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Review of Clinical Trials Testing the Effectiveness of Clinician Intervention Approaches to Prevent Sexually Transmitted Diseases in Adolescent Outpatients

Bradley O. Boekeloo, PhD, MS and Melinda A. Griffin, MS

University of Maryland, Department of Public and Community Health, College Park, Maryland 20742, 301-405-8546, FAX: 301-314-6598

Bradley O. Boekeloo: Boekeloo@umd.edu

Abstract

Objective—Identify approaches for improving clinician provision of sexually transmitted diseases (STDs) prevention services among outpatient adolescents.

Methods—Reviewed all peer-reviewed, published clinical trials identified through computerized searches (MEDLINE, PsychINFO) evaluating STD prevention services to outpatient adolescents by clinicians.

Results—Five trials were identified examining changes in clinician provision of STD prevention services. Two of these trials resulted in adolescent self-reported risk reduction but neither of these trials effectively demonstrated reductions in objectively measured STD incidence. Nine clinical trials were identified that compared clinician with non-clinician provision of STD prevention services. Four of these trials resulted in adolescent self-reported risk reduction, and one of these trials demonstrated a reduction in objectively measured STD incidence.

Conclusions—Trials indicate that improvement in outpatient adolescent STD incidence is possible with non-clinicians as interventionists, and perhaps clinicians as interventionists if clinicians are supported by other educational resources. Opportunities for personalized, interactive adolescent education appears key to intervention success. The clinician role that is tested in most trials is confined to a single brief encounter with little attention to: development of clinician skills, quality of psychosexual risk assessment and tailoring to meet individual adolescent need, systems-level resources and supports, the parental role, or the impact of incorporating prevention into an ongoing adolescent-clinician relationship.

Keywords

Adolescents; STD; HIV; prevention; clinicians; clinical trial

Introduction

An estimated nine million cases of sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), occur in persons age 15–24 in the United States each year

accounting for 48% of all new cases[1]. The Centers for Disease Control and Prevention (CDC) reports that STD is 50 to 100 times higher in the US than in other industrialized nations[2]. Human papillomavirus (HPV), trichomoniasis, and chlamydia account for 88% of new STDs among adolescents[1]. Short- and long-term consequences of STDs may include genital and other cancers, pelvic inflammatory disease, ectopic pregnancy, infertility, pre-term births, and low birth weight[3]. It is estimated that the direct medical cost of STDs among 15–24 year olds in the United States; excluding non-medical, indirect, and intangible costs, is \$6.5 billion[4]. HIV and HPV engender the highest direct medical costs among STDs in US youth, accounting for 90% of the total cost burden[4]. Rate of sexual activity is high and rate of condom use is low among US youth; 47% of high school students report having ever had sexual intercourse, 14% report having had more than four sex partners, and of those who are currently sexually active, 62% report using a condom the last time they had sexual intercourse[5].

As adolescents vary in psychosexual development and experience, and prevention counseling should be tailored to individual needs, the psychosexual history is integral to providing preventive services for STDs in clinical care. Clinicians are encouraged by Federal and professional guidelines to conduct thorough psychosexual histories and provide sexuality education, including STD prevention counseling, to adolescents on a regular basis as appropriate to all stages of adolescent development[6–11]. Even effective services for adolescents with STDs is reliant on an adequate sexual history given that many STDs, such as chlamydia, genital herpes, trichomoniasis, and human papillomavirus infections, are often asymptomatic[1].

Unfortunately, several measures suggest that clinicians have not fully adopted sexual assessment and STD prevention guidelines when caring for adolescents. While 72% of Colorado clinicians recently reported regularly taking a sexual history with female adolescents[12], 40% of California clinicians reporting taking a sexual history of all their adolescent patients[13]. A retrospective chart review of newly identified HIV infected adult patients revealed that, of those with a prior medical care encounter, all had chart notation indicating a missed trigger for HIV testing[14]. Nationally, 49% of pediatricians recently reported that they always counsel 13–18 year old adolescents about contraception and STD protection[15]. A recent national survey of high school students indicated 43% of females and 27% of males discussed STDs, HIV or pregnancy prevention in their primary-care visits[16]. Adolescent surveys about the specific topics they discussed in primary-care visits have indicated that when STD prevention is discussed, the discussion often tends to be superficial rather than specific and educational[17,18].

There are both clinician and adolescent barriers to addressing sexual risks in primary care. Clinician lack of STD training and beliefs that they: can effectively prevent STD, are responsible for STD prevention services, can provide routine STD screening that is cost-effective, have clarity regarding adolescent confidentiality, have adequate time and receive adequate reimbursement are all barriers to addressing STD prevention in primary care[12,19,20–23]. Adolescents' lack of psychosocial maturity, confidence in their confidentiality, feelings of self-esteem, perceived susceptibility, familiarity with the clinician, and positive attitudes toward discussing sexuality with the clinician are barriers to

discussing STD prevention with the clinician[18,24]. Different types of interventions have been studied to improve how STDs are addressed in primary care including clinician education and skills training[25,26], structural interventions in the office environment such as clinician prompts[27], interventions that focus on non-clinician channels of adolescent education[28], and priming adolescents to discuss sexual concerns with the clinician[29].

Considering the burden of STDs on adolescents and the health care system, and the limited way that STDs are often being addressed in adolescent primary care, models to improve STD prevention among adolescent patients are needed. This article examines the literature for clinical trials of interventions to improve STD assessment and prevention in outpatient medical settings with adolescents. The goals are to identify outpatient STD interventions that have been tested in clinical trials and published in the peer reviewed literature, examine this literature to elucidate the most promising methods that can be used to improve clinician provision of STD prevention to adolescents in outpatient settings, and identify potential gaps in this literature.

Methods

Controlled clinical trials eliminate many threats to internal validity present in many uncontrolled studies, and thereby, allow inference in regard to whether the observed effects are caused by the intervention [30,31]. A search for peer-reviewed, published clinical trials of interventions to improve outpatient STD (and HIV) sexual risk assessment, education, and risk reduction counseling among adolescents was conducted using the computer search programs MEDLINE and PsychINFO. Computer searches were limited to publications in English involving: clinical trials addressing sexual risk assessment, education, and STD prevention; patient populations under 25 years old, or with an average age no more than 25 years old or including subgroup analyses of patients below 25 years old; outpatient settings in the United States or other highly developed country; and study outcome measurements that could be quantified with the adolescent as the unit of analysis. Searches were not limited as to year of publication and the earliest publication year of identified publications was 1990. Studies involving physicians-in-training were excluded. Key words used in searches included the following sets. Sexual and STD was searched with the words “sex”, “sexual”, “sexuality”, “sexually transmitted disease”, “sexually transmitted infection”, “STI”, “STD”, and “HIV”. Risk assessment and risk reduction was searched with “risk assessment”, “risk reduction”, “sexual history”, “education”, “prevention”, “counseling”, “advice”, “training”, and “intervention”. Outpatient settings were searched with “office”, “clinic”, and “outpatient”. All retrieved abstracts were reviewed and all publications that clearly or possibly met the search limitations were retrieved in full. A final judgment about whether the article met the search criteria was made based on the full publication. The reference lists of retrieved publications were also searched for titles of publications that possibly met the selection criteria and, once retrieved in full, these publications were also reviewed to determine whether they met the selection criteria. Of these articles, articles that involved a clinician (physician, nurse practitioner, physician assistant) as an interventionist either in a control or experimental group were retained for further analysis.

Of the original publications identified using the search techniques, eight were excluded because the study sample did not meet age criteria although it included patients less than 25 years old[32–39], six were excluded because the study did not include a clinician as an interventionist although the sample included adolescent outpatients[40–45], two were excluded because the subjects were inpatients rather than outpatients[46–47], one was excluded because the trial did not involve clinicians and adolescents in a clinical setting[48], two were excluded because the study population was too old and another publication from the same study included a sub-analysis of adolescents less than 25 years old which was included[49,50], one was excluded due to insufficient description of study design to assess computer search criteria[51], and one had comparison groups of patients but patients all received the same STD prevention intervention[52]. The search resulted in 14 publications on 14 different trials that met search criteria, and these publications were then further segmented into two groups. An assessment was made of the 14 publications as to whether the clinical trial involved a clinician as an interventionist in an experimental rather than usual care or control condition, and five trials met this criteria[29,53–56]. The remaining nine outpatient clinical trials tested non-clinician interventions in comparison to some form of clinician standard care, utilizing other staff, the researchers, or educational tools to the exclusion of the clinician in an experimental condition to bring about change measured at the adolescent unit of analysis[28,57–64].

Once grouped, the following aspects of the trials were retrieved: setting and target population, study sample, study design and conditions, intervention characteristics, clinician behavior change or fidelity to the intervention (when clinicians were the experimental interventionists), adolescent outcomes, and authors' observed limitations of the trial. This analysis is presented in the Appendix, Tables 1 and 2.

Results

Trials of interventions to improve clinician provision of STD prevention services with outpatient adolescents

Settings and Study Populations—Five clinical trials were identified that examined the impact of changes in clinician provision of STD prevention services with adolescents in outpatient settings (Appendix Table 1). Outpatient settings of the trials included: Family physician offices[53], health maintenance organization primary care offices[29,56], hospital based adolescent medicine clinic[54], and a university health center[55]. Of note was that no STD clinics were included. The adolescent trial subjects were variable ages with a range across all trials from 12 through 25 years old. Four studies included both males and females[29,53–55] and one included only males[56]. Sample sizes of adolescents ranged from 90 to 1,195. Two study samples of adolescents were majority Black[29,54]. Only two of the studies described characteristics of the clinician study sample[29,53].

Study Methods—All five trials were randomized controlled trials[29,53–56]. Adolescents were randomly assigned to conditions. Follow-up varied from two months[54] to one year[56]. All five trials included some version of a “standard care” condition, which included a one time brief counseling intervention by the clinician, and an experimental

condition. Only one[54] of the total five trials described the content and duration of the usual care control condition. The experimental conditions included: a) brief risk assessment and risk reduction counseling with patient education materials[29,53], b) HIV counseling and testing[54,55], or personal health behavior consultation[56]. Two of the five trials provided a measure of clinician behavior change or fidelity to the intervention[29,53].

Study Outcomes—Four of the total five trials reported adolescent knowledge/attitude outcomes[29,53,55,56]. Two of the four trials reported improvements in knowledge/attitudes in the intervention relative to the control condition[29,56]. One trial reported that both the intervention and control conditions improved knowledge/attitudes resulting in no difference between the conditions[55].

Four of the total five trials included a measure of an adolescent self-reported behavioral outcome[29,53–55]. Two of the four trials reported less risk behavior in the experimental group at follow-up[29,55]. One of the two trials reported improvements in adolescent questioning of partners in the intervention relative to the control condition[55]. One of the two trials indicated increases in adolescent condom use and sexual activity[29]. One trial reported that both the intervention and control conditions improved risk reduction behaviors resulting in no differences between the conditions[54].

Two of the total five trials included a measure of an adolescent self-reported STD outcome[29,54]. One of the two trials reported improvements in STD outcomes in the intervention relative to the control condition[29]. The STD outcome in this one study was adolescent self-reported signs of STD at 9-month follow-up.

Critique of the Trials—Limitations of trials included lack of description regarding: the clinician sample and its external validity[54–56], the standard care condition protocol for contrast with the experimental condition[29,53,55,56], and measures describing clinician adherence to the study protocols to assess fidelity[54–56]. Furthermore, all the trials randomized adolescents to conditions, not clinicians, allowing for the possibility that clinicians carried intervention approaches across conditions. Also, statistical analysis of trials before 1999 ignored the ramifications of non-independence of adolescent subjects due to clustering within physician practice[54–56]. Finally, none of the trials followed self-reported differences in STD prevention with measurements of differences in medical record or laboratory documented STD outcomes. In spite of the limitations, two trials[29,55] reported more adolescent self-reported STD prevention behaviors at follow-up in the intervention condition than the usual care condition. They included interventions with detailed and individualized STD prevention discussion by the clinicians, and opportunity for interactive and participatory educational experiences for the adolescents. The one trial[29] in which experimental group adolescents reported both increased condom use at 3 month follow-up and reduced signs of STD at nine-month follow-up had an experimental intervention that included STD risk self-assessment and interactive education of adolescents via an audio program in preparation for the medical examination immediately followed by clinician counseling cued to adolescent self-reported risks.

Trials comparing clinician to non-clinician provision of STD prevention services in adolescent outpatients

Settings and Study Populations—Nine clinical trials were identified that compared the impact of clinician provision of STD prevention services with non-clinician provision of STD prevention services with adolescents in outpatient settings (Appendix Table 2). Outpatient settings of the trials included: Public STD clinics[28], urban family planning clinics[57], hospital adolescent clinics[58,64], STD clinic[59], medical center STD clinic[61], an adolescent health clinic affiliated with a medical school[62], family health center[63].

The trial adolescent subjects were variable ages with a range across all trials from 13 through 30 years old. Three studies included both males and females[28,60,61], one included only males[59], and five included only females[57,58,62–64]. Sample sizes of adolescents ranged from 75 to 4,328. Six study samples were majority Black[28,35–59,61,62] while two samples were majority White[60,63] and one sample was 47% White and 53% Black[64]. The characteristics of usual care clinicians was not described in any of the trials.

Study Methods—Eight of the nine trials were randomized controlled trials[28,57–62, 64] and one was a non-randomized comparison group trial[63]. In trials with randomization, adolescents were randomly assigned to conditions. Follow-up varied from 1[63] to twelve months[28,57,58,60,61].

All of the nine trials included some version of a “standard care” by the clinician as the control condition although standard care varied across the studies. Standard care across studies included two 10 minute counseling sessions[28,63], single un-timed brief counseling session with the clinician[57–60,62,64], or two 20 minute counseling sessions[61]. The experimental conditions across the studies included: four counseling sessions with a counselor (3 hours 20 minutes)[28], two counseling sessions with a counselor (40 minutes) [28], four group sessions (8 hours)[57], eight group sessions (16 hours)[57], brief health educator counseling (30 minutes)[58], video (14 minutes)[59], brief health educator counseling (14 minutes)[59], five weekly health educator counseling sessions (5–7.5 hours) [60], five group sessions (5 hours)[61], a single group session (30–45 minutes)[62], peer delivered videotape and educational brochures[63], and a single group session with a video (minimum 25 minutes)[64].

Study Outcomes—Six of the total nine trials reported adolescent knowledge/attitude outcomes[58–61,63,64]. Two of the six trials reported improvements in knowledge/attitudes in the intervention relative to the control condition[58,59]. Two trials reported that both the intervention and control conditions improved knowledge/attitudes resulting in no differences between the conditions[63,64].

Seven of the total nine trials included a measure of an adolescent reported behavioral outcome[57–61,63,64] and one trial had a pharmacy confirmed, objective behavioral outcome[64]. Four of the seven trials reported improvements in risk reduction behaviors in the intervention relative to the control condition[57,58,60,64]. Two trials reported that both

the intervention and control conditions improved risk reduction behaviors resulting in no differences between the conditions[59,61].

Four of the total nine trials included a measure of an adolescent STD outcome[28,60–62]. These outcomes included either adolescent self-reported STD[60], a review of medical records for laboratory confirmed episodes of STD[28,62], or a combination of clinical and laboratory findings[61]. One of the four trials reported improvements in STD outcomes in the intervention relative to the control condition[28].

Critique of the Trials—Limitations of trials included the lack of description of the clinician sample that delivered the usual care and its external validity[28,57–64], and measures describing clinician adherence to the study protocols to assess fidelity[54–56]. Also, statistical analysis of all trials ignored the ramifications of non-independence of adolescent subjects due to clustering within physician or clinic. A strength of two trials[61,62], however, was that they followed self-reported STD prevention with measurements of differences in medical record or laboratory documented STD outcomes. Unfortunately, neither of these trials demonstrated differences in STD prevention behaviors and outcomes between conditions. The four trials[57,58,60,64] that reported more adolescent self-reported STD prevention behaviors at follow-up in the experimental condition than the usual care control condition all included detailed STD prevention education and interactive, participatory opportunities for adolescents to formulate a personalized risk reduction plan. The one trial[28] that did not measure behaviors but reported reduced laboratory confirmed STD incidence at follow-up had experimental interventions that included STD risk self-assessment, and interactive education and counseling of adolescents to facilitate commitment to a personalized, realistic risk reduction plan.

Discussion

Do trials show that clinicians can improve their effectiveness in preventing STDs among adolescents? This examination of identified trials evaluating clinician intervention approaches to prevention of STDs in adolescent outpatients provides a summary of research-in-progress rather than a clear answer. The identified trials focus on varied adolescents, in varied settings, with varied approaches to intervention. Most studies have design limitations and fail to provide clear evidence that provision of STD prevention services by clinicians themselves can be improved. Nevertheless, the seven trials[28, 29,55,57,58,60,64] that reported success in reducing outpatient adolescent STD risk-taking share some common elements. Most importantly, they tend to include interactive educational opportunities for adolescents to: assess their own risks, develop personalized, realistic plans for self protection, and address barriers to change. Social Cognitive Theory has been a successful framework in sexual risk reduction interventions among adolescents and it emphasizes personalized, interactive learning activities for skill-building to enhance self-efficacy[65–67]. Typical educational approaches used by busy clinicians in time-restricted visits are limited by the barriers described at the beginning of this report, and may not include interactive opportunities for skill-building. Future research and clinician guideline development should examine realistic clinician roles and responsibilities in adolescent STD

prevention services, and incorporate educational resources that can enhance clinicians' approaches.

In reviewing these trials, difficulties of evaluating clinicians as interventionists are evident. Most of these trials use clinicians in limited patient interactions that require limited amounts of clinician time. In the trials that do attempt to evaluate enhanced clinician effectiveness, the study designs are flawed because patients are randomly assigned to conditions and the same clinicians serve as both control providers as well as experimental intervention providers. Hence, contamination among study conditions is a concern when interpreting the findings. Many studies also try to build on brief clinician interactions with adolescents by using ancillary staff or educational tools to improve STD prevention effectiveness. These studies limit exploration of different possibilities for clinician involvement in STD prevention, and clinician provision of STD prevention services is often set up by design to be less effective than the experimental intervention condition. Although it may be possible in some settings to defer STD prevention to non-clinicians, the primary, and often only, intensively educational interaction that adolescents have in their health care is with their clinician. Furthermore, clinician STD prevention guidelines are written with the clinician as interventionist rather than ancillary staff.

Appreciating the complexity and difficulty of conducting adolescent STD prevention trials in busy outpatient settings, many of these trials have limitations in regard to study design, sample selection, intervention approach, and outcome measurement which the authors themselves articulate. Two of the trials show particularly promising findings, however, in terms of reduction in adolescent STD infection outcomes.

The report by Bolu, Lindsey, Kamb et al. shows that decreased STD infection is possible with adolescent outpatients[28]. Unfortunately, the trial does not demonstrate that clinicians themselves can provide an improved level of STD prevention. The report describes a trial in five public STD clinics with characteristics of a strong study design: randomized controlled trial, large sample size (n=4,328), one year follow-up, and incident STD outcomes determined by objective laboratory testing[28]. Subgroup analysis reveal that adolescents assigned to receive either 40 or 200 minutes of counseling with a trained counselor experience less STD incidence over the one-year follow-up than adolescents that receive 10 minutes of education with the clinician.

The report by Boekeloo, Schamus, Simmens et al. suggests that clinician discussion with adolescents about STD risk can be enhanced to achieve decreased adolescent STD risk[29]. The randomized controlled trial indicates that priming adolescents for their health examination with an audio sexual risk self-assessment and education program, and then providing the self-assessment along with educational brochures to the clinician increases adolescent-clinician STD prevention discussion and subsequently, adolescent condom use and possible STD infection. Unfortunately, the trial relies on adolescent self-reported STD outcomes, and lacks the necessary sample size and power for STD outcome evaluation.

A final trial of note is that reported by Shafer, Tebb, Pantell et al. because it demonstrates a practical intervention to improve clinician group practice, and it provides a model study

design[68]. The study design randomizes pediatric clinics and utilizes objective laboratory determined STD outcomes. The intervention relies on a clinician team-based approach in which barriers are identified, solutions are developed, and progress is monitored for ongoing problem solving. Although it addresses STD testing, this trial design could be used to address STD prevention.

Considering evidence that adolescent outpatient STD prevention is generally at lower levels than is recommended in professional guidelines, trials of models to improve this type of care are warranted. Unfortunately, the trials we identified provide mixed evidence on the success of interventions to improve the effectiveness of brief STD patient education rendered by clinicians themselves in routine medical visits. To improve outpatient STD prevention services to adolescents, clinician intervention and the overall outpatient visit must be enhanced with the support of educational resources. In regard to facilitating clinician intervention, future STD prevention trials in outpatient settings should test: how group practices can use team-oriented continuous quality improvement approaches to improve clinician STD prevention[68], how health care systems can better prepare adolescents and clinicians for the medical encounter[29,69], methods of developing provider psychosexual risk assessment and prevention counseling skills[25], one-on-one clinician counseling and other models of primary care that address precursors common to all unwanted sexual outcomes[70,71], different forms of counseling targeted toward different stages in adolescent psychosexual development and behavioral objectives[72,73], how different language used regarding sexuality is understood and acted upon by adolescents[74], opportunities afforded by repeated contact between clinicians and adolescents as part of an ongoing primary care relationship[75]. In regard to enhancing outpatient visits with other educational resources, future STD prevention trials in outpatient settings should test: new technologies to facilitate clinician STD prevention such as web-based patient assessment and education[76,29], ancillary staff involvement in STD prevention services[28], and how clinicians can use the outpatient visit to facilitate parental monitoring of adolescents to improve STD prevention[77].

There are a number of possible limitations of this literature review. Experts in literature retrieval have documented the limitations of computer literature searches including incomplete search databases, complexity and difficulty of ascertaining the most effective search algorithms, imperfect index terms, and publication bias toward statistically significant findings[78]. Although the authors used multiple peer-reviewed literature search strategies and attempted to exhaust all computer search options, it is possible that relevant trials were not identified. Furthermore, relevant intervention trials may not be published in the peer reviewed literature or indexed by the computer databases that were used, and thus, these trials may not be included in this literature review. The authors only included peer-reviewed, published studies in this literature review. Finally, the authors attempted to extract only information that was available in the publications and made no attempt to clarify information with the publications' authors. Hence, the review is limited to the information that the authors' were able to find in the articles.

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Table 1
Trials of Interventions to Improve Clinician Provision of STD Prevention Services with Adolescent Outpatients

Citation	Setting and Target Population	Study Sample	Study Design and Conditions	Intervention Characteristics	Clinician Behavior Change or Fidelity	Adolescent Outcomes	Authors' Observed Limitations
Proude, D'este, & Ward, 2004 [53]	<i>Setting:</i> Family physician offices <i>Sample Frame:</i> Physicians recruited via ads in professional media. English speaking patients aged 18–25 recruited by receptionists (n=342 eligible). <i>Location:</i> Australia	<i>Number Participants:</i> 23 family physicians 312 patients <i>Participant Characteristics:</i> Physicians: 61% female, 83% Australian trained Patients: 71% female, 70% Australian born, 47% aged 18–21	<i>Design:</i> RCT with 3 month follow-up <i>Conditions:</i> Patients randomized to groups: Control--Usual care with a question about smoking Experimental--Physicians asked patients about STD, pregnancy, & hepatitis B & C risks, advised patients based on their responses and provided resources including condoms & educational pamphlets	<i>Interventionist:</i> Control--Physician Experimental--Physician <i>Format:</i> Control--One on one Experimental--One on one <i>Length:</i> Control--variable Experimental--variable	Physicians indicated 92% experimental & 96% control group compliance with study protocol. At follow up, 58% of the experimental patients recalled receiving the resources at follow up, and 68% of the experimental group recalled receiving advice about safe sex.	<i>Knowledge/Attitudes:</i> Risk perception of HIV, STD, or unwanted pregnancy did not change significantly. <i>Behaviors:</i> No significant differences were observed in the number of new partners and sexual behaviors at follow-up for both groups. <i>STD:</i> Not addressed	Potential limitations included the small sample size of physicians and patients, attrition rate, majority female sample, and use of indirect self-report measures.
Boekeloo, Schamus, Simmens, Cheng, O'Conner, & D'Angelo, 1999[29]	<i>Setting:</i> HMO primary care offices <i>Sample Frame:</i> Consecutive patients 12–15 years old receiving general health exams (n=524 eligible). <i>Location:</i> Washington, DC	<i>Number Participants:</i> 215 adolescents 19 pediatricians <i>Participant Characteristics:</i> Pediatricians: Mean age: 42.5 (range of 31–64), 68.4% White, 68.4% Female Patients: 50% female, 53% 13 yrs., 65% Black	<i>Design:</i> RCT with 3 & 9-month follow-up by phone <i>Conditions:</i> Patients randomized to: Control--Usual general health examination Experimental--Patient received risk assessment and education tools, provider received tools and brochures in bag placed on exam room	<i>Interventionist:</i> Control--Pediatrician Experimental--Researcher then pediatrician <i>Format:</i> Control--One on one Experimental--One on one <i>Length:</i> Control--variable Experimental--14 minute pre-visit audiotape and sexual self-risk assessment and STI/HIV prevention education followed by variable physician counseling.	At exit interview, 92% said doctor reviewed risk assessment, 73% said doctor used educational tools. Of the same adolescents, 75% had condom brochure, 80% had abstinence brochure, and 73% had parent brochures. At exit interview,	<i>Knowledge/Attitudes:</i> Experimental group reported more knowledge and positive attitudes at exit interview. <i>Behaviors:</i> Experimental adolescents were more sexually active and reported more frequent condom use at 3 month follow up. <i>STD:</i> Adolescent-reported signs of STD were lower in experimental group at 9 months.	Potential limitations included limited generalizability due to low participation and the selective sample. Possible intervention contamination between groups of adolescents could have also occurred due to randomization at the patient level only.

Citation	Setting and Target Population	Study Sample	Study Design and Conditions	Intervention Characteristics	Clinician Behavior Change or Fidelity	Adolescent Outcomes	Authors' Observed Limitations
Mansfield, Conroy, Emans, & Woods, 1993[54]	<i>Setting:</i> Hospital-based adolescent clinic <i>Sample Frame:</i> Consecutive adolescents aged 15–19 with an STD (n=97 eligible). <i>Location:</i> Northeastern United States	<i>Number of Participants:</i> 90 adolescents <i>Adolescent Characteristics:</i> 92% female, 81% black, Experimental mean age: 18.1 (SD 2.2 years), Standard care mean age: 17.1 (SD 1.6 years).	<i>Design:</i> RCT with ~ 2 month follow up <i>Conditions:</i> Patients randomized to: Control--Standard care (risk assessment, counseling, HIV pamphlet, & free condoms) Experimental-- Standard care + detailed discussion about HIV perceived susceptibility, risks & prevention, condom efficacy, drug use and an HIV test	<i>Interventionist:</i> Control--Physician Experimental--Physician <i>Format:</i> Control--One on one Experimental--One on one <i>Length:</i> Control--10 minutes Experimental--20 minutes	No data on physician fidelity was reported.	<i>Knowledge/Attitudes:</i> Not addressed. <i>Behaviors:</i> Self-report condom use increased among both groups. Both groups reported decreased sexual activity. <i>STD:</i> No significant differences were reported among groups for newly acquired STD's or HIV testing.	Potential limitations were the reliance on self-report data, the short follow up time frame, the use of telephone follow up protocol, and the limited potential for generalizations due to the select sample.
Wenger, Greenberg, Hilborne, Kusseling, Mangotich, & Shapiro, 1992[55]	<i>Setting:</i> University health center <i>Sample Frame:</i> Consecutive university students at least 18 years of age attending the outpatient clinic for general medical problems (n=2196 eligible). <i>Location:</i> Major American university	<i>Number of Participants:</i> 435 <i>Participant Characteristics:</i> 72% female, 61% white, 78% undergraduate, Mean age: 23 (SD 5 years)	<i>Design:</i> RCT with 6 month follow up <i>Conditions:</i> Patients randomized to: Control--usual care Experimental 1-- educational module only Experimental 2-- educational module and HIV antibody testing	<i>Interventionist:</i> Control--Physicians Experimentals: Physicians <i>Format:</i> Control--One on one Experimentals--Small group sessions <i>Length:</i> Control--Variable Experimentals--1 hour total (video: 11 minutes, lecture: 15 minutes, role-play: 15 minutes, discussion: 15 minutes)	No data on physician fidelity was reported.	<i>Knowledge/Attitudes:</i> HIV knowledge increased in all groups. <i>Behaviors:</i> Those in the education & testing group were more likely than the other 2 groups to ask partners more questions about HIV risk. Those in the education only group were more likely than the control group to ask questions. <i>STD:</i> Not addressed.	Potential limitations included the self-reporting of behaviors, the potential for self-selection bias due to the participants having to volunteer to participate, the nature of HIV antibody testing and difficulties ensuring that students obtain their results.

Citation	Setting and Target Population	Study Sample	Study Design and Conditions	Intervention Characteristics	Clinician Behavior Change or Fidelity	Adolescent Outcomes	Authors' Observed Limitations
Danielson, Marcy, Plunkett, Wiest, & Greenlick, 1990[56]	<p><i>Setting:</i> HMO ambulatory care offices</p> <p><i>Sample Frame:</i> Males aged 15–18 receiving care at the sites in previous 18 months were recruited by telephone (n=2,602 eligibles).</p> <p><i>Location:</i> Portland, OR & Vancouver, WA</p>	<p><i>Number Participants:</i> 1,195</p> <p><i>Adolescent Characteristics:</i> <5% Black, <4% Asian,</p>	<p><i>Design:</i> RCT with 12 month follow up</p> <p><i>Conditions:</i> Patients randomized to: Control--Usual care Experimental--Personal health consultation + slide-tape program.</p>	<p><i>Interventionist:</i> Control--Practitioners (NP, PA, RN) Experimental--Practitioners</p> <p><i>Format:</i> Control: One on one Experimental--One on one</p> <p><i>Length:</i> Control--variable Experimental--1 hour</p>	No data on physician fidelity was reported.	<p><i>Knowledge/Attitudes:</i> Experimental group sustained increased HIV knowledge at 12 months and had more positive attitudes towards birth control pill use at follow up. Experimental group improved sexual patience among inexperienced males.</p> <p><i>Behaviors:</i> Not addressed.</p> <p><i>STD:</i> Not addressed.</p>	The authors did not specifically address potential limitations.

Table 2
Trials Comparing Clinician to Non-Clinician Provision of STD Prevention Services with Adolescent Outpatients

Citation	Setting and Target Population	Study Sample	Study Design and Conditions	Intervention Characteristics	Adolescent Outcomes	Authors' Observed Limitations
Bolt, Lindsay, Kamb, Kentk Zenilman, Douglas, Malotte, Rogers, & Pieterman, 2004[28]	<i>Setting:</i> Public STD clinics <i>Sample Frame:</i> English speakers aged 14 and older who received an STD exam and reported vaginal sex within the past 3 months (n=13,471 eligible). <i>Location:</i> Baltimore, Denver, Long Beach, Newark, & San Francisco	<i>Number Participants:</i> 4,328 <i>Adolescent Characteristics:</i> 56.8% male; 51.6% under age 25; 59.7% African American/Black	<i>Design:</i> RCT with 3, 6, 9, & 12 month follow-up <i>Conditions:</i> Experimental 1--4 sessions counseling aimed at changing attitudes, self-efficacy, norms, and risk reduction behaviors Experimental 2-- sessions of counseling on risk assessment & review of HIV tests. Control--2 sessions of personalized education on HIV/STD, HIV test results (similar to standard care)	<i>Interventionist:</i> Experimental 1-- Counselors Experimental 2-- Counselors Control--Physicians <i>Format:</i> All one-one <i>Total Length:</i> Experimental 1--3 hours & 20 minutes, Experimental 2--40 minutes, and Control--10 minutes.	<i>Knowledge/Attitudes:</i> Not addressed. <i>Behaviors:</i> Not reported. STD: Youth sub-groups of both experimental groups had significantly fewer STD's when compared to the youth sub-group of Controls.	Potential limitations included power calculations based only on total rather than sub-group samples, inadequate reporting of non-participants, and limited generalizability due to specificity of the sample.
Ehrhardt Exner, Hoffman, Silberman, Leu, Miller, & Levin, 2002[57]	<i>Setting:</i> Planned Parenthood Clinic <i>Sample Frame:</i> English speaking females aged 18--30 who reported heterosexual activity within the past year were recruited. <i>Location:</i> Brooklyn, NY	<i>Number Participants:</i> 360 <i>Adolescent Characteristics:</i> 72% African-American/Black, 16.9% Latino, Mean age: 22 years	<i>Design:</i> RCT with 1, 6, & 12 month follow-up <i>Conditions:</i> Experimental 1--Eight informational sessions Experimental 2--Four informational sessions Control--Interview & usual care	<i>Interventionist:</i> Experimental 1-- Researchers Experimental 2-- Researchers Control--Physicians <i>Format:</i> Experimental 1--Group sessions Experimental 2--Group sessions Control--One on one <i>Total Length:</i> Experimental 1--16 hours Experimental 2--8 hours Control--variable	<i>Knowledge/Attitudes:</i> Not addressed. <i>Behaviors:</i> Experimental groups reported fewer sexual encounters & more condom use at 1 month follow up. Experimental groups were also safer at the 6 month follow up. At the 12 month follow up, the 8 session experimental group reported more safe behavior. STD: Not addressed.	Potential limitations included the limited generalizability of the results due to selective sample, and possible self-report and self-selection biases.
Shrier, Andheta, Goodman, Chiou, Lyden, & Emans, 2001[58]	<i>Setting:</i> Urban children's hospital adolescent clinic <i>Sample Frame:</i> Female adolescents below age 24 seeking treatment of cervicitis or pelvic inflammatory disease (n=239 eligible).	<i>Number Participants:</i> 123 <i>Adolescent Characteristics:</i> 49% Black, 18% Hispanic, Median age: 17.2, Range: 13.9--22.0	<i>Design:</i> RCT with 1, 3, 6, & 12 month follow up <i>Conditions:</i> Control--Standard STD education Experimental--Individualized session (STD transmission, condom use, educational materials) + videotape.	<i>Interventionist:</i> Control--Physician educators Experimental--Female health educators <i>Format:</i> All one on one <i>Total Length:</i> Control--variable Experimental--30 minutes	<i>Knowledge/Attitudes:</i> At one month, experimental group had greater STD knowledge. At one and six month follow up, same group had more positive attitudes towards condom use. <i>Behaviors:</i> Experimental group reported less risky sex with non-main partners at 6 month follow up. STD: Not addressed	Potential limitations were the small and selective sample which affected the power and potential ability to generalize the results, and the potential self-selection bias.

Citation	Setting and Target Population	Study Sample	Study Design and Conditions	Intervention Characteristics	Adolescent Outcomes	Authors' Observed Limitations
Delamater, Wagstaff, & Havens, 2000[59]	<i>Location:</i> Boston, MA <i>Setting:</i> STD clinic <i>Sample Frame:</i> African American males ages 15–19 seeking care at the clinic were recruited (n=635 eligibles). <i>Location:</i> Not reported.	<i>Number Participants:</i> 562 <i>Adolescent Characteristics:</i> Male African Americans. Mean age: 18.3 (SD 1.2)	<i>Design:</i> RCT with 1 & 6 month follow up <i>Conditions:</i> Control--Standard care Experimental 1--Videotape Experimental 2--Health educator	<i>Interventionist:</i> Control--Physician Experimental 1--Researcher Experimental 2--Health Educator <i>Format:</i> All one on one <i>Total Length:</i> Control--Variable Experimental 1 & 2--both 14 minutes	<i>Knowledge/Attitudes:</i> Health educator experimental group reported more knowledge, positive attitudes towards condoms, and greater condom use self-efficacy at both follow up periods. <i>Behaviors:</i> All adolescents reported higher frequency of condom use. <i>STD:</i> Not addressed.	Potential limitations included the selective sample, the reduced risk resulting from reduced feelings of vulnerability, and the presentation of condoms as an incentive could have influenced the participants' behaviors resulting in a threat to internal validity.
Metzler, Biglan, Noell, Ary, & Ochs, 2000[60]	<i>Setting:</i> Public STD clinics <i>Sample Frame:</i> Patients aged 15–19 who had engaged in risky sexual encounters within the previous 3 months and were patients of the clinics were recruited. <i>Location:</i> Oregon	<i>Number Participants:</i> 339 <i>Adolescent Characteristics:</i> 68% Female, 68% White, 68% 17 or older, Mean age males: 17.6, Mean age females: 17.0	<i>Design:</i> RCT with 3, 6, & 12 month follow up <i>Conditions:</i> Control--Standard care Experimental--5 weekly 60- to 90-minute sessions focusing on reducing risky sexual behavior, increasing ability to handle social situations, & increasing willingness to succumb to behavior change	<i>Interventionist:</i> Control--Physician counselors <i>Format:</i> All one on one <i>Total Length:</i> Control--variable Experimental--5 to 7.5 hours	<i>Knowledge/Attitudes:</i> No differences. <i>Behaviors:</i> At 3 month follow up, experimental group reported engaging in less sexual encounters. At 6 month follow up, experimental group reported fewer partners, less non-monogamous partners, fewer sexual contacts with strangers, and less use of marijuana before or during sex. <i>STD:</i> No differences reported.	Potential limitations include self-selection bias and selective sample, reliance on self-report behaviors, and questionable validity of the measures. Also, difficulty in data management due to time constraints and attrition at follow up were potential limitations.
Branson, Peterman, Cannon, Ransom, & Zaidi, 1998[61]	<i>Setting:</i> Medical Center STD clinic <i>Sample Frame:</i> Individuals with a new problem and STD reported within the past 5 years (n=1,681 eligibles). <i>Location:</i> Houston	<i>Number Participants:</i> 964 <i>Adolescent Characteristics:</i> 56% male, 90% Black, 47.5% aged 13–24	<i>Design:</i> RCT with 2, 6, 9, & 12 month follow up <i>Conditions:</i> Control--Standard care(2 20 minute sessions) Experimental--Enhanced counseling(4 sessions within 2 weeks, booster after 2 months)	<i>Interventionist:</i> Control--Physicians Experimental--Counselors <i>Format:</i> Control--One on one Experimental--Small groups <i>Total Length:</i> Control--40 minutes Experimental--5 hours	<i>Knowledge/Attitudes:</i> No differences. <i>Behaviors:</i> No differences, all participants reported decreased risky sexual behavior. <i>STD:</i> No differences.	Potential limitations included the inconsistent attendance at all sessions, self-report and social desirability bias.
Smith, Weinman, & Parrilli, 1997[62]	<i>Setting:</i> Teen health clinics affiliated with a medical school <i>Sample Frame:</i> Consecutive female adolescents aged	<i>Number Participants:</i> 205 <i>Adolescent Characteristics:</i> 72.7% Black, 17.6% Hispanic, Mean age: 17.32 (SD 1.55 years)	<i>Design:</i> RCT with 6 month follow up <i>Conditions:</i> Control--Standard care Experimental--Condom motivation education (video, condom use, & Q&A)	<i>Interventionist:</i> Control--Physician Experimental--STD educator <i>Format:</i> Control--One on one Experimental--Small groups (4–8 females) <i>Total Length:</i> Control--Variable Experimental--30–45 minutes (video: 15 minutes)	<i>Knowledge/Attitudes:</i> Not addressed. <i>Behaviors:</i> Not addressed. <i>STD:</i> No differences on the return status and rate of infection among the groups.	Potential limitations included no measure of condom use nor sexual activity during the post-treatment, minimal data collected on other behavioral and psychological aspects.

Citation	Setting and Target Population	Study Sample	Study Design and Conditions	Intervention Characteristics	Adolescent Outcomes	Authors' Observed Limitations
	13–20 with an STD. 13–20 with an STD. <i>Location:</i> Houston					
Quirk, Godkin, & Schwenzfeier, 1993[63]	<i>Setting:</i> Family health center <i>Sample Frame:</i> All scheduled females aged 14–25. <i>Location:</i> Worcester, MA	<i>Number</i> <i>Participants:</i> 214 <i>Adolescent Characteristics:</i> 49% White, 35.5% Latino, 11.7% African American, Mean age: 20.3 years	<i>Design:</i> Comparison group trial with 1 month follow up <i>Conditions:</i> Experimental 1--Peer-delivered intervention: videotape & educational brochures. Experimental 2--Provider-delivered intervention: patient centered counseling.	<i>Interventionist:</i> Experimental 1--Peer educators Experimental 2--Health care providers <i>Format:</i> All one on one reported <i>Total Length:</i> Experimental 1--not reported Experimental 2--no more than 10 minutes.	<i>Knowledge/Attitudes:</i> No differences, both conditions exhibited and sustained improved knowledge and attitudes regarding AIDS. <i>Behaviors:</i> No changes. <i>STD:</i> Not addressed.	Potential limitations included use of a comparison group rather than a true control group, low rate of follow-up, and reliance on self-reported behavior.
Rickert, Gottlieb, & Jay, 1990[64]	<i>Setting:</i> Medical clinics <i>Sample Frame:</i> Adolescent females between ages 13 and 21 (n=82 eligibles). <i>Location:</i> Arkansas Children's Hospital	<i>Number</i> <i>Participants:</i> 75 <i>Adolescent Characteristics:</i> 47% white, 53% black	<i>Design:</i> RCT <i>Conditions:</i> Control--Adolescent questions about AIDS & AIDS brochure, Experimental 1--Lecture following CDC guidelines about HIV/AIDS & questions/answer session, Experimental 2--Education, question/answer session & videotape on condom use	<i>Interventionist:</i> All conditions--Professional staff <i>Format:</i> All conditions included small group education sessions <i>Total Length:</i> Not reported, experimental 2 group included a 25 minute video	<i>Knowledge/Attitudes:</i> Adolescent knowledge increased among both experimental groups compared to the control group. <i>Behaviors:</i> Condom attainment improved significantly among experimental group 2 when compared to the other groups. <i>STD:</i> Not addressed.	Potential limitations included the small sample size and therefore limited generalizability, and lack of a follow-up period.