

Best-Evidence Interventions: Findings From a Systematic Review of HIV Behavioral Interventions for US Populations at High Risk, 2000–2004

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The United States continues to experience steady increases in the estimated numbers of persons living with HIV/AIDS and relatively stable overall trends in HIV diagnoses.^{1,2} Given the challenges of further reducing HIV infection rates and developing an effective vaccine,^{3,4} it is critical to focus on behavioral prevention efforts that are based on the best available scientific evidence. The Institute of Medicine has called for evidence-based decisionmaking across all public health sectors⁵ and recommends that HIV-prevention efforts utilize interventions of proven efficacy to avert as many new infections as possible.⁶ In accordance with the Institute of Medicine, the Centers for Disease Control and Prevention (CDC) emphasizes evidence-based behavioral interventions as part of its national HIV-prevention strategic plan and recommends that health departments^{7,8} and community-based organizations⁹ implement evidence-based behavioral interventions.

Given the vast amount and heterogeneity of scientific literature available, identifying evidence-based behavioral interventions is a daunting task. The complexity and variation in study designs, evaluation methods, analytic approaches, and data reporting make it extremely difficult to assess the quality of, and interpret the findings from, an evaluation study. As a result, an entire area of research has focused on reviewing the quality of individual studies and grading the totality of the scientific evidence for decisionmaking.^{10–15} Therefore, it is unrealistic to expect all HIV-prevention providers to be able to critically evaluate the literature and accurately identify interventions with proven efficacy. For this reason, the identification of evidence-based behavioral interventions would serve as a valuable resource for those responsible for developing national, state, and local HIV prevention plans.

Objectives. The Centers for Disease Control and Prevention's HIV/AIDS Prevention Research Synthesis Team conducted a systematic review of US-based HIV behavioral intervention research literature from 2000 through 2004 to identify interventions demonstrating best evidence of efficacy for reducing HIV risk.

Methods. Standard systematic review methods were used. Each eligible study was reviewed on the basis of Prevention Research Synthesis Team efficacy criteria that focused on 3 domains: study design, implementation and analysis, and strength of evidence.

Results. Eighteen interventions met the criteria for best evidence. Four targeted HIV-positive individuals. Of those targeting populations at risk for HIV, 4 targeted drug users, 6 targeted adults at risk because of heterosexual behaviors only, 2 targeted men who have sex with men, and 2 targeted youths at high risk. Eight interventions focused on women, and 13 had study samples with more than 50% minority participants. Significant intervention effects included increased condom use and reductions in unprotected sexual intercourse, number of sexual partners, injection drug use or needle sharing, and newly acquired sexually transmitted infections.

Conclusions. Most of the best-evidence interventions are directly applicable for populations in greatest need of effective prevention programs; however, important gaps still exist. (*Am J Public Health.* 2007;97:133–143. doi:10.2105/AJPH.2005.076182)

Many investigators have performed quantitative systematic reviews, including meta-analyses, to estimate the overall effectiveness of subsets of HIV interventions^{16–23} or qualitative systematic reviews to identify effective strategies within a particular subgroup of individuals.^{24–27} To our knowledge, none has sought to systematically review the literature across all populations to identify each HIV behavioral intervention that met rigorous scientific criteria and demonstrated efficacy. The CDC's HIV/AIDS Prevention Research Synthesis (PRS) Team developed such a process, which utilized standard systematic review methods.^{28,29} The evidence-based interventions identified in the first PRS review from 1988 to 1996 were published in the *Compendium of HIV Prevention Interventions With Evidence of Effectiveness*.³⁰ This *Compendium* was later updated to include proven interventions published up to 2000.³¹

The selection criteria used in the *Compendium*^{30,31} reflected the state of the science at that time, and neither the criteria nor the findings have been updated in several years. In an effort to update previous work and focus on the most relevant scientific evidence reflecting the current state of the HIV epidemic, the PRS Team conducted a systematic review of the US-based HIV behavioral intervention research literature from 2000 through 2004. The purpose of our review was to help CDC's HIV-prevention partners with their strategic planning process by evaluating the quality of scientific evidence from each intervention study and identifying specific behavioral interventions that have demonstrated the best scientific evidence of efficacy (*best-evidence interventions*) in reducing HIV-related risk behaviors, sexually transmitted disease (STD), or HIV incidence.

METHODS

Search Strategy

The PRS Team developed a cumulative database of HIV/AIDS and STD behavioral prevention research literature through a comprehensive systematic search strategy, including automated and manual search components. The automated search is conducted annually in 4 electronic databases (EMBASE, MEDLINE, PsycINFO, and SocioFile, including AIDSLINE before December 2000) and was most recently conducted for our review in November 2004.^{32–35}

Manual searches were conducted biannually to identify articles not yet indexed, with the most recent search for our review occurring in January 2005. Members of the PRS Team screened all issues published within the most recent 6 months of 32 prespecified journals to locate relevant reports. The PRS Team also examined the reference lists, screened HIV/AIDS e-mail discussion lists, and reviewed unpublished manuscripts submitted to the team by study authors.

Eligibility of Citations

The citation inclusion criteria are available as a supplement to the online version of this article. Citations included in our review must have focused on outcome evaluations of HIV/AIDS or STD behavioral interventions conducted in the United States or its territories and must be published or accepted for publication between 2000 and 2004. In addition, eligible citations had to present data for relevant biological measures, HIV-testing behavior, or sexual or drug-injection behaviors that directly impact the risk of HIV transmission.

Our review focused only on behavioral interventions delivered to the individual or small group. Interventions delivered to the entire community, or a segment of a community, are typically evaluated using serial cross-sectional samples (unlinked over time). Because many of the criteria used in our review to determine best evidence of efficacy are not applicable to this type of evaluation design, interventions delivered to the community were excluded ($n=10$) and will be evaluated in a separate review.

For our review, particular attention was given to behavioral interventions or

prevention activities supported by CDC HIV-prevention funds for which national guidelines or recommendations do not already exist. Because substance-abuse treatment and needle-exchange programs are not supported by CDC HIV-prevention funds and our review was to help CDC's HIV-prevention partners, those programs were not included. These strategies were shown to be effective in previous reviews and, thus, should be considered in comprehensive prevention programs.^{36,37} Interventions that strictly address HIV testing or partner counseling and referral services were not included because the CDC already requires all grantees to conduct these programs on the basis of existing CDC guidelines.^{38–40} Interventions explicitly targeting school-based youths were not included in our review because the CDC's Division of Adolescent and School Health focuses on evidence-based recommendations for school-based HIV-prevention programs.^{41–43} In addition, policy interventions (e.g., changing pharmacy or HIV name reporting laws) were not considered because they are not readily implemented by health departments, community-based organizations, or other prevention providers.

Efficacy Criteria for Best Evidence

The criteria developed for our review were based on a thorough PRS review of the literature⁴⁴ and repeated consultations with methodology experts and behavioral intervention research scientists. The resulting efficacy criteria focus on several aspects of a study: quality of study design, quality of implementation and analysis, and strength of evidence. For an intervention to be determined as providing best evidence of efficacy, each of the criteria must be met (available as a supplement to the online version of this article). More detailed rationale for the criteria are provided elsewhere.⁴⁵

First, a clear description of the intervention was required in order to understand what was being tested. A member of the PRS Team contacted the first author to request formal documentation (e.g., intervention manuals) that would provide more details than a publication. The criteria for quality of study design included a prospective design, an appropriate and concurrent comparison arm, and assignment to study arms either by randomization

or a method with minimal bias. For quality of study implementation, the criteria included assessing the outcome(s) at least 3 months after the intervention while retaining at least 70% of enrolled participants in each arm. The criteria for quality of analysis included the performance of appropriate cluster-level analyses when assignment was done at the cluster level, the analysis of participants in study arms as originally assigned, and the analysis of participants regardless of intervention exposure.

To meet the strength of evidence criteria, a study must have demonstrated significant positive evidence and no significant negative evidence for the intervention in reducing HIV risk. The statistically significant ($P \leq .05$) and positive intervention effect had to be evident for at least 1 relevant outcome measure, at least 3 months postintervention, and with a minimum retention rate of 70% for both study arms. Finally, the evaluation study could not be based on fewer than 50 participants per arm nor exhibit any additional limitations considered to be a fatal flaw.

Qualitative Data Coding

For each eligible citation, linked citations reporting on a single study were identified. Pairs of trained content analysts independently coded the efficacy criteria for each eligible study, including all linked citations. All discrepancies were reconciled. The first author was contacted to provide missing data or clarifications as needed. Final efficacy determination for each study was reached by PRS group consensus.

RESULTS

By the end of January 2005, the comprehensive search strategy identified 100 unique studies that were eligible for this efficacy review (Figure 1). Of these studies, 18 behavioral interventions (18%) were identified as best evidence,^{46–76} which means they were determined to have sufficient quality and strength of evidence to infer a significant effect on reducing HIV risk. The study population and intervention characteristics of the 18 interventions are described in Tables 1 and 2, respectively. Table 3 provides the contact information for intervention materials or technical assistance.

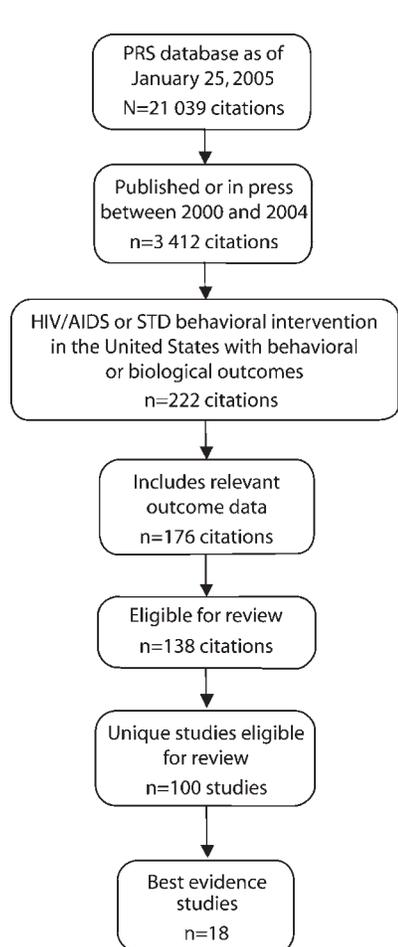


FIGURE 1—Results of the PRS systematic review for intervention efficacy, 2000–2004.

Population Characteristics

Among the target groups (Table 1), which are not mutually exclusive, the majority ($n=9$) of the best-evidence interventions targeted heterosexual adults. Five interventions targeted drug users, 4 targeted HIV-positive individuals, and 3 targeted high-risk youths. Three targeted men who have sex with men (MSM) and included both gay- and non-gay-identified, predominantly older White men.

Thirteen of the 18 best-evidence interventions had study samples consisting of greater than 50% minority participants (range, 58%–100%). Four of these included only African Americans^{48,67–71,75,76}; 1 included only Hispanics⁶³; and 1 included only African Americans and Hispanics.^{65,66} The 5 interventions comprised mostly of White participants had

study samples with sizeable proportions of minority participants (range, 26% to 49%).

Overall, 8 interventions focused exclusively on women or adolescent females,^{46,48,50–52,59,65–72} and another intervention targeted women in relationships while including their male partners in the study sample (i.e., 50% women).^{53–55} Of the 9 interventions for women, 8 included mostly minority women (range, 58%–100%).^{48,50–55,59,65–72} All 5 interventions that targeted drug users included mostly minority participants (range, 77%–100%), with 2 interventions focusing exclusively on African American women^{67–71} and 1 focusing exclusively on Hispanic drug injectors.⁶³ Of the 3 interventions targeting high-risk youths,^{48,64,75,76} 2 targeted African American youths.^{48,75,76}

Of the 4 interventions that targeted persons living with HIV, 1 focused on sexually active women, 2 focused on both males and females and also included large proportions of gay or bisexual men, and 1 targeted MSM.^{60,61,64,72–74} All 4 of these interventions for persons living with HIV included large proportions of minorities (range, 49%–85%).

All interventions were evaluated in urban geographical areas, except 1 intervention for drug users was implemented among residents of a semirural community in Puerto Rico.⁶³ Most of the interventions were evaluated among participants with relatively low socioeconomic status. Nine of the 10 reporting unemployment status consisted of mostly unemployed participants.^{46,47,53–55,59,62,67–74} An additional 4 studies provided information regarding income or public housing that indicated participants were of low socioeconomic status.^{50–52,60,61,65,66,75,76}

Intervention Characteristics

All best-evidence interventions relied on at least 1 behavioral change theory or model, with the most common being Social Cognitive Theory ($n=7$), Social Learning Theory ($n=4$), AIDS Risk Reduction Model ($n=3$), Information-Motivation-Behavior Model ($n=3$), and the Theory of Gender and Power ($n=3$) (not mutually exclusive). As shown in Table 2, the most frequent intervention settings were research sites ($n=8$), community or public areas ($n=5$), health care clinics ($n=4$), HIV or STD service clinics ($n=3$), and

community-based agencies ($n=3$). The most commonly reported types of staff delivering the interventions were nonpeer “facilitator” or “group leader” ($n=7$), peer ($n=6$), counselor ($n=4$), or therapist ($n=3$) and they matched the target population on gender, race/ethnicity, HIV-seropositivity, or drug use for 12 of the interventions.

The duration of the interventions varied, with 2 delivered in 1 to 3 sessions, 8 delivered in 4 to 6 sessions, and 8 delivered in more than 6 sessions (Table 2). Three interventions provided services on repeated occasions (e.g., case management)^{56–58,63,65,66} and 2 provided booster or maintenance sessions.^{50–52,56–58} The total amount of intended intervention exposure ranged from 1 to 32 hours, with most interventions having a moderate length, ranging from 9 to 18 hours. The 3 that provided repeated services were probably moderate in length although total exposure time was not reported.

Although the content of these interventions differed, most interventions included skill building: technical (e.g., condom use), personal (e.g., relaxation), or interpersonal (e.g., communication). Live demonstrations or the opportunity to practice the application of male condoms was provided in 14 interventions; 4 of these included female condoms as well. Ten interventions included personal skills building components for decisionmaking or problem solving. Six interventions, 3 of which targeted persons who are HIV-positive, included components for stress reduction, stress management, or relaxation. Communication skills, such as negotiation or assertiveness for safer sex, were demonstrated, practiced, or role-played in 13 interventions. In addition, 16 interventions involved the development of plans or setting goals for risk reduction, and 9 addressed the identification and management of triggers for risky sex. Five interventions explicitly encouraged social or group support for participants. Finally, the 2 interventions that targeted African American youths included a sexual abstinence component within the broader framework of a more comprehensive risk-reduction message.^{48,75,76}

Effects of the Interventions

The majority of the significant intervention effects corresponded to the reduction of

TABLE 1—Study Population Characteristics of Best Evidence Interventions (n = 18): 2000–2004

Author, Year	Target Population ^{a,b}	Target Group	No. ^c	Gender, % Male/Female	Race, %						Mean Age (Range)
					African American	Hispanic	White	Other	Asian/Pacific Islander	American Indian/ Alaska Native	
Baker, 2003 ⁴⁶	Low-income heterosexual women	Heterosexual adults	287	0/100	29	3	54	6	3	5	30
Carey, 2004 ⁴⁷	Sexually active psychiatric outpatients	Heterosexual adults	408	45/54	21		67	12			37
DiClemente, 2004 ⁴⁸	Sexually active African American adolescent females	High-risk youths	522	0/100	100						16 (14–18) ^d
Dilley, 2002 ⁴⁹	MSM	MSM	248	100/0	3	11	74	6	6		33 (18–49) ^d
Ehrhardt, 2002 ^{50–52}	Heterosexual women attending family-planning clinics	Heterosexual adults	360	0/100	72	17	10		0.3		22 (18–30) ^d
El-Bassel, 2003 ^{53–55}	African American and Latino heterosexual couples	Heterosexual adults	217 ^e	50/50	55 ^f	39 ^f		6 ^f			38 (18–55) ^d
EXPLORE Team, 2004 ^{56–58}	HIV- MSM	MSM	4295	100/0	7	15	72	6			34
Hobfoll, 2002 ⁵⁹	Low-income inner-city women attending urban clinics	Heterosexual adults	935	0/100	55		42	3			21 (16–29) ^d
Kalichman, 2001 ^{60,61}	HIV+ men and women	HIV+ adults	328	70/30	74		22	4			40
Latkin, 2003 ⁶²	Low-income, African American drug users	Drug users	250	61/39	94		5	1			39
Robles, 2004 ⁶³	Hispanic, out-of-treatment drug injectors	Drug users	557	89/11		100					NR (18–65) ^d
Rotheram-Borus, 2004 ⁶⁴	HIV+ substance-abusing youth	HIV+, high-risk youths, drug users	175	78/22	26	42	23	8			23 (16–29)
Shain, 2004 ^{65,66}	Mexican American and African American women diagnosed with an STD in public health clinics	Heterosexual adults	775	0/100	23	77					21 (14–43)
Sterk, 2003 ^{67–70}	Inner-city, HIV-, sexually active, out-of-treatment, crack-using or IDU African American women	Heterosexual adults, drug users	333	0/100	100						41 (18–59)
Wechsberg, 2004 ⁷¹	Inner-city, sexually active, out-of-treatment, crack-using African American women	Heterosexual adults, drug users	762	0/100	100						37
Wingood, 2004 ⁷²	Sexually active HIV+ female clinic patients	HIV+, heterosexual adults	366	0/100	84		15	1			35 (18–50) ^d
Wolitski, 2005 ^{73,74}	HIV+ MSM	HIV+, MSM	811	100/0	23	17	51	7	1	1	42 (20–89)
Wu, Stanton, 2003 ^{75,76}	Low-income African American youths	High-risk youths	817	42/58	100						14 (13–16)

Notes. MSM = men who have sex with men; HIV- = HIV-negative; HIV+ = HIV-positive; STD = sexually transmitted disease; IDU = injection drug using; NR = not reported. Additional information about the efficacy review and the interventions identified can be found at <http://www.cdc.gov/hiv/topics/research/prs/index.htm>.

^aBaseline sample, some information obtained from authors.

^bAs specified by author.

^cStudy sample at assignment or enrollment (many include more than 2 study arms).

^dEligibility criteria.

^eCouples.

^fPercentages based on all subjects; 6% includes White, Asian/Pacific Islander, and other.

TABLE 2—Intervention Characteristics of Best Evidence Interventions (n = 18): 2000–2004

Author, Year	Intervention Name ^{a,b}	Target Group	Type of Setting	Unit of Delivery	Deliverer	No. of Sessions	Total Time, Hours	Intervention Effects ^c
Baker, 2003 ⁴⁶	Choices	Heterosexual adults	NR	Group	Male and female teams of psychotherapists of different ethnic backgrounds	16	32	↓ new STD
Carey, 2004 ⁴⁷	HIP	Heterosexual adults	Psychiatric outpatient clinic	Group	Therapist; female and male facilitators	10	10	↓ UVI, ↓ no. sexual partners
DiClemente, 2004 ⁴⁸	SIHLE	High-risk youths	Family medicine clinic	Group	African American female health educator and peer educators	4	16	↑ condom use, ↓ new sexual partners, ↓ UVI, ↓ new STD
Dilley, 2002 ⁴⁹	Personalized Cognitive Risk-Reduction Counseling ^d	MSM	HIV testing clinic	Individual	Licensed mental health counselors	1 session and HIV C&T	1 (for 1 session only)	↓ UAI
Ehrhardt, 2002 ⁵⁰⁻⁵²	Project FIO (8 sessions)	Heterosexual adults	Planned Parenthood clinic	Group	Two female facilitators (1 matching ethnic background of participants)	8 sessions and 1 2-hour booster, 9 months after baseline	16 plus 2-hour booster	↓ UVI/UAI, ↓ VI/AI
El-Bassel, 2003 ⁵³⁻⁵⁵	Project Connect (couple or woman-alone)	Heterosexual adults	Private office in hospital outpatient clinic	Individual and group	Ethnically matched female social workers	6	12	↑ condom use, ↓ UVI
EXPLORE Team, 2004 ⁵⁶⁻⁵⁸	EXPLORE ^e	MSM	Study site, in the field, or by telephone	Individual	Counselors	10 sessions, maintenance session every 3 months, and HIV C&T every 6 months	10 (for 10 sessions only)	↓ UAI, ↓ URAI
Hobfoll, 2002 ⁵⁹	Communal Efficance-AIDS Prevention	Heterosexual adults	Hospital-based clinic and free-standing community-based clinics	Group	Female facilitators	6	9 to 12	↑ condom use
Kalichman, 2001 ^{60,61}	Healthy Relationships	HIV+ adults	Community AIDS service organization	Group	Male and female community-based facilitators (1 was an HIV+ peer counselor)	5	10	↓ UAI/UVI, ↓ AI/VI, ↑ condom use, ↓ no. of non-HIV+ sexual partners, ↓ UAI/UVI with non-HIV+ sexual partners, ↓ AI/VI with non-HIV+ sexual partners ^f
Latkin, 2003 ⁶²	SHIELD	Drug users	Study site and community locations for outreach	Group	Male and female indigenous peer paraprofessional facilitators and peer outreach worker	10	15	↓ needle sharing, ↓ IDU, ↑ condom use

Continued

TABLE 2—Continued

Robles, 2004 ⁶³	MIP	Drug users	Drug treatment centers, study site, or community locations for outreach	Individual	Case manager, outreach worker, and registered nurse	6 weekly intervention sessions, case management for 1.5 months, and 2 sessions of HIV C&T	NR	↓ IDU, ↓ needle sharing
Rotheram-Borus, 2004 ⁶⁴	CLEAR (in person)	HIV+, high-risk youths, drug users	Community agency, residence, or community sites	Individual	Licensed therapist or clinical social worker	18	27	↑ condom use, ↑ condom use with HIV- sexual partners
Shain, 2004 ^{65,66}	Project S.A.F.E. (standard version) ^g	Heterosexual adults	Study site and STD clinic	Individual and Group	Nurse clinician and ethnically matched female facilitator	3 sessions, STD counseling and treatment, and repeated HIV C&T	9 to 16.5 (for sessions only)	↓ unprotected sex, ↓ no. sexual partners, ↓ new STD
Sterk, 2003 ⁶⁷⁻⁷⁰	Female- and Culturally Specific Negotiation	Heterosexual adults, drug users	Study site	Individual	Counselor and female health facilitator	4	2 to 2.5	↓ sex with paying sexual partners, ↓ trade sex for money, ↑ condom use, ↓ IDU
Wechsberg, 2004 ⁷¹	Women's Co-op	Heterosexual adults, drug users	Study sites (church basement, residential building)	Individual and group	African American community peers	4	3 to 4.3	↓ unprotected sex
Wingood, 2004 ⁷²	WILLOW	HIV+, heterosexual adults	Study site and HIV service clinic	Group	HIV+ African American female peer educator and female health educator	4	16	↓ UVI, ↑ condom use, ↓ new STD
Wolitski, 2005 ^{73,74}	SUMIT Enhanced Peer-led	HIV+, MSM	Study site	Group	HIV+ MSM peer facilitators	6	18	↓ URAI with HIV- or serostatus-unknown sexual partners
Wu, Stanton, 2003 ^{75,76}	FOK + ImPACT ^h	High-risk youths	Residence and community sites	Group	Group leader and interventionist	9 (8 FOK, 1 ImPACT)	12 (FOK) plus >20 minutes (ImPACT)	↓ unprotected sex

Notes. NR = not reported; ↓ = decrease in or lower levels of; ↑ = increase in or greater levels of; STD = sexually transmitted disease; UVI = unprotected vaginal intercourse; MSM = men who have sex with men; HIV C&T = HIV/AIDS counseling and testing; UAI = unprotected anal intercourse; VI = vaginal intercourse; AI = anal intercourse; URAI = unprotected receptive anal intercourse; HIV+ = HIV-positive; IDU = injection drug use; HIV- = HIV-negative. Additional information about the efficacy review and the interventions identified can be found at <http://www.cdc.gov/hiv/topics/research/prs/index.htm>.

^aSome information obtained from personal correspondence with authors.

^bAcronym for intervention name was used as reported or as obtained from author; if not, a short description or study name was used.

^cStatistically significant intervention effects on relevant outcome measures as compared with the control or standard of care comparison group.

^dThe Personalized Cognitive Risk-Reduction Counseling plus diary intervention was also found to be efficacious, but was not shown to be more efficacious than the Personalized Cognitive Risk-Reduction Counseling intervention.

^eThis intervention was found to be effective only after 1 maintenance session (12 months after baseline) and after 2 maintenance sessions (18 months after baseline); both findings were 3 months after maintenance session.

^fNon-HIV+ refers to those individuals who are not known to be HIV-positive (they could be HIV-negative or not know their HIV status).

^gSAFE enhanced was also found to be efficacious, but was not shown to be more efficacious than SAFE standard.

^hThe intervention with the boosters was found to have insufficient evidence of efficacy.

unprotected sexual intercourse (n=12 studies). The 3 interventions that targeted MSM significantly reduced any unprotected anal intercourse or unprotected receptive anal intercourse. Although not all behaviors were assessed in every study, other significant intervention effects reported were increased condom use (n=8), reduced number of sexual partners (n=3), and reduced injection drug use or needle-sharing behavior (n=3). All 5 interventions for drug users targeted sex-related risk behaviors; 4 were successful in reducing those behaviors.^{62,64,67-71} Three of the 5 interventions for drug users targeted and successfully reduced injection-related risk behaviors.^{62,63,67-70}

Significant intervention effects on behaviors were identified over a range of follow-up times, from 3 to 12 months after the intervention. Four interventions were identified as having produced a significant reduction in new STDs over a minimum of 12 months after exposure to the intervention. The intervention that measured HIV incidence did not significantly reduce the number of new infections.⁵⁶⁻⁵⁸

DISCUSSION

Our review identified 18 behavioral interventions, reported from 2000 through 2004, with the best evidence of efficacy in reducing HIV risk. Most importantly, many of these newly identified efficacious interventions targeted populations disproportionately affected by the HIV/AIDS epidemic and in need of effective prevention tools. There are 6 newly identified best-evidence interventions that are directly applicable for African American or Hispanic heterosexual women at risk for HIV infection^{50-55,59,65-71} and 2 directly applicable for African American youths at high risk.^{48,75,76} Three best-evidence interventions are appropriate for minority injection drug users^{62,63,67-70}; 1 directly applicable for injection drug-using women.⁶⁷⁻⁷⁰ In alignment with 1 of the key strategies of the CDC's Advancing HIV Prevention Initiative,⁷⁷ 4 best-evidence interventions for persons living with HIV were identified.^{60,61,64,72-74}

This set of best-evidence interventions can serve as an important resource for the development of HIV-prevention strategic plans at

the national, state, and local levels. Providers of HIV prevention can use the findings of our review to select evidence-based intervention(s) best suited for their community's needs. To remain a valuable resource to all HIV-prevention providers, our review must be updated frequently to incorporate new scientific evidence. The PRS Team continually updates its database system and plans to report on the updated efficacy findings annually.

Research Gaps

Although it is encouraging that many efficacious interventions identified in our review target important populations, several gaps still remain. Some of the populations hardest hit by the HIV/AIDS epidemic or at greatest risk of infection or transmission were not represented. These populations include African American, Hispanic, and other MSM of color,^{2,78-81}; young MSM, particularly young African American and Hispanic MSM⁸¹⁻⁸⁴; substance-using MSM⁸⁵⁻⁸⁷; transgender persons⁸⁷⁻⁹⁰; HIV-positive intravenous drug users⁹¹; and rural populations.⁹² The identification of effective intervention approaches with these populations should be accorded the highest priority in future research.

Future research should also focus on broadening the applicability of already proven interventions through assessing their generalizability, studying their effectiveness, and adapting them when necessary. Within our review, the interventions were identified as efficacious after being evaluated with a particular target population, in a particular setting, and often within a single site. It is unclear whether these findings would extend beyond the particular target population or setting used in the original research. Additional research should be conducted to determine whether these efficacious interventions work among other high-risk groups or in settings not represented in the original study.

Related to generalizability is the issue of effectiveness. These interventions were evaluated in relatively rigorous and controlled research environments, which typically do not reflect real-world circumstances. An efficacious intervention does not necessarily translate into an effective real-world program; it also depends on other factors such as the quality of program implementation, availability, and

acceptance.⁹³⁻⁹⁶ The extent to which these proven interventions will work once translated into practice has yet to be systematically evaluated. In addition, interventions often need to be adapted to address different social, cultural, or contextual factors of various settings and populations as a way to fulfill unmet prevention needs until additional evidence is available. Although the adaptation of a proven intervention may have a better chance of being effective than the implementation of a newly developed and untested intervention, rigorous effectiveness studies would help evaluate this. Thus, targeted research is needed to determine ways to improve an intervention's effectiveness in real-world settings, particularly when it has been adapted.

Implications for Prevention

This efficacy review is intended to serve as a resource through its identification of evidence-based behavioral interventions that should be considered for use in HIV-prevention efforts. It is not meant to guide intervention implementation once an intervention has been chosen. Many aspects of the intervention that are not provided here (e.g., intervention manuals) are necessary for translating these interventions into practice. Two CDC projects—Replicating Effective Programs⁹⁷ and Diffusion of Effective Behavioral Interventions⁹⁴—were initiated to help prevention providers with translating research into practice by packaging and disseminating evidence-based behavioral interventions. Six interventions identified in our review have completed this process^{60,61} or are currently going through this process and will soon be disseminated^{48,63,64,72,75,76} (Table 3). The remaining interventions will be considered by these 2 CDC projects for future packaging and dissemination.

Limitations

It is worthwhile to note that several interventions considered in our review narrowly missed the best-evidence criteria for reasons such as group retention rates slightly lower than 70% or follow-up time less than 3 months after the intervention.⁹⁹⁻¹⁰⁹ These interventions, which consisted of innovative approaches or targeted high-risk groups, are promising and should be considered for

TABLE 3—Contact Information for Best Evidence Interventions (n = 18): 2000–2004

Author, Year	Intervention Name ^a	Contact Information ^b
Baker, 2003 ⁴⁶	Choices	Blair Beadnell, PhD, e-mail: blairb@u.washington.edu
Carey, 2004 ⁴⁷	HIP (Health Improvement Project, HIV-Prevention)	http://www.chb.syr.edu/staff_member.php?url_id=1
DiClemente, 2004 ⁴⁸	SiHLE (Sistering, Informing, Healing, Living, and Empowering)	Ralph J. DiClemente, PhD, e-mail: rdiclem@sph.emory.edu; Diffusion of Effective Behavioral Interventions, CDC, http://www.effectiveinterventions.org (in 2008)
Dilley, 2002 ⁴⁹	Personalized Cognitive Risk-Reduction Counseling	James W. Dilley, MD, e-mail: jdilley@itsa.ucsf.edu
Ehrhardt, 2002 ⁵⁰⁻⁵²	Project FIO (The Future Is Ours) (8 session)	Anke A. Ehrhardt, PhD, e-mail: ehrharda@child.cpmc.columbia.edu
El-Bassel, 2003 ⁵³⁻⁵⁵	Project Connect (couple or woman-alone)	Nabila El-Bassel, DSW, e-mail: ne5@columbia.edu
EXPLORE Team, 2004 ⁵⁶⁻⁵⁸	EXPLORE	http://www.explorestudy.org
Hobfoll, 2002 ⁵⁹	Communal Effectance-AIDS Prevention	Steven E. Hobfoll, PhD, e-mail: shobfoll@kent.edu
Kalichman, 2001 ^{60,61}	Healthy Relationships	Diffusion of Effective Behavioral Interventions, CDC, http://www.effectiveinterventions.org
Latkin, 2003 ⁶²	SHIELD (Self-Help in Eliminating Life-threatening Diseases)	Carl A. Latkin, PhD, e-mail: clatkin@jhsph.edu
Robles, 2004 ⁶³	MIP (Modelo de Intervencion Psicomedica)	Rafaela R. Robles, EdD, e-mail: jcreyes@ucaribe.edu; Diffusion of Effective Behavioral Interventions, CDC, http://www.effectiveinterventions.org (in 2007)
Rotheram-Borus, 2004 ⁶⁴	CLEAR (Choosing Life: Empowerment, Actions, Results) (in person)	http://chipts.ucla.edu/interventions/manuals/intervclear.html ; Diffusion of Effective Behavioral Interventions, CDC, http://www.effectiveinterventions.org (in 2007)
Shain, 2004 ^{65,66}	Project S.A.F.E. (Sexual Awareness For Everyone) (standard version)	Sociometrics Inc, http://www.socio.com
Sterk, 2003 ⁶⁷⁻⁷⁰	Female- and Culturally Specific Negotiation	Claire Sterk, PhD, e-mail: csterk@sph.emory.edu
Wechsberg, 2004 ⁷¹	Women's Co-op	Wendee Wechsberg, PhD, e-mail: wmw@rti.org
Wingood, 2004 ⁷²	WILLOW (Women Involved in Life Learning From Other Women)	Gina M. Wingood, ScD, MPH, e-mail: gwingoo@sph.emory.edu; Diffusion of Effective Behavioral Interventions, CDC, http://www.effectiveinterventions.org (in 2007)
Wolitski, 2005 ^{73,74}	SUMIT Enhanced Peer-led	Richard Wolitski, PhD, e-mail: rwolitski@cdc.gov
Wu, Stanton, 2003 ^{75,76}	Focus on Kids (FOK) + Informed Parents and Children Together (ImPACT)	Bonita Stanton, MD, e-mail: bstanton@dmc.org; Diffusion of Effective Behavioral Interventions, CDC, http://www.effectiveinterventions.org (in 2008)

Note. CDC = Centers for Disease Control and Prevention. Additional information about the efficacy review and the interventions identified can be found at <http://www.cdc.gov/hiv/topics/research/prs/index.htm>.

^aIf intervention name was not reported or obtained from author, a short description or study name was used.

^bIdentifying an intervention as having best evidence for efficacy does not necessarily mean it should be packaged and disseminated.

more rigorous evaluations in the future to definitively determine efficacy. Although it is important to acknowledge that the community-level interventions excluded from our review may be efficacious, they will be evaluated in a separate review that utilizes criteria more suitable for community-level studies.⁹⁵ In addition, other efficacious interventions may exist that were not adequately evaluated (e.g., no comparison arm) or that have not yet been evaluated. Until these interventions are rigorously evaluated, evidence for causality is lacking.

Our review did not attempt to rank the interventions or their evaluations, which clearly vary in terms of the type and complexity of intervention, study quality, and magnitude, significance, and consistency of findings. Some interventions, for example, led to long-term reductions in several risk behaviors, whereas others produced short-term reductions that

were not maintained over time. All of these best-evidence interventions met the minimal PRS criteria for scientific evidence of efficacy; however, some may be more appropriate, feasible, effective, or sustainable in real-world settings than others. In addition, our review did not assess cost-effectiveness. Future studies on the cost-effectiveness and potential cost-saving of each of these interventions would contribute to the understanding of their potential public health impact. Consideration of these more practical aspects would help to prioritize which interventions should be translated into practice.

Finally, our review relied on the information reported in peer-reviewed scientific publications. The information necessary for making our determination of best evidence was often unclear, not reported, or not available from the first author. We encourage authors to follow the Consolidated Standards of Reporting

Trials^{110,111} and Transparent Reporting of Evaluations With Nonrandomized Designs¹¹² statements when reporting on their intervention evaluations. This would not only improve the data reporting quality of evaluations but would also improve the quality of systematic reviews including the evaluations. In addition, we were unable to link primary outcome hypotheses to the reported findings, often because of the lack of clarity in reporting study hypotheses. This information could help prioritize the relevance and importance of each intervention. Perhaps the recent efforts in promoting the public registration of all clinical trials will help to resolve this over time.^{113,114}

Conclusions

Behavioral intervention research efforts for HIV prevention have successfully resulted in many efficacious interventions in recent years. On the basis of the PRS efficacy

criteria, this comprehensive systematic review of HIV behavioral interventions from 2000 to 2004 has identified 18 interventions with proven efficacy to reduce HIV-related risk behaviors or sexually transmitted infections. Most of these evidence-based interventions fill current gaps by targeting populations at high risk for HIV infection or transmission. Research is still needed, however, to address some populations with the greatest need for effective prevention tools. As the evidence-based interventions identified in our review are included in national, state, and local HIV prevention plans, prevention efforts will have a better chance of preventing new HIV infections and can collectively make an impact on the HIV epidemic in the United States. Continually incorporating the best scientific evidence into HIV prevention strategic planning will be essential for any sustainable impact. ■

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Note. The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

Contributors

C.M. Lyles led the writing, abstracted data, and reviewed studies for evidence of efficacy. L.S. Kay, N. Crepez, and J.H. Herbst helped with writing, abstracted data, and reviewed studies for evidence of efficacy. W.F. Passin, A.S. Kim, and S.M. Rama conducted most of the data abstraction and qualitative data coding from the original evaluation reports and reviewed studies for evidence of efficacy. S. Thadiparthi developed and managed the database used to summarize the data. J.B. DeLuca and M.M. Mullins led the systematic search efforts to identify all relevant evaluation studies.

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Human Participant Protection

No human participants were involved in this study.

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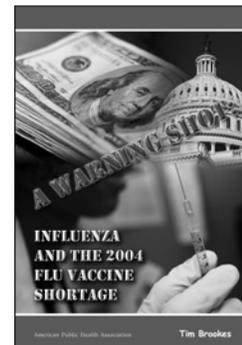
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Appendix. Inclusion and Efficacy Criteria

Citation Inclusion Criteria

- ◆ HIV/AIDS/STD behavioral intervention
- ◆ Study was an outcome evaluation
- ◆ Initial outcome evaluation report was published or “in press” in 2000-2004
- ◆ Based in the U.S. (or U.S. territories)
- ◆ Relevant outcome data were used to evaluate the intervention:
 - *Behaviors* that directly impact HIV risk – sex risk behaviors (e.g. abstinence, condom use, number of sex partners, condom negotiation, refusal to have unsafe sex) or drug injection behaviors (e.g., frequency of injection drug use, needle sharing) – or HIV testing behaviors
 - *Biologic* measures of HIV risk or other sexually/parentally-transmitted infections (prevalence or incidence measures of Hepatitis, HIV, other STDs)
- ◆ Intervention was delivered to the individual or small-group and not exclusively at the community-level
- ◆ Intervention focus was other than any of the following:
 - Substance abuse treatment only
 - Needle Exchange
 - HIV testing only
 - Partner Counseling and Referral Service only
 - School-based prevention programs
 - Policy

Efficacy Criteria for Best Evidence

Intervention Description

- ◆ Key aspects of the intervention were described (e.g. who, what, where, when, and how)

Study Quality – Intended Study Design

- ◆ Prospective study design
 - an evaluation that begins prior to or at the time of exposure to the intervention, then assesses outcome(s) at a later date after exposure to the intervention

- ♦ Appropriate and concurrent comparison arm
 - a wait-list control, a standard of care, or an intervention hypothesized to have less of an impact on HIV risk reduction; example of an inappropriate comparison arm for the purposes of our review - the same intervention with female deliverers instead of male deliverers and no a-priori directional hypothesis
- ♦ Random or minimal biased assignment of participants to study arms

Study Quality – Implementation and Analysis

- ♦ At least a 3-month follow-up assessment for each study arm
- ♦ At least a 70% retention rate at a single follow-up for each study arm
- ♦ Use of appropriate cluster-level analyses if assigned to study arms by cluster or group (e.g. neighborhood, couples, clinic)
- ♦ Analysis of subjects in study arms as originally allocated
- ♦ Analysis of subjects regardless of intervention exposure (i.e., *not* analyzed based on how much of the intervention they actually received)

Strength of Evidence – Significant Positive Intervention Effects

- ♦ Positive and statistically significant ($p \leq .05$) intervention effect in ≥ 1 relevant outcome measure
 - a positive intervention effect is defined here as a greater reduction in HIV risk behaviors or disease incidence, or a greater increase in HIV protective behaviors, in the intervention arm relative to the comparison arm
- ♦ Effect at ≥ 3 months *post-intervention* follow-up for *both* intervention and comparison arms
- ♦ Retention (at the follow-up time exhibiting an effect) was $\geq 70\%$ in each arm
- ♦ Effect was between intervention arm and an appropriate comparison arm
- ♦ Effect based on a 2-sided test and $\alpha = .05$ (or more stringent)
- ♦ Effect among post-intervention levels or among pre-post changes in measures
- ♦ If nonrandomized assignment, either no statistical differences in baseline levels of the outcome *or* baseline differences controlled for in the analysis
- ♦ If pre-post changes used in analysis, measures at each time were identical, including same recall period

Strength of Evidence – Negative Intervention Effects and Limitations

- ♦ No negative and statistically significant ($p < .05$) intervention effect for any relevant outcome
 - a negative intervention effect is defined here as a greater increase in HIV risk behaviors or disease incidence, or a greater decrease in HIV protective behaviors, in the intervention arm relative to the comparison arm
- ♦ No other statistically significant harmful intervention effect on other outcomes
- ♦ If intervention had a replication evaluation, no significant negative intervention effects

Overall Fatal Flaw

- ♦ No evidence that any additional limitation was a fatal flaw