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HIV Sexual Risk-Reduction Interventions for Youth:

A Review and Methodological Critique of Randomized Controlled Trials

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The authors review and provide a methodological critique of randomized controlled studies of HIV risk reduction interventions that measured sexual risk behavior outcomes with adolescents. Studies conducted in school, community, and health care settings were reviewed. Overall, 13 of 23 interventions (57%) were effective in reducing sexual risk behavior. Methodological strengths of extant studies included an emphasis on a theoretical framework, evaluation of both individualized and group-intervention formats, use of multiple assessments of risk behavior (including biological outcomes), and inclusion of efficacy and effectiveness trials. Methodological limitations included limited evaluation of theoretical mediators of risk reduction, failure to report effect sizes, and lack of sustained findings. Inconsistencies were found in data analytic procedures and reporting, including how nested designs, skewed data, and attrition were addressed. Recommendations for designing methodologically rigorous interventions are provided.

Keywords: *adolescence; HIV; sexual behavior; prevention; randomized controlled trial*

Adolescents have been identified as one of the most vulnerable groups for acquiring human immunodeficiency virus (HIV) and other sexually transmitted diseases (STDs). People younger than the age of

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25 account for one half of new HIV infections (Centers for Disease Control and Prevention [CDC], 1998a), and acquired immunodeficiency syndrome (AIDS) is the ninth leading cause of death in this age group (National Center for Health Statistics, 2000). The highest rates of adolescent AIDS cases are among young men who have sex with men (MSM), minority inner-city youth, and adolescent females (CDC, 1998a, 2000a). Sexual risk behavior, such as sex without a condom, accounts for 72% of HIV infections (CDC, 2000a) and also results in 3 million adolescents becoming infected with STDs each year (CDC, 1998b).

Clearly, adolescents are an appropriate target for HIV prevention efforts. Since the onset of the AIDS epidemic, numerous educational and behavioral interventions have been implemented for youth with varying success in reducing risk. The earliest interventions focused on providing AIDS-related education with the assumption that improving knowledge would lead youth to protect themselves. Numerous studies document that education alone is insufficient to reduce risky sexual behavior (e.g., Kirby, Barth, Leland, & Fetro, 1991). As the theoretical understanding of HIV risk reduction expanded to include behavioral and emotional factors associated with HIV risk, theoretically based interventions incorporated behavioral skills training and strategies to improve attitudes related to HIV prevention. Despite these advances in HIV prevention science, there remain many discrepancies in this literature with respect to intervention outcomes, components of interventions, and methods for evaluating effectiveness in reducing sexual risk behavior.

Inconsistencies in the HIV prevention literature, coupled with alarming rates of HIV/STDs in this population, demonstrate the urgent need to develop empirically validated HIV risk reduction interventions. A literature review of HIV risk reduction interventions can inform the development of future interventions by identifying useful theoretical frameworks, key components of successful interventions, and methodological strengths and weaknesses of extant research. However, there are only a few published reviews of adolescent HIV

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prevention interventions. Furthermore, existing reviews have focused on educational interventions only (Applegate, 1998), interventions evaluated with nonbehavioral outcomes (i.e., attitudes or knowledge of HIV) (Kim, Stanton, Li, Dickersin, & Galbraith, 1997), or interventions restricted to certain settings, such as schools (Kirby et al., 1994). In contrast, the current review focuses on adolescent HIV risk reduction research where investigators measured sexual behavior outcomes using a randomized controlled trial design.

Therefore, the aims of this article are to provide a review and methodological critique of HIV risk reduction interventions for adolescents that employed a randomized, controlled design and measured sexual risk behavior as an outcome variable. This article will provide a review of this literature, including study samples, settings, and findings. The review is followed by a methodological critique that identifies strengths and weaknesses in the published literature across multiple domains, including theoretical application, intervention features and delivery, study design, measurement, and data analysis. This critical review may supplement the outcome evaluations provided by recent meta-analyses of the adolescent HIV risk reduction interventions (Jemmott & Jemmott, 2000; Marsh, Johnson, & Carey, 2003).

METHOD

The sample of studies was generated from (a) computerized literature searches of PsycINFO, AIDSLINE, MEDLINE, and CINAHL, using the keywords and descriptors "HIV," "AIDS," "STD," "prevention," "education," "risk reduction," "intervention," "adolescent(s)," "teen(s)," and "youth"; and (b) reference sections from empirical articles and reviews. To ensure confidence in the conclusions of this review, a priori criteria were established for assessing the internal validity of the individual studies. Only studies that met four inclusion criteria were included.

First, this review was limited to studies that used primarily teenage samples (mean ages ≤ 19 years old or, for studies that did not report the mean age, the age range was within 13 to 19 years). Second, this review included only randomized controlled trials (RCTs), the stron-

gest design for evaluating interventions because it permits the most unbiased comparison of intervention effects, eliminates many potential threats to internal validity present in uncontrolled studies (Campbell & Stanley, 1966), and improves the ability to infer causation to the intervention for effects observed (Mantell, DiVittis, & Auerbach, 1997). Thus, limiting this review to only RCTs improves the level of confidence in the conclusions drawn. Third, the primary outcomes were sexual risk behaviors (e.g., frequency of unprotected sex, condom use). Interventions designed to increase rates of HIV testing were not included unless they also had specific sexual risk reduction outcomes. Finally, only studies published in peer-reviewed journals prior to September 2000 were included.

SAMPLE OF STUDIES

The literature search yielded 97 studies that provide data from an HIV risk reduction intervention. Eighty-eight of 97 studies (91%) met the age criteria for this review. Among these 88 studies, 67 (76%) employed a controlled design. Forty-three of the 67 controlled studies (64%) randomly assigned individuals (or other units of participants) to conditions. Of the 43 RCTs, 22 (51%) measured sexual behavior change. Twenty-two studies met all the inclusion criteria and served as the sample of studies for the present review. These studies are noted in the References section with an asterisk (*).

REVIEW OF HIV RISK REDUCTION RCTs

The 22 studies in this review reflect the broad scope of HIV prevention in terms of the samples chosen, settings used, intervention design and content, and findings. Table 1 provides extensive details regarding the study design, setting, theoretical foundation, sample characteristics, descriptions of the intervention, significant outcomes, and data analysis for all 22 studies. In the sections that follow, study populations, settings, and key findings are described.

(Text continues on page 162)

TABLE 1
HIV Sexual Risk Reduction Interventions With Adolescents: Randomized, Controlled Trials

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
Boekeloo et al. (1999)						
Effectiveness trial <i>Setting:</i> primary care pediatric office <i>Type of control:</i> SCC <i>Intervention condition(s):</i> E: ASSESS HIV/STD prevention program C: usual clinic care <i>Assessments:</i> pre-, postintervention, 3- and 9-mo. F/U <i>Theory:</i> • SCT • TRA	<i>Targeted pop.:</i> young adolescents <i>N</i> = 215 <i>Age M (SD):</i> NR <i>Age range:</i> 12-15 yrs. Female = 50% Black = 65% White = 19% Other = 13% Hispanic = 3%	ASSESS condition <i>Sessions:</i> 1 (length NR) <i>Dose:</i> NR <i>Format:</i> individual <i>Interventionist:</i> pediatrician <i>Intervention techniques:</i> • 14-min audiotaped sexual risk assessment that covered STD/HIV prevention • Discussion about sexual issues • Risk-reduction brochures	Usual care control <i>Sessions:</i> 1 (length NR) <i>Dose:</i> NR <i>Format:</i> individual <i>Interventionist:</i> NA <i>Intervention techniques:</i> • general health assessment only	Youth in the experimental intervention reported • Higher rates of condom use at last intercourse than control participants at 3-mo. (But not 9-mo.) F/U • Fewer possible signs of STDs at 9-mo. F/U than control youth	• <i>Unit of rand.:</i> individual • <i>Attrition rate:</i> 7% at 3 mos., 8% at 9 mos. • 3- and 9-mo. Follow-ups were conducted by phone	• Conducted focus groups with adolescents, parents, and health care providers • Intervention procedures were inconsistent with the theoretical model used (i.e., condom-use skills and self-efficacy were addressed using a brochure rather than with practice and guidance)

(continued)

TABLE 1: (continued)

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
Coyle et al. (1999) Effectiveness trial <i>Setting:</i> public high school <i>Type of control:</i> SCC <i>Intervention condition(s):</i> E: Safer Choices C: Standard knowledge-based HIV curriculum <i>Assessments:</i> baseline, 7-mo. F/U <i>Theory:</i> • SCT • Social influence theory	<i>Targeted pop.:</i> high school youth <i>N</i> = 3,869 <i>Age M (SD):</i> NR <i>Age range:</i> 14-18 yrs. <i>Ethnicity:</i> Female = 53% White = 31% Hispanic = 27% Asian/Pacific Islander = 18% Black = 17% Other = 7%	Safer Choices curriculum <i>Sessions:</i> 10 (length NR) <i>Dose:</i> 8-10 hrs est. <i>Format:</i> group (classroom) <i>Interventionist:</i> teacher and 2 peer leaders <i>Intervention techniques:</i> • Mastery-experiences, role-plays, peer facilitation, homework with parents	Standard HIV curriculum <i>Sessions:</i> NR <i>Dose:</i> NR <i>Format:</i> group (classroom) <i>Interventionist:</i> NR <i>Intervention techniques:</i> NR	<i>Risk reduction outcomes:</i> • Sexually-active students in the Safer Choices condition reported less frequent unprotected intercourse and were more likely to have used condoms at last intercourse than control students	• <i>Unit of rand.:</i> schools • Conducted multilevel analyses to account for clustering of students within schools • <i>Attrition rate:</i> 5% • Reported effect sizes • Very large sample size • Large number of exploratory analyses were run without control for Type I error rate	• Intervention was designed to impact both individual and environmental influences for sexual risk reduction. • Comprehensive intervention that addressed HIV, STD, and pregnancy prevention • No information was provided on the control condition

DeLamater, Wagstaff, & Havens (2000)

<p>Effectiveness trial <i>Setting:</i> STD clinic <i>Type of controls:</i></p> <ul style="list-style-type: none"> • SCC • Comparison intervention (health educator) <p><i>Intervention condition(s):</i> E1: videotape intervention E2: health educator intervention C: standard care condition</p> <p><i>Assessments:</i> pre, post, 1- and 6-mo. F/U</p> <p><i>Theory:</i></p> <ul style="list-style-type: none"> • Self-regulation model • Self-efficacy 	<p><i>Targeted pop.:</i> African American males 15-19 years <i>N</i> = 562 <i>Age M (SD):</i> 18.3 (1.2) <i>Age range:</i> 15-19 yrs. Female = 0% Black = 100%</p>	<p>Videotape <i>Sessions:</i> 1 (14 min) <i>Dose:</i> 0.25 hr <i>Format:</i> video <i>Interventionist:</i> none</p> <p><i>Intervention techniques:</i></p> <ul style="list-style-type: none"> • Video covered perceived risk, motivation, self-efficacy and skills • Health educator <p><i>Sessions:</i> 1 (14 min) <i>Dose:</i> 0.25 hr <i>Format:</i> individual <i>Interventionist:</i> health educator</p> <p><i>Intervention techniques:</i></p> <ul style="list-style-type: none"> • Discussed risk for STDs/HIV • Tailored prevention messages • Skills training 	<p>Standard care <i>Sessions:</i> NA <i>Dose:</i> NA <i>Format:</i> NA <i>Interventionist:</i> health care provider</p> <p><i>Intervention techniques:</i> information only</p>	<ul style="list-style-type: none"> • Number of partners: NS • Frequency of vaginal sex: NS • Condom use: NS 	<p><i>Unit of rand.:</i> individual</p> <ul style="list-style-type: none"> • Thorough assessment of condom use behaviors • <i>Attrition rate:</i> NR • 6-mo. F/U data was only collected for one third of participants 	<ul style="list-style-type: none"> • Conducted formative research at the STD clinic and with African American young males • Video and health educator conditions were time-matched • Intervention format was appropriate for clinic setting
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(continued)

TABLE 1: (continued)

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
Gillmore et al. (1997)—health clinic sample						
Effectiveness trial <i>Setting:</i> public health clinic <i>Type of control:</i> Comparison <i>Intervention condition(s):</i> E1: video + comic book C: comic book <i>Assessments:</i> pre, post (in person), 3- and 6-mo. F/U (by mail) <i>Theory:</i> • SCT • TRA	<i>Targeted pop.:</i> High-risk, sexually active African American and White teens <i>N</i> = 168 <i>Age M (SD):</i> 17.1 (NR) yrs. <i>Age range:</i> 14-19 yrs. Female = 58% White = 54% Black = 46%	Video + comic book condition <i>Sessions:</i> 1 (length NR) <i>Dose:</i> NR <i>Format:</i> individual <i>Interventionist:</i> none; self-instruction <i>Intervention techniques:</i> • Comic book: Addressed HIV/STD info and condom negotiation skills • 27-min video: Peer modeling of condom use skills	Comic book-only condition <i>Sessions:</i> 1 (length NR) <i>Dose:</i> NR <i>Format:</i> individual <i>Interventionist:</i> self-instruction <i>Intervention techniques:</i> • Comic book: Addressed HIV/STD info and condom negotiation skills	• Condom use for intercourse: NS • Number of sexual partners: NS	• <i>Unit of rand.:</i> youth recruited in a given week were assigned randomly to conditions. • <i>Unit of analysis:</i> individual • <i>Attrition rate:</i> 15% at 3 mos.; 18% at 6 mos. • Data collected in person and by mail • Interpretation of the results is limited due to large number of analyses without control for Type I error rate	• Formative research included elicitation surveys and focus groups • Brief, self-instructed intervention

Gillmore et al. (1997)—juvenile detention facility

<p>Effectiveness trial <i>Setting:</i> juvenile detention center <i>Type of control:</i> 2 comparison conditions <i>Intervention condition(s):</i> E1: video + comic book E2: group skills training C: comic book <i>Assessments:</i> baseline, postintervention (in person), 3- and 6-mo. F/U (by mail) <i>Theory:</i> • SCT • TRA</p>	<p><i>Targeted pop.:</i> High-risk, sexually active African American and White teens <i>N</i> = 228 <i>Age M (SD):</i> 15.7 (NR) yrs. <i>Age range:</i> 13-18 yrs. Female = 46% Black = 52% White = 48%</p>	<p>Group skills training condition <i>Sessions:</i> 2 (4 hrs) <i>Dose:</i> 8 hrs <i>Format:</i> group <i>Interventionist:</i> 1 adult facilitator and 2 peer tutors <i>Intervention techniques:</i> • Interactive games • Group discussion • Skills training • Video + comic book</p>	<p>Video + comic book condition <i>Sessions:</i> 1 (NR) <i>Dose:</i> NR <i>Format:</i> individual <i>Interventionist:</i> self-instruction <i>Intervention techniques:</i> • Comic book: 27-min video • Comic book only <i>Sessions:</i> 1 <i>Dose:</i> NR <i>Format:</i> individual <i>Interventionist:</i> self-instruction <i>Intervention techniques:</i> • Comic book</p>	<ul style="list-style-type: none"> • Condom use for intercourse: NS • Number of sexual partners: NS 	<ul style="list-style-type: none"> • <i>Unit of rand.:</i> youth recruited in a given week were randomly assigned to conditions. • <i>Unit of analysis:</i> individual • <i>Attrition rate:</i> 29% at 3 mos.; 24% at 6 mos. • Interpretation of the results is limited due to the large number of analyses conducted without control for Type I error rate • Assessment data collected in person and by mail 	<ul style="list-style-type: none"> • Formative research included elicitation surveys and focus groups • Brief, self-instructed intervention
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(continued)

TABLE 1: (continued)

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
Jemmott, Jemmott, & Fong (1992)						
Efficacy trial <i>Setting:</i> public high school (Sat.) <i>Type of control:</i> APC <i>Intervention condition(s):</i> E: AIDS risk reduction C: career opportunities <i>Assessments:</i> baseline, post, 3-mo. F/U <i>Theory:</i> • TRA	<i>Targeted pop.:</i> Black adolescent males <i>N</i> = 157 <i>Age M (SD):</i> 14.6 (1.7) <i>Age range:</i> NR Female = 0% Black = 100%	AIDS risk reduction intervention <i>Sessions:</i> 1 (5 hrs) <i>Dose:</i> 5 hrs <i>Format:</i> group <i>Interventionist:</i> 1 Black adult facilitator <i>Intervention techniques:</i> • Interactive exercises, videos, and games • Skills training • Role-play	Career opportunities control condition <i>Sessions:</i> 1 (5 hrs) <i>Dose:</i> 5 hrs <i>Format:</i> group <i>Interventionist:</i> 1 Black adult facilitator <i>Intervention techniques:</i> • Interactive exercises, videos, and games	• At 3-mo. F/U, male youth in the AIDS intervention reported having coitus on fewer days, less frequent unprotected coitus and anal sex, fewer sex partners, and fewer nonmonogamous partners than males in the control condition	• <i>Unit of rand.:</i> individual • Did not provide a test of group equivalence after randomization • <i>Attrition rate:</i> 4%	• Assessed the effect of facilitator's gender on outcomes • Control intervention was time- and contact-matched to AIDS intervention • Showed that social desirability did not account for findings • Limited F/U period

Jemmott, Jemmott, & Fong (1998)

<p>Efficacy and effectiveness trial <i>Setting:</i> public middle schools (Sat.) <i>Type of control:</i> APC <i>Intervention condition(s):</i> E1: safer sex HIV intervention E2: abstinence HIV intervention C: health promotion intervention <i>Assessments:</i> baseline, post, 3-mo., 6-mo., 12-mo. F/U <i>Theory:</i></p> <ul style="list-style-type: none"> • SCT • TPB • TRA 	<p><i>Targeted pop.:</i> African American adolescents <i>N</i> = 659 <i>Age M (SD):</i> 11.8 (NR) yrs. <i>Age range:</i> NR Female = 53% Black = 100%</p>	<p>E1: safer sex E2: abstinence <i>Sessions:</i> 2 (4 hrs) <i>Dose:</i> 8 hrs <i>Format:</i> group <i>Interventionist:</i> 1 African American adult male or female facilitator or 2 peer co-facilitators <i>Intervention techniques:</i></p> <ul style="list-style-type: none"> • Group discussions, videos, games, brainstorming, experiential exercises, skill-building activities 	<p>C: Health promotion <i>Sessions:</i> 2 (4 hrs) <i>Dose:</i> 8 hrs <i>Format:</i> group <i>Interventionist:</i> 1 African American adult male or female facilitator or 2 peer co-facilitators <i>Intervention techniques:</i></p> <ul style="list-style-type: none"> • Group discussions, videos, games, brainstorming, experiential exercises, skill-building activities 	<ul style="list-style-type: none"> • E2 youth less likely to have sexual intercourse at 3-mo. F/U • Among sexually experienced youth, at 6 and 12 mos., E1 had less intercourse and unprotected intercourse at 12 mos. than E2 or C • At 3 mos., E1 had more condom use than E2 or C • At all follow-ups, E1 youth reported more condom use than controls • At 12 mos., E1 and E2 youth reported more condom use than controls 	<ul style="list-style-type: none"> • <i>Unit of rand.:</i> individual • Randomly assigned participants to receive adult or peer facilitators • Employed strategies to improve the validity of self-report data • Analyzed data with an intention-to-treat approach • <i>Attrition rate:</i> 3% at 3 mos.; 6% at 6 mos.; 7% at 9 mos. 	<ul style="list-style-type: none"> • First RCT of an abstinence intervention • Long-term F/U • Control intervention was time- and contact-matched to the safer sex and abstinence interventions • Intervention effects did not differ depending on whether intervention groups were led by an adult vs. peer co-facilitators.
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(continued)

TABLE 1: (continued)

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
Jemmott, Jemmott, Fong, & McCaffree (1999)						
Efficacy trial <i>Setting:</i> Public middle schools (Sat.) <i>Type of control:</i> APC <i>Intervention condition(s):</i> E: HIV intervention C: health education <i>Assessments:</i> post, 3- and 6-mo. F/U <i>Theory:</i> • SCT • TPB • TRA	<i>Targeted pop.:</i> African American youth <i>N</i> = 496 <i>Age M (SD):</i> 13.2 (.94) yrs. <i>Age range:</i> NR Female = 54% Black = 100%	E: HIV intervention <i>Sessions:</i> 1 (5 hrs) <i>Dose:</i> 5 hrs <i>Format:</i> group <i>Interventionist:</i> Adult facilitator <i>Intervention techniques:</i> • Group discussions, videos games, experiential exercises, skills-building activities, role-playing	C: Health education <i>Sessions:</i> 1 (5 hrs) <i>Dose:</i> 5 hrs <i>Format:</i> group <i>Interventionist:</i> Adult facilitator <i>Intervention techniques:</i> • Group discussions, videos games, experiential exercises, skills-building activities	• Youth in the HIV intervention had less risk-associated sexual behavior, less unprotected coitus, less frequent anal sex, and anal sex with fewer partners than those in the control condition at 6-mo. F/U; these effects were not present at 3-mo. F/U	• <i>Unit of rand.:</i> individual • Did not provide a test of group equivalence after randomization • <i>Attrition rate:</i> 3% at 3 mos.; 7% at 6 mos. • Procedures were used to improve the validity of self-reported data • Provided evidence of construct validity for theoretical variables	• Control intervention was time- and contact-matched to the HIV intervention • Assessed the impact that facilitator characteristics (gender and ethnicity) and the composition of intervention groups (same vs. mixed sex groups) had an impact on intervention outcomes

Kipke, Boyer, & Hein (1993)

<p>Efficacy trial <i>Setting:</i> community-based agency—after- school program <i>Type of control:</i> WLC <i>Intervention condition(s):</i> E: AIDS Risk Reduction & Skills Training (ARREST) intervention C: Wait-list control <i>Theory:</i> • HBM • SCT</p>	<p><i>Targeted pop.:</i> minority, inner-city youth <i>N</i> = 87 <i>Age M (SD):</i> 13.8 (NR) yrs. <i>Age range:</i> 12-16 yrs. Female = 55% Hispanic = 59% Black = 41%</p>	<p>ARREST intervention <i>Sessions:</i> 3 (1.5 hrs) <i>Dose:</i> 4.5 hrs <i>Format:</i> group <i>Interventionist:</i> 2 adult AIDS educators <i>Intervention techniques:</i> • Group discussion • Instruction • Skills-training • Take-home exercises</p>	<p>Wait-list control <i>Sessions:</i> 0 <i>Dose:</i> NA <i>Format:</i> NA <i>Interventionist:</i> NA <i>Intervention techniques:</i> NA</p>	<ul style="list-style-type: none"> • Number of sexual encounters: NS • Number of sexual partners: NS • Condom use: NS 	<ul style="list-style-type: none"> • <i>Unit of rand.:</i> individual • Did not report attrition rate • Limited power due to small sample size • Large number of statistical tests without control for Type I error for this sample size 	<ul style="list-style-type: none"> • Measured behavioral skills using videotaped role-play assessment of high-risk situations • Short F/U period
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(continued)

TABLE 1: (continued)

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
Kirby, Korpi, Adivi, & Weissman (1997)						
Effectiveness trial <i>Setting:</i> public middle schools <i>Type of control:</i> SCC <i>Intervention condition(s):</i> E: Project SNAPP (Skills and knowledge for AIDS and Pregnancy Prevention) curriculum C: existing curriculum <i>Assessments:</i> baseline, 5- and 17-mo. F/U <i>Theory:</i> • HBM • SCT	<i>Targeted pop.:</i> seventh-graders <i>N</i> = 1,657 <i>Age M (SD):</i> 12.3 (NR) <i>Age range:</i> NR Female = 54% Hispanic = 64% Asian = 13% Black = 9% Other/NR = 9% White = 5%	Intervention curriculum (Project SNAPP) and existing curriculum <i>Sessions:</i> 8 (1-hr) <i>Dose:</i> 8 hrs <i>Format:</i> group (classroom) <i>Interventionist:</i> Peer educators <i>Intervention techniques:</i> • Interactive games • Sexual communication and negotiation skills training • Problem-solving/decision-making activities • Modeling, practice, and feedback • HIV+ youth and teenage mother as speakers	Existing curriculum only (HIV, STD, and pregnancy prevention) <i>Sessions:</i> NR <i>Dose:</i> NR <i>Format:</i> group (classroom) <i>Interventionist:</i> NR <i>Intervention techniques:</i> • Primarily didactic presentations	• Delayed onset of sex: NS • Frequency of intercourse: NS • Number of partners: NS • Use of condoms: NS	• <i>Unit of rand.:</i> classrooms • Unit of analysis was individual; tests were NS • <i>Attrition rates:</i> 7% at 5 mos.; 3% at 17 mos. • Reported control of Type I error • Reported effect sizes	• Conducted extensive formative research • Large sample size • Addressed abstinence and safer sex behaviors • Long-term F/U period • No information was provided on the control condition

Levy et al. (1995)

Effectiveness trial
Setting: public junior high school
Type of control: SCC
Intervention condition(s): E: YAPP (Youth AIDS Prevention Project) curriculum
C: existing AIDS education
Assessments: baseline, 1-year F/U
Theory:
• SCT
• Social influences model

Targeted pop.: African American junior-high-school-age youth
N = 2,392
Age M (SD): NR
Age range: seventh-grade students
Female = 51%
Black = 59%
White = 24%
Hispanic = 13%
Other = 4%

YAPP intervention
Sessions: 10 (1-hr) in seventh grade and 5 (1-hr) booster sessions in eighth grade
Dose: approx. 15 hrs
Format: group (classroom)
Interventionist: health educator
Intervention techniques:
• Decision-making skills
• Sexual resistance and negotiation skills
• Active learning techniques
• Class discussions
• Video presentations
• Group exercises
• Homework assignments

Existing AIDS education
Sessions: NR
Dose: NR
Format: group (classroom)
Interventionist: teacher
Intervention techniques: NR

• At 1-year F/U, students in the treatment condition were more likely to report ever having used condoms with foam than students in the control condition.

• *Unit of rand.:* school districts
• Unit of analysis was individual; did not account for students nested within school districts.
• *Attrition rate:* 30% at 12 mos.
• Psychometric data were not provided for the measures

• Comprehensive program designed to prevent HIV, STDs, and substance abuse
• Included 5 booster sessions 1 year after the intervention
• Assessed sexual behavior change in students who became sexually active during the year of the intervention evaluation
• No information was provided on the control condition

(continued)

TABLE 1: (continued)

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
Mansfield, Conroy, Emans, & Woods (1993)						
Effectiveness trial <i>Setting:</i> hospital-based adolescent clinic <i>Type of control:</i> SCC <i>Intervention condition(s):</i> E: HIV education and counseling C: standard care <i>Assessments:</i> baseline 2-mo. F/U <i>Theory:</i> • NR	<i>Targeted pop.:</i> sexually active high-risk adolescents <i>N</i> = 90 <i>Age M (SD):</i> 17.6 (NR) <i>Age range:</i> NR Female = 92% Black = 81% Hispanic = 8% White = 4% Other = 7%	HIV education and counseling intervention <i>Sessions:</i> 1 (30-min) <i>Dose:</i> 0.5 hrs <i>Format:</i> individual <i>Interventionist:</i> physician <i>Intervention techniques:</i> • Individualized risk assessment • Condom use counseling • Additional HIV prevention counseling with physician (20 min)	Standard care intervention <i>Sessions:</i> 1 (10-min) <i>Dose:</i> 0.17 hrs <i>Format:</i> individual <i>Interventionist:</i> physician <i>Intervention techniques:</i> • Individualized risk assessment • Condom use counseling	• Number of partners: NS • Condom use: NS • Abstinence: NS • Contracted a new STD: NS	• <i>Unit of rand.:</i> individual • <i>Attrition rate:</i> 8% at 2 mos. • Psychometric data not reported for the measures • Pre-, post-, within-group differences were found • F/U assessments were conducted in person and by phone	• Pilot study • Brief, individualized intervention • Appropriate intervention for busy clinic setting • Study lacked a theoretical foundation • Only used a short-term F/U

Metzler, Biglan, Noell, Ary, & Ochs (2000)

<p>Effectiveness trial <i>Setting:</i> public STD clinics <i>Type of control:</i> SCC <i>Intervention condition(s):</i> E: behavioral intervention MAC-Choice (monogamy, abstinence, and condoms) C: usual care <i>Assessments:</i> baseline, 3- and 6-mo. F/U <i>Theory:</i></p> <ul style="list-style-type: none"> • IMB • SCT • Behavioral-ecological model 	<p><i>Targeted pop.:</i> sexually active teens receiving care for STD <i>N</i> = 339 <i>Age M (SD):</i> NR <i>Age range:</i> 15-19 yrs. Female = 68% White = 68% Black = 12% Other = 11% Hispanic = 3% American Indian = 3% Asian = 3%</p>	<p>MAC-Choice intervention <i>Sessions:</i> 5 (1-1.5 hrs) <i>Dose:</i> 5-7.5 hrs <i>Format:</i> Individual <i>Interventionist:</i> behavior change counselor <i>Intervention techniques:</i></p> <ul style="list-style-type: none"> • Risk reduction goal setting • Skills training • Difficulties (emotionally and practically) in implementing risk reduction • Behavioral self-management • Focused on unique risk factors for each participant 	<p>Usual care control <i>Sessions:</i> 1 <i>Dose:</i> NR <i>Format:</i> Individual <i>Interventionist:</i> nurse <i>Intervention techniques:</i></p> <ul style="list-style-type: none"> • Clinic exam • Possible discussion with nurse about risk reduction or provision of pamphlets 	<ul style="list-style-type: none"> • At 6-mo. F/U, intervention youth reported fewer sexual partners, fewer nonmonogamous partners, and fewer sexual contacts with strangers than did control participants. 	<ul style="list-style-type: none"> • <i>Unit of rand.:</i> individual • <i>Attrition rate:</i> 54% at 3 mos.; 53% at 6 mos.; 69% at 12 mos. • 12-mo. F/U data were not analyzed due to large attrition rate • Analyzed data with an intention-to-treat approach • Reported medium effect sizes for the intervention 	<ul style="list-style-type: none"> • Individualized multisession intervention • Intervention addressed affective states associated with sexual risk behavior change • Assessed behavioral skills to refuse unprotected sex and negotiate for safer sex alternatives
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(continued)

TABLE 1: (continued)

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
Orr, Langefeld, Katz, & Caine (1996)						
Effectiveness trial <i>Setting:</i> STD and family planning clinics <i>Type of control:</i> SCC <i>Intervention condition(s):</i> E: behavioral intervention C: standard education control <i>Assessments:</i> baseline and 6-mo. F/U <i>Theory:</i> • HBM	<i>Targeted pop.:</i> sexually active female adolescents <i>N</i> = 209 <i>Age M (SD):</i> 17.9 (1.7) yrs. <i>Age range:</i> 14-19 yrs. Female = 100% Black = 55% Hispanic = NR White = NR Other = NR	Behavioral intervention <i>Sessions:</i> 1 (10-20 min) <i>Dose:</i> 0.25 hrs <i>Format:</i> Individual <i>Interventionist:</i> research assistant <i>Intervention techniques:</i> • STD pamphlet • Behavioral skills training • Modeling, behavioral rehearsal and feedback	Standard education control <i>Sessions:</i> 1 (10-20 min) <i>Dose:</i> 0.25 hrs <i>Format:</i> Individual <i>Interventionist:</i> nurse <i>Intervention techniques:</i> • STD pamphlet • Emphasized condom use for STD/HIV prevention	• The frequency of condom use in the past 6 mos. was greater among youth who received the behavioral intervention than those in the control condition.	• <i>Unit of rand.:</i> clinics • <i>Unit of analysis:</i> individual; used nonparametric tests • <i>Attrition rate:</i> 46% at 6 mos.	• Effective brief, individualized intervention • Appropriate length and format for the a clinic setting • Time matched control condition • Used a biomarker of condom use (tissue culture for C. Trachomatis infection) at F/U

Rotheram-Borus, Gwadz, Fernandez, & Srinivasan (1998)

<p>Efficacy and effectiveness trial <i>Setting:</i> social service agency for youth <i>Type of control:</i> NTC <i>Intervention condition(s):</i> E1: 7-session intervention E2: 3-session intervention C: no treatment <i>Assessments:</i> baseline, 3-mo. F/U <i>Theory:</i></p> <ul style="list-style-type: none"> • SCT 	<p><i>Targeted pop.:</i> high-risk minority youth <i>N</i> = 151 <i>Age M (SD):</i> 18.1 (1.9) <i>Age range:</i> 13-24 yrs. Female = 52% Black = 53% Hispanic = 39% Other = 8%</p>	<p>E1: 7-session HIV prevention intervention <i>Sessions:</i> 7 (1.5 hrs) <i>Dose:</i> 10.5 hrs E2: 3-session HIV prevention intervention <i>Sessions:</i> 3 (3.5-hr) <i>Dose:</i> 10.5 hrs <i>Format:</i> group <i>Interventionist:</i> 2 adult co-facilitators <i>Intervention techniques:</i></p> <ul style="list-style-type: none"> • Goal setting, skills training, and practice • Social and self-rewards for positive changes • Risk-reduction feelings, thoughts, and actions 	<p>No treatment condition <i>Sessions:</i> 0 <i>Dose:</i> NA <i>Format:</i> NA <i>Interventionist:</i> NA <i>Intervention techniques:</i> NA</p>	<ul style="list-style-type: none"> • At 3-mo. F/U, the number of partners was lower for youth who attended the 7-session intervention than youth in the 3-session condition • Youth in E1 reported less unprotected vaginal and anal sex than youths in the E2 or Control conditions. 	<ul style="list-style-type: none"> • <i>Unit of rand.:</i> individual • <i>Attrition rate:</i> 16% at 3 mos. 	<ul style="list-style-type: none"> • Measured condom-application and sexual communication skills with role-plays • Evaluated the timing of interventions and found that multiple sessions spaced over a longer time are associated with greater risk reduction. • Intervention procedures well-tied to SCT
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(continued)

TABLE 1: (continued)

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
Slonim-Nevo, Auslander, Ozawa, & Jung (1996)						
Efficacy and effectiveness trial <i>Setting:</i> residential centers for child welfare agencies <i>Type of control:</i> WLC <i>Intervention condition(s):</i> E1: skills-training E2: discussion-only C: wait-list <i>Assessments:</i> pre, post, and 9-12 month F/U <i>Theory:</i> • Cognitive-behavioral principles	<i>Targeted pop.:</i> delinquent, abused, or neglected youth <i>N</i> = 358 <i>Age M (SD):</i> 14.7 (1.6) yrs. <i>Age range:</i> 12-18 yrs. Female = 44% White = 54% Black = 46%	E1: Skills-training <i>Sessions:</i> 9 (1.5-2 hrs) <i>Dose:</i> 13.5-18 hrs <i>Format:</i> group (same sex and age cohort) <i>Interventionist:</i> 2 adults <i>Intervention techniques:</i> skills-training, modeling, role-plays E2: Discussion-only <i>Sessions:</i> 9 (1.5-2 hrs) <i>Dose:</i> 13.5-18 hrs <i>Format:</i> group (same age and age cohort) <i>Interventionist:</i> 2 adults <i>Intervention techniques:</i> • Group discussion • Problem-solving techniques	Wait-list control <i>Sessions:</i> 0 <i>Dose:</i> NA <i>Format:</i> NA <i>Interventionist:</i> NA <i>Intervention techniques:</i> NA	• Casual sex: NS • Unprotected vaginal sex: NS • Unprotected anal sex: NS	• <i>Unit of rand.:</i> residential center • Did not account for clustering of participants within each residential center. • <i>Attrition rate:</i> 25% at posttest; 39% at 9-12 month F/U • Differential attrition among conditions • Type I error control was not provided	• Long-term F/U • Varied the method of delivery (skills-training vs. group discussion) of an HIV prevention intervention

St. Lawrence, Brasfield, et al. (1995)

<p>Effectiveness trial <i>Setting:</i> publicly funded health center <i>Type of control:</i> APC <i>Intervention condition(s):</i> E: Behavioral Skills Training (BST) "Becoming a Responsible Teen (BART)" C: HIV education <i>Assessments:</i> baseline, 2-, 6-, and 12-mo. F/U <i>Theory:</i></p> <ul style="list-style-type: none"> • IMB • SCT 	<p><i>Targeted pop.:</i> African American adolescents <i>N</i> = 246 <i>Age M (SD):</i> 15.3 (1.4) yrs. <i>Age range:</i> 14-18 yrs. Female = 72% Black = 100%</p>	<p>BST intervention <i>Sessions:</i> 8 (1.5-2 hrs) <i>Dose:</i> 12-16 hrs <i>Format:</i> group <i>Interventionist:</i> 2 adults, male and female <i>Intervention techniques:</i></p> <ul style="list-style-type: none"> • HIV/AIDS education • Problem solving • Self-management • HIV+ youth speaker • Video • Group discussion • BST • Cognitive skills-training 	<p>HIV education intervention <i>Sessions:</i> 1 (2 hrs) <i>Dose:</i> 2 hrs <i>Format:</i> group <i>Interventionist:</i> 2 adults, male and female <i>Intervention techniques:</i></p> <ul style="list-style-type: none"> • HIV/AIDS education • Games • Group discussion • Activities 	<ul style="list-style-type: none"> • BST youth had higher rates of condom use and lower rates of anal sex at all follow-ups and less oral sex than controls at 6- and 12-mo. F/U. • Among sexually active youth, rates of sexual activity (abstinence) were lower among BST youth at 12-mon. F/U. • Among sexually inexperienced youth, more controls initiated sexual activity by 12-mo. F/U than BST youth. 	<p><i>Unit of rand.:</i> individual <i>Attrition rate:</i> 9% at 12 mos. • Examined the moderating effects of gender and prior sexual activity on intervention outcome.</p>	<ul style="list-style-type: none"> • Conducted formative research • Incorporated cognitive skills-training in the intervention • Assessed assertiveness skills with role-play scenarios. • Control condition was not time-matched to the intervention (12-16 hrs vs. 2 hrs) • Long-term F/U
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(continued)

TABLE 1: (continued)

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
St. Lawrence, Crosby, Belcher, Yazdani, & Brasfield (1999)						
Efficacy trial <i>Setting:</i> correctional facility <i>Type of control:</i> APC <i>Intervention conditions:</i> E: skills-training C: anger management <i>Assessments:</i> Pre-, post-intervention, and 6 mos. after release <i>Theory:</i> • IMB • SCT	<i>Targeted pop.:</i> Incarcerated male youths <i>N</i> = 361 <i>Age M (SD):</i> 15.8 (0.7) <i>Age range:</i> NR Female = 0% Black = 70% White = 28% Hispanic = 2% Native American < 1%	E: Sexual risk reduction skills-training <i>Sessions:</i> 6 (1-hr) <i>Dose:</i> 6 hrs <i>Format:</i> group <i>Interventionist:</i> male & female adults <i>Intervention techniques:</i> • Peer modeling using a video • Practice • Skills training	C: Anger management <i>Sessions:</i> 6 (1-hour) <i>Dose:</i> 6 hrs <i>Format:</i> group <i>Interventionist:</i> male & female adults <i>Intervention techniques:</i> • Peer modeling using a video • Practice • Skills training	• Unprotected sex: NS • Condom use: NS • Number of partners: NS • Within-condition findings were significant for both groups on these 3 outcomes.	• <i>Unit of rand:</i> individual • <i>Attrition rate:</i> 3% at posttest; 11% 6 mos. after release from correctional facility	• Technology transfer to the correctional site staff. • Understudied and high-risk group—incarcerated youth • Control group was equally engaging to youth and addressed important skills (anger management) for incarcerated youth

St. Lawrence, Jefferson, Alleyne, & Brasfield (1995)

<p>Effectiveness trial <i>Setting:</i> residential treatment facility for substance-dependent youth <i>Type of control:</i> APC <i>Intervention condition(s):</i> E: behavioral skills training C: HIV education <i>Assessments:</i> baseline and 2-mo. F/U <i>Theory:</i></p> <ul style="list-style-type: none"> • IMB • SCT 	<p><i>Targeted pop.:</i> substance-dependent youths in treatment <i>N</i> = 34 <i>Age M (SD):</i> 15.6 (NR) <i>Age range:</i> 13-17 Female = 26% White = 84% Black = 16%</p>	<p>BST condition <i>Sessions:</i> 6 (1.5 hrs) <i>Dose:</i> 11 hrs <i>Format:</i> group (same-gender) <i>Interventionist:</i> 3 adult group leaders <i>Intervention techniques:</i></p> <ul style="list-style-type: none"> • HIV/AIDS education • Problem solving • Self-management • Video • Group discussion • BST • Cognitive skills-training 	<p>HIV education condition <i>Sessions:</i> 6 (1.5 hrs) <i>Dose:</i> 11 hrs <i>Format:</i> group (same-gender) <i>Interventionist:</i> 3 adult group leaders <i>Intervention techniques:</i></p> <ul style="list-style-type: none"> • HIV/AIDS education • Games • Group discussion • Activities 	<ul style="list-style-type: none"> • At 2-mo. F/U, youth in the BST condition reported less sex with casual or nonmonogamous partners and required less treatment for STDs than youths in the control condition 	<p><i>Unit of rand.:</i> not clearly specified; small groups or individual</p> <ul style="list-style-type: none"> • Small sample size and large number of tests • Did not report control of Type I error rate. • Did not report what sexual behaviors were measured. Only measures with significant findings were provided 	<ul style="list-style-type: none"> • Time- and contact-matched control condition • Pilot study • Corroborated self-reported sexual data with a measure of treatment for STDs • Assessed short-term impact only • Incorporated cognitive skills-training in the intervention
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(continued)

TABLE 1: (continued)

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
Stanton et al. (2000)						
Efficacy trial <i>Setting:</i> public housing development <i>Type of control:</i> APC <i>Intervention condition(s):</i> E: parental monitoring intervention C: goal-setting intervention <i>Assessments:</i> baseline, 2- and 6-mo. F/U <i>Theory:</i> • SCT	<i>Targeted pop.:</i> parents of minority, urban, low-income adolescents <i>N</i> = 237 teen & parent dyads <i>Median age:</i> 13.6 yrs. <i>Age range:</i> 12-16 Female = 49% Black = 100%	Parental monitoring intervention <i>Sessions:</i> 1 (1-1.5 hrs) <i>Dose:</i> 1-1.5 hrs <i>Format:</i> delivered to parent-teen dyad in their home <i>Interventionist:</i> 1 adult <i>Intervention techniques:</i> • 22-min video: ImPACT (Informed Parents and Children Together) video • HIV prevention information, discussion, skills-training, and role-plays (condom use and parent-teen communication)	Goal-setting intervention <i>Sessions:</i> 1 (1-1.5 hrs) <i>Dose:</i> 1-1.5 hrs <i>Format:</i> delivered to parent-teen dyad in their home <i>Interventionist:</i> 1 adult <i>Intervention techniques:</i> • 22-min video that emphasized skills education and career training • Discussion • Exercises for parent only	• Abstinence at 2- and 6-mo. F/U: NS	• <i>Unit of rand.:</i> parent-teen dyad • Unit of analyses were dyad and individual • Only one measure of sexual behavior (abstinence) was provided • <i>Attrition rate:</i> 12% at 2 mos.; 14% at 6 mos.	• Conducted extensive qualitative research with parents, high-risk youth, and parent-teen dyads • Intervention was delivered to parent-teen dyads in their homes • Questionnaires were presented verbally and visually by use of a talking computer • Control condition was time and contact equivalent

Stanton et al. (1996)

Effectiveness trial
Setting: public housing developments
Type of control: APC
Intervention condition(s): E: decision-making AIDS intervention
 C: AIDS prevention intervention
Assessments: baseline, 6- and 12-mos.
Theory:
 • SCT
 • PMT

Targeted pop.: low-income, urban African American early adolescents
N = 383 (76 friendship groups)
Median age: 11.3 yrs.
Age range: 9-15
 Female = 44%
 Black = 100%

Decision-making AIDS prevention intervention
Sessions: 8 (7 1.5 hour sessions and 1 day-long session)
Dose: 18.5 hrs approx.
Format: group; friendship groups attended the intervention together
Interventionist: 2 adults; 1 was gender-matched
Intervention techniques:
 • Videos, games
 • Skills training
 • Group discussions
 • Role-plays, lectures
 • Storytelling

AIDS prevention intervention
Sessions: 8 (7 1.5-hr sessions and 1 daylong session)
Dose: 18.5 hrs approx.
Format: group; not delivered to friendship groups
Interventionist: 2 adults; 1 was gender-matched
Intervention techniques:
 • Videos
 • Group discussion
 • Lecture

• Condom use was greater among intervention youths compared to control youths at 6 mos. but not at 12 mos.

• *Unit of rand.:* groups of same-age and sex friends
 • Units of analyses were friendship groups and individual
 • Analyzed data with an intention-to-treat approach
 • *Attrition rate:* 21% at 6 mos.; 27% at 12 mos.

• Delivered intervention to naturally-formed friendship groups
 • Extensive pilot testing of the intervention
 • Measures were delivered verbally and visually by use of a talking computer
 • Long-term F/U

(continued)

TABLE 1: (continued)

<i>Study Design</i>	<i>Sample Description</i>	<i>Experimental Intervention(s)</i>	<i>Control Intervention(s)</i>	<i>Outcome Measures</i>	<i>Data Analysis</i>	<i>Comments</i>
Walter & Vaughan (1993)						
Efficacy trial <i>Setting:</i> public high schools <i>Type of control:</i> NTC condition(s): E: AIDS-preventive curriculum C: No treatment <i>Assessments:</i> baseline, 3-mo. F/U <i>Theory:</i> • HBM • MSI • SCT	<i>Targeted pop.:</i> urban, minority adolescents <i>N</i> = 1,201 <i>Age M (SD):</i> 15.7 (1.4) yrs. <i>Age range:</i> 12-20 yrs. Female = 58% Black = 37% Hispanic = 35% White & Other = 28%	E: AIDS-preventive curriculum <i>Sessions:</i> 6 (50-min) sessions <i>Dose:</i> approx. 5 hrs <i>Format:</i> group (classroom) <i>Interventionist:</i> teacher <i>Intervention techniques:</i> • Role-play • Rehearsal • Skills-training	C: No treatment <i>Sessions:</i> none <i>Dose:</i> none <i>Format:</i> NA <i>Interventionist:</i> NA <i>Intervention techniques:</i> NA	At 3 mos., youth in the AIDS intervention reported • using condoms on a consistent basis, • having intercourse with only one partner (i.e., practicing monogamy), and • reducing the frequency of intercourse with high-risk partners more than control youth	• <i>Unit of rand.:</i> classroom • <i>Unit of analysis:</i> individual • Did not account for students nested within classrooms due to low power and small classroom number • <i>Attrition rate:</i> 28% at 3 mos. Differential attrition across treatment conditions	• Extensive formative research including a needs assessment of theoretical variables • No information was provided on the control condition

Workman, Robinson, Cotler, & Harper (1996)

<p>Effectiveness trial <i>Setting:</i> Parochial high school <i>Type of control:</i> APC <i>Intervention condition(s):</i> E: HIV prevention C: womanhood intervention <i>Assessments:</i> baseline 1 week post <i>Theory:</i> • SCT</p>	<p><i>Targeted pop.:</i> inner-city minority adolescent females <i>N</i> = 60 <i>Age M (SD):</i> 15 (NR) <i>Age range:</i> 14-17 yrs. Female = 100% Black = 43% Hispanic = 57% White = 0 Other = 0</p>	<p>E: HIV/AIDS prevention intervention <i>Sessions:</i> 12 (30-min) <i>Dose:</i> 6 hrs <i>Format:</i> group <i>Interventionist:</i> college student <i>Intervention techniques:</i> • Group discussions • Didactic info • Skills-training • Modeling, behavioral rehearsal with feedback</p>	<p>C: Womanhood intervention <i>Sessions:</i> 12 (30-min) <i>Dose:</i> 6 hrs <i>Format:</i> group <i>Interventionist:</i> college student <i>Intervention techniques:</i> • Group discussions</p>	<ul style="list-style-type: none"> • Multivariate measure of AIDS preventive behaviors (abstinence, condom use, number of partners, IDU, IDU partners): NS 	<ul style="list-style-type: none"> • <i>Unit of rand.:</i> individual • <i>Attrition rate:</i> 0% at 1-week F/U • Small sample size • Did not test baseline equivalence of conditions • Controlled for Type I error rate 	<ul style="list-style-type: none"> • Only used a 1-week F/U period
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NOTE: Statistically significant outcomes based on differences between intervention conditions are reported. The study by Gillmore et al. (1997) reported on intervention findings with two different samples, resulting in two entries in this table. APC = attention placebo control; C = control condition; DTC = delayed treatment control; E = experimental condition; F/U = follow-up; HBM = health belief model; hr = hour; IMB = information motivation behavior skills model; min = minute; mo. = month; MSI = model of social influence; NA = not applicable; NR = not reported; NS = not significant; NTC = no treatment control; PMT = protection motivation theory; pop. = population; post = postintervention; pre = preintervention/baseline; rand. = randomization; SCC = standard care control; SCT = social cognitive theory; TGP = theory of gender and power; TPB = theory of planned behavior; TRA = theory of reasoned action; yrs. = years.

STUDY POPULATIONS

Sample sizes in the studies ranged from 34 for a pilot study (St. Lawrence, Jefferson, Alleyne, & Brasfield, 1995) to 3,869 for a large-scale, school-based study (Coyle et al., 1999). The median and mean sample size were 326 youths and 549 (*SD* 833) youths, respectively. Only 4 of 23 studies (17%) used a sample of less than 100. Sample characteristics, including the targeted population, are provided in Table 1, column 2.

One approach to HIV prevention is to target adolescent populations that have been identified at high-risk for HIV/STDs, such as inner-city minority youth. Studies that targeted high-risk youth identified high-risk populations based on ethnicity, location, and prior risk behavior. Seven studies were conducted exclusively with African American youth, and another 7 studies had samples of more than 50% African American participants. Given the disproportionate number of African American youth infected with HIV, the finding that 64% of RCTs were conducted primarily with African American youth is, from a public health perspective, quite appropriate. Four studies reported using samples of predominately Hispanic youth, a group also at high risk for HIV. Six studies targeted minority youth who live in inner-city areas (Kipke, Boyer, & Hein, 1993; Rotheram-Borus, Gwadz, Fernandez, & Srinivasan, 1998; Stanton et al., 2000; Stanton et al., 1996; Walter & Vaughan, 1993; Workman, Robinson, Cotler, & Harper, 1996). In sum, 18 studies (82%) were conducted with urban minority youth, a group that has been disproportionately affected by HIV. Other high-risk youth also targeted were youth in treatment for substance dependence (St. Lawrence, Jefferson, et al., 1995), incarcerated youth (Gillmore et al., 1997; St. Lawrence, Crosby, Belcher, Yazdani, & Brasfield, 1999), and youth who were abused or neglected (Slonim-Nevo, Auslander, Ozawa, & Jung, 1996). Three studies targeted youth based on high-risk behavior by conducting studies in STD clinics (DeLamater, Wagstaff, & Havens, 2000; Metzler, Biglan, Noell, Ary, & Ochs, 2000; Orr, Langefeld, Katz, & Caine, 1996) because adolescent patients in STD clinics have been found to have high rates of sexual risk behaviors (e.g., Heffernan, Chiasson, & Sackoff, 1996).

A second, and more general, approach to HIV prevention is to broadly target the adolescent population and thereby include youth with varying degrees of HIV risk. For example, 5 studies targeted adolescents from schools (Coyle et al., 1999; Kirby, Korpi, Adivi, & Weissman, 1997) and primary care settings (Boekeloo et al., 1999; Gillmore et al., 1997; Mansfield, Conroy, Emans, & Woods, 1993). Sexually inexperienced youth are good candidates for HIV prevention because previous research has shown that it is more difficult to achieve behavioral change in teens who have already initiated sex (Kirby et al., 1991). Three RCTs targeted younger adolescents between the ages of 10 and 14 (Jemmott, Jemmott, & Fong, 1998; Kirby et al., 1997; Stanton et al., 1996), and 3 studies had samples of predominately sexually inexperienced youth (Levy et al., 1995; Kirby et al., 1997; Workman et al., 1996).

Thus, a clear strength of this literature is a focus on both general and high-risk adolescent populations. A broad primary prevention approach ensures that youth who are not engaging in high-risk behaviors receive prevention services before they initiate risky sex. An additional benefit is that results are generalizable to the larger adolescent population. In contrast, a targeted approach addresses the most needy groups of youth to make the greatest impact on reducing new cases of HIV (Kalichman, 1998). The cost of this targeted approach is that results only can be generalized to the specific population and the intervention has less "reach."

However, some high-risk groups are not well represented in this literature. Only 1 RCT has been conducted with gay and lesbian teenagers, and it also included young adults (Rotheram-Borus, Murphy, Fernandez, & Srinivasan, 1998). This is a particularly vulnerable population given the recent increase in rates of HIV among young MSM (CDC, 2000b). The lack of studies in this area may reflect the difficulty in identifying sources of gay and lesbian youth and the practical difficulties of conducting a RCT in a rare setting where these youth could be identified (i.e., a gay community center) without contamination between conditions. Youth with mental illness are another vulnerable group for HIV/STDs that have not been targeted for RCT prevention studies despite elevated risk for HIV (Carey, Weinhardt, & Carey, 1995). Prevention efforts are beginning to address HIV positive

(HIV+) populations (Rotheram-Borus et al., 2001) with goals that are consistent with primary HIV prevention (i.e., preventing new HIV infections) and secondary HIV prevention (i.e., reducing further health risks to those already infected).

STUDY SETTINGS

Interventions were conducted in a variety of settings that can be categorized as schools, community sites, and health care settings. In school-based studies, interventions were implemented in high schools (Coyle et al., 1999; Walter & Vaughan, 1993), junior high schools (Kirby et al., 1997; Levy et al., 1995), and a parochial school (Workman et al., 1996). These interventions were implemented as part of the school curricula and were offered to a broad range of students, consistent with a broad primary prevention approach.

The Safer Choices curriculum (Coyle et al., 1999) illustrates how many school-based interventions are implemented and evaluated. In this study, 20 high schools were randomly assigned to receive Safer Choices (the experimental curriculum) or a standard, knowledge-based AIDS curriculum. A unique feature of this intervention was the dual focus on strategies that influenced both individual risk factors (i.e., attitudes, behavioral skills) and social environments (e.g., peer resources). A teacher and two peer leaders delivered the curriculum in regular classrooms over 10 class periods. Consistent with the theoretical framework, mastery experiences, role-plays, peer facilitation, and parent-teen communication were emphasized. Initial findings for 3,677 students at a 7-month follow-up showed that students who received Safer Choices reported less frequent unprotected intercourse and were more likely to have used condoms at last intercourse than students in the control curriculum.

The Safer Choices study highlights several potential advantages of school-based interventions, including access to large numbers of youth (95% of youth are enrolled in school) (National Center for Education Statistics, 1997), which allows for large-scale intervention projects that can potentially influence behavior change at the individual and peer-group level (Kirby et al., 1997) and the ability to examine behavioral change longitudinally. Schools are an ideal setting to reach

sexually inexperienced youth because most teens are enrolled in school before initiating sexual activity (DiClemente, 1993). However, limitations of school-based programs are that measuring sexual behavior is often prohibited by school districts (e.g., DiClemente et al., 1989), and the findings cannot be generalized to out-of-school youth.

Community settings. Concerns have been raised about how to improve access to HIV prevention programs for youth not enrolled in school who often have higher rates of sexual risk behaviors (Walter & Vaughan, 1993). Eleven interventions were conducted in community settings and provided unique access to vulnerable and difficult-to-reach youth. The sites included social service agencies (Rotheram-Borus, Gwadz et al., 1998; Slonim-Nevo et al., 1996), public housing developments (Stanton et al. 1996, 2000), and detention centers (Gillmore et al., 1997; St. Lawrence et al., 1999). These sites provide access to high-risk adolescent populations and use of intervention strategies that are tailored specifically for the needs of that population.

In addition, four RCTs were conducted in after-school settings. They differ from the school-based interventions because they were not implemented as part of the school curriculum or by teachers during regular school hours. Instead, these studies were implemented by research staff after school hours (Jemmott, Jemmott, & Fong, 1992, 1998; Jemmott, Jemmott, Fong, & McCaffree, 1999; Kipke et al., 1993). The studies by Jemmott et al. (1992, 1998, 1999) were conducted with African American youth at schools. Unlike most school-based studies, these HIV risk reduction interventions targeted a population of high-risk teens. The most comprehensive of these studies (Jemmott et al., 1998) was conducted with 659 youth who were randomly assigned to receive an abstinence, safer sex, or health promotion intervention. In this methodologically rigorous study, the interventions were structurally similar in that they were delivered in two 4-hour sessions by an adult facilitator or two peer leaders and included identical activities. The interventions used skills building, group discussions, videos and games, and emphasized personal responsibility. A short-term effect of the abstinence intervention was found at 3-month follow-up. The safer sex intervention demonstrated efficacy in

reducing the frequency of intercourse and unprotected intercourse at 12 months compared to a control condition.

Health care settings. Sexual health settings, such as STD and family planning clinics, are uniquely suited to provide access to high-risk youth. In contrast to schools, where there is a mix of sexually active and inexperienced youth, adolescents who attend sexual health clinics have higher rates of HIV risk behaviors, STDs, and other behaviors associated with risky sex (e.g., alcohol and drug use) (Metzler et al., 2000). Many adolescents who attend public clinics face obstacles to receiving health care and prevention services (e.g., lack of health insurance). Eight (36%) RCTs were conducted in health care facilities, including STD and family planning clinics (DeLamater et al., 2000; Gillmore et al., 1997; Metzler et al., 2000; Orr et al., 1996), a health center (St. Lawrence, Brasfield et al., 1995), hospital (Mansfield et al., 1993), primary care office (Boekeloo et al., 1999), and treatment facility for substance abuse (St. Lawrence, Jefferson, et al., 1995).

For example, Orr et al. (1996) recruited 209 female clients from three STD and family planning clinics, randomly assigning them to either a behavioral intervention or a standard educational intervention. The behavioral intervention was individualized and lasted 10 to 20 minutes; a research assistant provided HIV/STD information and modeled behavioral skills including condom application and negotiation skills. Control patients received STD and condom information. Six months after receiving the brief intervention, adolescents in the behavioral condition reported greater condom use than those in the education-only condition.

Providing prevention services in conjunction with health care means that teens receive interventions when their awareness of the consequences of risky sex is heightened. Also, HIV prevention programs should also reduce rates of recurrent STDs, further reducing the risk of HIV transmission (CDC, 1998b). Disadvantages of implementing interventions in clinic settings are attrition and the limited time available for such interventions.

Thus, a second major strength of the adolescent HIV prevention research literature is that RCTs have been conducted in multiple set-

tings. These interventions have varied in dose, content, how they are implemented, and in outcomes. School-based studies commonly involve large sample sizes, and interventions are delivered in classrooms over multiple sessions. Community-based studies are often targeted to high-risk teens and are implemented in small groups; they occur in a variety of locations ranging from after-school programs to detention centers. Interventions in health care settings are more likely to be brief, single-session interventions. Together, RCTs conducted in school, community, and health care settings provide youth with valuable HIV prevention services that might not otherwise be available to them.

INTERVENTION FINDINGS

Intervention effects in reducing HIV risk were evaluated with one or more sexual risk behaviors, including reduced frequency of penetrative sex or unprotected sex, number of sexual partners, diagnosis of STDs, and increased condom use or abstinence. Among sexually inexperienced youth, delay of onset of sex was also used as an outcome. Table 2 provides a summary of the sexual risk reduction outcomes for each RCT at each assessment period.

The 22 studies evaluated 23 interventions (Gillmore et al., 1997 report findings for two samples). Of the 23 interventions, 13 (57%) achieved significant risk reduction effects. In no case did the experimental intervention do worse than the control intervention. Figure 1 shows the number of studies that measured each outcome variable, as well as the number of studies that reported between-condition effects. Across studies, frequency of unprotected sex was reduced in 75% of studies that measured this outcome. Condom use was improved in 53% of studies that measured this outcome. Number of partners was reduced only in 27% of studies. The lowest rates of behavior change were found for abstinence, which improved in only 14% of studies that measured it. These findings are confirmed by a recent meta-analysis of 21 studies for youth (Jemmott & Jemmott, 2000), which found small effect sizes for each of these outcome variables. Additional outcomes were found in the 23 interventions. Reductions in the frequency of sex were achieved in 5 of 12 studies (42%). The finding

TABLE 2
Sexual Risk Behavior Outcomes of HIV Risk Reduction Interventions for Adolescents (N = 22)

Authors and Year	Sample Size ^a	Intervention Conditions	Assessments	Delay Onset ^b	Abstinence ^c	Sexual Risk Behavior Outcomes									
						Frequency of Sex			Frequency of Unprotected Sex			Condom use	No. of Partners	Risk Index ^e	STD ^f
						Vag. ^d	Oral	Anal	Vag. ^d	Oral	Anal				
School-based interventions															
Coyle et al., 1999	3,869	E v. C	7 mo.	0		0				*		*	0		0
Kirby et al., 1997	1,657	E v. C	5 mo.	0		0						0	0		
			17 mo.	0		0			0	0					
Levy et al., 1995	312 ^g	E v. C	12 mo.			0						*	0		
Walter & Vaughan, 1993	1,201	E v. C	3 mo.		0	*						*		*	0
Workman et al., 1996	111	E v. C	1 wk.												0
Community-based interventions															
Gillmore et al. (1997) ^h	228	E1 ⁱ v. C	3 mo.									0	0		
			6 mo.							0	0				
		E2 v. C	3 mo.							0	0				
			6 mo.							0	0				
		E1 v. E2	3 mo.						0	0					
6 mo.							0	0							

Jemmott et al., 1992	157	E v. C	3 mo.			*	*	*	*			
Jemmott et al., 1998	659	E1 ^j v. C	3 mo.	0	0	0	0	*	*			
			6 mo.	0	0	*	*	*	*			
			12 mo.	0	0	*	*	*	*			
		E2 v. C	3 mo.	*	0	*	0	0	0	0		
			6 mo.	0	0	0	0	0	0	0		
			12 mo.	0	0	0	0	0	*	*		
		E1 v. E2	3 mo.	0	0	0	0	0	*	*		
			6 mo.	0	0	*	0	0	0	0		
			12 mo.	0	0	*	*	*	0	0		
Jemmott et al., 1999	496	E v. C	3 mo.		0		0	0	0	0		
			6 mo.		0		*	*		*	*	
Kipke et al., 1993	87	E v. C	1 mo.			0			0	0		
Rotheram-Borus et al., 1998	151	E1 ^k v. C	3 mo.		0		*	*		0		
			E2 v. C.	3 mo.		0		0	0		0	
			E1 v. E2	3 mo.		0		*	*		*	
Slonim-Nevo et al., 1996	358	E1 ^l v. C	9-12 mo.				0	0		0		
			E2 v. C	9-12 mo.			0	0		0		
			E1 v. E2	9-12 mo.			0	0		0		
St. Lawrence, et al., 1999	361	E v. C	6 mo. ^m							0		
Stanton et al., 2000	237	E v. C	2 mo.		0							
			6 mo.		0							
Stanton et al., 1996	383	E v. C	6 mo.						*			
			12 mo.						0			

(continued)

TABLE 2: (continued)

Authors and Year	Sample Size ^a	Intervention Conditions	Assessments	Delay Onset ^b	Abstinence ^c	Sexual Risk Behavior Outcomes									
						Frequency of Sex			Frequency of Unprotected Sex			Condom use	No. of Partners	Risk Index ^e	STD ^f
						Vag. ^d	Oral	Anal	Vag. ^d	Oral	Anal				
Clinic-based interventions															
Boekeloo et al., 1999	215	E v. C	3 mo.			0	0	0			0	*	0		
			9 mo.			0	0	0			0	0	0	*	
DeLamater et al., 2000	562	E1 ^h v. C	1 mo.			0	0	0				0	0		
			6 mo.			0	0	0			0	0	0		
		E2 v. C	1 mo.			0	0	0			0	0	0		
			6 mo.			0	0	0			0	0	0		
		E1 v. E2	1 mo.			0	0	0			0	0	0		
6 mo.			0	0	0			0	0	0					
Gillmore et al. (1997)	168	E1 ^o v. C	3 mo.								0	0			
			6 mo.							0	0				
Mansfield et al., 1993	90	E v. C	2 mo.		0						0	0		0	
Metzler et al., 2000	339	E v. C	3 mo.			0						0	0		0
			6 mo.			0					0	*	0		0
Orr et al., 1996	209	E v. C	6 mo.								*			0	

Clinic-based interventions

St. Lawrence, Brasfield et al., 1995	246	E v. C	2 mo.	0	0	0	0	*	*	0
			6 mo.	0	0	0	*	*	0	
			12 mo.	*	*	0	*	*	0	
St. Lawrence, Jefferson et al., 1995	34	E v. C	2 mo.		*P				*	

NOTE: Intervention effects are provided for sexual risk behavior outcome variables for between-condition findings (i.e., comparison of experimental and control intervention conditions). Significant effects ($p \leq .05$) are indicated by an asterisk (*) and nonsignificant effects are indicated by 0. C = control intervention condition; E = experimental intervention condition; mo. = month; v. = versus; wk. = week.

- a. Baseline sample size.
- b. Delay onset of sexual activity among sexually inexperienced youth.
- c. Abstinence during the assessment period among youth who were previously sexually active.
- d. Vaginal sex (intercourse).
- e. Multivariate measures of sexual risk.
- f. Diagnosis or treatment for a sexually transmitted disease.
- g. Youth who initiated sexual activity between baseline and 1-year follow-up.
- h. Gillmore et al. (1997) report findings for two samples at different sites. Separate entries are provided for each sample.
- i. E1: Video intervention; E2: Skills-based intervention.
- j. E1: Safer sex intervention; E2: Abstinence intervention.
- k. E1: HIV intervention given over 7 sessions; E2: same HIV intervention given over 3 sessions.
- l. E1: Skills-training intervention; E2: group discussion only intervention.
- m. Six months after release from detention center.
- n. E1: Experimental videotape intervention; E2: Health educator intervention.
- o. E1: Video intervention; E2: Skills-based intervention.
- p. With casual and nonmonogamous partners.

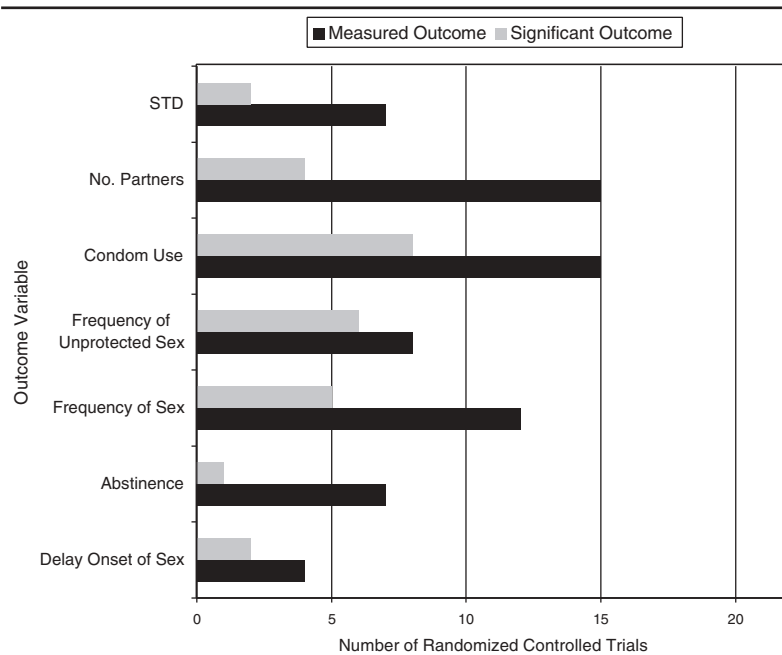


Figure 1. Sexual risk reduction outcome variables measured by 22 randomized, controlled HIV risk reduction interventions with adolescents. The direction of the variables indicates greater HIV risk reduction, such as reduced STDs, sexual partners, frequency of sex or unprotected sex, and greater condom use, abstinence, and delay of onset of sex.

that 29% of the studies that measured STD outcome reported reductions in STDs is important. Delay of sex among sexually inexperienced youth was found in 2 of 4 studies. Reductions in sexual risk (i.e., frequency of unprotected sex, increased condom use) were achieved more often than reductions in sexual activity (i.e., frequency of sex, abstinence).

In summary, many adolescent HIV risk reduction interventions have been effective but are associated with small effect sizes. Characteristics of effective interventions remain unknown. Improved understanding of what factors are associated with effective interventions is most likely to occur if the methodology of research studies is enhanced. Toward the latter goal, we provide a methodological critique of extant research and suggestions for the design of new studies.

CRITIQUE OF THE LITERATURE

To identify the strengths and limitations of this literature, we review six methodological features of the 22 RCTs. These features correspond to the columns of Table 1 and include the use of theory, intervention content and format, measurement, study design, and data analysis.

USE OF THEORY TO GUIDE INTERVENTIONS

The need to base risk reduction interventions on theory is widely acknowledged. In this literature, an explicit theoretical rationale was provided in all but 1 study (see Table 1, column 1). Together, the 22 studies drew from 10 different theories of behavior change, and 68% of studies cited more than one theory. Social cognitive theory (SCT) (Bandura, 1986, 1994) was the most commonly applied theory (18 of 22 studies). Three additional theories were noted as the guiding framework in 4 or more studies: the theory of reasoned action (Fishbein & Ajzen, 1975), health belief model (Rosenstock, Strecher, & Becker, 1994), and the information-motivation-behavioral skills (IMB) model (Fisher & Fisher, 1992). Descriptions of these theories and empirical findings for HIV risk reduction have been well described elsewhere (Fisher & Fisher, 2000). The consistent use of theory is a strength of this literature, and it provides an opportunity to assess how theories were applied to HIV risk reduction interventions.

Several strengths were noted in how theory was used to guide the selection and administration of intervention components. Interventions guided by SCT provided opportunities for skills acquisition by using modeling by peers or leaders, practice, feedback, and guidance. Efforts were also made to provide youth with social reinforcement for behaviors learned in HIV interventions by practicing skills with parents (Stanton et al., 2000), peer reinforcement (e.g., Walter & Vaughan, 1993), and fostering peer groups to support HIV-preventive actions (Coyle et al., 1999). Similarly, interventions guided by the IMB model provided behavioral skills components that addressed interpersonal behaviors for risk reduction (e.g., negotiation of condom use), behavioral self-management techniques (Metzler et al.,

2000), and cognitive strategies for implementing risk-reduction behavior (St. Lawrence, Brasfield et al., 1995).

Although many interventions identify a guiding theory, the process of how theories are used to design and implement interventions is rarely described. One exception is the development of the Safer Choices intervention (Coyle et al., 1999). These authors documented a systematic process of applying social cognitive (Bandura, 1986) and social influence theories (Fisher, 1988) to develop specific intervention components (Coyle et al., 1996). Theoretical determinants of risk behavior were identified for each theory. Intervention strategies with empirical support were then identified for each determinant. Finally, intervention strategies were designed to be consistent with the theoretical method. This process ensured that each intervention component was theoretically based and can serve as a useful heuristic for intervention development.

Despite the wide use of theory, limitations were found in how studies applied theory to interventions, such as the use of intervention techniques that are inconsistent with the theoretical framework. For example, some studies based on SCT provided skills training using a brochure or other passive learning experience (Boekeloo et al., 1999; Gillmore et al., 1997). According to SCT, in order for skills to be learned, individuals must have good models of behavior and the opportunity to practice and refine skills. Similarly, self-efficacy is typically influenced through the acquisition of behavior skills. However, some studies sought to influence self-efficacy through vicarious experiences (e.g., videos) that do not provide opportunities for practice and feedback (DeLamater et al., 2000; Gillmore et al., 1997).

Second, there remain promising theories of behavior change that have not been investigated, such as the transtheoretical model (Prochaska, DiClemente, & Norcross, 1992). This model has been used to reduce sexual risk behavior among adult women (Stark et al., 1998). However, it has not been used for adolescent HIV prevention. Assessment of an individual's stage of change, followed by stage-related intervention activities, may be an appropriate strategy for individualized interventions (Prochaska, Reddings, Harlow, Rossi, & Velicer, 1994), especially with youth who lack motivation to change. Research is needed to evaluate strategies to enhance readiness-to-

change risk behavior, including motivational interviewing (Miller & Rollnick, 1991). There is growing evidence that motivational strategies may augment skills-based interventions (Carey & Lewis, 1999).

Third, although adolescents may have different intervention needs than adults (i.e., greater opportunities for skills practice), theories of health behavior change are not specific to adolescents. Developmental factors, such as the timing of initiation of sexual activity (Zabin & Hayward, 1993) and cognitive development (e.g., Irwin & Millstein, 1992), have been found to influence adolescent sexual risk taking. However, developmental factors are often not included in health behavior theories. Fisher, Williams, Fisher, and Malloy (1999) have suggested that to effectively apply a general theory to a specific population, formative research is required to determine the needs of the population. Only 2 studies described formative research related to theory (Stanton et al., 1996; Walter & Vaughan, 1993). Future studies can better apply theory to intervention design by determining the needs of the population, including developmental factors, prior to implementing the intervention.

A final limitation in the use of theory is that many studies measured only one theoretical mediator of behavior change. Studies that fail to assess mediators immediately postintervention or that only include one potential mediator are unable to document the process of behavior change. Assessing theoretical mediators is difficult because there are few available standardized measures of theoretical constructs, and researchers tend to develop their own measures, which makes comparisons across studies difficult.

In summary, the extant studies emphasized a theoretical framework. Most often, this was SCT combined with another theory. Most interventions included components and techniques that were consistent with their theoretical framework. Coyle et al. (1996) have provided an excellent example of how theory can be used to develop an intervention. Limitations found in the application of theory included the lack of attention to developmental factors in theoretical models and failure to measure theoretical mediators of risk-reduction change. Future interventions can better apply theory by providing a rationale for using a particular theory over another, using a heuristic (e.g., Coyle

et al. 1996), and measuring theoretical variables so that mediational analyses can be conducted.

INTERVENTION FORMAT AND DELIVERY

As shown in Table 1 (columns 3 and 4), there has been considerable variation in the content, format, and delivery of risk reduction interventions. Identifying optimal strategies for implementing interventions and topics covered is essential to designing future interventions. At least three aspects of intervention format and delivery have implications for intervention effectiveness. The first is the group or individual format of sessions. The majority of studies delivered interventions in a small group format (64%), taking advantage of prosocial processes (e.g., reinforcement for changed behaviors, norm change, and vicarious learning experiences).

To capitalize on the peer influences of adolescent friendships, 1 study randomized 383 youth and their naturally formed friendship groups to an HIV-prevention intervention that youth attended with their friends or to a control HIV-prevention condition (Stanton et al., 1996). This group format was used to maximize the positive social influences by addressing social norms. After 6 months, youth who attended the intervention with friends reported higher condom use.

In contrast to a group format, individualized interventions can better personalize risk information to the individual but have not been widely implemented. None of the interventions conducted in community or school settings delivered individualized interventions. However, 6 of the 8 studies conducted in health care settings delivered interventions to individuals (Boekeloo et al., 1999; DeLamater et al., 2000; Gillmore et al., 1997; Mansfield et al., 1993; Metzler et al., 2000; Orr et al., 1996). Among these, 2 were effective in increasing condom use (Boekeloo et al., 1999; Orr et al., 1996) and reducing the number of sexual partners (Metzler et al., 2000).

Individualized interventions are appropriate in clinical settings because they match standard practices and tend to be briefer and more flexible than group interventions. Tailoring an intervention to an individual should be more efficient, private, and perhaps effective. They

should also reduce attrition associated with multiple-session interventions. One study has compared a group intervention to an individualized approach, but neither approach led to risk reduction (Gillmore et al., 1997). More research is needed to compare individual and group approaches and to develop effective brief, single-session, individualized interventions.

Dose and timing. Other potentially important aspects of intervention format include the dose (i.e., hours of contact) and the number and spacing of sessions. Intervention dose varied from 0.25 to 18.5 hours ($M = 7.1$). Community-based interventions had the largest dose ($M = 9.1$ hours), followed closely by school-based ($M = 8.6$ hours) and health-care interventions, which were more brief ($M = 3.8$ hours). Although multisession interventions may be required to change sexual risk behavior in youth (e.g., Kirby et al., 1997), many such interventions have not been successful (e.g., Gillmore et al., 1997). Furthermore, results from a meta-analysis demonstrate that number of sessions and dose are not associated with outcome (Jemmott & Jemmott, 2000).

Brief interventions can reduce the costs and retention difficulties associated with lengthy interventions. Multiple-session interventions require more staff and resources than briefer interventions. This may limit the number of youth who can receive the intervention. They also have the added complication of retaining participants across multiple sessions. Stanton et al. (1996) found that youth who attended more sessions used condoms more at follow-up than did youth who attended fewer sessions. Interventions requiring multiple sessions may limit participation because some youth lack transportation or child care. Brief interventions can provide efficient interventions that are tailored to their specific circumstances. An alternative to providing lengthy interventions is the use of "booster" sessions after the formal intervention is over to prevent a "relapse" to risky behavior (Stanton et al., 1996). Given that many interventions show only short-term effects, booster sessions may provide a means of sustaining intervention effects. Outcomes from the study by Levy et al. (1995) showed that a 10-session intervention followed by 5 booster sessions

improved condom use among junior high students. This approach is promising and may provide a way to access youth over time and across different developmental transitions.

In summary, group interventions have the advantages of fostering social support among members and using peer norms to promote risk reduction. Individual interventions provide a more private alternative well suited to clinic settings, but they have not been widely evaluated. Thus far, interventions with multiple sessions or long doses have been no more successful than those with shorter doses.

MEASUREMENT

A methodological concern in evaluating HIV-prevention interventions is the use of self-report. Given the limitations of self-report data, researchers have suggested strategies to improve the accuracy of these measures (Weinhardt, Forsyth, Carey, Jaworski, & Durant, 1998). One strength of extant studies is their use of such strategies to reduce potential self-report bias. For example, most studies (73%) measured three or more sexual behavior outcomes (see Table 2). Providing multiple assessments of sexual behavior can (a) demonstrate consistency across measures and (b) capture a broader range of sexual risk behavior. Additional strategies to improve the accuracy of self-report data included using code names to emphasize confidentiality and encourage candor (Kipke et al., 1993) and emphasizing the social responsibility of answering honestly so that better HIV programs can be developed (Jemmott et al., 1998). In most studies, assessments were not conducted by the interventionists to reduce bias in providing favorable responses. Some researchers provided evidence that sexual risk behavior data were not correlated with a measure of social desirability (e.g., Jemmott et al., 1998).

Seven investigators used biological outcomes (i.e., STDs) to supplement self-report. Incident STDs provide an imperfect biomarker for condom use (Orr et al., 1996), because self-reported condom use should be associated with fewer STDs. In the 2 studies that reported reductions in STDs, reductions in unprotected sex (St. Lawrence, Jefferson, et al., 1995) and increases in condom use (Orr et al., 1996)

were also reported. The use of biomarkers for sexual activity provides indirect evidence of the accuracy of self-report measures.

With respect to intervention outcomes, the most frequently measured outcomes were number of partners and condom use (15 studies), whereas delay of onset of sex was measured in only 4 studies (see Figure 1). As shown in Table 2, interventions were less effective in promoting abstinence, and relatively few studies measured delay of onset of sexual activity. Empirically validated interventions for sexually inexperienced youth are needed. Another limitation is that some studies assessed condom use at last intercourse rather than during the entire assessment period, which limits the generalizability of this finding. In addition, many studies assessed "intercourse" and failed to specify vaginal, anal, or oral intercourse. Use of "relative frequency" data rather than "absolute frequency," or count data, is encouraged (Schroder, Carey, & Vanable, in press). Last, few studies reported effect sizes or discussed clinically meaningful intervention effects, which we recommend to facilitate comparisons across studies.

ASSESSMENTS

Conclusions about effectiveness vary as a result of when assessments are conducted and the follow-up duration (Kazdin, 1992). Because adolescent sexual behavior is variable and marked by periods of inactivity, the spacing of assessments must afford sufficient time for sexual behaviors to occur. Seven RCTs conducted follow-up assessments only up to 3 months postintervention, and 4 of these were effective (Jemmott et al., 1992; Rotheram-Borus, Gwadz, et al., 1998; St. Lawrence, Jefferson, et al., 1995; Walter & Vaughan, 1993). However, such relatively brief follow-ups test only for immediate intervention impact. Without longer follow-up data, inferences cannot be made about the stability of change over time. Five studies had lengthy follow-up periods of 1 year or longer, and 3 of 5 studies demonstrated effects at 12-month follow-up (Jemmott et al., 1998; Levy et al., 1995; St. Lawrence, Brasfield, et al., 1995). As more effective interventions are identified, an important issue for future studies will be how to sustain intervention effects. A related concern is the use of a single

assessment because, regardless of when it is given, it is likely to miss low frequency sexual behaviors. Ten studies used a single assessment to determine intervention effects. Multiple assessments are more appropriate.

STUDY DESIGN

A selected methodological strength of the studies in this review was the use of a randomized, controlled design. Although RCTs provide a scientifically rigorous method of hypothesis testing, they are often not feasible in settings where it is difficult to control for intervention contamination between conditions (e.g., homeless shelters). Because RCTs require the use of a control condition, they may be inappropriate for hard-to-teach teens who are in need of services, such as runaway youth (Rotheram-Borus, Koopman, Haignere, & Davies, 1991). Given the practical and ethical barriers to employing a RCT, the studies in this review have the advantage of yielding outcomes that are less likely to be influenced by uncontrolled factors than nonrandomized, uncontrolled studies.

Efficacy trials. The use of a RCT study design is associated with two categories of studies: efficacy and effectiveness trials (see Table 1, column 1). The results of an RCT are typically used to determine efficacy: that is, the extent to which an intervention produces a beneficial result under "ideal" experimental conditions in which internal validity is maximized (Nathan, Stuart, & Dolan, 2000). Efficacy studies use no-treatment or wait-list controls or a comparison intervention with different content than the experimental intervention. By testing the intervention in an experimental situation, the sensitivity to detect potential differences between conditions is enhanced, reducing the number of participants needed to detect a treatment effect (Ostrow & Kalichman, 2000).

Among the 23 tests of interventions in the 22 studies, 6 were efficacy trials (Jemmott et al., 1992, 1998; Kipke et al., 1993; St. Lawrence et al., 1999; Stanton et al., 2000; Walter & Vaughan, 1993). Two studies compared an experimental intervention to a no-treatment control condition (Rotheram-Borus, Gwadz, et al., 1998; Walter & Vaughan,

1993), and 2 additional studies used a wait-list control condition (Kipke et al., 1993; Slonim-Nevo et al., 1996). Ethical concerns about excluding control youth were addressed by assigning more participants to the experimental condition (Walter & Vaughan, 1993) or by offering the intervention to control participants after the trial was completed.

With no-treatment or wait-list controls, there is the potential for differential demand characteristics (i.e., participants in experimental condition have more contact with intervention group and leaders). Five studies used a time- and contact-matched control intervention to reduce demand characteristics (Jemmott et al. 1992, 1998, 1999; St. Lawrence et al., 1999; Stanton et al., 2000). For example, Jemmott et al. (1992) compared their risk-reduction intervention to a career opportunities control condition that was identical in dose, format, interventionist characteristics, and intervention techniques. Adolescents found both interventions enjoyable and beneficial. Two studies are noteworthy for their use of a time- and contact-matched comparison condition that was equally relevant to the participants, including a skills-based anger management control for incarcerated male youth (St. Lawrence et al., 1999) and health promotion conditions for African American youth (Jemmott et al., 1998).

Effectiveness trials. A RCT may also be used in effectiveness studies, which addresses whether an intervention demonstrates an effect when implemented in real-world circumstances that maximize external validity and generalizability (Nathan et al., 2000). Control conditions in effectiveness trials are interventions that represent a standard of care or an alternative intervention with similar content. These designs minimize the bias due to demand characteristics as well as differential reactions to treatments of different topics (i.e., more positive reaction to HIV-intervention than to career-planning control). Effectiveness trials require a larger sample size because the differential effect of two HIV prevention interventions is likely to be smaller than that between an active treatment and a no-treatment control (Ostrow & Kalichman, 2000).

The majority of studies (61%) in this review were effectiveness trials. Ideally, effectiveness trials are completed after a successful effi-

cacy study. However, in practice, HIV-prevention interventions are rarely tested in this fashion because of the urgency for prevention programs for youth and the time and resources required to evaluate an intervention's efficacy and effectiveness. In school settings, for example, HIV-prevention programs are often already in place and many are mandatory (e.g., Levy et al., 1995). Tests of new interventions tend to be compared to existing programs to determine whether they are associated with greater reductions in risk behavior (e.g., Kirby et al., 1997). Three of the five school-based interventions employed this research design (Coyle et al., 1999; Kirby et al., 1997; Levy et al., 1995). Standard care controls were used in 9 studies in primary care settings (Boekeloo et al., 1999; Mansfield et al., 1993), STD clinics (DeLamater et al., 2000; Metzler et al., 2000; Orr et al., 1996), and in schools where an experimental curriculum was compared to a standard HIV education curriculum (Coyle et al., 1999; Kirby et al., 1997; Levy et al., 1995; Workman et al., 1996).

Use of a standard care control group in health care settings, such as that used by DeLamater et al. (2000), allows researchers to demonstrate that a new intervention can augment the educational programs already provided. A problem with this literature, however, is that the dose and other details of the standard care condition are often unspecified, which makes it difficult to interpret intervention findings. In addition, one drawback of making a comparison to standard care is that well-designed interventions may require more time, which can open the possibility of nonspecific factors, such as special treatment or attention (i.e., the Hawthorne effect) to account for intervention effects.

A different approach is the use of an alternative HIV prevention intervention as a control condition. This design was used in 8 studies. For example, in 1 study, two AIDS prevention interventions were compared that provided identical information except that the experimental condition emphasized decision-making skills (Stanton et al., 1996).

Three studies are unique in their use of two control conditions to attempt to demonstrate efficacy and effectiveness (Jemmott et al., 1998; Rotheram-Borus, Gwadz, et al., 1998; Slonim-Nevo et al.,

1996). For example, Jemmott et al. (1998) compared a safer sex intervention to an alternative abstinence condition that differed in its approach to risk reduction. Both conditions were also compared to contact- and time-matched control conditions to demonstrate efficacy. The findings showed that their experimental intervention was efficacious (i.e., reduced HIV risk when tested under ideal experimental conditions) and effective in reducing risk behavior compared to an abstinence-based intervention.

DATA ANALYSIS

Analysis of sexual behavior data is challenging, and both strengths and weaknesses were noted in the studies. All but 3 studies tested preintervention group differences to confirm that randomization succeeded in creating equivalent groups (Kazdin, 1992). Studies that found group differences on key demographic or outcome variables appropriately controlled for those variables in subsequent statistical tests. Another aspect of data analysis involves matching the unit of analysis with the unit of randomization. Nine studies randomized participants in units other than individual (i.e., classrooms, clinics), but data analyses that would have accounted for clustering of participants in their analyses was reported in only 4 of the studies. By analyzing studies at the individual level, the potential interactive effects of the classroom, clinic, or school are obscured (Kalichman, 1998).

Interpretation of the results in some RCTs was limited due to the large number of statistical tests conducted with small samples (e.g., Kipke et al., 1993) or because large numbers of tests were conducted without stating whether Type I error rate was controlled. Only 3 studies reported effect sizes for their findings (Coyle et al., 1999; Kirby et al., 1997; Metzler et al., 2000). Furthermore, sexual behavior measures tend to be positively skewed and must be transformed before performing statistical tests that assume normality. More than half of the studies analyzed data with tests that assume normality (i.e., analysis of covariance) but did not describe whether the data were normally distributed or whether the transformations were needed. Inconsistencies in data analysis make interpretation of findings difficult, espe-

cially across studies. Several new methods for the analysis of nonnormal data (e.g., mixed models) are available but have not widely been used (Schroder et al., in press).

This literature can be improved by the consistent reporting of effect sizes, which allow for comparisons across studies and for determination of clinical as well as statistical significance. Investigators need to analyze data at the unit of randomization to account for clustering of participants in randomization units. However, the reduced number of randomization units limits statistical power to detect group differences, and this should be noted as a limitation of the study. If statistical tests are used that require an assumption of normality, procedures for transforming sexual behavior variables and whether such transformations were effective should be reported.

POTENTIAL THREATS TO INTERNAL AND EXTERNAL VALIDITY

The confidence with which we can draw inferences from the RCTs depends on how well threats to internal and external validity are minimized. For example, attrition is encountered frequently in prevention trials with adolescents and can compromise the internal validity of a study when there is differential loss among conditions.

Attrition. There was considerable variation in attrition rates among the RCTs and not all studies reported rates of attrition. To show that attrition does not bias intervention findings, researchers need to demonstrate that attrition did not differ among conditions; however, 14 studies (64%) did not report a test of differential attrition. The highest rates of attrition were reported in studies conducted in STD clinics. For example, Metzler et al. (2000) reported attrition rates of 54%, 53%, and 69% at 3-, 6-, and 12-month follow-ups, respectively. Orr et al. (1996) reported 46% attrition at 6-month follow-up. Because parental consent to participate is usually not required in settings where youth seek reproductive or STD services, retention of youth in studies is made even more difficult because parents cannot be contacted without the adolescents' permission, limiting the ways in which youth can be tracked over time. RCTs conducted in public health clinics reported much lower attrition rates, ranging from 18% at 6-month follow-up

(Gillmore et al., 1997) to 9% at 12-month follow-up (St. Lawrence, Brasfield, et al., 1995). Several studies reported very low rates of attrition, such as 6% attrition at 6 months (Jemmott et al., 1999). Retention procedures for these studies included frequent reminder letters and phone calls as well as the availability of makeup sessions.

Intervention dropouts can cause selection bias in the final sample, limiting the external validity of the study (Kalichman, 1998). This bias can be reduced by using an intention-to-treat approach in which data are analyzed for all participants, regardless of whether they received the entire intervention. Intention-to-treat analyses have the advantage of maintaining the validity of the RCT by including noncompliant participants. Furthermore, because this approach accounts for noncompliance that is likely when the intervention is used in practice, it is consistent with demonstrating intervention effectiveness. Three studies reported the number of intervention sessions attended and used an intention-to-treat analysis (Jemmott et al., 1998; Metzler et al., 2000; Stanton et al., 1996). When an intention-to-treat approach is not used, as is true for the majority of studies in this review, noncompliant participants are excluded and bias is introduced into the results that may favor the intervention.

Special treatment or reactions of controls. A problem noted in reviewing many of the RCTs was the lack of information provided about the control condition. Without such information, it is impossible to determine whether bias due to special treatment of participants occurred. Studies that used a no-treatment, wait-list, or a very brief control cannot rule out the alternative interpretation that nonspecific attention given to participants in the experimental intervention may explain the observed effects.

An impressive feature of the studies is that most described procedures for ensuring intervention fidelity. These procedures included using manualized interventions, interventionist checklists of completed activities, and monitoring of fidelity through audiotaped intervention sessions or random observation. Another strength was noted in the number of studies that designed interventions to be appropriate for the setting. This was achieved by (a) making intervention length appropriate for the school or clinic setting, (b) having interventions

conducted by regular staff at the sites (e.g., teachers or health care professionals), and (c) providing manuals and training at sites where studies were conducted (e.g., Levy et al., 1995; St. Lawrence et al., 1999). The importance of disseminating empirically validated interventions has been emphasized (Auerbach & Coates, 2000) but remains a continuing challenge.

SUMMARY

This article reviewed 22 randomized, controlled HIV risk reduction interventions with adolescents that measured sexual risk behavior outcomes. Overall, these studies provide considerable evidence for the efficacy and effectiveness of HIV prevention programs for adolescents. We also identified strengths and weaknesses in sample selection, theoretical framework, study design, intervention content and format, outcome measures, and data analysis; and we provided numerous suggestions to improve future research. We encourage continued efficacy trials designed to refine existing programs and to evaluate new approaches to prevention that yield larger and more durable effects. We also encourage effectiveness trials to disseminate efficacious programs more widely. Development and dissemination of theoretically guided, developmentally appropriate, and empirically tested interventions can help to reduce the alarming incidence of HIV infection among vulnerable adolescents.

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