clinics; 1 trial in a psychiatric clinic, 1 trial in a university health clinic; 1 trial in Australia	Fair-Good	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.	.

No. of studies	Design	Limitations	Consistency	Applicability	Overall Quality	Summary of Findings	Comment
Adolescents							
4[18-20,25]	RCT	Limited number of trials with significant heterogeneity in populations, interventions, and measurement of outcomes.	No serious inconsistencies	Trials conducted in urban areas; 3 trials in predominantly AA and/or Hispanic adolescents	Fair-Good	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 and sexually active adolescents: One study showed a transient increase of vaginal sex in young adolescents receiving a low-intensity counseling intervention at 3 months, OR 2.46, 95%CI (1.04-5.84); but NOT at 9 months, and no increase in overall sexual activity at either followup. Another study in an HMO setting showed no evidence of earlier sexual debut in male adolescents receiving a moderate-intensity counseling intervention.	Risk reduction counseling only.
KQ5. female condoms							
3[29-31]	1 RCT, 2 cluster RCT	Limited number of trials with significant heterogeneity in populations and interventions.	No inconsistencies	One in US STI clinic; one in Thai sex workers in Thailand; and one in rural Kenya	Fair	All three studies suggest that counseling women to use female condoms and providing female condoms in addition to male condoms offers similar protection against bacterial STIs as counseling women to use male condoms and providing male condoms.	Overall use of female condoms was low- about 7 percent of women in the Kenyan RCT and 12% of sex acts in the Thai RCT.

Abbreviations: GC= Gonorrhea; HSV= Herpes simplex virus; HPV= human papilloma virus; BV= bacterial vaginosis; ARRM= AIDS Risk Reduction Model; dx= diagnosed; RR= Relative Risk; OR= Odds Ratio; IG= Intervention Group; CG= Control Group; hx= history' (c)= calculated; NR= not reported; FP= family practice

References

(1) U.S.Preventive Services Task Force. Preventing HIV and other STDs. In: Williams & Wilkins, editor. *Guide to Clinical Preventive Services*. Baltimore: 1996: 723-737.

(2) Weinstock H, Berman S, Cates W. Sexually transmitted diseases among American youth: incidence and prevalence estimates, 2000. *Perspect Sex Reprod Health* 2004; 36(1):6-10.

(3) Center for Disease Control. Trends in Reportable Sexually Transmitted Diseases in the United States, 2004.

(4) Gallant JE.. HIV counseling, testing, and referral. *Am Fam Physician* 2004; 70(2):295-302.

(5) Chesson HW, Blandford JM, Gift TL, et al. The estimated direct medical cost of sexually transmitted diseases among American youth, 2000. *Perspect Sex Reprod Health* 2004; 36(1):11-19.

(6) Henderson Z, Tao G, Irwin K. Sexually transmitted disease care in managed care organizations. *Infect Dis Clin North Am* 2005; 2005(2):491-511.

(7) Fairbrother G, Scheinmann R, Osthimer B, et al. Factors that influence adolescent reports of counseling by physicians on risky behavior. *J Adolesc Health 37(6):467-76,* 2005.

(8) Millstein SG, Igra V, Gans J. Delivery of STD/HIV preventive services to adolescents by primary care physicians. *J Adolesc Health* 1919;(4):249-57, 1996.

(9) Koumans EH, Sternberg MR, Motamed C,et, al.. Sexually Transmitted Disease Services at US Colleges and Universities. 2005.

(10) Ashton MR, Cook RL, Wiesenfeld HC et al. Primary care physician attitudes regarding sexually transmitted diseases. *Sex Transm Dis 29(4):246-51,* 2002.

(11) Harris RP, Helfand M, Woolf SH et al. Current methods of the US Preventive Services Task Force: a review of the process. *Am J Prev Med* 2001; 20(3 Suppl):21-35.

(12) Boyer CB, Barrett DC, Peterman TA et al. Sexually transmitted disease (STD) and HIV risk in heterosexual adults attending a public STD clinic: evaluation of a randomized controlled behavioral risk-reduction intervention trial. *AIDS* 1997; 11(3):359-367.

(13) Carey MP, Carey KB, Maisto SA, et al. Reducing HIV-risk behavior among adults receiving outpatient psychiatric treatment: results from a randomized controlled trial. *J Consult Clin Psychol* 2004; 72(2):252-268.

(14) Kamb ML, Fishbein M, Douglas JM, Jr., et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial. Project RESPECT Study Group. *JAMA* 1998; 280(13):1161-1167.

(15) Scholes D, McBride CM, Grothaus L, et al. A tailored minimal self-help intervention to promote condom use in young women: results from a randomized trial.[see comment]. *AIDS 17(10):1547-56,* 2003.

(16) Shain RN, Piper JM, Newton ER et al. A randomized, controlled trial of a behavioral intervention to prevent sexually transmitted disease among minority women. *N Engl J Med* 1999; 340(2):93-100.

(17) Shain RN, Piper JM, Holden AE et al. Prevention of gonorrhea and Chlamydia through behavioral intervention: results of a two-year controlled randomized trial in minority women. *Sex Transm Dis* 2004; 31(7):401-408.

(18) Boekeloo BO, Schamus LA, Simmens SJ, et al. A STD/HIV prevention trial among adolescents in managed care. *Peds 103(1):107-15,* 1999.

(19) DiClemente RJ, Wingood GM, Harrington KF, et al. Efficacy of an HIV prevention intervention for African American adolescent girls: a randomized controlled trial. *JAMA* 2004; 292(2):171-179.

(20) Jemmott JB, III, Jemmott LS, Braverman PK, et al. HIV/STD risk reduction interventions for African American and Latino adolescent girls at an adolescent medicine clinic: a randomized controlled trial. *Arch Pediatr Adolesc Med* 2005; 159(5):440-449.

(21) Bolu OO, Lindsey C. Is HIV/sexually transmitted disease prevention counseling effective among vulnerable populations?: a subset analysis of data collected for a randomized, controlled trial evaluating counseling efficacy (Project RESPECT). *Sex Transm Dis 31(8):469-74,* 2004.

(22) Ehrhardt AA, Exner TM, Hoffman S, et al. A gender-specific HIV/STD risk reduction intervention for women in a health care setting: short- and long-term results of a randomized clinical trial. *AIDS Care 14(2):147-61,* 2002.

(23) Proude EM, D'Este C, Ward JE. Randomized trial in family practice of a brief intervention to reduce STI risk in young adults. *Fam Pract* 2004; 21(5):537-544.

(24) Wenger NS, Greenberg JM, Hilborne LH et al. Effect of HIV antibody testing and AIDS education on communication about HIV risk and sexual behavior. A randomized, controlled trial in college students. *Annals of Internal Medicine 117(11):905-11,* 1992.

(25) Danielson R. Reproductive health counseling for young men: what does it do? *Family Planning Perspectives 22(3):115-21,* 1990.

(26) Hobfoll SE, Jackson AP, Lavin J et al. Reducing inner-city women's AIDS risk activities: a study of single, pregnant women. *Health Psychology 13(5):397-403,* 1994.

(27) Korte JE, Shain RN, Holden AE, Piper JM, Perdue ST, Champion JD et al. Reduction in sexual risk behaviors and infection rates among African Americans and Mexican Americans. *Sexually Transmitted Diseases 31(3):166-73,* 2004.

(28) Soper D, Shoupe D. Prevention of vaginal trichomoniasis by compliant use of the female condom. *Sexually Transmitted Diseases* 1993;(3).

(29) Feldblum PJ, Kuyoh MA, Bwayo JJ et al. Female condom introduction and sexually transmitted infection prevalence: results of a community intervention trial in Kenya. *AIDS 15(8):1037 -44,* 2001.

(30) Fontanet AL, Saba J, Chandelying V, et al. Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: results from a randomized controlled trial. *AIDS 12(14):1851-9,* 1998.

(31) French PP, Latka M, Gollub EL, et al. Use-effectiveness of the female versus male condom in preventing sexually transmitted disease in women.[comment]. *Sex Transm Dis 30(5):433-9,* 2003.

(32) Koblin B, Chesney M, Coates T. Effects of a behavioural intervention to reduce acquisition of HIV infection among men who have sex with men: the EXPLORE randomised controlled study. *Lancet* 2004; 364(9428):41-50.

(33) Li X, Stanton B, Feigelman S et al. Unprotected sex among African-American adolescents: a three-year study. *J Natl Med Assoc* 2002; 94(9):789-796.

(34) Metcalf CA, Malotte CK, Douglas JM, Jr. et al. Efficacy of a booster counseling session 6 months after HIV testing and counseling: a randomized, controlled trial (RESPECT-2). *Sex Transm Dis* 2005; 32(2):123-129.

(35) Nyamathi AM, Kington RS, Flaskerud Jet al. Two-year follow-up of AIDS education programs for impoverished women. *Western Journal of Nursing Research 21(3):405-25,* 1999.

(36) Gottlieb SL, Douglas JM, Jr., Foster M et al. Incidence of herpes simplex virus type 2 infection in 5 sexually transmitted disease (STD) clinics and the effect of HIV/STD risk-reduction counseling. *J Infect Dis* 2004; 190(6):1059-1067.

(37) Harvey SM, Henderson JT, Beckman, S et al. A randomized study of a pregnancy and disease prevention intervention for Hispanic couples. *Perspectives on sexual and reproductive health 36(4):162-9,* 2004.

(38) Smoak ND, Scott-Sheldon LA, Johnson BT et al. Sexual risk reduction interventions do not inadvertently increase the overall frequency of sexual behavior: a meta-analysis of 174 studies with 116,735 participants. *J Acquir Immune Defic Syndr* 2006; 41(3):374-384.

(39) Pealer LN, Peterman TA, Newman DR et al. Are counselor demographics associated with successful human immunodeficiency virus/sexually transmitted disease prevention counseling? *Sex Transm Dis* 2004; 31(1):52-56.

(40) Jemmott JB, III, Jemmott LS, Fong GT et al. Reducing HIV risk-associated sexual behavior among African American adolescents: testing the generality of intervention effects. *Am J Community Psychol* 1999; 27(2):161-187.

(41) Weller S, Davis K. Condom effectiveness in reducing heterosexual HIV transmission. *Cochrane Database Syst Rev* 2001;(3):CD003255.

(42) Weller S, Davis-Beaty K. The effectiveness of male condoms in prevention of sexually transmitted diseases. *Cochrane Database of Systematic Reviews* 2005;(4).

(43) Ness RB, Randall H, Richter HE et al. Condom use and the risk of recurrent pelvic inflammatory disease, chronic pelvic pain, or infertility following an episode of pelvic inflammatory disease. *Am J Public Health* 2004; 94(8):1327-1329.

(44) Manhart LE, Koutsky LA. Do condoms prevent genital HPV infection, external genital warts, or cervical neoplasia? A meta-analysis. *Sex Transm Dis* 2002; 29(11):725-735.

(45) Wald A, Langenberg AG, Link K et al. Effect of condoms on reducing the transmission of herpes simplex virus type 2 from men to women.[see comment]. *JAMA 285(24):3100 -6,* 2001.

(46) Minnis AM, Padian NS. Effectiveness of female controlled barrier methods in preventing sexually transmitted infections and HIV: current evidence and future research directions. *Sexually Transmitted Infections 81(3):193-200,* 2005.

(47) Melendez RM, Hoffman S, Exner T et al. Intimate partner violence and safer sex negotiation: effects of a gender-specific intervention. *Archiv Sexual Beh32(6):499-511,* 2003.

(48) Wingood GM, DiClemente RJ, Harrington KF et al. Efficacy of an HIV Prevention Program Among Female Adolescents Experiencing Gender-Based Violence. *American Journal of Public Health* 96[6], 1085-1090. 2006.

(49) Sweat M, O'Donnell C, O'Donnell L. Cost-effectiveness of a brief video-based HIV intervention for African American and Latino sexually transmitted disease clinic clients. *AIDS 15(6):781-7,* 2001.

(50) Cohen DA, Wu SY, Farley TA. Comparing the cost-effectiveness of HIV prevention interventions. *J Acquir Immune Defic Syndr* 2004; 37(3):1404-1414.

(51) O'Donnell CR, O'Donnell L, San Doval A, et al. Reductions in STD infections subsequent to an STD clinic visit. Using video-based patient education to supplement provider interactions. *Sexually Transmitted Diseases 25(3):161-8,* 1998.

(52) Cohen DA, Wu SY, Farley TA. Comparing the cost-effectiveness of HIV prevention interventions. *J Acquir Immune Defic Syndr* 2004; 37(3):1404-1414.

(53) Harrington KF, DiClemente RJ, Wingood GM et al. Validity of self-reported sexually transmitted diseases among African American female adolescents participating in an HIV/STD prevention intervention trial. *SexTransm Dis 28(8):468 -71,* 2001.

(54) Zenilman JM. Behavioral interventions--rationale, measurement, and effectiveness. *Infectious Disease Clinics of North America* 2005;(2):541-562.

(55) Peterman TA, Lin LS, Newman DR et al. Does measured behavior reflect STD risk? An analysis of data from a randomized controlled behavioral intervention study. Project RESPECT Study Group. *Sex Transm Dis 27(8):446-51,* 2000.

(56) Shain RN, Perdue ST, Piper JM et al. Behaviors changed by intervention are associated with reduced STD recurrence: The importance of context in measurement. *Sex Transm Dis 29(9):520 -529,* 2002.

(57) Johnson WD, Hedges LV, Diaz RM et al. Interventions to modify sexual risk behaviors for preventing HIV infection in men who have sex with men. *Cochrane Database of Systematic Reviews* 2005.

(58) Coyle SL, Needle RH, Normand J. Outreach-based HIV prevention for injecting drug users: a review of published outcome data. *Public Health* 1999; 113(Supplement 1):19-30.

(59) Herbst JH, Beeker C, Mathew A, et al. The Effectiveness of Individual-, Group-, and Community-Level HIV Behavioral Risk-Reduction Interventions for Adult Men Who Have Sex with Men A Systematic Review. *Am J Prev Med* 2007; 32(4 Suppl):38-67.

(60) Chou R, Huffman LH, Fu R et al. Screening for HIV: a review of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med* 2005; 143(1):55-73.

(61) Hoffman S, Exner TM, Leu CS et al. Female-condom use in a gender-specific family planning clinic trial. *American Journal of Public Health 93(11):1897 -903,* 2003.

(62) Feldblum PJ BJK. The female condom and STDs: design of a community intervention trial. *Annals of epidemiology* 1910;(6).

APPENDIX A

METHODS

Appendix A. Table 1. Search strategies

Systematic Evidence Review Search
PubMed search to identify systematic reviews

#115 Search #114 NOT (case report [ti] OR editorial [ti] OR editorial [pt] OR letter [pt] OR newspaper article [pt])
#114 Search #80 NOT #62 Field: All Fields, Limits: English
#113 Search #112 NOT (case report [ti] OR editorial [ti] OR editorial [pt] OR letter [pt] OR newspaper article [pt]) Limits: English
#112 Search #61 NOT #59 Field: All Fields, Limits: English
#111 Search #57 AND #58 NOT (case report [ti] OR editorial [ti] OR editorial [pt] OR letter [pt] OR newspaper article [pt]) Limits: English
#110 Search #57 AND #58 Field: All Fields, Limits: English
#108 Search #107 AND (in process [sb] OR publisher [sb])
#107 Search #106 AND #58
#106 Search #101 AND #105
#105 Search #52 OR #53 OR #54 OR #55 OR #102 OR #103 OR #104
#104 Search "patient education"[tiab]
#103 Search "health education"[tiab]
#102 Search "health promotion"[tiab]
#101 Search #82 OR #83 OR #84 OR #85 OR #86 OR #87 OR #88 OR #89 OR #90 OR #91 OR #92 OR #93 OR #94 OR #95 OR #96 OR #97 OR #98 OR #99 OR #100
#100 Search "sexually transmitted"[tiab]
#99 Search stis[tiab]
#98 Search sti[tiab]
#97 Search stds[tiab]
#96 Search std[tiab]
#95 Search syphilis[tiab]
#94 Search gonorrhea[tiab]
#93 Search chlamydia[tiab]
#92 Search hpv[tiab]
#91 Search "human papillomavirus"[tiab]
#90 Search "genital warts"[tiab]
#89 Search "condylomata acuminata"[tiab]
#88 Search hsv[tiab]
#87 Search "genital herpes"[tiab]
#86 Search "herpes simplex"[tiab]
#85 Search "hepatitis c"[tiab]
#84 Search "hepatitis b"[tiab]
#83 Search aids[tiab]
#82 Search hiv[tiab]
#81 Search #80 NOT #62
#80 Search #79 NOT #59
#79 Search #78 AND #58
#78 Search #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75 OR #76 OR #77
#77 Search "Sexually Transmitted Diseases, Viral/prevention and control"[MeSH:NoExp]
#76 Search "Sexually Transmitted Diseases, Bacterial/prevention and control"[MeSH:NoExp]
#75 Search "Sexually Transmitted Diseases/prevention and control"[MeSH:NoExp]
#74 Search "Syphilis/prevention and control"[MeSH:NoExp]
#73 Search "Gonorrhea/prevention and control"[MeSH]
#72 Search "Chlamydia Infections/prevention and control"[MeSH:NoExp]
#71 Search "Condylomata Acuminata/prevention and control"[MeSH]
#70 Search "Herpes Genitalis/prevention and control"[MeSH]
#69 Search "Herpes Simplex/prevention and control"[MeSH:NoExp]
#68 Search "Hepatitis C, Chronic/prevention and control"[MeSH]
#67 Search "Hepatitis C/prevention and control"[MeSH:NoExp]
#66 Search "Hepatitis B, Chronic/prevention and control"[MeSH]
#65 Search "Hepatitis B/prevention and control"[MeSH:NoExp]
#64 Search "Acquired Immunodeficiency Syndrome/prevention and control"[MeSH]
#63 Search "HIV Infections/prevention and control"[MeSH:NoExp]
#62 Search #61 NOT #59
#61 Search #60 AND #58

Appendix A. Table 1. Search strategies

#60 Search #40 AND intervention*[tiab]
#59 Search #57 AND #58
#58 Search systematic review* [tiab] OR systematic literature review* OR meta-analysis [pt] OR meta-analysis [ti] OR metaanalysis [ti] OR meta-analyses [ti] OR evidence-based medicine OR (evidence-based AND (guideline [tiab] OR guidelines [tiab] OR recommendations)) OR (evidenced-based AND (guideline [tiab] OR guidelines [tiab] OR recommendation*)) OR consensus development conference [pt] OR health planning guidelines OR guideline[pt] OR cochrane database syst rev OR acp journal club OR health technol assess OR evid rep technol assess summ OR evid based dent OR evid based nurs OR evid based ment health OR clin evid
#57 Search #40 AND #56
#56 Search #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55
#55 Search "motivational interview*"[tiab]
#54 Search advise[tiab]
#53 Search advice[tiab]
#52 Search counsel*[tiab]
#51 Search "teaching materials" [MeSH:NoExp]
#50 Search "student health services" [MeSH:NoExp]
#49 Search "preventive health services" [MeSH:NoExp]
#48 Search "physician's role" [MeSH:NoExp]
#47 Search "behavior therapy" [MeSH:NoExp]
#46 Search "cognitive therapy" [MeSH:NoExp]
#45 Search "directive counseling" [MeSH:NoExp]
#44 Search "counseling" [MeSH:NoExp]
#43 Search "patient education" [MeSH:NoExp]
#42 Search "health education" [MeSH:NoExp]
#41 Search "health promotion" [MeSH:NoExp]
#40 Search #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39
#39 Search "Sexually Transmitted Diseases, Viral"[MeSH:NoExp]
#38 Search "Sexually Transmitted Diseases, Bacterial"[MeSH:NoExp]
#37 Search "Sexually Transmitted Diseases"[MeSH:NoExp]
#36 Search "Syphilis"[MeSH:NoExp]
#35 Search "Gonorrhea"[MeSH]
#34 Search "Chlamydia Infections"[MeSH:NoExp]
#33 Search "Condylomata Acuminata"[MeSH]
#32 Search "Herpes Genitalis"[MeSH]
#31 Search "Herpes Simplex"[MeSH:NoExp]
#30 Search "Hepatitis C, Chronic"[MeSH]
#29 Search "Hepatitis C"[MeSH:NoExp]
#28 Search "Hepatitis B, Chronic"[MeSH]
#27 Search "Hepatitis B"[MeSH:NoExp]
#26 Search "Acquired Immunodeficiency Syndrome"[MeSH]
#25 Search "HIV Infections"[MeSH:NoExp]

Key Questions 1, 2, 3, 4
Database: Ovid MEDLINE(R) <1966 to December 31 2006>
Search Strategy:
---
1 HIV Infections/
2 Acquired Immunodeficiency Syndrome/
3 Hepatitis B/
4 Hepatitis B, Chronic/
5 Hepatitis C/
6 Hepatitis C, Chronic/
7 Herpes Simplex/
8 Herpes Genitalis/
9 Herpes Labialis/
10 Condylomata Acuminata/
11 Warts/
12 Chlamydia Infections/

Appendix A. Table 1. Search strategies

13 Gonorrhea/
14 Syphilis/
15 Papillomavirus Infections/
16 Papillomavirus, Human/
17 Human papillomavirus 6/
18 Human papillomavirus 11/
19 Human papillomavirus 16/
20 Human papillomavirus 18/
21 Trichomonas Infections/
22 Trichomonas Vaginitis/
23 Sexually Transmitted Diseases/
24 Sexually Transmitted Diseases, Bacterial/
25 Sexually Transmitted Diseases, Viral/
26 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
27 health promotion/
28 health education/
29 patient education/
30 counseling/
31 directive counseling/
32 cognitive therapy/
33 behavior therapy/
34 physician's role/
35 preventive health services/
36 student health services/
37 teaching materials/
38 counsel$.ti,ab.
39 advice.ti,ab.
40 advise.ti,ab.
41 motivational interview$.ti,ab.
42 prevention intervention$.ti,ab.
43 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42
44 26 and 43
45 Safe Sex/
46 Unsafe Sex/
47 Sexual Behavior/
48 45 or 46 or 47)
49 43 and 48
50 HIV Infections/pc [Prevention & Control]
51 Acquired Immunodeficiency Syndrome/pc [Prevention & Control]
52 Hepatitis B/pc [Prevention & Control]
53 Hepatitis B, Chronic/pc [Prevention & Control]
54 Hepatitis C/pc [Prevention & Control]
55 Hepatitis C, Chronic/pc [Prevention & Control]
56 Herpes Simplex/pc [Prevention & Control]
57 Herpes Genitalis/pc [Prevention & Control]
58 Herpes Labialis/pc [Prevention & Control]
59 Condylomata Acuminata/pc [Prevention & Control]
60 Warts/pc [Prevention & Control]
61 Chlamydia Infections/pc [Prevention & Control]
62 Gonorrhea/pc [Prevention & Control]
63 Syphilis/pc [Prevention & Control]
64 Papillomavirus Infections/pc [Prevention & Control]
65 Trichomonas Infections/pc [Prevention & Control]
66 Trichomonas Vaginitis/pc [Prevention & Control]
67 Sexually Transmitted Diseases/pc [Prevention & Control]
68 Sexually Transmitted Diseases, Bacterial/pc [Prevention & Control]
69 Sexually Transmitted Diseases, Viral/pc [Prevention & Control]
70 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69
71 intervention$.ti,ab,hw.
72 70 and 71

Appendix A. Table 1. Search strategies

73 44 or 49 or 72
74 limit 73 to (clinical trial or controlled clinical trial or randomized controlled trial)
75 clinical trials/ or controlled clinical trials/ or randomized controlled trials/
76 double-blind method/ or random allocation/ or single-blind method/
77 random$.ti,ab.
78 75 or 76 or 77
79 73 and 78
80 74 or 79
81 limit 80 to english language
82 limit 81 to yr="1983 - 2006"

Database: PsycINFO <1985 to April Week 3 2006>
Search Strategy:
---
1 sexually transmitted diseases/
2 Acquired Immune Deficiency Syndrome/
3 Human Immunodeficiency Virus/
4 GONORRHEA/
5 HERPES GENITALIS/
6 HERPES SIMPLEX/
7 AIDS Prevention/
8 SYPHILIS/
9 HEPATITIS/
10 Sexual Risk Taking/
11 safe sex/
12 Psychosexual Behavior/
13 sexually transmitted.ti,ab,id. [title,abstract,key concept]
14 aids.ti,ab,id.
15 hiv.ti,ab,id.
16 hepatitis b.ti,ab,id.
17 hepatitis c.ti,ab,id.
18 herpes.ti,ab,id.
19 condylomata acuminata.ti,ab,id.
20 warts.ti,ab,id.
21 chlamydia.ti,ab,id.
22 gonorrhea.ti,ab,id.
23 papillomavirus.ti,ab,id.
24 hpv.ti,ab,id.
25 trichomonas.ti,ab,id.
26 syphilis.ti,ab,id.
27 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
28 Health Education/
29 Health Promotion/
30 Behavior Therapy/
31 Behavior Change/
32 Behavior Modification/
33 Client Education/
34 COUNSELING/
35 Preventive Medicine/
36 student personnel services/
37 Lifestyle Changes/
38 advice.ti,ab,id.
39 advise.ti,ab,id.
40 counsel$.ti,ab,id,hw. [title,abstract,key concept,subject heading word]
41 prevention intervention$.ti,ab,id,hw.
42 motivational interview$.ti,ab,id,hw.
43 behavio$ intervention$.ti,ab,id,hw.
44 Health Behavior/
45 44 and intervention$.ti,ab,id,hw.
46 health promotion.ti,ab,id.

Appendix A. Table 1. Search strategies

47 health education.ti,ab,id.
48 behavio$ therapy.ti,ab,id.
49 behavio$ change$.ti,ab,id.
50 behavio$ modification$.ti,ab,id.
51 client education.ti,ab,id.
52 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 45 or 46 or 47 or 48 or 49 or 50 or 51
53 27 and 52
54 random$.ti,ab,id,hw.
55 clinical trial$.ti,ab,id,hw.
56 controlled trial$.ti,ab,id,hw.
57 54 or 55 or 56
58 53 and 57
59 limit 58 to english language
60 limit 59 to yr="1988 - 2007"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <4th Quarter 2006>
Search Strategy:
---
1 sexually transmitted.ti,ab,hw.
2 hiv.ti,ab,hw.
3 acquired immunodeficiency.ti,ab,hw.
4 human immunodeficiency virus.ti,ab,hw.
5 acquired immune deficiency.ti,ab,hw.
6 hepatitis b.ti,ab,hw.
7 hepatitis c.ti,ab,hw.
8 hpv.ti,ab,hw.
9 papillomavirus.ti,ab,hw.
10 trichomonas.ti,ab,hw.
11 syphilis.ti,ab,hw.
12 gonorrhea.ti,ab,hw.
13 chlamydia.ti,ab,hw.
14 hsv.ti,ab,hw.
15 herpes simplex.ti,ab,hw.
16 condylomata.ti,ab,hw.
17 warts.ti,ab,hw.
18 herpes genitalis.ti,ab,hw.
19 herpes labialis.ti,ab,hw.
20 safe sex.ti,ab,hw.
21 unsafe sex.ti,ab,hw.
22 sexual behavio$.ti,ab,hw.
23 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
24 health promotion.ti,ab,hw.
25 health education.ti,ab,hw.
26 patient education.ti,ab,hw.
27 counsel$.ti,ab,hw.
28 advice.ti,ab,hw.
29 advise.ti,ab,hw.
30 motivational interview$.ti,ab,hw.
31 prevention intervention$.ti,ab,hw.
32 cognitive therapy.ti,ab,hw.
33 physician's role.ti,ab,hw.
34 preventive health services.ti,ab,hw.
35 student health services.ti,ab,hw.
36 teaching materials.ti,ab,hw.
37 behavio$ intervention$.ti,ab,hw.
38 behavio$ therapy.ti,ab,hw.
39 behavio$ change$.ti,ab,hw.
40 behavio$ modification$.ti,ab,hw.
41 client education.ti,ab,hw.
42 preventive medicine.ti,ab,hw.

43 (health behavio$ and intervention$).ti,ab,hw.
44 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43
45 23 and 44
46 limit 45 to yr="1988 - 2005"

Key Question 5
Database: Ovid MEDLINE(R) <1966 to December 31 2006>
Search Strategy:
---
1 Condoms, Female/
2 female condom$.ti,ab.
3 1 or 2
4 Disease Transmission/
5 Incidence/
6 incidence.ti,ab.
7 disease prevention.ti,ab.
8 efficac$.ti,ab.
9 effective$.ti,ab.
10 (epidemiology or prevention control or transmission).fs.
11 4 or 5 or 6 or 7 or 8 or 9 or 10
12 3 and 11
13 limit 12 to english language
14 limit 13 to yr="1988 - 2006"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <3rd Quarter 2006>
Search Strategy:
---
1 condoms, female/
2 female condom$.ti,ab.
3 1 or 2

Appendix A. Table 2. Inclusion/exclusion criteria

Definition of STI and included diseases:

Inclusions:

An STI (sexually transmitted infection) is a bacterial or viral illness that is transmitted through sexual contact, including, but not limited to, anal, vaginal, or oral sex. Infections include, but are not limited to:

- HIV
- Hepatitis B
- Hepatitis C
- Herpes simplex virus (HSV) (1 and 2)
- Human papillomavirus (HPV)
- Chlamydia
- Gonorrhea
- Syphilis
- Trichomonas

Exclusions:

There are other methods by which the bloodborne STIs (HIV, hepatitis B and C) can be acquired. These methods include maternal-fetal transmission, transfusions, inadvertent needlesticks, and sharing needles or injection equipment with an infected person. These methods of transmission, and the counseling measures that could potentially reduce them, will not be included in the Task Force's research or final recommendations.

Interventions:

This review will only systematically examine sexual behavioral counseling interventions. Other types of preventive interventions will only be referenced if offered with counseling targeting sexual behavior change. There are a number of counseling intervention options that have been studied. A useful way to group types of interventions for the purpose of USPSTF recommendations is to classify them by: 1) primary care feasible or conducted, 2) primary care referable, 3) community non-referral, which includes population-based interventions.

Our review of the literature will consider health care system influences related to counseling interventions. Health-care-system interventions, however, is not included as a separate category for inclusion.

Inclusions:

1. Primary care feasible or conducted
   Behavioral counseling interventions must have been conducted in a primary care research setting or judged to be feasible in 'usual' primary care.
   i. Target: involve individual-level identification of being a patient or in need of intervention
   ii. Delivery: usually involve primary care physicians, other physicians, nurses, nurse practitioners, physician assistants, or related clinical staff (i.e. health educators, other counselors); OR, the intervention will be seen as connected to the health care system by the participant
   iii. Format: to individuals or small groups (i.e., 15 or less); do not primarily involve group-level interventions outside the primary care setting; generally does not involve more than eight group sessions and the intervention period is no longer than 12 months
   iv. Location: anywhere, as long as linked to primary care (as outlined above)
   v. Examples: could include any number of behavioral intervention (e.g., cognitive behavioral counseling, motivational enhancement activities, skills training, and counseling plus testing or plus provision of condoms)
2. Primary care referable:
   In order to be feasible for primary care referral, the intervention needs to be conducted as part of a healthcare setting, or be widely available in the community at a national level.

Appendix A. Table 2. Inclusion/exclusion criteria

Exclusions:

1. Community, non-referral
    i. Community programs (i.e. worksite programs, school programs)
    ii. Social marketing (i.e. media campaigns)
    iii. Policy (i.e. local and state public or health policy)

Settings:

Inclusions:

Primary care settings (including pediatric, OB/GYN, internal medicine, family practice, family planning, military, adolescent and school based health clinics) in the United States. Mental health clinics will be included to the extent that they provide primary care is being addressed in these clinics.

Research based at specialty clinics, including STI, GU clinics, and HIV testing sites should be considered if little evidence based in the primary care office setting is available.

Research based in other English speaking industrialized countries, as defined by United Nations' Human Development Index 1 countries, should be considered if little evidence based in the United States. We will include research based in any country for key question 5.

Exclusions:

Correctional facilities, school-based programs, substance abuse treatment facilities, HIV clinics, inpatient hospital units, and community-based groups and activities centered outside the primary care clinician's customary work setting.

Research based in developing countries, as defined by the Human Development Index.

Populations:

Inclusions:

When possible, key questions will be addressed for each population separately:

1. Adults:
    a. General population- Female, Male
    b. High-risk- Female, Male
2. Adolescents (12 to 18 years old or as defined by trial):
    a. Sexually active- Female, Male
    b. Pre-sexual debut- Female, Male
3. Pregnant women

The definition of "high-risk" is complex and is approached in numerous ways within the literature. Our definition of "high-risk" is consistent with that used in the USPSTF STI and HIV screening recommendations. These high-risk groups include both behavioral risk factors and demographic risks.

1. Behavior-based (modifiable):
    a. Multiple sexual partners
    b. Infected partner or high-risk partner
    c. Inconsistent or improper use of barrier contraception
    d. Abuses drugs/ has sexual relations under the influence of mind-altering substances
    e. Exchanges sex for drugs or money

2. Demographic-based (non-modifiable):

High-risk persons have also been identified by subpopulation based upon total prevalence of STIs within that group. Studies using subpopulations to classify risk have identified periodically vulnerable groups, including:

    a. African Americans (both male and female)
    b. Latinos (both male and female)

Appendix A. Table 2. Inclusion/exclusion criteria

c. Adolescents and young adults (under 25 years old)
d. Intravenous drug users (IDUs) or previous IDUs
e. Men who have sex with men (MSM)
f. Sex workers
g. The mentally ill
h. The mentally disabled
i. Low-income persons in urban settings
j. Inmates or former inmates
k. Military recruits
l. High number of total lifetime sexual partners
m. Previous or present history of STI

Exclusions:

Persons with HIV

Study Design:

Inclusions:

English language only. For key questions 1, 2, 3, 4 only include randomized controlled trials and non-randomized controlled trials published after 1987 (1988- present).

For key question 5, we will include cohort studies (prospective, retrospective) and nested case-control studies. Depending on the evidence available to adequately address key question 3, we may include cross-sectional and case-control studies.

Exclusions:

For key questions 1, 2, 3, 4 we will exclude all observational studies.
For key question 5, we will exclude mathematical modeling.

Outcomes:

Inclusions:

Trials with outcome assessment of greater than 60% of participants with a minimum of a three-month follow-up.

1. Sexual behavior changes
    a. Risky behaviors (e.g., multiple (new) partners; high-risk partners; UAI, UVI, or other contact with bodily fluids; sex while intoxicated with alcohol or other substances; sex in exchange for money or drugs)
    b. Protective behaviors (e.g, abstinence; mutual monogamy; delay initiation of intercourse or age of sexual debut; decrease contact with bodily fluids with male condom, other physical barrier methods, chemical barriers, or other changes in sexual behavior)

2. STI incidence and related morbidity and mortality
    a. Symptomatic and asymptomatic infection (i.e. testing, self-report)
    b. Major sequelae of STIs (as outlined by the Institute of Medicine, 1997)

Exclusions:

Any trial with greater than 40% attrition or no outcome assessment beyond three months.

1. Attitude, knowledge, ability changes and self efficacy including, but not limited to:
    a. STI risk and transmission knowledge, knowledge of protective behaviors
    b. Perception of HIV/STI risk in self or partners
    c. Regretted intercourse
    d. Participation in AIDS-related community activities

e. Sexual negotiation skills (for condom use or saying “no”)/perceived powerlessness
f. Scheduling a health-care appointment or discussing its importance with family
g. Intention to use protective barriers
h. Carrying barrier protection

2. Self-esteem

Appendix A. Table 3. USPSTF hierarchy of research design and quality rating criteria[1]

Hierarchy of Research Design

I	Properly conducted randomized controlled trial (RCT)
II-1:	Well-designed controlled trial without randomization
II-2:	Well-designed cohort or case-control analytic study
II-3:	Multiple time series with or without the intervention; dramatic results from uncontrolled experiments
III:	Opinions of respected authorities, based on clinical experience; descriptive studies or case reports; reports of expert committees

Design-Specific Criteria

Systematic Reviews

Criteria:

- Comprehensiveness of sources considered/search strategy used
- Standard appraisal of included studies
- Validity of conclusions
- Recency and relevance are especially important for systematic reviews

Case-Control Studies

Criteria:

- Accurate ascertainment of cases
- Nonbiased selection of cases/controls with exclusion criteria applied equally to both
- Response rate
- Diagnostic testing procedures applied equally to each group
- Measurement of exposure accurate and applied equally to each group
- Appropriate attention to potential confounding variables

Randomized Controlled Trials and Cohort Studies

Criteria:

- Initial assembly of comparable groups
    - -for RCTs: adequate randomization, including first concealment and whether potential confounders were distributed equally among groups.
    - -for cohort studies: consideration of potential confounders with either restriction or measurement for adjustment in the analysis; consideration of inception cohorts
- Maintenance of comparable groups (includes attrition, cross-overs, adherence, contamination)
- Important differential loss to follow-up or overall high loss to follow-up
- Measurements: equal, reliable, and valid (includes masking of outcome assessment)
- Clear definition of the interventions
- All important outcomes considered
- Analysis: adjustment for potential confounders for cohort stuidies, or intention-to-treat analysis for RCTs

Diagnostic Accuracy Studies

Criteria:

- Screening test relevant, available for primary care, adequately described
- Study uses a credible reference standard, performed regardless of test results
- Reference standard interpreted independently of screening test
- Handles indeterminate result in a reasonable manner
- Spectrum of patients included in study
- Sample size
- Administration of reliable screening test

Appendix A. Table 3. USPSTF hierarchy of research design and quality rating criteria[1]

Appendix B. Reference List

1. Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow CD, Teutsch SM et al. Current methods of the US Preventive Services Task Force: a review of the process. *Am J Prev Med* 2001; 20(3 Suppl):21-35.

Appendix A. Table 4. Systematic evidence reviews used as source documents

Reference
Compendium of HIV Prevention Interventions with Evidence of Effectiveness. In: Project CsHAPRS. Department of Health and Human Services, editor. 2009.
Albarracin D, McNatt PS, Klein CT, Ho RM, Mitchell AL, Kumkale GT. Persuasive communications to change actions: an analysis of behavioral and cognitive impact in HIV prevention. *Health Psychol* 2003; 22(2):166-177.
Applegate M. AIDS education for adolescents: A review of the literature. 1998.
Ashery RS, Carlson RG, Falck RS, Siegal HA, Wang J. Female condom use among injection drug- and crack cocaine-using women. *American Journal of Public Health 85(5):736-7,* 1995.
Booth RE, Watters JK. How effective are risk-reduction interventions targeting injecting drug users?*AIDS 8(11):1515 -24,* 1994.
Burke BA. Motivational interviewing: A meta-analysis of controlled clinical trials. 2006.
Burke BL, Arkowitz H, Menchola M. The efficacy of motivational interviewing: A meta-analysis of controlled clinical trials. 2006.
Cook RL, Rosenberg MJ. Do spermicides containing nonoxynol-9 prevent sexually transmitted infections? A meta-analysis. *Sex Transm Dis* 1998; 25(3):144-150.
Coyle SL, Needle RH, Normand J. Outreach-based HIV prevention for injecting drug users: a review of published outcome data. *Public Health Reports 113 Suppl 1:19-30,* 1998.
Darbes L, Kennedy G, Peersman G, Rutherford G, Zohrabyan L. Behavioral interventions for decreasing HIV infection in racial and ethnic minorities in high-income economies. *Cochrane Database of Systematic Reviews* 2005.
DiClemente RJ, Milhausen R, Sales JM, Salazar LF, Crosby RA. A programmatic and methodologic review and synthesis of clinic-based risk-reduction interventions for sexually transmitted infections: research and practice implications. *Semin Pediatr Infect Dis* 2005; 16(3):199-218.
Ehrhardt AA, Exner TM. Prevention of sexual risk behavior for HIV infection with women. *AIDS 14 Suppl 2:S53-8,* 2000.
Elias CJ, Coggins C. Female-controlled methods to prevent sexual transmission of HIV. [Review] [50 refs]. *AIDS 10 Suppl 3:S43 -51,* 1996.
Elwy AR, Hart GJ, Hawkes S, Petticrew M. Effectiveness of interventions to prevent sexually transmitted infections and human immunodeficiency virus in heterosexual men: a systematic review. *Arch Intern Med* 2002; 162(16):1818-1830.
Exner TM, Seal DW, Ehrhardt AA. A review of HIV interventions for at-risk women. *AIDS and Behavior* 1997; 1(2):93-124.
Exner TM, Gardos PS, Seal DW, Ehrhardt AA. HIV sexual risk reduction interventions with heterosexual men: the forgotten group. *AIDS and Behavior* 1999; 3(4):347-358.
Fullerton D, Holland J, Oakley A. AIDS: Safety, sexuality and risk.
Gibson DR, McCusker J, Chesney M. Effectiveness of psychosocial interventions in preventing HIV risk behaviour in injecting drug users. *AIDS* 1998; 12(8):919-929.

Appendix A. Table 4. Systematic evidence reviews used as source documents

Reference
Grunseit A. Impact of HIV and sexual health education on the sexual behaviour of young people: a review update. 1997
Jemmott JB, III, Jemmott LS. HIV risk reduction behavioral interventions with heterosexual adolescents. *AIDS 14 Suppl 2:S40 -52,* 2000.
Johnson-Masotti AP, Wienhardt LS, Pinkerton SD, Otto-Salaj LL. Efficacy and cost-effectiveness of the first generation of HIV prevention interventions for people with severe and persistent mental illness. *Journal of Mental Health Policy and Economics* 2003; 6:23-25.
Johnson WD, Hedges LV, Ramirez G, Semaan S, Norman LR, Sogolow E et al. HIV prevention research for men who have sex with men: a systematic review and meta-analysis. *J Acquir Immune Defic Syndr* 2002; 30 Suppl 1:S118-S129.
Johnson WD, Hedges LV, Diaz RM. Interventions to modify sexual risk behaviors for preventing HIV infection in men who have sex with men. *Cochrane Database of Systematic Reviews* 2005;(4).
Johnson WD, Holtgrave DR, McClellan WM, Flanders WD, Hill AN, Goodman M. HIV intervention research for men who have sex with men: a 7-year update. *AIDS Education & Prevention 17(6):568 -89,* 2005.
Kalichman SC, Carey MP, Johnson BT. Prevention of sexually transmitted HIV infection: a meta-analytic review of the behavioral outcome literature. *Ann Behav Med* 1996; 18(1):6-15.
Kelly JA. Sexually transmitted disease prevention approaches that work. Interventions to reduce risk behavior among individuals, groups, and communities. *Sexually Transmitted Diseases 21(2 Suppl):S73 -5,* 1994;-Apr.
Kelly JA. HIV risk reduction interventions for persons with severe mental illness. *Clinical Psychology Review 17(3):293-309,* 1997.
Kim N, Stanton B, Li X, Dickersin K, Galbraith J. Effectiveness of the 40 adolescent AIDS-risk reduction interventions: a quantitative review. *J Adolesc Health* 1997; 20(3):204-215.
Manhart LE, Holmes KK. Randomized controlled trials of individual-level, population-level, and multilevel interventions for preventing sexually transmitted infections: what has worked. *Journal of Infectious Diseases* 2005; 191(Supplement 1):S7-S24.
Minnis AM, Padian NS. Effectiveness of female controlled barrier methods in preventing sexually transmitted infections and HIV: current evidence and future research directions. *Sexually Transmitted Infections 81(3):193-200,* 2005.
Mize SJ, Robinson BE, Bockting WO, Scheltema KE. Meta-analysis of the effectiveness of HIV prevention interventions for women. *AIDS Care* 2002; 14(2):163-180.
Morrison-Beedy D, Nelson LE. HIV prevention interventions in adolescent girls: what is the state of the science? *Worldviews on Evidence-Based Nursing* 2004; 1(3):165-175.
Mullen PD, Ramirez G, Strouse D, Hedges LV, Sogolow E. Meta-analysis of the effects of behavioral HIV prevention interventions on the sexual risk behavior of sexually experienced adolescents in controlled studies in the United States. *J Acquir Immune Defic Syndr* 2002; 30 Suppl 1:S94-S105.
Musaba E, Morrison CS, Sunkutu MR, Wong EL. Long-term use of the female condom among couples at high risk of human immunodeficiency virus infection in Zambia. *Sexually Transmitted Diseases 25(5):260-4,* 1998.

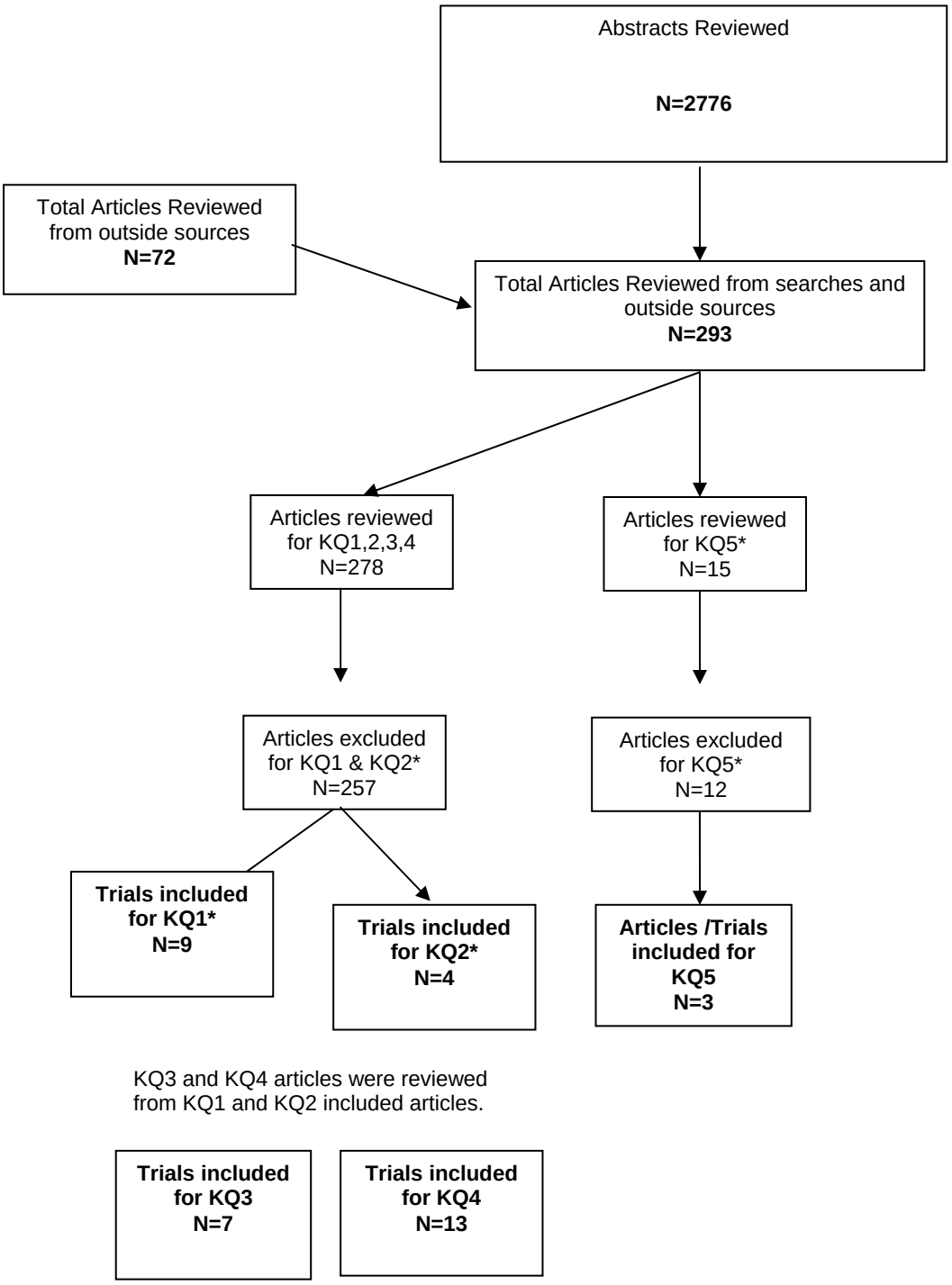
Appendix A. Table 4. Systematic evidence reviews used as source documents

Reference
Neumann MS, Johnson WD, Semaan S, Flores SA, Peersman G, Hedges LV et al. Review and meta-analysis of HIV prevention intervention research for heterosexual adult populations in the United States. *J Acquir Immune Defic Syndr* 2002; 30 Suppl 1:S106-S117.
Oakley A, Fullerton D. Risk, knowledge and behaviour: HIV/AIDS education programmes and young people. 1994.
Oberdorfer A, Oberdorfer AL, Tran DT. Behavioural interventions for preventing hepatitis B and/or C. *Cochrane Database of Systematic Reviews* 2005;(4).
Pedlow CT, Carey MP. HIV sexual risk-reduction interventions for youth: a review and methodological critique of randomized controlled trials. *Behav Modif* 2003; 27(2):135-190.
Pedlow CT, Carey MP. Developmentally appropriate sexual risk reduction interventions for adolescents: rationale, review of interventions, and recommendations for research and practice. *Ann Behav Med* 2004; 27(3):172-184.
Peersman G. Interventions for preventing HIV infection in young people in developing countries. *Cochrane Database of Systematic Reviews* 2005.
Ray S, van De WJ, Mason P, Ndowa F, Maposhere C. Constraints faced by sex workers in use of female and male condoms for safer sex in urban zimbabwe. *Journal of Urban Health 78(4):581-92,* 2001.
Rees R, Kavanagh J, Burchett H, Shepherd J, Brunton G, Harden A et al. HIV health promotion and men who have sex with men (MSM): a systematic review of research relevant to the development and implementation of effective and appropriate interventions. 2004.
Robin L, Dittus P, Whitaker D, Crosby R, Ethier K, Mezoff J et al. Behavioral interventions to reduce incidence of HIV, STD, and pregnancy among adolescents: a decade in review. *Journal of Adolescent Health* 2004; 34(1):3-26.
Rotheram-Borus MJ, Cantwell S, Newman PA. HIV prevention programs with heterosexuals. *AIDS* 2000; 14 Suppl 2:S59-S67.
Savage DF, Lhotska L. Recommendations on feeding infants of HIV positive mothers. WHO, UNICEF, UNAIDS guidelines. *Adv Exp Med Biol* 2000; 478:225-230.
Schrappe M, Lauterbach K. Systematic review on the cost-effectiveness of public health interventions for HIV prevention in industrialized countries. *AIDS* 1998; 12 Suppl A:S231-S238.
Semaan S, Des J, Sogolow E, Johnson WD, Hedges LV, Ramirez G et al. A meta-analysis of the effect of HIV prevention interventions on the sex behaviors of drug users in the United States. *J Acquir Immune Defic Syndr* 2002; 30 Suppl 1:S73-S93.
Shepherd J, Weston R, Peersman G, Napuli IZ. Interventions for encouraging sexual lifestyles and behaviours intended to prevent cervical cancer. *Cochrane Database of Systematic Reviews* 2005.
Stephenson JM, Imrie J, Sutton SR. Rigorous trials of sexual behaviour interventions in STD/HIV prevention: what can we learn from them? *AIDS* 2000; 14 Suppl 3:S115-S124.
Sweat M. Counseling and testing for preventing HIV infection. *Cochrane Database of Systematic Reviews* 2005.
Tholandi M, Kennedy G, Wilkinson D. Female condom for preventing heterosexually transmitted HIV infection in women. *Cochrane Database of Systematic Reviews* 2005.

Appendix A. Table 4. Systematic evidence reviews used as source documents

Reference
Underhill K, Montgomery P, Operario D. Abstinence-based programs for HIV infection prevention in high-income countries. *Cochrane Database of Systematic Reviews* 2005.
Van Damme L, Rosenberg ZF. Microbicides and barrier methods in HIV prevention. *AIDS 13 Suppl A:S85 -92,* 1999.
van Empelen P, Kok G, van Kesteren NM, van den BB, Bos AE. Effective methods to change sex-risk among drug users: a review of psychosocial interventions. *Social Science and Medicine* 2003; 57(9):1593-1608.
Ward DJ, Rowe B, Pattison H, Taylor RS. Behavioural interventions to reduce the risk of sexually transmitted infections in genitourinary medicine clinic patients: a systematic review. 2004. Birmingham: West Midlands Health Technology Assessment Collaboration, Department of Public Health and Epidemiology, University of Birmingham (WMHTAC).
Ward DJ, Rowe B, Pattison H, Taylor RS, Radcliffe KW. Reducing the risk of sexually transmitted infections in genitourinary medicine clinic patients: a systematic review and meta-analysis of behavioural interventions. *Sex Transm Infect* 2005; 81(5):386-393.
Weinhardt LS, Carey MP, Johnson BT, Bickham NL. Effects of HIV counseling and testing on sexual risk behavior: a meta-analytic review of published research, 1985-1997. *Am J Public Health* 1999; 89(9):1397-1405.
Weller S, Davis-Beaty K. The effectiveness of male condoms in prevention of sexually transmitted diseases [Protocol]. *Cochrane Database of Systematic Reviews* 2005.
Wilkinson D, Ramjee G, Tholandi M, Rutherford G. Nonoxynol-9 for preventing vaginal acquisition of HIV infection by women from men. *Cochrane Database of Systematic Reviews* 2005.
Wilkinson D, Ramjee G, Tholandi M, Rutherford G. Nonoxynol-9 for preventing vaginal acquisition of sexually transmitted infections by women from men. *Cochrane Database of Systematic Reviews* 2005.
Wingood GM, DiClemente RJ. HIV sexual risk reduction interventions for women: a review. *Am J Prev Med* 1996; 12(3):209-217.
Wolitski RJ, MacGowan RJ, Higgins DL, Jorgensen CM. The effects of HIV counseling and testing on risk-related practices and help-seeking behavior. *AIDS Educ Prev* 1997; 9(Supplement B):52-67.
Yamada J, DiCenso A, Feldman L, Cormillott P, Wade K, Wignall R. A systematic review of the effectiveness of primary prevention programs to prevent sexually transmitted diseases in adolescents. 1999

Appendix A: Literature retrieval process: Figure 1. Search results and article flow by Key Question



* Total of 19 articles representing 13 unique trials for KQ 1 and KQ 2.

APPENDIX B

EVIDENCE TABLES

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference	**Study Design**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
	Locatation			
USPSTF Quality				
	Population			
Adult				
Carey 2004[13]	RCT	**Inclusion:** Ages 18 and over ; sexually active in past year; alcohol or drug use in past year; diagnosis of major mood or thought disorder per SCID; ability to participate per MMSE; minimal literacy per REALM	**N Randomized** Total:408 IG: 142 CG1: 140 CG2: 126 **Age**(median) Total:36.5 IG: 57.7 CG1: 37.2 CG2: 36.8 **%Male** Total:46% IG: 44% CG1: 46% CG2: 47% **Race** %African-American Total: 21% IG: 26% CG1: 20% CG2: 16% **SES** No HS graduation: 33% Employed:17% **Other:** % with hx STI: 38% ***Frequency unprotected sex acts in past 3 -mo*** IG: 14.0 CG1: 10.8 CG2: 11.6 ***# of partners in past 3 mo*** IG: 1.25 CG1: 1.41 CG2: 1.24	HIV Risk-reduction; information, role-play, harm reduction, motivational techniques to enhance readiness to change
Fair	Syracuse, NY; urban Outpatient psychiatric Adults with mental illness plus co-morbid alcohol or substance abuse	**Exclusion:** NR		

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference **USPSTF Quality**	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
Adult **Carey 2004**[13] **Fair**	**Adult** **Intervention Arms** IG: Standard outpatient psychiatric care, which included HIV education at discretion of provider + 10-session HIV risk reduction intervention CG1: Standard outpatient psychiatric care, which included HIV education at discretion of provider + 10-session substance use reduction intervention CG2: Standard outpatient psychiatric care, which included HIV education at discretion of provider **Format** IG:Group CG1: Group CG2: Usual Care **Intensity** IG: 10 sessions over 5 wks CG1:10 sessions over 5 wks CG2: Usual Care **Delivery** IG: 1 male + 1 female facilitator, masters or doctoral level mental health clinician CG1:1 male + 1 female facilitator, masters or doctoral level mental health clinician CG2: Usual Care	**F/U Time** Approximately 3-, 6-, 9-mo **%F/U** (overall) 3-mo=92% 6-mo=89% 9-mo=88%	**6-mo** ***% with self-report of newly dx STI*** N, % at baseline, % mean, p IG: 123, 10%, 2% CG1: 121, 8% , 8%, p<0.013 CG2: 110, 7%, 5% , p<0.046 p values adjusted for STI at baseline, (odds ratios are not reported)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Adult	**Adult**	
Carey 2004[13]	***Mean # of UVI acts in past 3 mo***	N
	3-mo	
	N, Mean # UVI	
Fair	IG: 123, 9.5	
	CG1: 121, 8.1	
	CG2: 110, 10.0	
	6-mo	
	N, Mean # UVI	
	IG: 123, 7.2	
	CG1: 121, 8.8	
	CG2: 110, 8.0	
	(p values for condition x time interaction effects)	
	IG vs. CG1: p=0.001	
	IG vs. CG2:p=0.004	

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

	Study Outcomes				
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Adult **Carey 2004[13]** **Fair**	**Adult** ***mean # of partners in past 3 mo*** (p values for condition x time interaction effects) **3-mo** N, mean # partners IG: 123, 0.93 CG1: 121, 1.02 CG2: 110, 1.12 **6-mo** IG: 123, 0.97 CG1 : 121, 0.95 CG2: 110, 0.07 (p values for condition x time interaction effects) IG vs. CG1: , p=0.339 IG vs. CG2: , p=0.037 ***mean # of casual partners in past 3 mo*** **3-mo** N, mean # partners IG: (n=123); 0.21 CG1: (n=121); 0.33 CG2: (n=110); 0.47 **6-mo** N, mean # partners IG: 123, 0.30 CG1: 121, 0.30 CG2: 110, 0.48 (p values for condition x time interaction effects) IG vs. CG1: p=0.015 IG vs. CG2: p=0.001	N	N	**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)**	N (only reported on knowledge, attitudes and skills)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference	**Study Design**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
	Locatation			
USPSTF Quality				
	Population			
Shain 2004[17] **Project SAFE 2** **Fair**	RCT TX; urban PHC- (STI clinic) Hispanic and African American women; non-viral STI positive	**Inclusion:** age 15-45, women, nonviral STI, English speaking **Exclusion:** if <18 and used 'hard' drugs and dropped out of school	**N Randomized** Total: 690, data for those with f/u at years 1 and 2 (N=775 originially randomized) IG1: 209 IG2: 232 CG: 249 **Age** IG1: 20.4 IG2: 20.8 CG: 21.6 **% Male** Total: 0% **Race** % Hispanic IG1: 73.7% IG2: 81.9% CG: 74.7% % African American IG1: 26.3% IG2: 18.1 % CG: 25.3% **SES** Annual Income per capita IG1: $3852 IG2: $3348 CG: $3720 Education (yr) IG1: 10.8 IG2: 10.5 CG: 10.8	Cultural and sex specific adaptation of AIDS Risk Reduction Model (ARRM)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference **USPSTF Quality**	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
Shain 2004[17] **Project SAFE 2** **Fair**	**Intervention** IG1: CG standard counseling plus multicomponent sessions including discussions, games, video, behavior modeling and role play (see previous Project SAFE) IG2: CG standard counseling plus IG1 intervention with the option of attending 5 monthly support group sessions CG: Standard counseling by CDC guidelines **Format** IG1: Small group (not specified) IG2: Small group (not specified) CG: Individual **Intensity** IG1: Three sessions, 3 hours, 1x week for 3 consecutive weeks IG2: Three sessions, 3 hours, 1x week for 3 consecutive weeks, plus option of attending 5 monthly support group sessions of unspecified duration CG: One 15 minute session **Delivery** IG1: Trained female faciliator, matched ethnicity IG2: Trained female faciliator, matched ethnicity CG: Nurse Clinician	**F/U Time** 1 year, 2 year retention rates **% F/U** 1 year 91.4% Biological outcomes: 91.4% IG1: 92.4% IG2: 90.1% CG: 92.8% 2 year 91.2% Biological outcomes: 90.7% IG1: 89.9% IG2: 90.8% CG: 92.8%	***% with episodes of reinfection (with gonorrhea, chlamydia, or both)*** **1-year** IG1: 25.1%(55/219) IG2: 20.3%(48/236) CG: 26.8%(68/254) **2-year** IG1: 18.5% (39/211) IG2: 20.7% (49/237) CG: 23.1% (59/255) ***adjusted infection rate, adjusting for age, ethnicity, education, exposure time, and substance abuse risk*** **1-year** IG1: 15.7%, p=0.006 IG2: 15.4%, p=0.004 CG: 26.8% **2-year** IG1=14.7%, p=0.03 IG2=14.8%, p,0.03 CG=23.1% ***odds ratio of those with recurrent STI, adjusting for age, ethnicity, education, exposure time, and substance abuse risk*** **1-year** IG1: 0.51 (0.31-0.83) IG2: 0.50 (0.31-0.80)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Shain 2004[17]	NR (outcomes were collected)	N
Project SAFE 2		
Fair		

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes					
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Shain 2004[17] **Project SAFE 2** **Fair**	***% reporting multiple partners (more than 1) over past year*** **1-year** IG1 : 42.5%, p=0.001 IG2: 43.2%, p=0.01 CG : 55.3% **2-year** IG1: 37.6%, p<0.005 IG2: 36.2%, p<0.002 CG: 50.8%	N	***% with unprotected sex with untreated or incompletely treated partner (year 1 only)*** IG1: 7.8%, p=0.001 IG2: 10.2%, p=0.01 CG: 18.1%	**No increase in number of sex partners** **No increase in STI incidence (by testing)**	N (other than compliance, see other behavioral outcomes)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference **USPSTF Quality**	**Study Design** **Locatation** **Population**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
Shain 2004[17] **Project SAFE 2** **Fair**			**STI risk** % with STI (current) GC IG1: 21.1%, IG2: 22.8%, CG: 18.1% Chlamydia IG1: 78.5%, IG2: 82.3%, CG: 73.1% Trichomonas IG1: 16.7%, IG2: 11.6%, CG: 17.7% Syphilis IG1: 2.9%, IG2: 3.9%, CG: 6.8% % with multiple partners in past year IG1: 63.5% IG2: 64.0% CG: 66.5%	

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference **USPSTF Quality**	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
Shain 2004[17] **Project SAFE 2** **Fair**			**2-year** IG1: 0.57 (0.34-0.96) IG2: 0.58 (0.36-0.94)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Shain 2004[17]		
Project SAFE 2		
Fair		

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes					
Study Reference	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
USPSTF Quality					
Shain 2004[17]					
Project SAFE 2					
Fair					

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference **USPSTF Quality**	**Study Design** **Locatation** **Population**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
Scholes 2003[15] **Fair**	RCT WA, NC; NR Managed care practice Young adult women; non-mongamous sexually active	**Inclusion:** Clinic visit in past 6-mo; Unmarried, sexual intercourse with male partner in last 6 mo **Exclusion:** Pregnant, in monogamous relationship > 12-mo	**N Randomized** Total: 1210 IG: 596 CG: 614 **Age** Total: 21 IG: 21 CG: 21 **% male** 0 **Race** %African American Total: 19% IG: 19% CG: 19% %Other Total: 12% IG: 12% CG: 12% **SES** Employed fulltime Total: 42% IG: 42% CG: 43 % **STI risk** % with hx/dx of STI Total: 27% IG: 27% CG: 26% Proportion unprotected sex (c) Total: 46% IG: 46% CG: 45% % multiple partners in past year Total: 18% IG: 17% CG: 19%	Tailored minimal self-help intervention, based in multiple social science theories (e.g., transtheoretical model, AIDS risk-reduction, theory of reasoned action), designed to increase condom use

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference **USPSTF Quality**	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
Scholes 2003[15] **Fair**	**Intervention** IG: tailored self-help intervention consisting of two rounds of individually tailored materials - a 12-page self-help magazine-style booklet (which included male and female condoms, a condom carrying case and instructions on using condoms) and a tailored booster feedback newsletter, send after the 3-mo survey. CG: Usual Care (not specified) **Format** IG: Print CG: NR **Intensity** IG: 2 sets of tailored materials - one after baseline and the 2nd after the 3 mo survey CG: NR **Delivery** IG: Self-administered CG: NR	**F/U Time** 3 mo (not reported separately); 6 mo (reported separately and combined w 3-mo) **% F/U** **3-mo** IG: 91% CG: 87% **6-mo** IG: 88% CG: 85%	**6-mo** ***% with self reported STI dx in past 3 mo*** Mean % , IG: 3.5% CG: 3.6% OR unadjusted 0.95 (0.49, 1.83) OR adjusted 0.97 (0.48, 1.96), p=0.93

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Scholes 2003[15] **Fair**		**6-mo** ***% with ANY use of condoms in past 3mo*** IG: 72.8% CG: 63.0% OR unadjusted 1.57 (1.18, 2.10) OR adjusted 1.86 (1.32, 2.65), p=0.0005 ***% with CONSISTENT use of condoms in past 3mo*** IG: 33.5% CG: 36.8% OR unadjusted 1.16 (0.87, 1.54) OR adjusted 1.24 (0.89, 1.73), p=0.21

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

	Study Outcomes				
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Scholes 2003[15] **Fair**	N	N	N	**No increase in unprotected sex or decrease in condom use** **No increase in STI incidence (by self report)**	N (only reported on knowledge, attitudes and skills)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference	**Study Design**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
	Locatation			
USPSTF Quality				
	Population			
Ehrhardt 2002[22] **Hoffman 2003**[61]	RCT	**Inclusion:** clients of the clinic, age 18-30; fluent comprehension of English; heterosexual activity within prior year	**N Randomized** Total:360 IG1: 128 IG2: 112 CG: 120	AIDS Risk Reduction Model (ARRM) Goals: (1) increase knowledge; (2) improve communication and decision-making; (3) identify/ modify risk factors and antecedents
	Brooklyn, NY; urban		**Age** Total: 22.3	
Project FIO	Planned Parenthood clinic	**Exclusion:** Blood transfusion 1980-1985; IVDU in past year; HIV+; pregnant or trying to get pregnant	**% Male** 0	
Good	adult heterosexual women		**Race** <u>Total</u> %African American: 72.5% %Hispanic: 16.9%	
			SES <u>Total</u> Below poverty line:26% mean 12.8 years of education median per capita income $6057	
			STI risk % with hx of STI: 58.3% frequency unprotected sex acts in past 3 mo: 17.23 % with multiple partners in past 3 mo: 23.4% For subgroup analysis % with reported recent intimate partner physical violence= 42%	

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
USPSTF Quality			
Ehrhardt 2002[22] **Hoffman 2003**[61] **Project FIO** **Good**	**Intervention** IG1: 4 week STD/HIV prevention intervention IG2: 8-week STD/HIV prevention intervention CG: Assessment only **Format** IG1: Group IG2: Group CG: N/A **Intensity** IG1: Four 2 hour sessions + 1 booster session at 9 months IG2: Eight 2 hours sessions + 1 booster session at 9 months CG: N/A **Delivery** IG1: NR IG2: NR CG: N/A	**F/U Time** 6-mo; 12-mo **%F/U** 6-mo IG1: 95% IG2: 89% CG: 87% 12-mo IG1: 96% IG: 98% CG: 96%	N

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Ehrhardt 2002[22] **Hoffman 2003[61]** **Project FIO** **Good**	**12-mo** ***'model predicted' mean # unprotected acts in past 3 mo*** text reads IG2 had on average 4 fewer UVI/UAI than control, p=0.00 ***% maintaining or improving safer sex behavior (proportion decreasing number of unprotected acts or maintaining no unprotected acts)*** IG1: 66.4% IG2: 72.7% CG: 61.7% adjusted OR (IG2 to CG) 1.65 (0.94, 2.90)	**12-mo** ***% using condom (male/female) in past 3-mo*** IG1: NR IG2: 18% increase, p=0.06 CG: NR

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes					
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Ehrhardt 2002[22] **Hoffman 2003**[61] **Project FIO** **Good**	N	N	***Alternative risk reduction strategy (# sex occasions; outercourse; refusing sex; leaving relationship; choosing not to get involved with new partner; mutual HIV testing) at 12 mo*** text states no difference between groups at 12-mo f/u	**No increase in unprotected sex or decrease in condom use**	N (other than alternative risk reduction strategies and communication skills)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference	**Study Design**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
	Locatation			
USPSTF Quality				
	Population			
Melendez 2003[47]		**Inclusion:** report of recent intimate partner violence in past 12 months on baseline assessement	**N Randomized** **Total:**152	
Project FIO			**Age** Total: 23	
Fair			**Race** Total %African American: 75% %Hispanic: 21%	
			SES Total Below poverty line:37%	
			STI risk % with hx of STI: 75%	

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
USPSTF Quality			
Melendez 2003[47]			
Project FIO			
Fair			

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Melendez 2003[47] **Project FIO** **Fair**	**6-mo** ***% maintaining or improving safer sex behavior (proportion decreasing number of unprotected acts or maintaining no unprotected acts)*** IG1: 64% IG2: 74% CG: 64% adjusted OR (IG2 to CG) 1.63 (0.68, 3.89) **12-mo** ***% maintaining or improving safer sex behavior (proportion decreasing number of unprotected acts or maintaining no unprotected acts)*** IG1: 69% IG2: 82% CG: 61% adjusted OR (IG2 to CG) 2.88 (1.17, 7.10)	

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes					
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Melendez 2003[47] **Project FIO** **Fair**			**6-mo** ***% using alternative strategy (defined above)*** IG1: 17% IG2: 25% CG: 12% adjusted OR (IG2 to CG) 2.70 (0.90, 8.14) **12-mo** ***% using alternative strategy (defined above)*** IG1: 23% IG2: 19% CG: 25% adjusted OR (IG2 to CG) 0.71 (0.26, 1.90)		

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference **USPSTF Quality**	**Study Design** **Locatation** **Population**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
Shain 1999[16] **Project SAFE (named in subsequent article)** **Good**	RCT TX; urban PHC- (STI clinic) Hispanic and African American women; non-viral STI positive	**Inclusion:** Women, ages 15-45, nonviral STI, English speaking **Exclusion:** NR	**N Randomized** Total: 617 (n=549 in analysis) IG: 313 (n=285), CG: 304 (n=264) **Age** IG: 21.8, CG: 21.3 **% Male** 0 **Race** %Hispanic IG: 69.8 CG: 68.2 %African American IG: 30.2, CG: 31.8 **SES** Mo Income per capita IG: 243 CG: 267 Education (yr) IG: 10.8, CG: 10.8 **STI risk** % with STI (current) ***GC*** IG: 21.4%, CG: 20.8% *Chlamydia* IG: 67.0%, CG: 70.5% *Trichomonas* IG: 26.3%, CG: 20.8%	Cultural and sex specific adaptation of AIDS Risk Reduction Model (ARRM)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Reference USPSTF Quality	Study Intervention Study Intervention	Follow-Up	Biologic Outcomes

Shain 1999[16]
 	
Project SAFE (named in subsequent article)
 	
Good
	Intervention
	IG: Behavioral cognitive multicomponent sessions-discussions, games, videotape, behavior modleing, and role play (see Table 1)
	CG: Standard counseling by CDC guidelines
	Format
	IG: Small group (3-12 participants)
	CG: Individual
	Intensity
	IG: Three sessions, 3-4 hours each, 1x week for 3 consecutive weeks
	CG: One 15 minute session
	Delivery
	IG: Trained female facilitator; matched ethnicity
	CG: Nurse clinician
		Time Frame
		6-mo; 12-mo
		% F/U
		6-mo
		IG: 84%,
		CG: 80%
		12-mo
		IG: 91%,
		CG: 87%
		Total f/u at both 6 and 12mo
		IG: 79.6%
		CG: 75.0%
		Korte 2004
		6-mo
		100% (b/c excluded those lost to f/u not included in analyses)
			% with # episodes of infection (with gonorrhea, chlamydia, or both) during 12 mo study period
			p=0.01 between group assignments
			IG
			zero infections: 83.2% (237/285)
			one infection: 11.2% (32/285)
			two or more infections:5.6% (16/285)
			CG
			zero infections: 73.1% (193/264)
			one infection: 19.3% (51 /264)
			two or more infections: 7.6% (20/264)
			% or odds ratio of those with recurrent STI
			6-mo
			IG: 11.3% (30/265)
			CG: 17.2% (42/244)
			odds ratio (controlled for age and number of sex partners preceeding enrollment)
			OR: 0.58 (0.34-0.99), p=0.05
			12-mo
			IG: 16.8% (48/285)
			CG: 26.9% (71/264)
			OR: 0.52 (0.34-0.81), p=0.004

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Shain 1999[16]	N	N
Project SAFE (named in subsequent article)		
Good		

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes					
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Shain 1999[16] **Project SAFE (named in subsequent article)** **Good**	N	N	# sex occasions; outercourse; refusing sex; leaving relationship; choosing not to get involved with new partner; mutual HIV testing	**No increase in unprotected sex or decrease in condom use** **No increase in STI incidence (by self report)**	N (other than compliance, see other behavioral outcomes)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference **Locatation** **USPSTF Quality** **Population**	**Study Design**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
			Syphilis IG: 6.0% CG: 6.1% *# sex partners in past 3 mo* IG: 1.57 CG: 1.37 % pregnant IG: 27.2% CG: 33.3%	
Korte 2004[27] **Project SAFE** **Fair**		**Inclusion:** subset analyses of 477 women who attended all 3 study visits (for reinfection rates do report on 549 women) **Exclusion:** NR	**N Randomized** Total: 477 (or for reinfection rates n=549) IG: 249 CG: 228 **Age** age band reported by ethnicity **% men** 0 **Race** % African American (calculated) IG: 30.1% CG: 32.5% % Hispanic (calculated) IG: 69.9% CG: 67.5% **SES** Reported by ethnicity STI risk see Shain	

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
USPSTF Quality			
Korte 2004[27] **Project SAFE** **Fair**			**GC/chalmydia testing** **12-mo** **% with reinfection over 12 mo (entire study period)** African American IG: 23.3% (20/86) CG: 34.5% (29/84) p=0.10 Hispanic IG: 14.1%(28/199) CG: 23.3% (42/180) p=0.02

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Korte 2004[27]	N	N
Project SAFE		
Fair		

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

	Study Outcomes				
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Korte 2004[27] **Project SAFE** **Fair**	**12-mo** ***% reporting multiple partners*** African American IG: 61.3%(46/75) CG: 78.4%(58/74) p=0.02 Hispanic IG: 49.4%(86/174) CG: 54.5%(84/154) p=0.35	N	**12-mo** ***% non-compliant (sex with untreated or incompletely treated partner) over past year*** African American IG: 8.0%(6/75) CG: 13.5%(10/74) p=0.28 Hispanic IG: 10.9%(19/174) CG: 18.2%(28/154) p=0.06	**No increase in number of sex partners** **No increase in unprotected sex or decrease in condom use** **No increase in STI incidence (by testing)**	N (only reported communication skills)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference **USPSTF Quality**	**Study Design** **Locatation** **Population**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
Kamb 1998[14] **Project RESPECT** **Fair**	RCT MD, CO, CA, NJ; urban Public STD clinics General heterosexual population attending STI clinics	**Inclusion:** Ages 14 and over; agree to have HIV test, English speaking **Exclusion:** men who had male sexual partner in past 12 mo or who self-identified as bi- or homo-sexual	**N Randomized** Total: 5758 IG1: 1438 IG2: 1447 CG1: 1443 CG2: 1430 **Age (**median age) Total: 25 **% Male** Total: 57% **Race** Total %African American: 59% %Hispanic: 19% %White: 16% %Other: 6% **SES** Total Annual income <$5000: 42% Unemployed: 54% **STI risk** % with STI (current) IG1: 33% IG2: 31% CG1: 30% CG2: 33% # sex partners in past 3 mo IG1: 2.1 IG2: 2.3 CG1: 2.5 CG2: 2.4	Various risk reduction counseling models (IG) versus didactic (CG) IG1: Enhanced, based on theory of reasoned action and social cognitive theory. IG2: CDC's client centered HIV prevention counseling model. CG1 & CG2: Didactic messages (informational only); CG2 had no scheduled f/u

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference **USPSTF Quality**	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
Kamb 1998[14] **Project RESPECT** **Fair**	**Intervention** IG1: Four sessions, included behavioral goal setting, delivery of test results, formulating a risk -reduction plan IG2: Two same components as in IG1 but in 2 brief sessions CG1 and CG2: Two very brief didactic sessions, didactic prevention messages pertinent to their reported risks, and delivery of test results **Format** IG1: Individual IG2: Individual CG1 and CG2: Individual **Intensity** IG1: Four sessions, total of 200 mintes, completed over 3-4 wks IG2: Two sessions, total 40 minutes over 7-10 days CG1 and CG2: Two sessions, total 10 minutes over 7-10 days **Delivery** IG1: Trained counselors IG2: Trained counselors CG1 and CG2: Clinicians for session 1, counselor for session 2	**F/U Time** 3-mo; 6-mo; 9-mo; 12-mo for IG1; IG2; CG1. CG2 N/A **% F/U** 3-mo: 71%; 6-mo: 70%, 9-mo: 64%, 12-mo: 66% (follow up not reported for each IG, but in text stated no significant difference in f/u between groups)	**GC/chalymdia, syphillis, HIV** ***mean % testing positive for new STI*** **6-mo** IG1: 7.2%; RR 0.69 (0.54-0.88) IG2: 7.3%; RR 0.71 (0.58-0.89) CG1: 10.4% **12-mo** IG1: 11.5%; RR=0.78 (0.64-0.94) IG2: 12.0%; RR=0.81 (0.67-0.98) CG1: 14.6%

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Kamb 1998[14] **Project RESPECT** **Fair**	***mean % no unprotected sex, consistent (100%) condom use (and relative risk to CG1)*** **3-mo** IG1: 46%; RR=1.21 (1.09-1.35) IG2: 44%; RR=1.15 (1.03-1.27) CG1: 38% **6-mo** IG1: 39%; RR 1.14 (1.01-1.28) IG2: 39%; RR 1.12 (1.00-1.25) CG1: 34% **9 and 12 mo** no sig difference, numbers not reported	***mean % reporting any condom use*** **3-mo** IG1: 83%, p<0.05 IG2: 79% CG1: 76% **6-mo** IG1: 78%, p<0.05 IG2: 73% CG1: 73%

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes					
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Kamb 1998[14] **Project RESPECT** **Fair**	***% with 2 or more sex partners over past 3 mo (c)*** **3-mo** IG1: 29%, p<0.05 IG2: 28%, p<0.05 CG1: 34% **6-mo** IG1: 30% IG2: 30% CG1: 34% ***% with casual partners (c)*** **3-mo** IG1: 30% IG2: 27%, p<0.05 CG1: 34% **6-mo** IG1: 31% IG2: 30% CG1: 34%	N	N	**No increase in number of sex partners** **No increase in unprotected sex or decrease in condom use** **No increase in STI incidence (by testing)**	N (only reported communication skills)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference	**Study Design**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
	Locatation			
USPSTF Quality				
	Population			
Bolu 2004[21]				
Project RESPECT				
Fair				
Gottlieb[36] **2004**		**Inclusion:** Agree to have HIV test, English speaking	**N Randomized** Total: 1766, **Age** (median) Total: 24 **% Male** Total: 63 **Race** % African American: 52% STI risk see Kamb	
Project RESPECT		**Exclusion:** HSV2 seropositive or clinical dx of herpes, study participants who did not f/u with serologic testing		
Fair				

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Reference USPSTF Quality	Study Intervention	Follow-Up	Biologic Outcomes
Bolu 2004[21] **Project RESPECT** **Fair**			**GC/chalymdia, syphillis, HIV** ***mean % with newly dx STI, (adjusted) risk ratios for dx of new STI*** Adolescents (<20) IG1: 17.2%; RR 0.57 (0.37-0.90) IG2: 17.5%; RR 0.58 (0.37-0.92) CG1: 26.6% Young adults (20-25) IG1: 13.1%; RR 0.82 (0.56-1.2) IG2: 13.8%; RR 0.91 (0.62-1.3) CG1: 14.8% Adults (>25) IG1: 8.3%; RR 0.79 (0.54-1.16) IG2: 8.7%; RR 0.78 (0.53-1.13) CG1: 10.1% Male IG1: 11.4%; RR 0.73 (0.53-1.01) IG2: 12.6%; RR 0.76 (0.56-1.04) CG1: 14.3% Female IG1: 11.6%; RR 0.76 (0.53-1.08) IG2: 11.1%; RR 0.73 (0.51-1.04) CG1: 15.0%
Gottlieb[36] 2004 **Project RESPECT** **Fair**			**GC/chalmydia, HSV** ***incident HSV per 100py*** **12-mo** IG1: 10.3/100py; HR=0.80 (0.6-1.1) IG2: 11.8/100py; HR=0.9 (0.7-1.3) CG1: 12.9/100py

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Bolu 2004[21]	N	N
Project RESPECT		
Fair		
Gottlieb[36] 2004		N
Project RESPECT		
Fair		

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

	Study Outcomes				
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Bolu 2004[21] **Project RESPECT** **Fair**	N	N	N	**No increase in STI incidence (by testing)**	N
Gottlieb[36] 2004 **Project RESPECT** **Fair**	N	N	N	**No increase in STI incidence (by testing- HSV only)**	N

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference	**Study Design**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
	Locatation			
USPSTF Quality				
	Population			
Boyer 1997[12]	RCT	**Inclusion:** Attended specific public health STD clinic; age 18-35; heterosexual; residing in S.F.; high risk (previous STD;current symptoms of STD; sexual contact with person diagnosed with STD)	**N Randomized** Total:393 **Age** 18-35 **%male** Total: 67 (c) **Race** Total %African American: 46% %Hispanic: 15% %Caucasian: 29% %Other: 10% **SES** NR **STI Risk** % with hx of STI: 62% (c)	AIDS Risk Reduction Model (ARRM) Goals: Increase knowledge; improve communication and decision-making; identify/ modify risk factors and antecedents
Fair	San Francisco,CA; urban Public Health STD clinic Heterosexual adults with either: (1) previous STD, (2) current symptoms of STD, (3) sexual contact with person diagnosed with STD	**Exclusion:** non-English speaking; attending clinic for follow-up exam		

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference **USPSTF Quality**	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
Boyer 1997[12] **Fair**	**Intervention Arms** IG: risk assessment, video, written and verbal information, condoms and anatomical model, and interactive discussion to achieve goals of ARRM model. CG: standardized risk-reduction counseling **Intervention format** IG: Individual, in-person CG: Individual, in-person **Intensity** IG: Four 60-min sessions over 4 wks CG: One 15-min session **Delivery** IG:Trained counselors CG:Trained counselors	**F/U Time** 3-mo; 5- mo; assessed at any unscheduled visits at clinic within 6-mo of baseline interview **% F/U** IG: 67% CG: 75%	**chlamydia, gonorrhea, syphilis, trichomoniasis, HIV, HSV, HPV, BV** **6-mo** ***% with New/Probable STI*** Male IG: 6.8% (8/118) CG: 7.0% (10/143) Female IG: 21.8% (17/78) CG: 22% (11/50)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Boyer 1997[12]	***# UVI in past 2 mo (mean # UVI, N)***	***Mean sex with condom past 2 mo (mean %, N)***
Fair	**3-mo**	**3-mo**
	Male	Male*
	IG: 8.6, 66	IG: 56%, 66
	CG: 11.0, 96	CG: 42.3.0%, 96
	Female	*=p<0.05 at 3-mo
	IG: 5.6, 56	Female
	CG: 9.7, 40	IG: 52.9%, 56
	5-mo	CG: 48.9%, 40
	Male	**5-mo**
	IG: 9.1, 62	Male
	CG: 10.8, 94	IG: 52.4%, 62
	Female	CG: 44.5%, 94
	IG: 6.2, 59	Female
	CG: 12.9, 39	IG: 43.3%, 59
		CG: 45.1%, 39

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

	Study Outcomes				
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Boyer 1997[12] **Fair**	***# sex partners w/o condom use, in past 2 mo (mean # sex partners, N)*** **3-mo** Male IG: 0.8, 66 CG: 0.9, 96 Female IG: 0.8, 56 CG: 0.7, 40 5-mo (*=p<0.01 for men at 5mo) Male IG: 0.6, 62 CG: 0.9*, 94 Female IG: 0.8, 59 CG: 0.7, 39	N	N	**No increase in unprotected sex acts.** **No increase in STI incidence (by self-report)** **No increase in number of sex partners**	N (only reported on knowledge, attitudes and skills)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference **USPSTF Quality**	**Study Design** **Locatation** **Population**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
Wenger 1992[24] **Fair**	RCT CA University Health Clinic Heterosexual adults; university students	**Inclusion:** Student seeking care at university health clinic, 18 or older, literate in English, able to give informed consent **Exclusion:** men who self-identified as homo/bi-sexual	**N Randomized** Total: 370 IG1: 144 IG2: 136 CG: 90 **Age** Total: 23 IG1: 22 IG2: 23 CG: 23 **% Male** Total: 28% IG1: 28% IG2: 31% CG: 22% **Race** % white, Total: 61% IG1: 58% IG2: 58% CG: 69% **SES** NR **STI risk** % with STI (ever) Total: 23% IG1: 20% IG2: 25% CG: 26% median # of lifetime sexual partners Total: 4 IG1: 4 IG2: 4 CG: 4	NR

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference **USPSTF Quality**	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
Wenger 1992[24] **Fair**	**Intervention** IG1: Education only IG2: Education plus HIV testing education consisted of video, lecture, role-play, discussion, and distribution of written material CG: No further participation until f/u questionnaire offered a list of locations for free, anonymous HIV Ab testing **Format** IG: Small group (mean 8 students) CG: N/A **Intensity** IG: One session, approx 1 hour CG: N/A **Delivery** IG: MD CG: N/A	**F/U Time** 6 mo. **% F/U** IG1: 91%, IG2: 90%, CG: 81%	N

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference **USPSTF Quality**	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
Wenger 1992[24] **Fair**	***% with UVI/UAI with last sex partner*** **6-mo** IG1: 68% IG2: 63% CG: 61% p>0.15	N

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

	Study Outcomes				
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Wenger 1992[24] **Fair**	***mean number sex partners in last mo*** **6-mo** IG1: 0.70 IG2: 0.84 CG: 0.72 p>0.15	N	N	**No increase in number of sex partners** **No increase in unprotected sex or decrease in condom use**	NR (only reported on communication skills)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference **USPSTF Quality**	**Study Design** **Locatation** **Population**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
Proude 2004[23] **Fair**	RCT Australia; urban (implied) FP practices Young adults	**Inclusion:** (inclusion criteria for FP recruitment not specified); patient at participating FP practice, age 18-25 years, sufficient levels of English **Exclusion:** NR	**N Randomized** Total: 312 IG: 156 CG: 156 **Age** median age NR *% Age 18-21,* IG: 47% CG: 485 *% Age 22-25* IG: 53% CG: 52% **% Male** IG: 29 CG: 28 **Race** NR **SES** % equivalent of HS graduate IG: 68% CG: 67% **STI risk** % with multiple partners in past year IG: 14% CG: 14%	NR

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference **USPSTF Quality**	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
Proude 2004[23] **Fair**	**Intervention** IG: Behavioral advice based on brief risk assessment, and resources including- condoms, educational pamphlets on condom use, STIs and HIV, hep B (including on vaccination), alcohol and drug info services CG: Tobacco screening/counseling **Format** IG: Individual CG: Individual **Intensity** IG: One session , unspecified duration ('brief') CG: One session, unspecified duration **Delivery** IG: MD CG: MD	**F/U Time** 3-mo **% F/U** (agreed to f/U) IG: 66% (74%) CG: 69% (78%)	N

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference **USPSTF Quality**	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
Proude 2004[23] **Fair**	N	***% with condom use on first sex occasion with new partner*** **3-mo** IG: 73%(8/11) CG: 77%(10/13) p=0.813

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

	Study Outcomes				
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Proude 2004[23] **Fair**	***new sex partners over past 3 mo (c)*** IG1: 11/156 CG: 13/156	N	N	**No increase in number of sex partners** **No increase in unprotected sex or decrease in condom use**	N (only reported on communication skills)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference	**Study Design**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
	Locatation			
USPSTF Quality				
	Population			
Adolescent, Sexually Active				
Jemmott 2005[20]	RCT	**Inclusion:** African-American or Hispanic; patients of adolescent clinic; sexually experienced; Ages 12-19; read and speak English	**N Randomized** Total: 682 IG1: 235 IG2: 228 CG: 219	Culturally and developmentally appropriate interventions based on cognitive behavioral theories
Good	PA; urban		**Age** IG1: 15.53 IG2: 15.49 CG: 15.52	
	Adolescent medicine clinic	**Exclusion:** Pregnant; planned on moving out of area	**% male** Total: 0	
	Sexually active African American and Hispanic girls		**Race** %African American IG1: 68.1 IG2: 68 CG: 67.6 %Hispanic IG1: 31.9 IG2: 32.0 CG: 32.4	
			SES NR	
			STI risk % with STI (current) IG1: 22.8 IG2: 26.0 CG: 16.9 % sexually active in past 3 mo IG1: 85.6 IG2: 85.8 CG: 89.9 # days unprotected sex in past 3 mo IG1: 2.52 IG2: 3.22 CG: 3.02 % with multiple partners in past 3 mo IG1: 12.3% IG2: 18.9% CG: 16.4%	

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Reference USPSTF Quality	Study Intervention	Follow-Up	Biologic Outcomes
Adolescent, Sexu	**Adolescent, Sexually Active**		
Jemmott 2005[20] **Good**	**Intervention** IG1: Skills based HIV/STD risk reduction IG2: Information based HIV/STD risk reduction CG: Health promotion control that covered beliefs and skills relevant to behavior associatiated with risk of heart disease, cancse and stroke **Format** IG1: small group (2-10 participants); (groups discussions, videotapes, games, experiential excercises) IG2: small group (2-10 participants); (groups discussions, videotapes, games, experiential excercises) CG: small group (2-10 participants); (groups discussions, videotapes, games, experiential excercises) **Intensity** IG1: One session, 250 minutes IG2: One session, 250 minutes CG: One session, 250 minutes **Delivery** IG1: bachelors-level facilitator (African American females) with experience working with inner-city adolescents IG2: bachelors-level facilitator (African Americn females) with experience working with inner-city adolescents CG: bachelors-level facilitator (African American females) with experience working with inner-city adolescents	**F/U Time** 3 mo, 6 mo, 12 mo **% F/U** 3 mo Overall: 94.3% IG1: 96% (calc all subgroup rates) IG2: 92% CG: 95% 6 mo Overall: 92.8% IG1: 94% (calc all subgroup rates) IG2: 90% CG: 94% 12 mo Overall: 88.6% IG1: 89% (calc all subgroup rates) IG2: 86% CG: 91%	**GC, Chlamydia, Trich.** ***mean % testing positive for STI*** **6-mo** Unadjusted %, Adjusted % IG1: 15.5%, 15.8%, p=0.80 IG2: 16.0%, 15.5%, p=0.89 CG: 14.6%, 14.8% **12-mo** Unadjusted %, Adjusted % IG1: 10.8%, 10.5%, p=0.05 IG2: 16.0%, 14.4%, p=0.44 CG: 17.4%, 18.2%

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Adolescent, Sexu	**Adolescent, Sexually Active**	
Jemmott 2005[20]	***mean # days of sex w/o condom use in past 3 mo***	N
Good	**3-mo** Unadjusted , Adjusted IG1: 3.66, 3.71, p=0.95 IG2: 3.83, 3.56, p=0.89 CG: 3.52, 3.46 **6-mo** Unadjusted , Adjusted IG1: 2.99, 2.88, p=0.66 IG2: 3.17, 2.60, p=0.43 CG: 3.47, 3.26 **12-mo** Unadjusted , Adjusted IG1: 2.80, 2.27, p=0.002 IG2: 5.04, 4.04, p=0.32 CG: 5.73, 5.05	

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

	Study Outcomes					
Study Reference	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
USPSTF Quality					
Adolescent, Sexu	**Adolescent, Sexually Active**				
Jemmott 2005[20]	***mean % reporting multiple partners in past 3-mo***	N	***mean # of days of sex while intoxicated past 3 mo***	**No increase in number of sex partners**	N (only reported on knowledge, attitudes and skills)
Good	**3-mo** Unadjusted, Adjusted IG1: 10.7%, 10.9%, p=0.29 IG2: 15.8%, 15.1%, p=0.76 CG: 14.9%, 14.2%		**3-mo** Unadjusted, Adjusted IG1: 0.11, 0.10, p=0.03 IG2: 0.35, 0.29, p=0.98 CG: 0.29, 0.26	**No increase in unprotected sex or decrease in condom use**	
	6-mo Unadjusted, Adjusted IG1: 9.5%, 9.7%, p=0.12 IG2: 13.2%, 12.5%, p=0.54 CG: 15.1%, 14.3%		**6-mo** Unadjusted, Adjusted IG1: 0.10, 0.07, p=0.005 IG2: 0.20, 0.15, p=0.10 CG: 0.36, 0.31	**No increase in STI incidence (by testing)**	
	12-mo Unadjusted, Adjusted IG1: 7.4%, 6.9%, p=0.002 IG2: 11.4%, 10.7%, p=0.09 CG: 17.5%, 16.6%		**12-mo** IG1: 0.32, 0.42, p=0.37 IG2: 0.55, 0.53, p=0.65 CG: 0.65, 0.66		

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference **USPSTF Quality**	**Study Design** **Locatation** **Population**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
DiClemente 2004[19] **Good**	RCT GA, urban Community health agencies Sexually active, African American girls	**Inclusion:** 14-18y, African American, female, sexually active (vaginal intercourse past 6mo) **Exclusion:** NR	**N Randomized** Total: 522 IG: 251 CG: 271 **Age** IG: 15.99 CG: 15.97 **% Male** Total: 0% **Race** % African American: 100% **SES** Recipient of public assistance IG: 17.9% CG: 18.5% Education % did not complete 10th grade IG: 45.8 CG: 48.7 **STI risk** % with STI (current) *GC* IG: 5.6% CG: 4.8% *Chlamydia* IG: 19.2% CG: 15.9% *Trichomonas* IG1: 13.4% CG: 12.4% Frequency unprotected sex in past 6 mo IG: 4.81 CG: 4.23 % with new partner in past 30 days IG: 4.4% CG: 7.4%	Social cognitive theory and theory of gender and power as a basis for HIV prevention intervention; culturally tailored

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

	Study Intervention		
Study Reference	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
USPSTF Quality			
DiClemente 2004[19]	**Intervention** IG: Multicomponent sessions including discussions, behavior modeling and role play CG: Multicomponent sessions on nutrition and exercise **Format** IG: Small group (10-12 participants) CG: Small group (10-12 participants) **Intensity** IG: Four sessions, 4 hours, on consecutive Saturdays CG: Four sessions, 4 hours, 1x on consecutive Saturdays **Delivery** IG: Trained AA female health educator and two peers CG: NR	**F/U Time** 6-mo; 12-mo **% F/U** 6-mo IG: 90%, CG: 89.7% 12mo IG: 87.3%, CG: 88.9%	***STD incidence (crude) and OR over 12mo*** chlamydia IG: 2.1 per 100 person mo CG: 2.0 per 100 person mo OR: 0.17 (0.03-0.92) gonorrhea IG: 0.9 per 100 person mo CG: 0.7 per 100 person mo OR: 0.14 (0.01-3.02) trichomonas IG: 0.9 per 100 person mo CG: 1.2 per 100 person mo OR: 0.37 (0.09-1.46)
Good			

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
DiClemente 2004[19] **Good**	***episodes UVI past 30d (relative % change), past 6mo*** **6-mo** IG: 1.02, 3.77 CG: 2.02, 9.24 -50.69%, p=0.46; -64.23%, p=0.006 **12-mo** IG: 1.15, 5.77 CG: 2.04, 10.25 -39.26%, p=0.002; -39.31%, p=0.02	***% consistent condom use past 30d, past 6mo*** **6-mo** IG: 75.3, 61.3 CG: 58.2, 42.6 OR: 1.77 (0.97-3.20) OR: 2.48 (1.44-4.26) **12-mo** IG: 73.3, 58.1 CG: 56.5, 45.3 OR: 2.23 (1.17-4.27), OR= 2.14 (1.20-3.84)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes					
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
DiClemente 2004[19] **Good**	***% with new sex partner in past 30d*** **6-mo** IG: 2.7 CG: 7.4 OR: 0.29 (0.11-0.77), p=0.01 **12-mo** IG: 3.6 CG: 5.6 OR: 0.59 (0.19-1.84), p=0.36	N	N	**No increase in unprotected sex or decrease in condom use** **No increase in STI incidence (by testing)**	***self-reported pregnancy*** (unadjusted %, OR) **6-mo** IG: 3.6 CG: 7.0 OR 0.38 (0.15-0.96) **12-mo** IG: 6.0 CG: 8.5 OR 0.74 (0.30-1.82) (also reported on knowledge, attitudes and skills)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference	**Study Design**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
	Locatation			
USPSTF Quality				
	Population			
Adolescent, Pre Sexual Debut				
Boekeloo 1999[18]	RCT	**Inclusion:**12-15 years old, with appointment to see physician participating in study (primary care pediatrician at one of 5 practice sites, n=19)	**N Randomized** (N at exit interview) Total : 219 (215) IG: 105 (101) CG: 114 (114) **Age** Age 12-13 IG: 57%, CG: 49% **% Male** IG: 52% CG: 48% **Race** African American IG: 60% CG: 68% Caucasian IG: 21%, CG: 17% Hispanic IG: 4% CG: 3% Other IG: 15% CG: 12% **SES** NR **STI risk** % been treated for STI in past 3 mo IG: 7.5% CG: 4.5% % with vaginal intercourse in past 3 mo IG: 20% CG: 23%	ASSESS (Awareness, Skills, Self-efficacy/Self-esteem, and Social Support) based on social-cognitive theory and the Theory of Reasoned Action
Fair	DC; urban/suburban	**Exclusion:** NR		
	HMO			
	Young adolescents			

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Intervention			
Study Reference **USPSTF Quality**	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
Adolescent, Pre Sexual Debut			
Boekeloo 1999[18] **Fair**	**Intervention** IG: 15 minute audiotape which includes risk assessment; physician review of risk assessment and discussion, with props and brochures CG: Usual care with primary care pediatrician **Format** IG: Individual with audiotape portion **CG:N/A** **Intensity** IG: One session incorporated into general health exam and waiting period CG: N/A **Delivery** IG: Audiotape (two physicians); and primary care pediatrician CG: N/A	**F/U Time** 3-mo; 9-mo **% F/U** 3-mo IG: 89%, CG: 94% 9-mo IG: 89%, CG: 90%	***% told by doctor/nurse they had STD (self-reported)*** **3-mo** IG (n=93): 1.1% CG (n=107): 0.9% **9-mo** IG (n=94): 0% CG (n=103): 2.9% ***% been treated for an STD (self-reported)*** **3-mo** IG (n=93): 2.2% CG (n=107): 4.7% **9-mo** IG (n=94): 1.1% CG (n=103): 5.8%

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Adolescent, Pre	**Adolescent, Pre Sexual Debut**	
Boekeloo 1999[18]	N	***% and odds ratio with condom use at last vaginal intercourse among those who were sexually active over past 3 mo***
Fair		**3-mo** IG: 92%(23/25) CG: 57% (12/21) OR: 18.05 (1.27, 256.03)
		9-mo IG: 71%(22/31) CG: 70%(21/30) OR: 1.00 (0.31, 3.24)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

	Study Outcomes				
Study Reference	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
USPSTF Quality					
Adolescent, Pre	**Adolescent, Pre Sexual Debut**				
Boekeloo 1999[18] **Fair**	N	***% with vaginal sex in past 3 -mo*** **3-mo** IG: 27%(25/93) CG: 20%(21/107) OR: 2.46 (1.04, 5.84) **9-mo** IG: 31/94=33% CG: 30/103=29% OR: 1.64 (0.81, 3.34) ***% with any (vaginal, oral, anal) sex in past 3 mo*** **3-mo** IG: 29%(27/93) CG: 26%(30/107) OR: 1.55 (0.73, 3.32) **9-mo** IG: 39%(37/94) CG: 34%(35/103) OR=1.56 (0.79, 3.08)	N	Does report increase in % having vaginal sex at 3-mo. IG=27% CG=20% OR -2.46 (1.04, 5.84) (Not at 9-mo, Not for 'Any' vaginal,oral, and anal sex) No increase in unprotected sex or decrease in condom use No increase in STI incidence (by self report)	% self-reported pregnancy (gotten someone or been pregnant) **baseline, 3-mo** IG: 1.0%, 0% CG: 1.8%, 1.9% NS, p>0.05 **baseline, 6-mo** IG: 1.0%, 1.1% CG: 1.8%, 5.9% NS, p>0.05 (also reported on knowledge, attitudes and skills)

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Characteristics/Design		Study Population		
Study Reference	**Study Design**	**Participant Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Intervention theory description**
	Locatation			
USPSTF Quality				
	Population			
Danielson 1990[25]	RCT	**Inclusion:** boys 15-18 years receiving care at HMO	**N Randomized** Total: 1195 IG: NR CG: NR	NR
	OR,WA; urban		**Age** Reported % by year in High school Freshmen: 18% Sophomores: 34% Juniors: 24% Seniors: 24%	
Fair	HMO	**Exclusion:** NR	**% Male** Total: 100%	
	High school aged boys		**Race** %African American: <5% %Asian Pacific Islander <4%	
			SES Father employed full time: 86% Father graduated 4-year college: 44%	
			STI risk % sexually active in the past year: 37%	

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

	Study Intervention		
Study Reference	**Study Intervention**	**Follow-Up**	**Biologic Outcomes**
USPSTF Quality			
Danielson 1990[25] **Fair**	**Intervention** IG: Slide tape program with photos and information on sexual health, couple communication, and access to health services; and visit with health practionner- Q&A based on patient's interests, risk reduction counseling, modeling and rehearsing discussing sex and contraception with girlfriend CG: Scheduled consultation (intervention) was after the 1 year f/u assessment. **Format** IG: Individual CG: NR **Intensity** IG: One session, 1-hour medical appointment (30 min slide-tape/30min health practioner) CG: NR **Delivery** IG: Trained NP, PA or RN CG: NR	**F/U Time** 12-mo **% F/U** 12-mo: 81.3% (c)	N

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes		
Study Reference	**UAI or UVI (without condom unless otherwise specified)**	**Use of condom (male condom unless otherwise specified)**
USPSTF Quality		
Danielson 1990[25] **Fair**	**12-mo** main method of contraception used over past 12 mo, % by contraception for pill use see 'other positive outcomes' ***% using any contraceptive at most recent intercourse*** **12-mo** IG (n=262) 69.9% CG (n=260) 65.8% OR adjusted 1.51, p<0.05 OR adjusted for those who had not been sex active at baseline 2.53, p<0.01	**12-mo** ***% using condom at most recent intercourse*** IG (n=262) 33.3% CG (n=260) 35.8%

Appendix B. Table 1. Evidence Table for KQ1,2,3, 4

Study Outcomes					
Study Reference **USPSTF Quality**	**# of sex partners**	**Abstinence**	**Other behavioral outcomes**	**Adverse Outcomes**	**Other positive outcomes**
Danielson 1990[25] **Fair**	N	***mean % teen male sex active*** **12-mo** IG: 90% CG: 91% ***mean % teen male sex active (of those not previously sex active***) IG: 30% CG: 34%	N	**No increase in unprotected sex or decrease in condom use** **No earlier sexual debut**	**12-mo** % with partner using pill at most recent sexual intercourse, and adjusted OR IG (n=262) 32.4% CG (n=260) 23.9% OR 1.66, p<0.05

Appendix B Table 2. Evidence table key question 5

Study Characteristics/Design		Study Population		Study Intervention		Study Outcomes/Results
Study Reference	**Study Design** **Location** **Target population**	**Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Study Intervention**	**Follow-up**	**Outcomes/Results**
French 2003[31] **Fair**	RCT US; urban public STI clinic adult, female; low-income, minority	**Inclusion:** women attending clinic **Exclusion:** women attending solely for purpose of anonymous HIV testing, or brought to clinic as part of contact-tracing	**N Randomized** Total: 1442 IG: 855 CG: 587 **Age** IG: 28.1 CG: 28.8 **% Female** 100% **Race** % African American IG=85.4% CG=87.2% **SES** NR	**IG:** interactive, multimedia, small group sessions (up to five women) with video, condom samples, posters, pamphlets, and pelvic and penis models to practice condom application; lasting 10-20 minutes; given free female condoms during study period encouraged to use the female condom during vaginal and anal sex and were instructed to purchase flavored male condoms for oral sex (not advised to stop using other methods) **CG:** interactive, multimedia, small group sessions (up to five women) with video, condom samples, posters, pamphlets, and pelvic and penis models to practice condom application; lasting 10-20 minutes; given free male condoms during study period (format same as IG) encouraged to use male condoms during all types of sexual intercourse (not encouraged to stop using any other method of protection)	**F/U Time** not fixed, up to 1 year **% F/U** IG: 50.2% CG: 51.1% **mean number F/U visits** IG: 2.2 CG: 2.3	gonorrhea, chlamydia, early syphilis, trichomonas ***STI diagnosed at follow-up*** IG: 12.4%(106/855) CG: 15.8%(93/587) unadjusted OR- 0.75 (0.56-1.01), p=0.06 ***STI incidence at follow-up*** IG: 6.8 per 100 women months CG: 8.5 per 100 women months OR- 0.79 (0.59-1.06), p=0.11

Appendix B Table 2. Evidence table key question 5

Study Characteristics/Design		Study Population		Study Intervention		Study Outcomes/Results
Study Reference	**Study Design** **Location** **Target population**	**Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Study Intervention**	**Follow-up**	**Outcomes/Results**
Fontanet 1998[30] **Fair**	RCT Thailand; urban sex establishments Adult; Female; sex workers	**Inclusion:** Sex establishment-workers with reported multiple clients per day; by individual-18+, willing to use condoms as instructed, willing to keep a pictorial coital log for all sex acts (with client and non-commercial sex partners) **Exclusion:** using diaphragm, cervical cap and vaginal spermicides, evidence of IVDU	**N Randomized** IG: 249 CG: 255 **Age** *< 20 years* IG: 15%, CG: 17% *20-24 years* IG: 40%, CG: 38% *>24 years* IG: 45% CG: 44% **% Female** 100% **SES** no education IG:19%, CG:24% <6 y education, IG:72% CG:65% >6 y education IG: 9% CG: 12%	**IG:** male/female condom group- women propose a male condom to their clients as a first choice, but would have option of using female condom when clients refused or could not use a male condom also given counseling regarding transmission of HIV and other STIs, given free supply of condoms **CG:** male condom group- women propose a male condom to their clients, and if clients refused or could not use male condoms, they were instructed not to have sex also given counseling regarding transmission of HIV and other STIs, given free supply of condoms (same as IG)	**F/U Time** every 2 weeks for 24 weeks (about 6 months) **% F/U** IG: 95.7% CG: 88.3%	gonorrhea, chlamydia, trichomonas, or genital ulcer disease ***incidence rate of STIs (weighted geometric mean per 100 woman-weeks)*** IG: 2.81 CG: 3.69 incidence rate ratio (95% CI): 0.76 (0.50-1.16) ***coital log recorded acts with male and female condoms, failures (torn/slippage), unprotected acts*** ***percent with acts male condom*** IG: 88.2% CG: 97.5% ***percent with acts female condom*** IG: 12.0% CG: 0%

Appendix B Table 2. Evidence table key question 5

Study Characteristics/Design		Study Population		Study Intervention		Study Outcomes/Results
Study Reference	**Study Design** **Location** **Target population**	**Inclusion/Exclusion Criteria**	**Baseline Demographics**	**Study Intervention**	**Follow-up**	**Outcomes/Results**
Feldblum 2001[29] **Feldblum 2000**[62] **Good**	cluster RCT Kenya; rural agricultural sites adult, female; employed as agricultural worker	**Inclusion:** permanent employee, 18-50 yo, sexually active, willing to return for follow-up visits, give urine/vaginal samples, and answer questions about sexual activity and condom use **Exclusion:** pregnant, desire to become pregnant in coming year, using spermicidal contraceptive	**N Randomized** Total: 12 sites (1929 women) IG: 6sites (969 women) CG: 6 (960 women) **Age:** 33.1 **% Female** 100% **SES** completed primary school or less- "about 90%"	**IG:** Program relied on large/small group meetings, video presentations, puppetry, and other folk media, printed materials, individual counseling, given male and female condoms for all adults program delivered by trained clinic service providers, outreach workers, and plantation managers **CG:** Similar prevention program excluding information on female condoms, only given male condoms	**F/U Time** 6-mo, 12-mo **% F/U** <u>6-mo</u> IG: 90.0%(881/969) CG: 89.2%(856/960) <u>12-mo</u> IG: 82.2%(797/969) CG: 83.1%(798/960) ***at least one f/u*** 91% ***both f/u*** 82%	gonorrhea, chlamydia, or trichomonas ***crude prevalence of STI%*** <u>6-mo</u> IG: 17.1% CG: 17.6% <u>12-mo</u> IG: 18.2% CG: 18.4% ***association of STI prevalence*** IG: OR- 1.0 CG: OR- 1.1 (0.8, 1.6) ***consistent male condom use*** <u>6-mo</u> IG: 14% CG: 23% <u>12-mo</u> IG: 22% CG: 24% ***consistent female condom use*** <u>6-mo</u> IG=11% CG=NA <u>12-mo</u> IG: 7% CG: NA

Appendix B Table 3. Abbreviations for evidence tables

Abbreviation	Description
(c)	calculated
BV	Bacterial Vaginosis
CASI	computer assisted survey interviewing
CG	comparison or control group
dx	diagnosis
GC	gonococcus=gonorrhea
HMO	health maintenance organization
hosp	hospitalization
HPV	Human Papillomavirus
HR	high risk
HS	high school
HSV	Herpes Simplex Virus
hx	history of
IG	intervention group
IVDU	Injection (intravenous) drug use
mh	mental health
MMSE	Mini Mental Status Exam
N	No
NR	not reported
NYC-DOH	New York City Department of Health
oth	other
PC-C	primary care conducted
PC-F	primary care feasible
PC-R	primary care referable
PHC	public health clinic
PID	pelvic inflammatory disease
pos	positive
psych	psychiatric
rand	randomized/randomization
REALM	Rapid Assessment of Adult Literacy
s/s	signs and symptoms
SCID	Schedule of Affective Disorders
STi	Sexually Transmitted infection
sx	symptom(s)
U	Unsure
UAI	unprotected anal intercourse
UVI	unprotected vaginal intercourse
w	with
w/o	without
Y	Yes
yo	years old
HR	Hazard ratio
N/A	Not applicable
NP	Nurse practitioner
PA	Physicians Assistant
RN	Registered Nurse
PY	Person years
SES	Socioeconomic status

States are cited as postal abbreviations

Appendix C. Excluded studies table

Reference	Reason for exclusion
A gender and culture-specific HIV prevention programme significantly reduces risky sexual behaviours in African American adolescent girls. *Evidence-Based Healthcare and Public Health 9(1):67-68,* 2005.	Excluded study design
Aggleton P, Rivers K. Interventions for adolescents. In: Gibbney, editor. *Preventing HIV in Developing Countries: Biomedical and Behavioral Approaches.* New York: Plenum Press, 1999: 231-255.	Excluded study design
Anderson ES, Wagstaff DA, Heckman TG, et al. Information-Motivation-Behavioral Skills (IMB) Model: testing direct and mediated treatment effects on condom use among women in low-income housing. *Ann Behav Med* 2006; 31(1):70-79.	Incorrect setting
Artz L, Macaluso M, Meinzen-Derr J et al. A randomized trial of clinician-delivered interventions promoting barrier contraception for sexually transmitted disease prevention. *Sexually Transmitted Diseases 32(11):672-9,* 2005.	Does not meet USPSTF quality criteria
Baker A, Heather N, Wodak A et al. Evaluation of a cognitive-behavioural intervention for HIV prevention among injecting drug users. *AIDS 7(2):247-56,* 1993.	Incorrect setting
Belcher L, Kalichman S, Topping M et al. A randomized trial of a brief HIV risk reduction counseling intervention for women. *J Consult Clin Psychol* 1998; 66(5):856-861.	Comparative effectiveness study
Bellingham K, Gillies P. Evaluation of an AIDS education programme for young adults. *Journal of Epidemiology & Community Health 47(2):134-8,* 1993.	Incorrect population
Berkman A, Pilowsky DJ, Zybert PA et al. The impact of substance dependence on HIV sexual risk-reduction among men with severe mental illness. *AIDS Care* 2005; 17(5):635-639.	Comparative effectiveness study
Berkman A. Reducing Sexual Risk Behaviors of Men With Severe Mental Illness. *Psychiatric Services* 57[3], 417. 2006.	Comparative effectiveness study
Booth RE, Zhang Y. The challenge of changing drug and sex risk behaviors of runaway and homeless adolescents. *Child Abuse & Neglect 23(12):1295-1306 ,* 1999.	Incorrect setting
Bowen AM. Predicting increased condom use with main partners: Potential approaches to intervention. *Drugs & Society Vol 9, pp 57-74,* 1996.	Does not meet USPSTF quality criteria
Boyer CB, Shafer MA, Shaffer RA et al. Evaluation of a cognitive-behavioral, group, randomized controlled intervention trial to prevent sexually transmitted infections and unintended pregnancies in young women. *Preventive Medicine 40(4):420-31,* 2005.	Incorrect setting
Branson BM, Peterman TA, Cannon RO et al. Group counseling to prevent sexually transmitted disease and HIV: a randomized controlled trial. *Sex Transm Dis* 1998; 25(10):553-560.	Comparative effectiveness study
Braverman PK. Abstinence and safer sex HIV risk-reduction interventions for African-American adolescents. *Clin Pediatr (Phila)* 1999; 38(3):184-187.	Excluded study design
Bryan AD, Aiken LS, West SG. Increasing condom use: Evaluation of a theory-based intervention to prevent sexually transmitted diseases in young women. *Health Psychology Vol 15(5) Sep 1996, 371-382 http://www apa org/journals/hea html* 1996.	Incorrect setting
Calsyn DA, Saxon AJ, Freeman G, et al. Ineffectiveness of AIDS education and HIV antibody testing in reducing high-risk behaviors among injection drug users. *American Journal of Public Health 82(4):573-5,* 1992.	Incorrect population
Calsyn DA, Saxon AJ, Wells EA et al. Longitudinal sexual behavior changes in injecting drug users. *AIDS 6(10):1207-11,* 1992.	Excluded study design
Carballo-Dieguez A, Dolezal C, Leu CS et al. A randomized controlled trial to test an HIV-prevention intervention for Latino gay and bisexual men: lessons learned. *AIDS Care 17(3):314-28,* 2005.	Incorrect setting

Appendix C. Excluded studies table

Reference	Reason for exclusion
Carey MP, Braaten LS, Maisto SA et al. Using information, motivational enhancement, and skills training to reduce the risk of HIV infection for low-income urban women: a second randomized clinical trial. *Health Psychol* 2000; 19(1):3-11.	Incorrect setting
Carey MP, Maisto SA, Kalichman SC et al. Enhancing motivation to reduce the risk of HIV infection for economically disadvantaged urban women. *Journal of Consulting & Clinical Psychology 65(4):531-41,* 1997.	Incorrect setting
Chernoff RA, Davison GC. An evaluation of a brief HIV/AIDS prevention intervention for college students using normative feedback and goal setting. *AIDS Education & Prevention 17(2):91-104,* 2005.	Does not report designated outcomes
Choi KH, Lew S, Vittinghoff E et al. The efficacy of brief group counseling in HIV risk reduction among homosexual Asian and Pacific Islander men. *AIDS 10(1):81-7,* 1996.	Incorrect setting
Clark LR, Brasseux C, Richmond D et al. Effect of HIV counseling and testing on sexually transmitted diseases and condom use in an urban adolescent population. *Archives of Pediatrics & Adolescent Medicine 152(3):269-73,* 1998.	Excluded study design
Cohen D, Reardon K, Alleyne D et al. Influencing spermicide use among low-income minority women. *J Am Med Womens Assoc* 1995; 50(1):11-13.	Does not report designated outcomes
Cohen DA, Dent C, MacKinnon D et al. Condoms for men, not women. Results of brief promotion programs. *Sex Transm Dis* 1992; 19(5):245-251.	Does not meet USPSTF quality criteria
Cohen DA, MacKinnon DP, Dent C et al. Group counseling at STD clinics to promote use of condoms. *Public Health Rep* 1992; 107(6):727-731.	Does not meet USPSTF quality criteria
Collins P. HIV Prevention for Mentally Ill Men and Women. *Xth World Congress of Psychiatry, Madrid, Spain 23rd-28th August,* 1996.	Incorrect setting
Cottler LB, Compton WM, Ben Abdallah A et al. Peer-delivered interventions reduce HIV risk behaviors among out-of-treatment drug abuSERs. *Public Health Reports 113 Suppl 1:31-41,* 1998.	Comparative effectiveness study
Coyle K, Basen-Engquist K, Kirby D et al. Short-term impact of safer choices: a multicomponent, school-based HIV, other STD, and pregnancy prevention program. *Journal of School Health 69(5):181-8,* 1999.	Incorrect setting
Dallabetta G, Serwadda D, Mugrditchian D. Controlling Other Sexually Transmitted Diseases. 1999.	Excluded study design
Dancy BL , Marcantonio R. The long-term effectiveness of an HIV prevention intervention for low-income African American women. *AIDS education and prevention: official publication of the International Society for AIDS Education 2(2):95-108,* 2000.	Incorrect setting
Deren S, Davis WR, Beardsley M et al. Outcomes of a risk-reduction intervention with high-risk populations: the Harlem AIDS project. *AIDS Education & Prevention 7(5):379-90,* 1995.	Incorrect setting
DiClemente RJ, Wingood GM. A randomized controlled trial of an HIV sexual risk-reduction intervention for young African-American women. *JAMA : the journal of the American Medical Association 274(16):1271-6,* 1995.	Incorrect setting
Diers JA. *Efficacy of a stage-based counseling intervention to reduce the risk of HIV in women*. 2000.	Incorrect setting

Appendix C. Excluded studies table

Reference	Reason for exclusion
Dilley JW, Woods WJ, Sabatino J et al. Changing sexual behavior among gay male repeat testers for HIV: a randomized, controlled trial of a single-session intervention. *J Acquir Immune Defic Syndr* 2002; 30(2):177-186.	Comparative effectiveness study
Downs JS, Murray PJ, Bruine dB et al. Interactive video behavioral intervention to reduce adolescent females' STD risk: a randomized controlled trial. *Social Science & Medicine 59(8):1561 -72,* 2004.	Comparative effectiveness study
Dworkin SL, Exner T, Melendez R et al. Revisiting "Success": Posttrial Analysis of a Gender-Specific HIV/STD Prevention Intervention. *AIDS and Behavior* 10[1], 41-51. 2006.	Excluded study design
El Bassel N, Schilling RF. 15-month followup of women methadone patients taught skills to reduce heterosexual HIV transmission. *Public Health Reports 107(5):500-4,* 1992;-Oct.	Incorrect population
El Bassel N, Witte SS, Gilbert L et al. Long-term effects of an HIV/STI sexual risk reduction intervention for heterosexual couples. *AIDS & Behavior 9(1):1-13,* 2005.	Comparative effectiveness study
El Bassel N, Witte SS, Gilbert L et al. The efficacy of a relationship-based HIV/STD prevention program for heterosexual couples. *American Journal of Public Health 93(6):963-9,* 2003.	Comparative effectiveness study
Feldblum PJ, Chen-Mok M, Bwayo JJ et al. Intracluster correlation of STD prevalence in a community intervention trial in Kenya. *Lancet 354(9187):1356-7,* 1999.	Does not report designated outcomes
Feldblum PJ, Kuyoh M, Omari M et al. Baseline STD prevalence in a community intervention trial of the female condom in Kenya. *Sexually Transmitted Infections 76(6):454-6,* 2000.	Does not report designated outcomes
Ferguson SL. Evaluation of the effects of peer counseling in a culturally-specific adolescent pregnancy prevention program for african american females. *Disertation Abstracts International Section A: Humanities and Social Sciences Vol 60(9-A), Apr 2000, pp 3538* 1996.	Incorrect setting
Fisher JD, Fisher WA, Misovich SJ et al. Changing AIDS risk behavior: effects of an intervention emphasizing AIDS risk reduction information, motivation, and behavioral skills in a college student population. *Health Psychology 15(2):114-23,* 1996.	Incorrect setting
Flaskerud JH, Nyamathi AM, Uman GC. Longitudinal effects of an HIV testing and counseling programme for low-income Latina women. *Ethnicity & Health 2(1-2):89-103,* 1997;-Jun.	Comparative effectiveness study
Flowers P. Does bar-based, peer-led sexual health promotion have a community-level effect amongst gay men in Scotland? *Internation Journal of STD and AIDS 13(2):102-108,* 2002.	Incorrect setting
Fogarty LA, Heilig CM, Armstrong K et al. Long-term effectiveness of a peer-based intervention to promote condom and contraceptive use among HIV-positive and at-risk women. *Public Health Rep* 2001; 116 Suppl 1:103-119.	Incorrect population
From the Centers for Disease Control and Prevention. Contraceptive practices before and after an intervention promoting condom use to prevent HIV infection and other sexually transmitted diseases among women--selected US sites, 1993-1995. *JAMA 277(22):1752 -3,* 1997.	Excluded study design

Appendix C. Excluded studies table

Reference	Reason for exclusion
Gallagher TJ, Cottler LB, Compton WMI et al. Changes in HIV/AIDS risk behaviors in drug users in St. Louis: Applications of random regression models. *Journal of Drug Issues Vol 27(2) Spr 1997, 399-416 http://www2 criminology fsu edu/~jdi/* 1997.	Incorrect population
Gibson DR, Lovelle-Drache J, Young M,et al. Effectiveness of brief counseling in reducing HIV risk behavior in injecting drug users: Final results of randomized trials of counseling with and without HIV testing. *AIDS and Behavior Vol 3(1) Mar 1999, 3-12 http://www springeronline com/sgw/cda/frontpage/0,11855,4-40109-70-35538888-0,00 html?changeHeader=true* 1999.	Incorrect population
Gibson DR, Wermuth L, Lovelle-Drache J et al. Brief counseling to reduce AIDS risk in intravenous drug uSERs and their sexual partners: Preliminary results. *Counselling Psychology Quarterly Vol 2(1) 1989, 15-19 http://www tandf co uk/journals/carfax/09515070 html* 1989.	Incorrect population
Gielen AC, Fogarty LA. Promoting condom use with main partners: A behavioral intervention trial for women. *AIDS & Behavior 5(3):193-204,* 2001.	Incorrect population
Gielen AC, Faden RR, Kass NE et al. Evaluation of an HIV/AIDS education program in an urban prenatal clinic. *Womens Health Issues 7(4):269-78,* 1997;-Aug.	Excluded study design
Gillmore MR, Morrison DM, Richey CA et al. Effects of a skill-based intervention to encourage condom use among high risk heterosexually active adolescents. *AIDS Education & Prevention 9(1 Suppl):22-43,* 1997.	Comparative effectiveness study
Gold R, Rosenthal DA. Preventing unprotected anal intercourse in gay men: A comparison of two intervention techniques. *International Journal of STD & AIDS 6(2):89-94,* 1995.	Incorrect setting
Gollub EL, French P, Loundou A et al. A randomized trial of hierarchical counseling in a short, clinic-based intervention to reduce the risk of sexually transmitted diseases in women. *AIDS 14(9):1249-55,* 2000.	Comparative effectiveness study
Gollub EL. The female condom: tool for women's empowerment. *American Journal of Public Health 90(9):1377 -81,* 2000.	Study not evaluate bci
Greenberg J, Hennessy M, MacGowan R et al. Modeling intervention efficacy for high-risk women. The WINGS Project. *Evaluation & the Health Professions 23(2):123-48,* 2000.	Incorrect setting
Hajagos K, Geiser P, Parker B et al. Safer-sex education for persons with mental illness. *Journal of Psychosocial Nursing & Mental Health Services 36(8):33-7,* 1998.	Does not report designated outcomes
Harris RM, Bausell RB, Scott DE et al. An intervention for changing high-risk HIV behaviors of African American drug-dependent women. *Res Nurs Health* 1998; 21(3):239-250.	Incorrect population
Harvey SM, Henderston JT, Thorburn S, et al. A randomized study of a pregnancy and disease prevention intervention for Hispanic couples. *Perspectives on sexual and reproductive health 36(4):162-9,* 2004.	Comparative effectiveness study
Hetherington SE, Harris RM, Bausell RB et al. AIDS prevention in high-risk African American women: behavioral, psychological, and gender issues. *J Sex Marital Ther* 1996; 22(1):9-21.	Incorrect population

Appendix C. Excluded studies table

Reference	Reason for exclusion
Hewitt NB. Africentricity, HIV behavioral intervention, and HIV risk-associated behavior among African-American adolescents: A randomized controlled trial. *Dissertation Abstracts International: Section B: The Sciences and Engineering Vol 60(2-B), Aug* 1999.	Incorrect setting
Hobfoll SE, Jackson AP, Lavin J et al. Reducing inner-city women's AIDS risk activities: a study of single, pregnant women. *Health Psychology 13(5):397-403,* 1994.	Does not meet USPSTF quality criteria
Hobfoll SE, Jackson AP, Lavin J et al. Effects and generalizability of communally oriented HIV-AIDS prevention versus general health promotion groups for single, inner-city women in urban clinics. *Journal of Consulting & Clinical Psychology 70(4):950 -60,* 2002.	Does not meet USPSTF quality criteria
Hoffman JA, Klein H, Crosby H et al. Project neighborhoods in action: an HIV-related intervention project targeting drug abusers in Washington, DC. *J Urban Health* 1999; 76(4):419-434.	Comparative effectiveness study
Imrie J, Stephenson JM, Cowan FM et al. A cognitive behavioural intervention to reduce sexually transmitted infections among gay men: randomised trial. *BMJ* 2001; 322(7300):1451-1456.	Comparative effectiveness study
James NJ, Gillies PA, Bignell CJ. Evaluation of a randomized controlled trial of HIV and sexually transmitted disease prevention in a genitourinary medicine clinic setting. *AIDS* 1998; 12(10):1235-1242.	Does not meet USPSTF quality criteria
Jaworski BC, Carey MP. Effects of a brief, theory-based STD-prevention program for female college students. *Journal of Adolescent Health 29(6):417-25,* 2001.	Does not report designated outcomes
Jemmott JB, III, Jemmott LS, Fong GT. Abstinence and safer sex HIV risk-reduction interventions for African American adolescents: a randomized controlled trial.[see comment]. *JAMA 279(19):1529-36,* 1998.	Incorrect setting
Jemmott JB, III, Jemmott LS, Fong GT. Reductions in HIV risk-associated sexual behaviors among black male adolescents: effects of an AIDS prevention intervention.[erratum appears in Am J Public Health 1992 May;82(5):684]. *American Journal of Public Health 82(3):372-7,* 1992.	Incorrect setting
Jenkins PR, Jenkins RA, Nannis ED et al. Reducing risk of sexually transmitted disease (STD) and human immunodeficiency virus infection in a military STD clinic: evaluation of a randomized preventive intervention trial. *Clinical Infectious Diseases 30(4):730-5,* 2000.	Does not report designated outcomes
Johnson-Mallard V. The effects of an education/behavioral intervention on knowledge, perceived risk and self-efficacy for sexually transmitted infections in women. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 66[9-B], 4726. 2006.	Does not report designated outcomes
Kalichman SC, Cherry C, Browne-Sperling F. Effectiveness of a video-based motivational skills-building HIV risk-reduction intervention for inner-city African American men. *Journal of Consulting & Clinical Psychology 67(6):959-66,* 1999.	Comparative effectiveness study
Kalichman SC, Cherry C. Male polyurethane condoms do not enhance brief HIV-STD risk reduction interventions for heterosexually active men: results from a randomized test of concept. *International Journal of STD & AIDS 10(8):548-53,* 1999.	Incorrect population
Kalichman SC, Rompa D, Coley B. Experimental component analysis of a behavioral HIV-AIDS prevention intervention for inner-city women. *Journal of Consulting & Clinical Psychology 64(4):687-93,* 1996.	Comparative effectiveness study

Appendix C. Excluded studies table

Reference	Reason for exclusion
Kalichman SC, Williams E, Nachimson D. Brief behavioural skills building intervention for female controlled methods of STD-HIV prevention: outcomes of a randomized clinical field trial. *International Journal of STD & AIDS 10(3):174-81,* 1999.	Incorrect population
Kelly JA, McAuliffe TL, Sikkema KJ et al. Reduction in risk behavior among adults with severe mental illness who learned to advocate for HIV prevention. *Psychiatric Services 48(10):1283 -8,* 1997.	Comparative effectiveness study
Kelly JA, Murphy DA, Washington CD et al. The effects of HIV/AIDS intervention groups for high-risk women in urban clinics. *American Journal of Public Health 84(12):1918-22,* 1994.	Does not meet USPSTF quality criteria
Kelly JA, St Lawrence JS, Hood HV et al. Behavioral intervention to reduce AIDS risk activities. *Journal of Consulting & Clinical Psychology 57(1):60-7,* 1989.	Does not report designated outcomes
Kelly JA. Outcomes of hiv prevention interventions integrated in community clinics that serve persons with severe mental illness. *152nd Annual Meeting of the American Psychiatric Association Washington DC, USA 15-20th May,* 1999.	Does not meet USPSTF quality criteria
Kennedy MG, Mizuno Y, Hoffman R et al. The effect of tailoring a model HIV prevention program for local adolescent target audiences. *AIDS Education & Prevention 12(3):225-38,* 2000.	Does not report designated outcomes
Kiene SM, Barta WD. A brief individualized computer-delivered sexual risk reduction intervention increases HIV/AIDS preventive behavior. *Journal of Adolescent Health 39(3):404 -10,* 2006.	Does not report designated outcomes
Kirby D. Six school-based clinics: their reproductive health services and impact on sexual behavior. *Family Planning Perspectives Vol 23, pp 6-16,* 1991.	Study not evaluate bci
Koblin B, Chesney M, Coates T. Effects of a behavioural intervention to reduce acquisition of HIV infection among men who have sex with men: the EXPLORE randomised controlled study. *Lancet* 2004; 364(9428):41-50.	Incorrect setting
Koniak-Griffin D, Stein JA. Predictors of sexual risk behaviors among adolescent mothers in a human immunodeficiency virus prevention program. *Journal of Adolescent Health 38(3):297 e1 -11,* 2006.	Incorrect setting
Kotranski L, Semaan S, Collier K et al. Effectiveness of an HIV risk reduction counseling intervention for out-of-treatment drug users. *AIDS Education & Prevention 10(1):19-33,* 1998.	Comparative effectiveness study
Krauss BJ, Goldsamt L, Bula E et al. Pretest assessment as a component of safer sex intervention: a pilot study of brief one-session interventions for women partners of male injection drug users in New York City. *Journal of Urban Health 77(3):383-95,* 2000.	Does not report designated outcomes
Landis SE, Earp JL, Koch GG. Impact of HIV testing and counseling on subsequent sexual behavior. *AIDS Education & Prevention 4(1):61-70,* 1992.	Excluded study design
Latkin CA, Sherman S, Knowlton A. HIV prevention among drug users: outcome of a network-oriented peer outreach intervention. *Health Psychol* 2003; 22(4):332-339.	Incorrect population
Latkin CA. A personal network approach to AIDS prevention: an experimental peer group intervention for street-injecting drug users: the SAFE study. *NIDA Research Monograph 151:181-95,* 1995.	Incorrect setting
Lederman RP, Mian TS. The parent-adolescent relationship education (PARE) program: a curriculum for prevention of STDs and pregnancy in middle school youth. *Behavioral Medicine 29(1):33-41,* 2003.	Does not report designated outcomes

Appendix C. Excluded studies table

Reference	Reason for exclusion
Lee SK. Limitations of a university AIDS prevention program. *ACHPER Healthy Lifestyles J 41(4):4-8,* 1994.	Incorrect setting
Legardy JK, Macaluso M, Artz L, Brill I. Do participant characteristics influence the effectiveness of behavioral interventions? Promoting condom use to women. *Sexually Transmitted Diseases 32(11):665-71,* 2005.	Does not meet USPSTF quality criteria
Leukefeld C, Roberto H, Hiller M, Webster M, Logan TK, Staton-Tindall M. HIV prevention among high-risk and hard-to-reach rural residents. *Journal of Psychoactive Drugs 35(4):427-34,* 2003;-Dec.	Comparative effectiveness study
Leviton LC, Valdiserri RO, Lyter DW, Callahan CM, Kingsley LA, Huggins J et al. Preventing HIV infection in gay and bisexual men: experimental evaluation of attitude change from two risk reduction interventions. *AIDS Education & Prevention 2(2):95-108,* 1990.	Incorrect population
Li X, Stanton B, Feigelman S. Unprotected sex among African-American adolescents: a three-year study. *J Natl Med Assoc* 2002; 94(9):789-796.	Comparative effectiveness study
Lindenberg CS, Solorzano RM, Bear D et al. Reducing substance use and risky sexual behavior among young, low-income, Mexican-American women: comparison of two interventions. *Applied Nursing Research 15(3):137-48,* 2002.	Comparative effectiveness study
Linn JG, Neff JA, Theriot R et al. Reaching impaired populations with HIV prevention programs: a clinical trial for homeless mentally ill African-American men. *Cellular & Molecular Biology 49(7):1167-75,* 2003.	Comparative effectiveness study
Maher JE, Peterman TA, Osewe PL et al. Evaluation of a community-based organization's intervention to reduce the incidence of sexually transmitted diseases: a randomized, controlled trial. *South Med J* 2003; 96(3):248-253.	Does not meet USPSTF quality criteria
Makulowich GS. Culturally relevant behavioral intervention dramatically reduces STDs. *AIDS Patient Care STDS* 1999; 13(4):251-252.	Excluded study design
Makulowich GS. HIV and STD prevention update. Multisite HIV prevention trial. *AIDS Patient Care & Stds 12(9):725-7,* 1998.	Excluded study design
Margolin A, Beitel M, Schuman-Olivier Z. A controlled study of a spirituality-focused intervention for increasing motivation for HIV prevention among drug users. *AIDS Education & Prevention 18(4):311 -22,* 2006.	Does not report designated outcomes
Margolis HS, Handsfield HH, Jacobs RJ et al. Evaluation of office-based intervention to improve prevention counseling for patients at risk for sexually acquired hepatitis B virus infection. Hepatitis B-WARE Study Group. *American Journal of Obstetrics & Gynecology 182(1 Pt 1):1-6,* 2000.	Does not report designated outcomes
Marsch LA, Bickel WK. Efficacy of computer-based HIV/AIDS education for injection drug users. *American Journal of Health Behavior 28(4):316-27,* 2004;-Aug.	Incorrect setting
Martin SS, O'Connell DJ, Inciardi JA et al. HIV/AIDS among probationers: an assessment of risk and results from a brief intervention. *Journal of Psychoactive Drugs 35(4):435-43,* 2003;-Dec.	Comparative effectiveness study
McCoy CB, Chitwood DD, Khoury EL et al. The implementation of an experimental research design in the evaluation of an intervention to prevent AIDS among IV drug users. *Journal of Drug Issues Vol 20(2) Spr 1990, 215-222 http://www2 criminology fsu edu/~jdi/* 1990.	Comparative effectiveness study

Appendix C. Excluded studies table

Reference	Reason for exclusion
McCoy HV, Dodds SE, Nolan C. AIDS intervention design for program evaluation: The Miami Community Outreach Project. *Journal of Drug Issues Vol 20(2) Spr 1990, 223-243 http://www2 criminology fsu edu/~jdi/* 1990.	Comparative effectiveness study
McCoy HV, McCoy CB, Lai S. Effectiveness of HIV interventions among women drug uSERs. *Women & Health 27(1-2):49-66,* 1998.	Comparative effectiveness study
McKay A. Evaluation of a cognitive-behavioral, group, randomized controlled intervention trial to prevent sexually transmitted infections and unintended pregnancies in young women. Preventive Medicine 40, 420-431. *Canadian Journal of Human Sexuality 13(2):124-125,* 2004.	Excluded study design
Metcalf CA, Douglas JM, Jr., Malotte CK et al. Relative efficacy of prevention counseling with rapid and standard HIV testing: a randomized, controlled trial (RESPECT-2). *Sex Transm Dis* 2005; 32(2):130-138.	Comparative effectiveness study
Metzler CW, Biglan A, Noell J et al. A randomized controlled trial of a behavioral intervention to reduce high-risk sexual behavior among adolescents in STD clinics. *Behavior Therapy Vol 31(1) Win 2000, 27-54* 2000.	Does not meet USPSTF quality criteria
Miller B, Norton M, Jenson G et al. Impact Evaluation of Facts & Feelings A Home-based Video Sex Education Curriculum. *Family Relations* 1993;392-400.	Incorrect setting
Miller LC, Murphy ST, Clark LF et al. Hierarchical messages for introducing multiple HIV prevention options: promise and pitfalls. *AIDS Education & Prevention 16(6):509-25,* 2004.	Does not report designated outcomes
Miller RL, Klotz D. HIV prevention with male prostitutes and patrons of hustler bars: replication of an HIV preventive intervention. *American Journal Of Community Psychology 26(1):97-131,* 1998.	Incorrect setting
Morrison-Beedy D, Carey MP, Kowalski J et al. Group-based HIV risk reduction intervention for adolescent girls: evidence of feasibility and efficacy. *Research in Nursing & Health 28(1):3-15,* 2005.	Does not meet USPSTF quality criteria
Neaigus A, Sufian M, Friedman SR et al. Effects of outreach intervention on risk reduction among intravenous drug users. *AIDS Education & Prevention 2(4):253-71,* 1990.	Excluded study design
Nyamathi A, Flaskerud J, Keenan C et al. Effectiveness of a specialized vs. traditional AIDS education program attended by homeless and drug-addicted women alone or with supportive persons. *AIDS Education & Prevention 10(5):433-46,* 1998.	Incorrect setting
Nyamathi AM, Kington RS, Flaskerud J et al. Two-year follow-up of AIDS education programs for impoverished women. *Western Journal of Nursing Research 21(3):405-25,* 1999.	Incorrect population
Oakeshott P, Kerry S, Hay S et al. Condom promotion in women attending inner city general practices for cervical smears: a randomized controlled trial. *Family Practice 17(1):56-9,* 2000.	Does not report designated outcomes
O'Donnell CR, O'Donnell L, San Doval A et al. Reductions in STD infections subsequent to an STD clinic visit. Using video-based patient education to supplement provider interactions. *Sexually Transmitted Diseases 25(3):161-8,* 1998.	Does not meet USPSTF quality criteria
O'Leary A, Ambrose TK, Raffaelli M et al. Effects of an HIV risk reduction project on sexual risk behavior of low-income STD patients. *AIDS Education & Prevention 10(6):483-92,* 1998.	Does not meet USPSTF quality criteria

Appendix C. Excluded studies table

Reference	Reason for exclusion
O'Neill K, Baker A, Cooke M et al. Evaluation of a cognitive-behavioural intervention for pregnant injecting drug users at risk of HIV infection. *Addiction 91(8):1115-25,* 1996.	Incorrect population
Orr DP, Langefeld CD, Katz BP et al. Behavioral intervention to increase condom use among high-risk female adolescents. *J Pediatr* 1996; 128(2):288-295.	Does not meet USPSTF quality criteria
Otto-Salaj LL, Kelly JS, Stevenson Ly et al. Outcomes of a randomized small-group HIV prevention intervention trial for people with serious mental illness. *Community Mental Health Journal 37(2):123-44,* 2001.	Does not meet USPSTF quality criteria
Peragallo N, Deforge B, O'Campo P et al. A randomized clinical trial of an HIV-risk-reduction intervention among low-income Latina women. *Nursing Research 54(2):108-18,* 2005;-Apr.	Does not meet USPSTF quality criteria
Peterman TA, Tian LH, Metcalf CA et al. High incidence of new sexually transmitted infections in the year following a sexually transmitted infection: a case for rescreening. *Annals of Internal Medicine 145 (8):564 -72 ,* 2006.	Study not evaluate bci
Peterson JL, Coates TJ, Catania J et al. Evaluation of an HIV risk reduction intervention among African-American homosexual and bisexual men. *AIDS 10(3):319-25,* 1996.	Incorrect setting
Picciano JF, Roffman RA, Kalichman SC et al. A telephone based brief intervention using motivational enhancement to facilitate HIV risk reduction among MSM: A pilot study. *AIDS and Behavior Vol 5(3) Sep 2001, 251-262* 2001.	Does not report designated outcomes
Ploem C. The effects of two AIDS risk-reduction interventions on heterosexual college women's AIDS-related knowledge, attitudes and condom use. *Journal of Psychology & Human Sexuality 9(1):1-24,* 1997.	Does not report designated outcomes
Porche DJ. Condom effectiveness. *Journal of the Association of Nurses in AIDS Care 9(3):91-4,* 1998;-Jun.	Excluded study design
Read SJ, Miller LC, Appleby PR et al. Socially Optimized Learning in a Virtual Environment: Reducing Risky Sexual Behavior Among Men Who Have Sex With Men. *a* 6 A.D.	Comparative effectiveness study
Reduction of high-risk sexual behaviour among heterosexuals undergoing HIV antibody testing: a randomized clinical trial. *Disease Markers 9(6):354-5,* 1991;-Dec.	Country not applicable to us population
Rickert VI, Gottlieb A, Jay MS. A comparison of three clinic-based AIDS education programs on female adolescents' knowledge, attitudes, and behavior. *Journal of Adolescent Health Care 11(4):298-303,* 1990.	Does not report designated outcomes
Roffman RA, Picciano JE. HIV-prevention group counseling delivered by telephone: an efficacy trial with gay and bisexual men. *AIDS and Behavior 1(2):137-154,* 1997.	Incorrect setting
Ros, Bockting WO, Rugg DL, Robinson BB et al. A randomized controlled intervention trial of a sexual health approach to long-term HIV risk reduction for men who have sex with men: effects of the intervention on unsafe sexual behavior. *AIDS Education & Prevention 14(3 Suppl A):59-71,* 2002.	Incorrect setting
Rotheram-Borus MJ, Gwadz M, Fernandez MI et al. Timing of HIV interventions on reductions in sexual risk among adolescents. *American Journal of Community Psychology 26(1):73-96,* 1998.	Incorrect setting

Appendix C. Excluded studies table

Reference	Reason for exclusion
Rotheram-Borus MJ, Murphy DA, Fernandez MI et al. A brief HIV intervention for adolescents and young adults. - *American Journal of Orthopsychiatry* 1998; 68(4):553-564.	Incorrect setting
Rotheram-Borus MJ, Song J, Gwadz M et al. Reductions in HIV risk among runaway youth. *Prevention Science 4(3):173-87,* 2003.	Incorrect setting
Rotheram-Borus MJ. HIV prevention with persons with mental health problems. *Psychology, Health & Medicine* 11[2], 142-154. 2006.	Comparative effectiveness study
Roye C, Silverman PP, Krauss B. A Brief, Low-Cost, Theory-Based Intervention to Promote Dual Method Use by Black and Latina Female Adolescents: A Randomized Clinical Trial. *Health Educ Behav* 2006; .	Does not report designated outcomes
Russell NK, Boekeloo BO, Rafi IZ et al. Using unannounced simulated patients to evaluate sexual risk assessment and risk reduction skills of practicing physicians. *Academic Medicine 66(9 Suppl):S37-9,* 1991.	Study not evaluate bci
Sanderson CA, Jemmott JBI. Moderation and mediation of HIV-prevention interventions: Relationship status, intentions, and condom use among college students. *Journal of Applied Social Psychology Vol 26(23) Dec 1996, 2076-2099 http://www bellpub com/jasp/index htm* 1996.	Incorrect setting
Schilling RF, El Bassel N, Schinke SP et al. Building skills of recovering women drug users to reduce heterosexual AIDS transmission. *Public Health Reports 106(3):297-304,* 1991;-Jun.	Incorrect population
Schinke SP, Gordon AN, Weston RE. Self-instruction to prevent HIV infection among African-American and Hispanic-American adolescents. *Journal of Consulting & Clinical Psychology 58(4):432-6,* 1990.	Does not report designated outcomes
School-based interventions to prevent unprotected sex and HIV among adolescents. 1994.	Incorrect setting
Schroeder JR, Epstein DH, Umbricht A et al. Changes in HIV risk behaviors among patients receiving combined pharmacological and behavioral interventions for heroin and cocaine dependence. *Addict.Behav.* 31[5], 868-879. 2006.	Incorrect population
Sellers DE, McGraw SA, McKinlay JB. Does the promotion and distribution of condoms increase teen sexual activity? Evidence from an HIV prevention program for Latino youth. *Am J Public Health* 1994; 84(12):1952-1959.	Incorrect setting
Shlay JC, Mayhugh B, Foster M et al. Initiating contraception in sexually transmitted disease clinic setting: a randomized trial. *American Journal of Obstetrics & Gynecology 189(2):473-81,* 2003.	Comparative effectiveness study
Shoptaw S, Frosch D, Rawson RA et al. Cocaine abuse counseling as HIV prevention. *AIDS Education & Prevention 9(6):511-20,* 1997.	Study not evaluate bci
Shrier LA, Ancheta R, Goodman E et al. Randomized controlled trial of a safer sex intervention for high-risk adolescent girls. *Archives of Pediatrics & Adolescent Medicine 155(1):73-9,* 2001.	Incorrect population
Siegel DM, Aten MJ. Early effects of a school-based human immunodeficiency virus infection and sexual risk prevention intervention. *Archives of Pediatrics and Adolescent Medicine Vol 152, pp 961-942,* 1998.	Incorrect setting
Simbayi LC, Kalichman SC, Skinner D et al. Theory-based HIV risk reduction counseling for sexually transmitted infection clinic patients in Cape Town, South Africa. *Sexually Transmitted Diseases 31(12):727-33,* 2004.	Comparative effectiveness study

Appendix C. Excluded studies table

Reference	Reason for exclusion
Slap GB, Plotkin SL, Khalid N et al. A human immunodeficiency virus peer education program for adolescent females. *Journal of Adolescent Health 12(6):434-42,* 1991.	Excluded study design
Smith PB, Weinman ML, Parrilli J. The role of condom motivation education in the reduction of new and reinfection rates of sexually transmitted diseases among inner-city female adolescents. *Patient Education & Counseling 31(1):77-81,* 1997.	Does not report designated outcomes
Social-cognitive theory mediators of behavior change in the National Institute of Mental Health Multisite HIV Prevention Trial. *Health Psychology* 2001;(5):369-376.	Comparative effectiveness study
Solomon B, McGuinn L, Hoerlein M et al. Is human immunodeficiency virus sexual risk prevention intervention effective? *Archives of Pediatrics & Adolescent Medicine 155(10):1127-30,* 2001.	Excluded study design
Soper D, Shoupe D. Prevention of vaginal trichomoniasis by compliant use of the female condom. *Sexually Transmitted Diseases* 1993;(3).	Does not meet USPSTF quality criteria
Sorensen JL, London J, Heitzmann C et al. Psychoeducational group approach: HIV risk reduction in drug users. *AIDS Education & Prevention 6(2):95-112,* 1994.	Incorrect population
St Lawrence JS, Brasfield TL, Jefferson KW et al. Cognitive-behavioral intervention to reduce African American adolescents' risk for HIV infection. *Journal of Consulting & Clinical Psychology 63(2):221-37,* 1995.	Comparative effectiveness study
Stanton B, Fang X, Li X et al. Evolution of risk behaviors over 2 years among a cohort of urban African American adolescents. *Archives of Pediatrics & Adolescent Medicine 151(4):398-406,* 1997.	Incorrect setting
Stanton B, Guo J, Cottrell L et al. The complex business of adapting effective interventions to new populations: an urban to rural transfer. *Journal of Adolescent Health 37(2):163,* 2005.	Incorrect setting
Stanton B, Harris C, Cottrell L et al. Trial of an urban adolescent sexual risk-reduction intervention for rural youth: a promising but imperfect fit. *Journal of Adolescent Health 38(1):55,* 2006.	Incorrect setting
Stanton BF, Li X, Galbraith J et al. Sexually transmitted diseases, human immunodeficiency virus, and pregnancy prevention. Combined contraceptive practices among urban African-American early adolescents. *Archives of Pediatrics & Adolescent Medicine 150(1):17-24,* 1996.	Incorrect setting
Stanton BF, Li X, Ricardo I et al. A randomized, controlled effectiveness trial of an AIDS prevention program for low-income African-American youths. *Archives of Pediatrics & Adolescent Medicine 150(4):363-72,* 1996.	Incorrect setting
Steiner MJ, Hertz-Picciotto I, Taylor D et al. Retrospective vs. prospective coital frequency and menstrual cycle length in a contraceptive effectiveness trial. *Annals of Epidemiology 11(6):428 - 33,* 2001.	Study not evaluate bci
Sterk CE, Theall KP, Elifson KW et al. HIV risk reduction among African-American women who inject drugs: a randomized controlled trial. *AIDS & Behavior 7(1):73-86,* 2003.	Comparative effectiveness study
Sterk CE, Theall KP, Elifson KW. Effectiveness of a risk reduction intervention among African American women who use crack cocaine. *AIDS Education & Prevention 15(1):15-32,* 2003.	Comparative effectiveness study

Appendix C. Excluded studies table

Reference	Reason for exclusion
Stevens SJ, Estrada AL, Estrada BD. HIV sex and drug risk behavior and behavior change in a national sample of injection drug and crack cocaine using women. *Women & Health 27(1-2):25-48,* 1998.	Comparative effectiveness study
St Lawrence JS. Cognitive-behavioral group intervention to assist substance-dependent adolescents in lowering HIV infection risk. *AIDS Education and Prevention Vol 6, pp 425-435,* 1994.	Excluded study design
Susser E V. Human immunodeficiency virus sexual risk reduction in homeless men with mental illness. *Archives of General Psychiatry 55(3):266 -72,* 1998.	Incorrect setting
The NIMH Multisite HIV Prevention Trial: reducing HIV sexual risk behavior. The National Institute of Mental Health (NIMH) Multisite HIV Prevention Trial Group. *Science* 1998; 280(5371):1889-1894.	Comparative effectiveness study
Thompson SC, Kyle D, Swan J et al. Increasing condom use by undermining perceived invulnerability to HIV. *AIDS Education & Prevention 14(6):505-14,* 2002.	Incorrect setting
Towards effective intervention: Evaluating HIV prevention and sexual health education interventions. 1996.	Incorrect setting
Tucker T, Fry CL, Lintzeris N et al. Randomized controlled trial of a brief behavioural intervention for reducing hepatitis C virus risk practices among injecting drug uSERs. *Addiction 99(9):1157-66,* 2004.	Comparative effectiveness study
Turner JC, Korpita E, Mohn LA et al. Reduction in sexual risk behaviors among college students following a comprehensive health education intervention. *Journal of American College Health 41(5):187-93,* 1993.	Incorrect setting
Turner R. HIV counseling, testing do not necessarily change women's sexual behavior. *Family Planning Perspectives Vol 26, pp 282-3,* 1994.	Excluded study design
Valdiserri RO, Lyter DW, Leviton LC et al. AIDS prevention in homosexual and bisexual men: results of a randomized trial evaluating two risk reduction interventions. *AIDS 3(1):21-6,* 1989.	Comparative effectiveness study
Van Devanter N, Gonzales V, Merzel C et al. Effect of an STD/HIV behavioral intervention on women's use of the female condom. *American Journal of Public Health 92(1):109-15,* 2002.	Incorrect setting
Villarruel AM, Jemmott JB III, Jemmott LS. A randomized controlled trial testing an HIV prevention intervention for Latino youth. *Archives of Pediatrics & Adolescent Medicine 160(8):772 -7,* 2006.	Incorrect setting
Wagstaff DA, Delamater JD, Havens KK. Subsequent infection among adolescent African-American males attending a sexually transmitted disease clinic. *Journal of Adolescent Health 25(3):217-26,* 1999.	Excluded study design
Walker Z, Townsend J, Oakley L et al. Health promotion for adolescents in primary care: randomised controlled trial. *BMJ* 2002; 325(7363):524.	Does not report designated outcomes
Warner BD, Leukefeld CG. Assessing the differential impact of an hiv prevention intervention: who's putting the message into practice? *AIDS Education & Prevention 13(6):479-94,* 2001.	Comparative effectiveness study
Wechsberg WM, Lam WK, Zule WA et al. Efficacy of a woman-focused intervention to reduce HIV risk and increase self-sufficiency among African American crack abusers. *American Journal of Public Health 94(7):1165-73,* 2004.	Incorrect setting

Appendix C. Excluded studies table

Reference	Reason for exclusion
Weinhardt LS, Carey MP, Carey KB et al. Increasing assertiveness skills to reduce HIV risk among women living with a severe and persistent mental illness. *Journal of Consulting & Clinical Psychology 66(4):680 -4,* 1998.	Does not meet USPSTF quality criteria
Welsh MJ, Feldblum PJ, Kuyoh MA et al. Condom use during a community intervention trial in Kenya. *International Journal of STD & AIDS 12(7):469-74,* 2001.	Does not report designated outcomes
West SK , Munoz B. Risk factors for constant, severe trachoma among preschool children in Kongwa, Tanzania. *American journal of epidemiology 143(1):73-8,* 1996.	Country not applicable to us population
Williams ML, Bowen AM, Timpson SC et al. HIV prevention and street-based male sex workers: an evaluation of brief interventions. *AIDS Educ Prev* 2006; 18(3):204-215.	Incorrect setting
Witte SS, El-Bassel N, Gilbert L et al. Promoting female condom use to heterosexual couples: findings from a randomized clinical trial. *Perspectives on Sexual & Reproductive Health 38(3):148 -54 ,* 2006.	Comparative effectiveness study
Xu J, Wang J, Zhao N et al. The effectiveness of an intervention program in the promotion of condom use among sexually transmitted disease patients. *Chung-Hua Liu Hsing Ping Hsueh Tsa Chih Chinese Journal of Epidemiology 23(3):218-20,* 2002.	Non-english article
Zimmerman MA, Ramirez-Valles J, Suarez E et al. An HIV/AIDS prevention project for Mexican homosexual men: an empowerment approach. *Health Educ Behav* 1997; 24(2):177-190.	Excluded study design
Zimmers E, Privette G, Lowe RH et al. Increasing use of the female condom through video instruction. *Perceptual & Motor Skills 88(3 Pt 2):1071-7,* 1999.	Does not report designated outcomes

Appendix D: Studies in progress

Study Chair/ Principal Investigators	Title	Setting	Population	Intervention/Control	Outcomes	Status
Patterson, TL	STD Risk Reduction for Heterosexual Methamphetamine Users	Specific setting NR; study conducted in San Diego, CA	Both genders, ages 18 and older, current user of methamphetamine	(1) No maintenance counseling intervention program or (2) maintenance counseling program or (3) diet and exercise attention-control group	Sexual risk behaviors, HIV serostatus, STD infections	Completed
Stark, MJ	Reducing HIV and Domestic Violence Risk in Women Offenders	Specific setting NR; study conducted in Portland, OR	Females, ages 18 and older, who had been in jail or prison in the past year or currently on parole or probation; history of HIV-related behaviors in past year	(1) information on local HIV prevention resources or (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 MI aimed to reduce HIV and domestic violence	Biological testing for HIV and STIs, HIV risk behavior, experineces 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, ages 18-60, 45 days or less post 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 females, ages 18-39	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, ages 15-19	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 months	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 US and PR	Urban STD clinics (New York and San Juan, Puerto Rico)	Both genders, STD+ at basline, ages 18 and older	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, ages 14-20	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 if study includes biological assesment of STIs at follow up (these are noted to be done at baseline)	Currently recruiting

Study Chair/ Principal Investigators	Title	Setting	Population	Intervention/Control	Outcomes	Status
Bull, SS	A Tailored Interactive Website for Promoting Condom Use Among Young Adults	Patients recruited from urban health clinic or Planned Parenthood	Both genders, ages 18-25	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, ages 13-21	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 and older	Brief 23-minute 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 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; males and female, ages 18-44	Computer-delivered individualized intervention vs. HIV information comparison group	Condom use, risk behaviors	No longer recruiting
Jemmott, LS	Effects on Sexual Risk Behavior and STD Rate of Brief HIV/STD Prevention Interventions for African American Women in Primary Care Settings.	Primary care setting	African American females; ages	20-minute one-on-one HIV/STD behavioral skill-building intervention, 200-minute group HIV/STD behavioral skill-building intervention, 20-minute one-on-one HIV/STD information intervention, 200-minute group HIV/STD information intervention, or 200-minute health intervention control group	Risk behaviors, STI reduction	In Press